ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΕΙΡΑΙΑ – ΤΜΗΜΑ ΒΙΟΜΗΧΑΝΙΚΗΣ ΔΙΟΙΚΗΣΗΣ ΚΑΙ ΤΕΧΝΟΛΟΓΙΑΣ

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«Βελτιστοποίηση της αντιμετώπισης της βιολογικής ρύπανσης από πλοία και υποθαλάσσιες κατασκευές»

«Optimal protection measures / processes to avoid / combat biological pollution from ships and underwater structures»

ΜΑΡΙΑΝΝΑ ΨΩΜΑ

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Η παρούσα διπλωματική εργασία εκπονήθηκε στα πλαίσια του διατμηματικού μεταπτυχιακού προγράμματος «Οργάνωση και Διοίκηση Βιομηχανικών Συστημάτων» με κατεύθυνση «Συστήματα Διαχειρησης ενέργειας και Προστασίας Περιβάλλοντος».

Το Θέμα προτάθηκε από τον καθηγητή Κο Φραγκίσκο Μπατζιά, ο οποίος και καθοδήγησε την εργασία μαζί με την λέκτορα Κα. Χριστίνα Σιοντόρου.

Θα ήθελα να ευχαριστήσω θερμά αμφότερους, για την πολύτιμη συμβολή και την καθοδήγησή τους. Επίσης θέλω να ευχαριστήσω την συνάδελφο και υποψήφια διδάκτωρ, Ιωάννα Σαλάπα, η οποία συνέβαλλε στο στάδιο της τελικής σύνθεσης, καθώς και όλους τους συναδέλφους στο εργαστήριο Βιομηχανικής Διοίκησης και Τεχνολογίας του Πανεπιστημίου Πειραιά.

Η διπλωματική εργασία ερευνά μεθόδους αντιμετώπισης της βιολογικής ρύπανσης από πλοία και θαλάσσιες κατασκευές, ένα μείζον ζήτημα που απειλεί τα θαλάσσια και τα ωκεάνια συστήματα.

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1) Introduction

a) Invasive species and ballast water exchange

Non native, invasive species are one of the most destructive problems facing the world environment today. Transfer of these alien species, is done through either water exchange of vessels' ballast water tanks, either through transfer of organisms attached on ship's hull. Ballast tanks are filled with water in order ships to maintain stability. Shipping carries about 90% of world trade in volume and moves an estimated 10 billion tons of ballast water globally each year. This water frequently contains a multitude of living organisms. It has been estimated, that 7,000 species are carried around the world in ballast water every day. Ballast water is taken from coastal port areas and transported with the ship to the next port of call where the water may be discharged or exchanged. The ballast water of shipping vessels has been a primary method of alien species introduction throughout the world.

Transfer and introduction of non-indigenous species in ballast water causes significant human health, economic and environmental impacts worldwide. It is now accepted that the transport of unwanted organisms due to ships' ballasting procedures has jeopardized many of the earth's natural ecosystems. More recent data show that the rate of reported invasions has increased rapidly over the past 200 yr. Many of these species have become numerically or functionally dominant, and have significant impacts on population, community and ecosystem-level processes. The international shipping community and the International Maritime Organization (IMO), have been addressing the issue since the late 1980s. The International Convention for the Control and Management of Ships Ballast Water & Sediments was finally adopted in February 2004 requiring each ship to develop a Ballast Water Management Plan.

Ballast water regulations until 2004 recommended the exchanging of ballast water in the open ocean in order to minimize the risk of introducing non-native species. This method was effective because organisms from coastal waters are unlikely to survive in the open ocean and vice versa. Drawbacks to this method are: (1) it is difficult to completely remove sediments and residual water from the bottom of ballast tanks; (2) organisms stuck to the sides of the tank or structural supports within the tank will not be readily removed; and (3) during stormy or rough seas it is unsafe for a ship to exchange ballast water.

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Thus, organisms remaining inside the ballast tanks could be discharged at a later time into ports and harbors if the exchange failed to remove all organisms.

b) Alien Species Economic Impact

One of the worst marine species invasions occurred in the early 1980s when the North American comb jelly (*Mnemiopsis leidyi*) was introduced into the Black Sea through ballast water. It rapidly took hold and by 1989 an estimated 1 billion tones of the alien species was consuming vast quantities of fish eggs and larvae, as well as the zooplankton that commercially-important fish feed on. By 1992, the annual losses caused by drops in commercial catches of marketable fish were estimated to be at least USD 240 million.

The economic impacts of invasive alien species can be very large. The global cost associated with invasive species is estimated to be 1.400.000.000.000 USD annually. This includes costs for control, cleanup, economic losses and environmental damage. One way to address this problem is to remove or inactivate organisms that are found in ballast water. Successfully managing invasive species can provide long-term economic and environmental benefits, including conserving biodiversity and health of ecosystems.

c) New Ballast Water Regulations for Vessels

After more than 14 years of complex negotiations between IMO Member States, the International Convention for the Control and Management of Ships' Ballast Water and Sediments (BWM Convention) was adopted.

The new regulations will require each ship to develop a Ballast Water Management Plan that includes details and procedures for implementation of the selected option which will probably be the most appropriate water treatment option based on the particular ballast system and ship design. The proposed treatment regulation calls for a two phase implementation schedule. The Phase 1 implementation schedule for existing ships (those built prior to1 January 2012) with ballast water capacity of between 1,500 and 5,000 m3 will be required to meet this standard by their 1st dry docking after 1 January 2014. Ships with ballast water capacity of less than 1,500 m3 or greater than 5,000 m3 must meet the standard by their first drydocking after 1 January 2016. New vessels (those with build dates on or after 1 January 2012) will be required to meet it at delivery. The proposed Phase 2 standard is up to 1000 times more stringent than the Phase I (and IMO) standard. The Phase 2 discharge requirements must be met by new ships with a build date on or after 1 January 2016. For ships with a build date before1 January 2016, the

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compliance date is the first drydocking after 1 January 2016 or five years after a Phase 1 system was installed, whichever is later.

d) New Ballast Water Regulations for Offshore Units

Offshore units that are flying the flag of a party to the Convention will be required to have an International Ballast Water Management Certificate. Units flying the flag of a non-party to the Convention but operating in waters that are under the authority of a party to the Convention will have to carry a Certificate of Compliance with the Convention. Units flying a non-party flag and operating in non-party waters are not required to comply with the Convention.

Drilling and well intervention, wind turbine installation and accommodation units are generally considered to be units that must comply with the Convention. Production units permanently moored at one location for a lengthy period of time may not be required to comply with the Convention - refer to Article 3-2 of the Convention. These units may be exempted since ballast water is taken on and off the unit in the same waters.

For units with ballast water capacity of more than 5000 m3 that were constructed in 2011 or before, ballast water management exchange or treatment will be accepted until 2016. From 2016 (or not later than the first intermediate or renewal survey after 2016), only ballast water treatment will be accepted by the Convention. Until the Convention is ratified they can issue a Certificate of Compliance (for units flying flags that have authorized DNV) or Statement of Compliance (for other units) with the Convention.

e) Ballast Water Treatment Technologies

In the first part, we investigate the optimum ballast seawater treatment technology for shipboard installations in bulk carriers by means of multicriteria analysis.

In the second part we develop a methodological framework under the form of an algorithmic procedure, for optimizing in real time onboard ballast water treatment with tailored biocide mixtures.

In the third part, we develop a Knowledge Base (KB) to acquire/process/store/retrieve information at appropriate granularity level for choosing the best method for onboard ballast water treatment (BWT).

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During the Convention development process, considerable efforts were made to formulate appropriate standards for ballast water management. They are the ballast water exchange standard and the ballast water performance standard. Ships performing ballast water exchange shall do so with an efficiency of 95 per cent volumetric exchange of ballast water and ships using a ballast water management system (BWMS) shall meet a performance standard based on agreed numbers of organisms per unit of volume.

The Ballast Water Management Convention notes these and requires in Regulation B-3 that all ships install ballast water treatment (BWT) systems, and verify their performance according to limits on numbers of living organisms per volume of ballast discharge, as specified in Regulation D-2:

• less than 10 viable organism per m3 > 50μ in minimum dimension

• less than 10 viable organisms per ml < 50μ and > 10μ in minimum dimension and less than the following concentrations of indicator microbes:

• toxicogenic vibrio cholera, less than 1 colony forming unit (cfu) per 100 ml, or less than 1 cfu per 1 gram zooplankton samples

• Escherichia coli, less than 250 cfu per 100 ml; and intestinal enterococci, less than 100 cfu per 100 ml.

Since 2008, various flag Administrations have tested and granted type approval to (as this issue went to press) 18 BWT systems capable of meeting these discharge standards. IMO, meanwhile, has developed a list of 14 guidelines to clarify the Convention's requirements for approval of ballast water management systems. Several important implementation issues remain to be resolved, particularly regarding the sampling and testing of ballast water and enforcement of the regulations. In the second part of the thesis, it is proved that ultimate and intermediate causes of seawater contamination at the deballasting point can be investigated by means of Fault Tree Analysis (FTA). In the third part we investigate ballast water treatment optimization by developing a knowledge base. The stages employed for this development include selection of BWT methods, ontological mapping of ecosystems in the vicinity of ports and in open sea, optimization by using economic objective functions (including sensitivity analysis), fault tree synthesis/analysis (FTS/FTA), and structure of a meta-KB, interconnected with an Intelligent Agent (IA) as a support tool for successful knowledge exchange and networking. Certain case examples are presented to indicate the applicability of the KB developed herein when the objective is cost minimization under standard economic constraints.

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There are a number of proposed technical solutions for Ballast Water Treatment. The alternative technologies examined and weighted on the thesis first part are: Cavitation-Deoxygenation,; Cavitation-Ozonation,; Filtration-Electrolytic Chlorination,; Filtration-UV Irradiation,; Flocculation-Magnetic Separation,; Sedimentation by means of Hydrocyclone-Electrolytic Chlorination,.

f) Fouling and Biological Pollution

In the last part of the thesis, we investigate the dependence of the ship's maintenance on the hull corrosion and fouling. Fouling increases friction drag and blocks piping systems, affecting ship speed, fuel consumption and maneuverability. It also contributes to the spread of invasive alien species. Over the years, various materials and methods have been tried in the fight against fouling; including manual scrapping, use of copper sheathing, and the application of organic coatings with added biocides Organotin-based anti-fouling coatings were proven to be effective in controlling marine fouling on ships' hulls and were widely used from the 1970s onwards. Their success, however, was short-lived. Because organotin compounds leached from anti-fouling coatings were found to cause persistent toxicity to marine ecosystems, their use in anti-fouling systems was banned worldwide by the IMO's International Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention) which came into force in 2008. In recent years, copper-based anti-fouling coatings, mostly with booster biocides added, have successfully replaced the organotin-based products while low surface energy fouling releasing coating products, either silicone or fluoropolymer based, have also found increased use on commercial vessels.

Marine fouling also causes blockages and corrosion in seawater pipes, valves, pumps and heat exchangers, resulting in costly repair and maintenance.

Electrochemical methods using aluminium and copper anodes are widely used, while good monitoring and maintenance of the systems are also essential. Fouling on a ship's hull can lead to increases in fuel consumption of up to 40%. Research has shown that without the use of anti-fouling coatings, fuel use would rise by 200 million tonnes a year and carbon dioxide and sulphur dioxide emissions would rise by 640 million and 12 million tonnes respectively.

Today, new environmental regulations and increased awareness of environmental protection are pushing anti-fouling technology further. Shipowners are demanding high fuel efficiency, low ship gas emissions and longer maintenance cycles while paint makers continue to reduce the

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VOC content of paints and the toxic impacts of biocide release into the environment. The latest efforts are being directed at developing not only coating systems which combine effective anti-fouling performance with low or no toxicity to the marine environment, but also greener and more natural anti-fouling mechanisms which mimic the fouling resistance of many marine organisms. In the fourth part, we estimate the number N of ship's dry dockings during its lifetime as an equilibrium point in the trade off between maintenance and energy/environmental cost due to hull fouling promoted/accelerated by electrochemical corrosion and chemical/mechanical erosion. We also determine the factors contributing to vessel's 'increased maintenance expenditure' by means of Fault Tree Analysis (FTA) in its fuzzy version to count for uncertainty.

Part 1: Multicriteria Choice of Ballast Seawater Treatment Method for Shipboard Installations in Bulk Carriers

Abstract: - This work deals with multicriteria choice of ballast seawater treatment method for shipboard installations in bulk carriers of 60,000-90,000 DWT (i.e., of the Panamax-Kamsarmax vessel category). The alternatives examined are (alphabetically quoted): Cavitation-Deoxygenation, A_1; Cavitation-Ozonation, A_2; Filtration-Electrolytic Chlorination, A_3; Filtration-UV Irradiation, A_4; Flocculation-Magnetic Separation, A_5; Sedimentation by means of Hydrocyclone-Electrolytic Chlorination, A_6. The criteria used are (quoted in order of descending weight): lifecycle economic cost, f_1; lifecycle environmental cost, f_2; reliability, f_3; simplicity, f_4; maturity of technology, f_5; perspectives for further development, f_6. Fuzzy numbers were used for the assignment (by experts) of (i) weights to the elements of the input criteria vector and (ii) grades to the input preference matrix, in order to count for uncertainty. The output ranking vector

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was $A_4>A_1>A_2>A_3>A_6>A_5$, where the sigh '>' means 'better than' at both (low and high) resolution levels, indicating a robust solution. Sensitivity analysis was performed for all criteria used and the results are discussed. Relevant optimization techniques were also developed to generalize the methodology presented herein.

1.1 INTRODUCTORY ANALYSIS

The ballast seawater and sediments carried by ships have been identified as responsible for the transport of harmful invasive aquatic organisms and pathogens, which may change local ecosystems near the ports of discharge. Pimentel [1] estimated the total annual economic cost from invasive species (mainly as a result of ballast water transportation and hull fouling) for only the USA to be about 9 billion $ while Raaymakers [2] estimated this cost to be in the order of tens of billion $ on a worldwide basis. It is worthwhile noting that these amounts do not include environmental cost due to marine pollution that inevitably occurs when ballast water, carrying residues of biocides (produced *ad hoc* or added during ballasting) is discharged.

Evidently, we can determine the optimal concentration R_{opt} of such biocides/reagents in the ballast water, being also a measure of intensification of the (producing this reagent) corresponding process, by maximizing the respective benefit $B(R)=B_1(R)+B_2(R)$. The variable B_1 represents the degree/efficiency of elimination of invasive species in ballast water while the variable B_2 represents the avoidance of environmental damage due to toxic substances remaining in discharged seawater when deballasting takes place near the destination port; an economic measure of this damage in monetary terms is the expenditure required for the decontamination of discharged water, on condition that minimization of total cost (consisting of social and private cost) has been achieved, at least as an estimate. B_1 is an increasing function of R with a decreasing rate (i.e., $dB_1/dR>0$ and $d^2B_1/dR^2<0$), because of the validity of the Law of diminishing returns (LDR). B_2 is a decreasing function of R with a decreasing algebraic or increasing absolute rate (i.e., $dB_2/dR<0$ and $d^2B_2/dR^2<0$ or $d|dB_2/dR|/dR>0$), since the avoidance of environmental damage needs disproportionally more effort and resources to be achieved in the region of higher R-values. The R_{opt}-value is determined as the abscissa of the equilibrium point in the tradeoff between B_1 and B_2 at $B_{max}=(B_1+B_2)_{max}$, implying $d(B_1+B_2)/dR=0$ or $MB_1=MB_2$, where $MB_1=dB_1/dR$ and $MB_2=|dB_2/dR|$ are the marginal benefits.

In case of better quality control, because of either adopting more mature technology or development of pre-mature technology has already been achieved or 'learning by doing' has accumulated appropriate knowledge, B_2-curve moves upwards becoming also more flat, since the difference from the previous situation is more expressed in the region of higher R-values, where

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more intense conditions prevail; as a result, R_{opt} is shifting to R'_{opt}, where $R'_{opt}>R_{opt}$, as shown in Fig. 1a. In case that the ecosystem suffering the impact of discharged water is more sensitive to invasive and/or pollutant species (in comparison with what it was pre-estimated) the environmental damage or its equivalent abatement cost will increase, implying (i) movement of the B_2-curve downwards to its new position B''_2 and (ii) change of its form to a steeper one, since larger change is expected in the region of high R-values for the above mentioned reason; as a result, R_{opt} is shifting to R''_{opt}, where $R''_{opt}<R_{opt}$, as shown in Fig. 1b.

The analysis presented in the previous paragraph, indicates that more criteria should be considered for determining critical parameter values, which subsequently may be used for choosing the most appropriate method. This choice should take place among several alternative methods of ballast treatment leading to their ranking so that we may have the 'second best' option in case that the initially proposed alternative is proved inadequate.

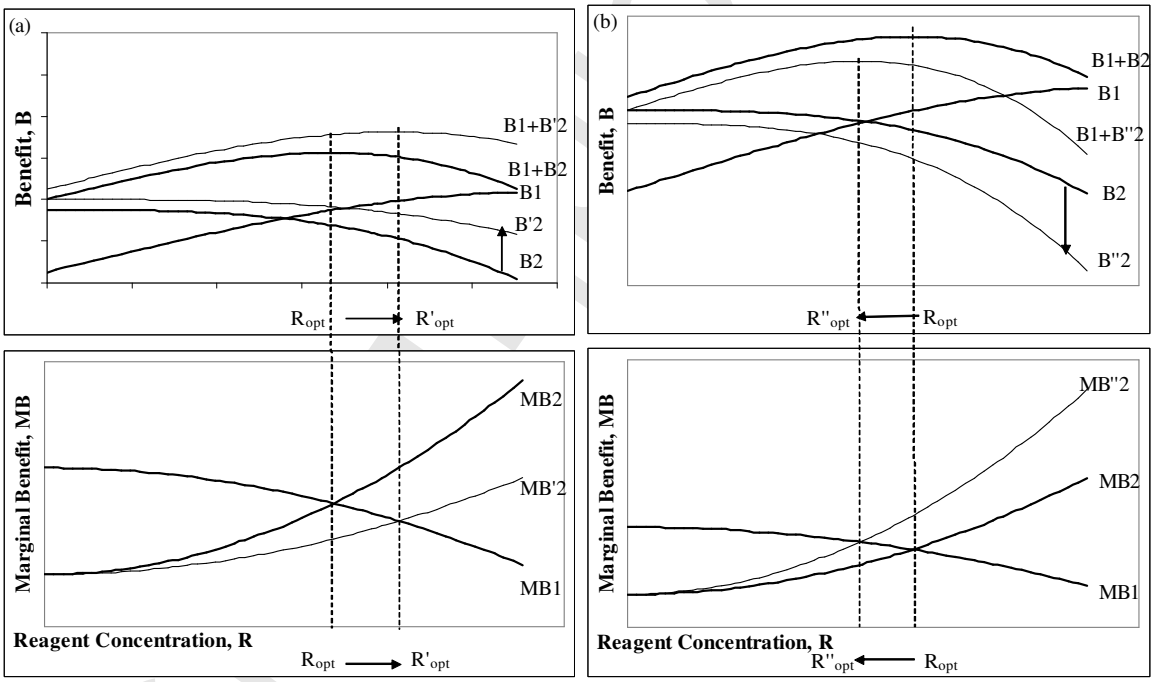

FIGURE 1. Dependence of partial benefits B_1 and B_2 (also marginal benefits MB_1 and MB_2) on reagent concentration R and shifting of optimal value R_{opt} in case of (a) better quality control and (b) an ecosystem proved to be more sensitive than it was pre-estimated.

1.2 METHODOLOGY

The objective function of the multicriteria problem under consideration is Max$\{f_1(a),\ldots, f_K(a) \mid a \in A\}$ where A is the set of T alternatives and f_k, k=1,…,K, are the K criteria used for evaluation of each ballast seawater treatment method. The computational procedure consists of two main steps: (i) the formulation of the preference matrix (K x T), where each element x_{kt} is the evaluation of alternative A_t according to criterion f_k, and (ii) the ranking of the alternatives, as a result of applying to the rules of the selected multicriteria analysis (MCA) method. PROMETHEE [3] is used as an outranking method, in its fuzzy version to count for uncertainty [4], allowing for incomparability (aRb) and weak preference (aQb) between the alternatives a, b, in addition to the strict preference (aPb) and indifference (aIb) that the 'classical' methods are based on.

The notion of a generalized criterion is used to construct an outranking relation by defining the preference index $\Pi(a,b) = \Sigma w_i P_i(a,b)/\Sigma w_i$ as the weighted average of the preference functions P_i, that quantifies the preference of the decision maker of alternative a over b, taking into consideration all the criteria. In terms of topology, the preference index values can be represented as a valued outranking graph, the nodes of which are the alternatives. By summing the column elements in each row of the outranking relation matrix, the flow leaving each node is obtained, which shows its outranking character, while by summing the row elements in each column, the entering flow is obtained for each alternative, which shows its outranked character.

By considering the leaving and entering flows, as well as the fact that the higher the leaving flow and the lower the entering flow the better the alternative, the partial preorder (PROMETHEE I) is obtained. Although the partial preorder carries more realistic information,

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sometimes the total preorder (PROMETHEE II) is requested to avoid any incomparabilities; this preorder is induced by the net flows. The generalized criterion used is a piecewise linear preference function $P = H(d) \in [0,1]$, where d is the difference of the evaluation of two alternatives a, b. The parameters of $H(d)$ are an indifference threshold q, the greatest value of d below which there is indifference, and a preference threshold p, the lowest value of d above which there is strict preference – the interval between q and p can be considered as the weak preference region.

To conclude a partial or complete preorder from the resulting fuzzy sets, the Tseng and Klein [5] method is used which makes pairwise comparison of the alternatives by calculating the (crisp) dominating areas in each pair consisted of triangular fuzzy sets (partial preorder); subsequently, the summation of the elements of each row (alternative) of the domination matrix gives a measure of the strength of each alternative that leads to the total preorder. The corresponding software we have developed and implemented in [6-8] incorporates the basic fuzzification/defuzzifi-cation methods for exporting the final partial preorder of alternatives (PRA) and total preorder of alternatives (TRA), as well as for performing sensitivity analysis as per the criteria used.

1.3 IMPLEMENTATION AND INTERPRETATION OF RESULTS

The methodology described above is implemented in the case of multicriteria ranking of ballast seawater treatment method for shipboard installations in bulk carriers of 60,000-90,000 DWT (i.e., of the Panamax-Kamsarmax vessel category). The choice of this category is based on the high popularity of these vessels for many decades; even the names refer to (i) the size limits (950 ft length including protrusions and 106 ft width over outer surface of the shell plating) for ships traveling through the Panama Canal and (ii) the upper size Panamax type ship able to load at the world's largest bauxite port of Kamsar in Equatorial Guinea.

The alternatives examined are (alphabetically quoted): Cavitation-Deoxygenation, A_1; Cavitation-Ozonation, A_2; Filtration-Electrolytic Chlorination, A_3; Filtration-UV Irradiation, A_4; Flocculation-Magnetic Separation, A_5; Sedimentation by means of Hydrocyclone-Electrolytic Chlorination, A_6. The criteria used are (quoted in order of descending weight): lifecycle economic cost, f_1; lifecycle environmental cost, f_2; reliability, f_3; simplicity, f_4; maturity of technology, f_5; perspectives for further development, f_6. Fuzzy numbers were used for the assignment (by experts) of (i) weights to the elements of the input criteria vector and (ii) grades to the input preference matrix, in order to count for uncertainty. The output ranking vector was

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$A_4>A_1>A_2>A_3>A_6>A_5$, where the sigh '>' means 'better than' at both (low and high) resolution levels, indicating a robust solution.

Details of the results are shown in Fig. 2, where partial ranking of alternatives (PRA) is shown as a set of circles with areas proportional to the crisp number S_j, which represents the corresponding relative value in the ranking vector. At low resolution (q=1.5, p=3.0) and high resolution (q=0.5, p=1.0) levels $S_4>S_1>S_2>S_3>S_6>S_5$, implying the above mentioned order. The method A_2, although it relies on ozone production, which is a very effective biocide, is ranked third because of (i) its corrosive action and (ii) the harmful by-products hypobromite ion, OBr^-, and hypobromous acid, HOBr, released in local marine environments, according to the following secondary reactions:

$O_3+Br^-\rightarrow OBr^-+O_2$ $O_3+OBr^-\rightarrow BrO_2^-+O_2$

$O_3+OBr^-\rightarrow Br^-+2O_2$ $O_3+ BrO_2^- \rightarrow BrO_3^- +O_2$

$2H_2O\leftrightarrow H_3O^+ +OH^-$ $HOBr+OBr^-\leftrightarrow H_2O+H_3O^+$

On the other hand, alternatives A5 and A6, based on magnetic separation and sedimentation by means of hydrocyclone, respectively, are ranked in the last places, since they lack reliability (f_3), maturity of technology (f_5), and exhibit high life cycle economic cost (f_1). Nevertheless, R&D efforts for improving such methods might be subsidized according to [9], at least their versions that look promising.

1.4 DISCUSSION AND CONCLUSIONS

The optimization technique presented in Introductory Analysis, can be now extended to include Process Intensification, I, as an independent variable. Since total cost C of intensification is the sum of economic and environmental costs, $C_1(I)$ and $C_2(I)$, respectively, we can determine I_{opt} as the abscissa of the equilibrium point in the tradeoff between C_1 and C_2 at $C_{min}=(C_1+C_2)_{min}$, implying $d(C_1+C_2)/dI=0$ or $MC_1=MC_2$, where $MC_1=dC_1/dI$ and $MC_2=|dC_2/dI|$ are the marginal costs

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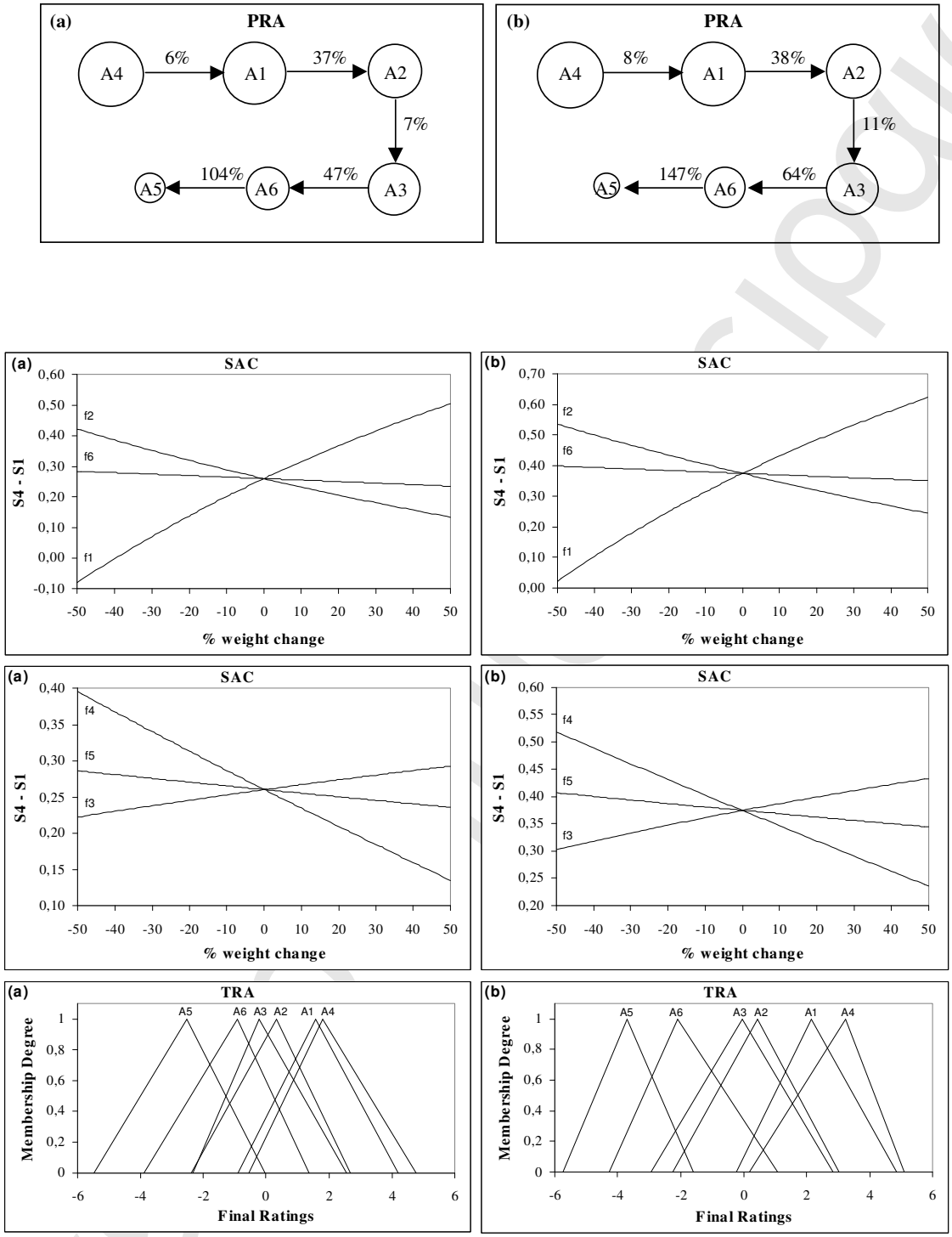

FIGURE 2. Partial ranking of alternative methods (PRA) for ballast water treatment, sensitivity analysis as regards each criterion (SAC) and total ranking of alternatives (TRA), at (a) low preferability resolution with medium *q, p* values and (b) high preferability resolution with low *q, p* values; the arrow '→' means 'better than', while the percentage on each arrow indicates how much the preceeding alternative is better. At both resolution levels, the alternative A_4 (Filtration-UV irradiation) prevails, while the SAC graphs indicate that this is a robust solution, since the difference (S_4-S_1) is almost always positive in the examined region of weights change.

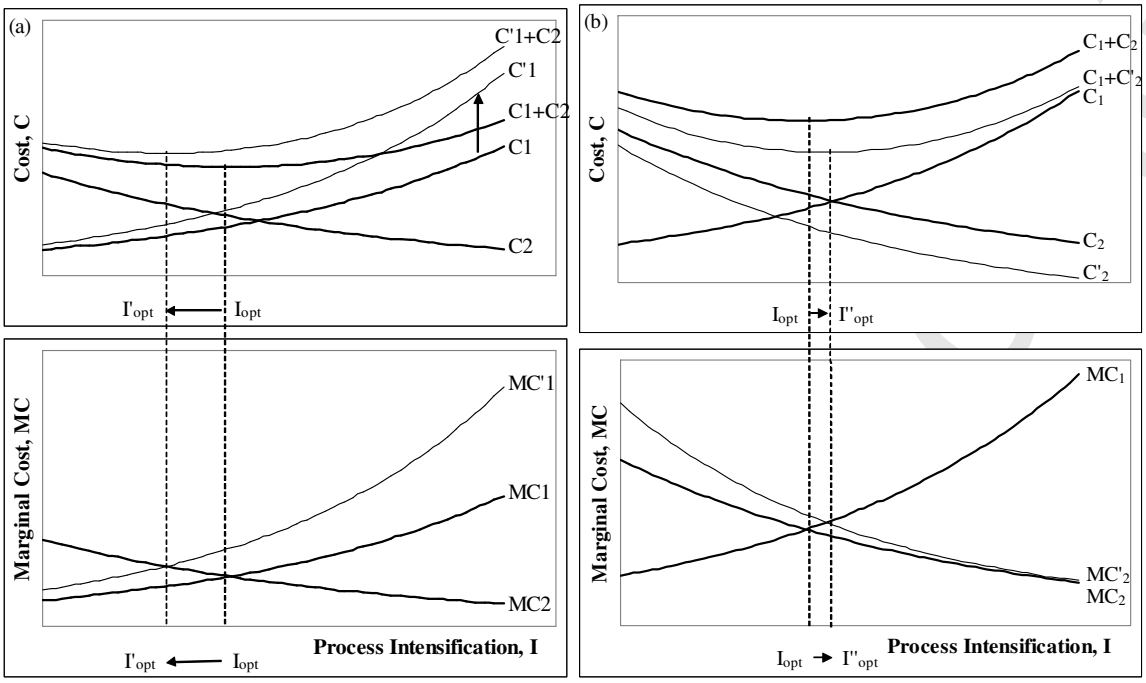

FIGURE 3. Dependence of partial costs C_1 and C_2 (also marginal costs MC_1 and MC_2) on process intensification I and shifting of optimal value I_{opt} in case of (a) energy price increase and (b) an ecosystem proved to be more tolerant/stable than it was initially estimated.

C_1, representing both, the disinfection cost for ballasting/deballasting and the decontamination cost for the water to be discharged, is an increasing function of I with an increasing rate (i.e., $dC_1/dI>0$ and $d^2C_1/dI^2>0$), since higher intensification implies higher contamination, which, in its turn, implies disproportionally higher cost for decontamination, according to the LDR, which exhibits general applicability in environmental engineering, as shown in [10]. On the other hand, C_2, representing the environmental damage to indigenous marine ecosystem after deballasting, is a decreasing function of I with an increasing algebraic or a decreasing absolute rate (i.e., $dC_2/dI<0$ and $d^2C_2/dI^2>0$ or $d|dC_2/dI|/dI<0$), since self-purification, and consequent tolerance/stability of the ecosystem, is enhanced when discharged water with lower concentration of contaminants (for unchanged decontamination cost, according to the well known in Economics *ceteris paribus* assumption) is mixed with the local water; the disproportionality is also due to the validity of LDR.

In case of energy price increase (e.g., due to increased demand over supply for gas/liquid hydrocarbons on a worldwide basis), C_1-curve moves upwards becoming also steeper, since the difference in energy cost will be higher in the region of high I-values, due to LDR, especially

when the disinfection process depends heavily on electric energy (e.g., electrolytic chlorination); as a result, I_{opt} is shifting to I'_{opt}, where $I'_{opt}<I_{opt}$, as shown in Fig. 3a. On the other hand, if the local indigenous ecosystem is more tolerant/stable than it was initially estimated (e.g., because of growth of indigenous predators using the 'pests' or 'invaders', included in the discharged waters, as prey) then C_2-curve moves downwards becoming also steeper, since the difference will be higher in the region of high I-values, corresponding to lower invasive species concentration in deballasting water; as a result, I_{opt} is shifting to I''_{opt}, where $I''_{opt}>I_{opt}$, as shown in Fig. 3b.

Obviously, the inverse economic/natural phenomena will take place in case of (i) energy price decrease (most likely in the short run, since ascending trend frequently prevails in the long run) or/and (ii) the invaders included in the discharged water prevail as predators in the ecosystem receiving the contaminated water after deballasting. Moreover, splitting or merging of criteria might be proved useful in case that examination at higher or lower, respectively, information granularity level is needed (see [11,12]).

In conclusion, it seems that determination of optimal values of independent variables (like biocide reagent concentration and intensification of the process producing the biocide), based on the tradeoff between environmental/technical and economic partial conflict dependent variables, may serve only as an approximation, since more variables, which cannot be directly quantified, enter this tradeoff under the form of criteria within a choice/preference matrix. Nevertheless, such rough optimization techniques are useful even at a conceptual level, providing the background for multicriteria analysis in a fuzzy version in order to count for uncertainty. We have proved, by means of a case example referring to ranking ballast seawater treatment methods for shipboard installations in bulk carriers, that multicriteria analysis can be successfully applied in this discipline giving realistic results.

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Part 2. Employing an Especially Designed Biocide Mixture for Onboard Ballast Water Treatment

Abstract: - The global movement of ballast water is considered today as the largest transfer mechanism for marine bioinvasion. Onboard wastewater treatment is the most efficient way to minimize risk for the recipient environment, yet its implementation is not straightforward, as it requires (i) in depth knowledge of marine ecology, (ii) skills and experience, and (iii) appropriate facilities. In this work, a methodological framework is presented, designed/developed by the authors under the form of an algorithmic procedure, for optimizing in real time onboard ballast water treatment with tailored biocide mixtures. Certain aspects critical to treatment operations are, also, discussed. It is proved that ultimate and intermediate causes of seawater contamination at the deballasting point can be investigated by means of Fault Tree Analysis (FTA).

2.1 Introductory Analysis

Ballast water is one of the major pathways of worldwide biological invasion in marine ecosystems [1,2]. The prevention of non-native species introduction in the recipient ecosystem of ballast water discharges is nowadays a high priority, also recognized as such by the International Maritime Organization (IMO) [3]. For this prevention, the appropriate ballast water treatment method should be chosen/adapted and performed onboard (necessitating the installation of the corresponding equipment) [2]. One of the first steps for successful selection is to determine the targeted alien invader or the most suspicious one, according to ecological maps, where indigenous and non-indigenous (potential invaders) species are registered for the most marine regions near ports. Several biocides can be prepared onboard by physical/chemical methods, like ozonation and electrolysis, while others are commercially available in a ready-to-use form [1, 3]. The latter case is examined herein, as the most simple and applicable, consisting of a three-step procedure for biocide treatment (which necessitates biocide preparation, occasionally by mixing different commercial products with a variety of chemical substances) in the corresponding three distinct life-cycle stages: ballasting, transit, deballasting.

From the environmental/economic point of view, the critical point in the biocide mixture design is deballasting. The total cost C(B) of the design consists of the partial costs $C_1(B)$ and $C_2(B)$ due to biocide cost and ecosystem risk, respectively, where B is the biocide concentration, used for treating the deballasting water. The optimal value of B is the abscissa at minimum total cost C_{min}. The partial cost $C_1(B)$ is an increasing function of B with an increasing rate (i.e., $dC_1/dB>0$, $d^2C_1/dB^2>0$), since the space limitations do not allow for scale economies (in

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comparison with optimal size and geometric scheme based on the criterion of minimum shell-surface for given volume or capacity). The partial cost $C_2(B)$ is a decreasing function of B with an increasing algebraic or decreasing absolute rate (i.e., $dC_2/dB<0$, $d^2C_2/dB^2>0$ or $d|dC_2/dB|/dB<0$), since risk for environmental damage due to adverse modification of the marine ecosystem is expected to be disproportionately higher in the region of low/inadequate B-values. For C_{min}, $dC/dB=0$ or $d(C_1+C_2)/dB=0$ or $MC_1=MC_2$, where $MC_1=dC_1/dB$ and $MC_2=|dC_2/dB|$ are the marginal values of C_1 and C_2, respectively.

In case that a novel, more effective (but more expensive) biocide is introduced for replacing the older reagent, C_1-curve is moving upwards becoming steeper, since the difference is greater in the region of high B-values; as a result, B_{opt} is shifting to its new position B'_{opt}, where $B'_{opt}<B_{opt}$ (Fig. 1a). At the same time, C_2-curve is moving downwards becoming more flat, since effectiveness

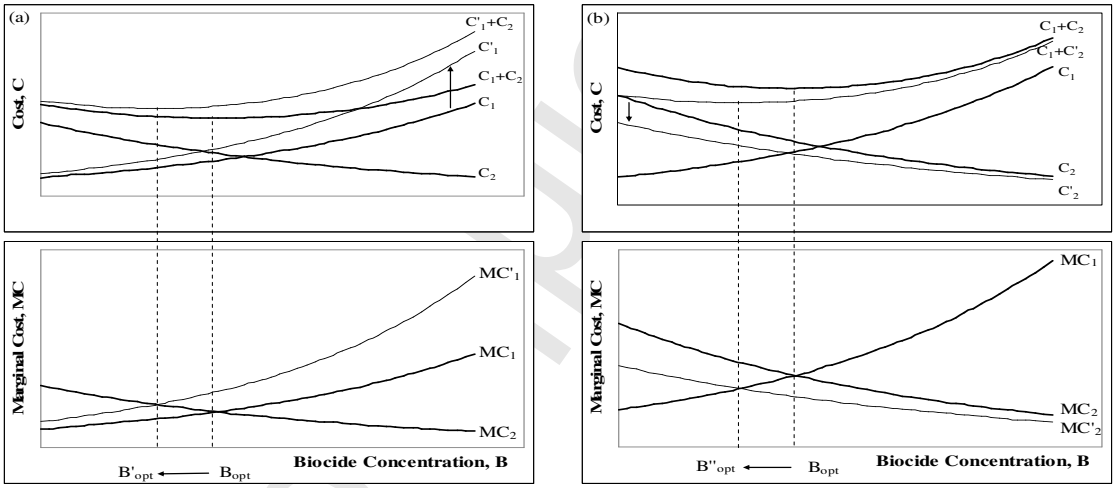

FIGURE 1. Dependence of partial costs C_1 and C_2 on biocide concentration B and shifting of optimal value B_{opt} in case that a novel, more effective (but more expensive) biocide is introduced for minimizing process cost and ecosystem risk.

is expected to be greater in the region of low B-values, where the eradication of harmful species with the old reagent was low/inadequate; as a result, B_{opt} is shifting to its new position B''_{opt}, where $B''_{opt}<B_{opt}$ (Fig. 1b). As a matter of fact, the introduction of the novel reagent implies certainly lower biocide concentration, although it is not *a priori* known whether the new C_{min} will also be lower.

Evidently, the problem we face is to maximize benefit by designing and applying biocide mixtures, which may be quite different in accordance with their spatiotemporal use: in ballast inflow, during residence in the tank, and in ballast outflow. This usage should be safe for the ship's crew, friendly to the environment, non-contributing to metal corrosion, and not entailing excessive cost.

2.2 Methodological Framework

As a contribution either to solving this problem or to improve the empirical application of biocide mixtures, the authors designed/developed a methodological framework, under the form of an algorithmic procedure with 26 activity stages and 6 decision nodes (interconnected as shown in Fig. 2), for optimizing onboard ballast water treatment with tailored biocide mixtures, is presented below.

1. Selection of information about the indigenous marine species at the area of ballasting that would be released at the port of destination during deballasting and invade the local biosystem, thus changing its state of equilibrium as described in predator prey dynamics [4-6]
2. Sampling and onboard measurements to confirm/specify the information.
3. Experimental design to check the effectiveness of various biocide mixtures on samples.
4. Performance of corresponding measurements and evaluation of results.
5. (Re)Starting the ballast seawater inflow while performing measurements (on an online/real time basis) before and after processing, which should include at least filtration and addition of the biocide mixture.
6. Inflow interruption and fault identification by means of Fault Tree Analysis (FTA).
7. Implementation of appropriate corrective/ remedial measures.
8. Redesign of mixture and inflow continuation.
9. Determination of the initial concentrations of pathogens or invasive species in the ballast tanks.
10. Computer-aided simulation of the abundance and species diversity changes occurring in transit to deballasting.
11. Identification of the 'critical' species.
12. Determination of the appropriate course of action.
13. Design of the new mixture doses and application.
14. Measurement of the result after applying the first dose.
15. Determination of divergence from estimated values.

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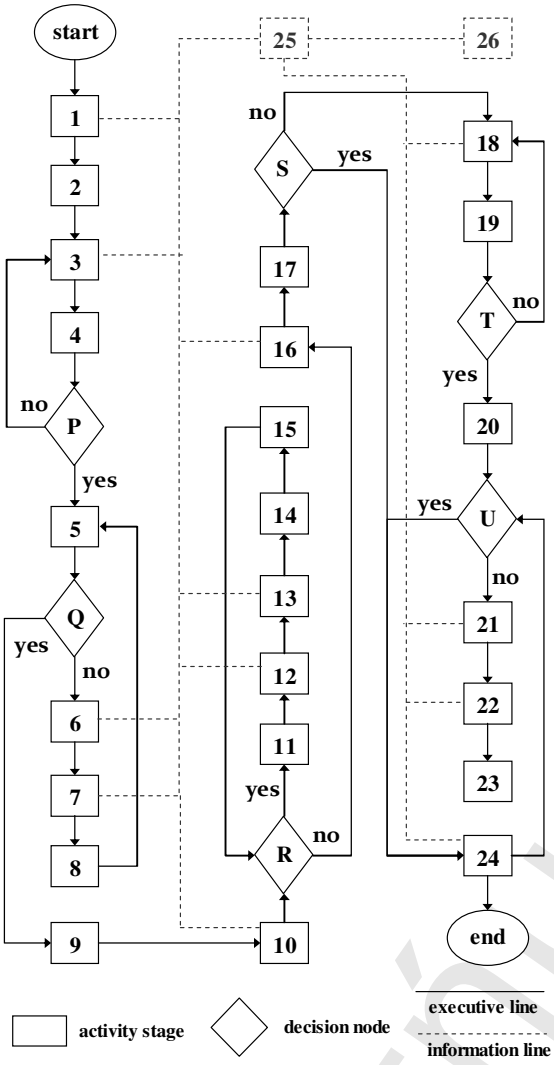

16. Selection of information about the vulnerability of species constituting the marine biosystem at the point of deballasting, when the ship is approaching its destination, and mapping of this information on an ontological platform, in order to elucidate predator-prey interrelations.
17. Sampling and onboard measurements to confirm/specify the information, when the ship is in the vicinity of the deballasting point.
18. Experimental design to check the effectiveness of various biocide mixtures on samples in order to prevent the destruction of the local ecosystem equilibrium.
19. Performance of corresponding measurements and evaluation of results.
20. (Re)Starting the ballast water outflow while performing measurements (on an online/real time basis) before and after the application of the biocide mixture.
21. Outflow interruption and fault identification by means of Fault Tree Analysis (FTA).
22. Implementation of appropriate corrective/ remedial measures.
23. Redesign of mixture.
24. Outflow/measurements continuation
25. Outflow termination and checking of ballast water tanks, according to relevant protocol.
26. Submission according to official guidelines.
27. Final measurement in the sea at the point of deballasting, according to the ship's internal protocol.
28. Development/operation/updating of an internal Knowledge Base (KB), including Fault Tree Synthesis (FTS) in the core of its structure/operation.
29. Searching in external KBs for data mining by means of an Intelligent Agent, according to [7].

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P. Has an effective biocide mixture been achieved?

Q. Are the results of these measurements in agreement with the environmental standards (if they exist) or the set *a priori* recommended values?

R. Is there any need for intervention by adding supplementary doses of a proper biocide mixture?

S. Is the ballast water bioburden safe for the local ecosystem?

T. Has an effective biocide mixture been achieved?

U. Are the results of these measurements in agreement with the environmental standards (if they exist) or the set *a priori* recommended values?

V. Are the port authorities demanding submission of relevant report?

2.3 Implementation

Fault tree analysis [8, 9], suggested in stages 6 and 21, is a suitable tool for assessing the efficiency of procedures and controls performed at ballasting, during transit and prior to deballasting, since any deficiencies, malfunctions or defects of the system are readily revealed, enabling a prompt and targeted intervention in order to reduce the risk for the recipient environment. As a case example, 'pathogen detection at the coastal area that ships deballast', was set as top event for implementing stage 21. An extract of the tree is shown in Fig. 3, whereas the code numbers are described below.

1.1 Land-derived contamination.

1.2 Ship-source pollution.

1.1.1 Land-sea transfer through sewage run-offs.

1.1.2 Facilitation of pathogen survival in degraded coastal marine habitat.

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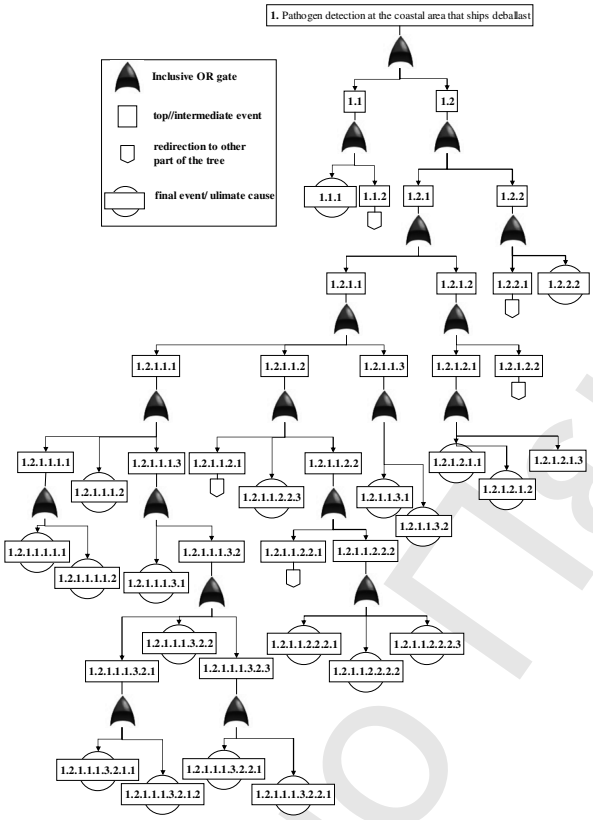

Figure 3. Extract of the fault tree synthesized to be used as a tool for assessing the efficiency of procedures and controls performed at ballasting, during transit and prior to deballasting by setting as top event the pathogen detection at the coastal area that ships deballast.

1.2.1.2 The establishment of a pathogenic community is induced by the discharged ballast water.

1.2.2.1 The pathogen is transferred through outer vessel colonization (hull fouling) in critical mass and in survival phase.

1.2.2.2 The pathogen is released during cleansing, routine maintenances, waste disposal.

1.2.1.1.1 Low efficiency of the treatment process.

1.2.1.1.2 Unsuitable treatment process.

1.2.1.1.3 Inadequate accuracy of the sterility assurance test performed at ballast water during discharge.

1.2.1.2.1 The large volumes of the ballast water discharged into the recipient environment, alter ecosystem-level processes (microenvironment, hydrology, nutrient cycling) and, subsequently modify community-level dynamics (abundance and biodiversity) possibly enabling pathogenic opportunism.

1.2.1.2.2 The enrichment of the recipient environment with the nutrient sources contained in the ballast water discharged (especially *Cyanophyta*, *Dinoflagellata*, *Bacillariophyta, Chlorophyta*, and *Mnemiopsis leidyi*) may have significant impact on the indigenous predator-prey dynamics possibly enabling pathogenic opportunism.

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1.2.1.1.1.1 The geometry of the tank does not permit optimum treatment.

1.2.1.1.1.2 The salinity and temperature of the ballast water are not concordant to the optimal operation range of the process

1.2.1.1.1.3 Development of resilience at transit between ballasting and deballasting at percentages higher than anticipated.

1.2.1.1.2.1 Underestimated ecological risk for the recipient environment due to the ballast water bioburden.

1.2.1.1.2.2 Underestimated abundance/biodiversity of the bioburden in the ballast water.

1.2.1.1.2.3 The basic management measure for ballast water includes water exchange at sea (empty/refill, flow-through or dilution methods) and complementary disinfection without bioburben testing or controls.

1.2.1.1.3.1 Method validation or instrument calibration is not concordant with specifications

1.2.1.1.3.2 Test results are not confirmed with a proper complementary test, particularly when values are near the quantification limit of the method.

1.2.1.2.1.1 High alteration of energy flow through the detrital pathways facilitate *archaea*, increasing the risk for *Lipothrixviridae*.

1.2.1.2.1.2 Redistribution and transformation of nutrients facilitate crustacean, increasing the risk for *Vibriae.*

1.2.1.2.1.3 Modification of microclimate (salt, temperature, pH, etc. conditions) facilitates the growth of organisms that could not previously survive at great numbers, resulting gradually in the establishment of new competitive interactions and a variety of impacts.

1.2.1.1.1.1.1 Tubing and valves that are outside the ‘treatment zone’ retain significant volumes of untreated ballast water

1.2.1.1.1.1.2 The tank of the ship shows deformations (dents, grooves and crannies) that may serve as hurdles for the efficient distribution of the processing solution.

1.2.1.1.2.2.1 The parameter values used for the community interaction models are inaccurate, especially the ones referring to nutrient cycling and abiotic parameters.

1.2.1.1.2.2.2 The initial estimations of tank population (number and species) are incorrect.

1.2.1.1.1.3.1 Short treatment periods that allow for the development of anti-stress mechanisms, especially in bacteria.

1.2.1.1.1.3.2 Insufficient biocidal activity that permitted the survival of a critical number of pathogens or pathogen-enabling microorganisms.

1.2.1.1.1.3.2.1 Denaturation of the biocide occurring due to inappropriate storage conditions or exceeding shelf-life.

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1.2.1.1.1.3.2.2 High *in situ* degradation and/or neutralization of the biocide due to cross-reactivity with either water biotic or abiotic moieties or other co-added treatment chemicals.

1.2.1.1.1.3.2.3 Settling of the biocide in the storage tank causes phase separation (in the cases of unstirred or poorly stirred tanks) resulting in pumping into the ballast tank lower effective concentrations of the chemicals at the given (measured) volumes.

1.2.1.1.2.2.2.1 The bioburden enumeration and identification test are not verified with exhaustive recovery testing.

1.2.1.1.2.2.2.2 Low representativeness of the sample tested either due to the sampling method used or the settling conditions that prevail in the ballast tank.

1.2.1.1.2.2.2.3 Method validation or instrument calibration is not concordant with specifications.

1.2.1.1.1.3.2.1.1 Due to agglomeration.

1.2.1.1.1.3.2.1.2 Due to sedimentation.

1.2.1.1.1.3.2.3.1 Stratification due to temperature or density differentiation.

1.2.1.1.1.3.2.3.2 Complicate geometry and improper pipes arrangement.

It is worthwhile noting the issues that the FTA results stress. Taking into consideration the final events 1.2.1.1.2, 1.2.1.1.2.2.1 and 1.2.1.1.2.2.2.3 and the intermediate events 1.2.1.1.3.1 and 1.2.1.1.3.2 (referring mainly to quality control and attributable to lack of quality assurance [1]), the strict implementation of good laboratory practices is indispensable for the reliability of measurements, referring to both, equipment and handling. Furthermore, skills and experience are required to deliver successful biocide treatment, in order to prevent faults as such described in nodes 1.2.1.1.1.3, 1.2.1.1.1.3.2 and 1.2.1.1.1.3.2.1 (referring to process deficiencies due to operator mishandlings [7]).

Nonetheless, the ship's geometry should be carefully considered when planning disinfection protocols [3], as deformations (node 1.2.1.1.1.1.2), and improper tubing installations (nodes 1.2.1.1.1.1.1 and 1.2.1.1.1.3.2.3.2) alter the diffusion patterns of chemicals. Evidently, effective onboard biocide treatment of ballast water should be performed by a trained chemist or chemical engineer with appropriate facilities, whereas certain ship plan modifications might be necessary.

2.4 Discussion

The implementation case presented may be considered as an operational problem that can be easily dealt with, provided that procedures follow the established standard by trained personnel. Other risk factors related to marine ecology, however, may present that are less easily identified and controlled. The introduction of new, non-pathogenic species (as phytoplankton or algae) into

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native ecosystems has nowadays become a major concern prompting the implementation of prevention measures [11, 12]. In some cases, these non-indigenous species have shown the ability to invade new environments and radically alter the structure and the functioning of native ecosystems, causing marked changes or threatening native biological diversity [12]. Therefore, the implementation of stage 16, referring to risk identification of the recipient ecosystem, should be based on ontological platforms(see relevant discussion in [13]) to fully elucidate ecosystem- and community-level processes in order to identify the vulnerability traits and facilitate prevention or restoration.

The change of ecosystem's equilibrium state quoted in stages 1,16 can be described by a Lotka-Volterra type model, i.e. as a pair of differential equations referring to a predator-prey dynamics. Such a model, is characterized by oscillations in the population size of both predator and prey, with the peak of the predator's oscillation lagging behind the peak of the prey's oscillation. The assumptions, upon which a model of this type is based, are:

I. The prey population will grow exponentially when the predator is absent
II. The predator population will starve in the absence of prey population (as opposed to switching to another type of prey)
III. Predators can consume infinite quantities of prey and
IV. There is no environmental complexity (in another words, both populations are moving randomly through a homogeneous environment)

The basic differential equation has the form:

$dP/dt = -qP$ (1)

i.e, it uses the product of the number of predators (P) and the predator mortality rate (q) to describe the rate of decrease of the predator population with respect to time (t). In the presence of prey, this decline is opposed by the predator birth rate, ca PN, which is determined by the consumption rate (Apn, where [a] is the attack rate multiplied by the product of the number of the predators [P] times the number of prey [N]) and by the predators ability to turn food into offspring (c). As predator and prey numbers (P and N, respectively) increase, their encounters become more frequent, but the actual rate of consumption will depend on the attack rate (a). the equation describing the predator population dynamics becomes:

$dP/dt = caPN - qP$ (2)

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the product ca P is the predator's numerical response, or the per capita increase as a function of prey abundance. The entire term, ca PN, expresses increase in the predator population as proportional to the product of predator and prey abundance. Similarly, the following equation describes the rate of increase of prey population with respect to time, where r is the growth of prey population, and Nis the abundance of the prey population:

$dN/dt=rN$ (3)

In the presence of predators, however, the prey population is prevented from increasing exponentially. The term for consumption rate from above (a PN) describes prey mortality, and the population dynamics of the prey can be described by the equation:

$dN/dt=rN-aPN$ (4)

The product of a and P is the functional response, or rate of prey capture as a function of prey abundance. Here the term a Pn reflects the fact that losses from the prey population due to predation are proportional to the product of predator and prey abundances.

Equations (2) and (4) describe predator and prey population dynamics in the presence of one another, and together make up the Lotka-Voltera predator-prey model. The model predicts a cyclical relationship between predator and prey numbers: as the number of predators (P) increases so does the consumption rate (aPN), tending to reinforce the increase in P. Increase in consumption rate, however, has an obvious consequence—a decrease in the number of prey(N), which in turn causes P(and therefore aPN) to decrease. As aPN decreases, the prey population is able to recover, and N increases. Now P can increase, and the cycle begins again. The graph in Fig.1 shows such a cyclical relationship as predicted by the model for hypothetical predator and prey populations in seawater.

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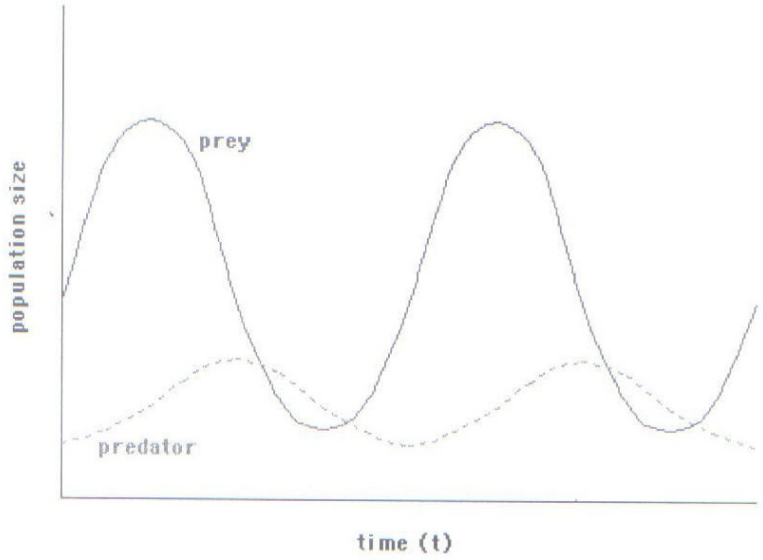

Fig.1: Cyclical Relationship for Hypothetic Predator and Prey populations in Seawater.

A good model must be simple enough to be mathematically tractable, but complex enough to represent the simulated system realistically. Realism is often sacrificed for simplicity, and one of the shortcomings of the Lotka-Voltera model is its reliance on rough assumptions. For example prey populations are limited by food resources and not just by predation, and no predator can consume infinite quantities of prey.

In the present work, the factor of adding predators to the P-population by the ballasting is suggested in as much as more effective predator species may be transferred–discharged. Moreover, both populations, (P and N) may drastically but unequally decrease by biocides (in case of deballasting water that contains such substances).

2.5 Conclusion

The functionality of the methodological framework we have developed for employing an especially designed biocide mixture to be used in onboard ballast water treatment, has been proved by means of FTA. In the case thoroughly analyzed and herein presented within an extract, the top event was ‘pathogen detection at the coastal area that ships deballast, while the final events, standing for the final causes, included faults due to both, design and operation. Since this implementation case may be considered as an operational problem that can be easily dealt with, provided that procedures follow the recommended practices, we have suggested corresponding

factors (namely predators or/and biocides) that should be added to a Lotka-Volera type model in order to present the simulated ecosystem more realistically. Such a suggestion can be also used for extending the KB already in service, functioning along with an Intelligent Agent, as shown in the algorithmic procedure that realizes the proposed methodological framework.

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Part 3: Development Of A Knowledge Base For Optimizing Ballast Seawater Processing

Abstract. This part deals with the development of a Knowledge Base (KB) to acquire/process/store/retrieve information at appropriate granularity level for choosing the best method for onboard ballast seawater treatment (BST). The stages employed for this development include selection of BST methods, ontological mapping of ecosystems in the vicinity of ports and in open sea, optimization by using economic objective functions (including sensitivity analysis), fault tree synthesis/analysis (FTS/FTA), and structure of a meta-KB, interconnected with an Intelligent Agent (IA) as a support tool for successful knowledge exchange and networking. Certain case examples are presented to indicate the

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applicability of the KB developed herein when the objective is cost minimization under standard economic constraints.

3.1 INTRODUCTION

Ships use ballast seawater to provide stability and maneuverability; water is taken on at one port when cargo is unloaded and usually discharged near another port when the ship is loaded. Because organisms, ranging in size from viruses to cramps (even to small/medium size fishes) living in the surrounding water or sediment, are taken on board with ballast water, there is a potential for the introduction of non-native organisms – called bio-invaders, alien species, Non-Indigenous Species (NIS) or exotic species – into ecosystems near the port of discharge. When comparing different ballast seawater treatment (BST) processes, each one of them should have been optimized in techno economic and environmental terms. Such an optimization procedure should be based on a continually enriched Knowledge Base (KB) since effectiveness of each process depends on a plethora of intrinsic and extrinsic variables/parameters, which (i) cannot be evaluated *a priori*, and (ii) change in the time/space domain. Since the function of this KB depends heavily on its initial structure, the re-design is necessary when the accumulation of new information leads to knowledge that cannot be processed by the available KB's service.

The re-design/re-engineering is performed by human intervention while the optimal time (not earlier, for saving invested resources, and not later, for not entailing excessive loss of reliability and risk to system's failure) for this remedial action is suggested by a meta-KB, incorporated into the overall managerial scheme. Evidently, the complexity of the system described above creates a problem without a standard way for solving it.

3.2 METHODOLOGY

For dealing with the problem mentioned in the last paragraph of Introduction, we have developed a methodological framework, under the form of an algorithmic procedure, with the subsequently described 17 activity stages and 5 decision nodes (interconnected as shown in Fig. 1):

1. Selection of BST methods.
2. Ontological mapping of ecosystems in the vicinity of ports and in open sea.

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3. Determination of (i) biocides production variables and (ii) effectiveness indices/parameters for each BST method.
4. Determination of the corresponding economic relations.

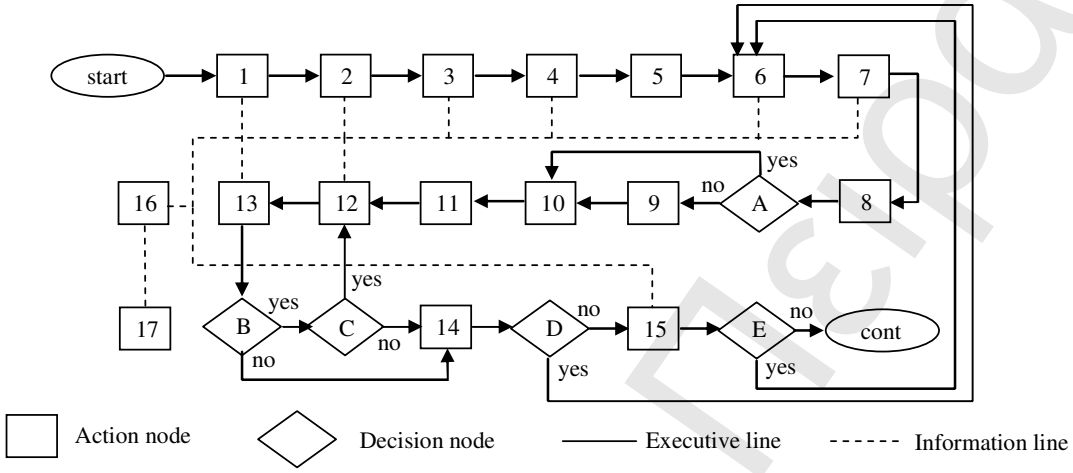

FIGURE 1. The knowledge-based methodological framework we have developed under the form of an algorithmic procedure for optimizing ballast seawater processing.

5. Sensitivity analysis round the optimal point (corresponding to minimum cost) of each independent variable.
6. KB design as an empty shell.
7. Filling of the empty shell with (i) relevant knowledge at various phenomenological levels, and (ii) appropriate information at corresponding granularity levels.
8. Testing by means of simulated data representing typical cases.
9. Corrective action as regards both, the structure and the function of KB, including the adjunct inference engine.
10. Operation of KB under real conditions and evaluation of its performance.
11. Collection and ranking of faults by structuring a Pareto distribution.
12. Fault tree synthesis/analysis (FTS/FTA) by setting as 'top event' the ranked first among the faults not examined so far by means of this dendritic structure, that may also serve for technology transfer [1,2].
13. Remedial proposals, testing of their effectiveness through experimentation, and performance of the corresponding corrective actions.

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14. Enrichment of the KB by incorporating/assimilating the new information and the additional knowledge acquired so far.
15. Cost-benefit analysis of the KB's partial revision.
16. Creation/operation/enrichment/updating of a meta-Knowledge Base (meta-KB).
17. Searching within external Bases by means of an Intelligent Agent (IA) [3].

A. Is this testing satisfactory according to pre-set standards?
B. Are there other faults ranked within the Pareto distribution?
C. Is the examination of the first of them justified in economic terms?
D. Does this enrichment lead necessarily to the KB redesign as regards its fundamental structure?
E. Is such a revision beneficial?

3.3 IMPLEMENTATION

We have implemented the methodology described above in the case of ballast seawater disinfection using electrolysis to produce sodium hypochlorite, according to the electrochemical reaction $NaCl+H_2O \rightarrow NaOCl+H_2$. The initial partial reaction is $2Cl^- - 2e^- \rightarrow Cl_2$. The elemental chlorine is hydrolyzed to form hypochlorous acid with free hydrogen formed as a by-product, which is the same reaction taking place when gaseous chlorine is dissolved in water [4]: $Cl_2+2H_2O \rightarrow 2HOCl+2H^+$. Hypochlorous acid dissociates into hypochlorite at the alkaline pH levels found in seawater: $HOCl \rightarrow OCl^- + H^+$. Hypochlorous acid is the active disinfectant when chlorine is dissolved in freshwater but the chemistry of seawater chlorination is different since it contains 50-70 mg/L bromide (Br^-) [4]. The level of bromide in seawater is in excess of the amount of chlorine used for disinfection. Bromide is oxidized by hypochlorite and hypochlorous acid to form bromite (OBr^-) and hypobromous acid (HOBr): $HOCl+Br^- \rightarrow HOBr+Cl^-$. The oxidation of bromide to HOBr at pH 8 in seawater reaches 99% completion in less than 10 s [5]. The level of chlorine-produced oxidants is measured as Total Residual Oxidant (TRO) mg Cl_2/L because both bromine and chlorine oxidants are formed and the standard total chlorine analytical methods do not differentiate between the two oxidants.

We have investigated the continuous improvement (leading to dynamic quasi-optimization) of this method by setting as top event in FTS/FTA (stage 12) a fault (namely 'inadequate disinfection efficiency') denoting deviation from the initially estimated optimal efficiency of the process. An extract of the tree is shown in Fig. 2, where the quantifiers corresponding to events

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can be represented by fuzzy numbers, to count for uncertainty, taking values in the universe of discourse defined by the faults that appear as indices (%), with terms L, M, H (Low, Medium, High, respectively, according to a three-point Likert Scale). The rules are set in the usual IF – THEN form; e.g., IF 1.3.1 is [M] AND 1.3.2 is [M] THEN 1.3 is [H], where the code numbers are described below:

1.1 Wrong hydraulics design/operation.

1.1.1 Wrong design of the electrolytic reactor.

1.1.2 Short residence time.

1.1.1.1 Inhomogeneity of electrolyte and the electric field due to reactor geometry.

1.1.1.2 Sudden flow transition from laminar to turbulent and *visa versa*.

1.1.2.1 Low reactor volume.

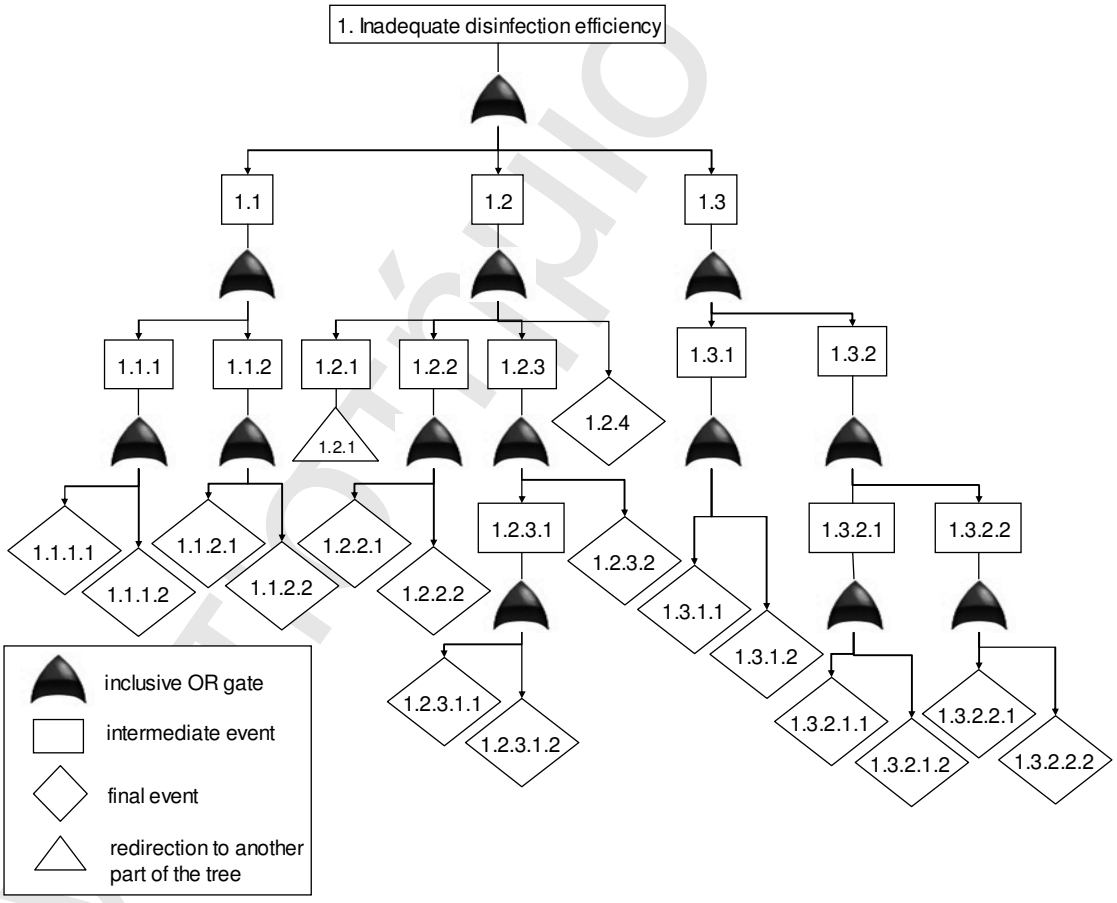

FIGURE 2. Extract of the fault tree synthesized to be used as a tool for improving ballast seawater processing by setting as top event the deviation from the initially estimated optimal efficiency of the electrochlorination process.

1.1.2.2 High volumetric ballast inflow.
1.2 Problem in electrical current supply.
1.2.1 Problem in main line of AC supply.
1.2.2 Problem in rectifying.
1.2.2.1 Failure in one phase of the 3-phase circuit.
1.2.2.2 Excessive ripple.
1.2.3 Loss of electrical contacts.
1.2.3.1 Loose mechanical contact.
1.2.3.1.1 Not firmly tight before starting the process
1.2.3.1.2 Strong eddy currents in seawater flow, due to turbulence in the vicinity of electrodes
1.2.3.2 Oxidation of current transmission wires, especially on welded junctions.
1.2.4 Uneven electrode areas, leading to uneven distribution of electrolytic field.
1.3 Insufficient biocidal activity
1.3.1 Reduced chloride yield.
1.3.1.1 Initial overestimation.
1.3.1.2 Lower seawater salinity level.
1.3.2 Reduced radical concentration.
1.3.2.1 Short life span.
1.3.2.1.1 Misestimation in the initial simulation or mechanism selection.
1.3.2.1.2 Consumption due to reaction with seawater contaminants.
1.3.2.2 Insufficient yield of free radicals.
1.3.2.2.1 Defective electrodes.
1.3.2.2.2 Initial misestimation in the electrolysis mechanism.

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3.4 DISCUSSION AND CONCLUDING REMARKS

The economic relations to be determined in stage 4 should include private and social (environmental) cost. The latter is connected with externalities, since environmental goods have not a market value while a corresponding value may be estimated by means of methods (e.g., Willingness To Pay/Willingness To Accept – WTP/WTA) used in Experimental Economics. A certain kind of uncertainty appears also in cost-benefit analysis of the KB's partial revision (stage 15), since the advantage when using the KB can be quantified (as subjective assignment of weights/grades) only by the stakeholders, serving as experts in such a case; this kind of tacit/implicit knowledge is temporarily stored in the KB, subject to short-term revision when new information lead to change of exerts' opinion.

In conclusion, we have indicated the functionality of the methodological framework presented herein under the form of an algorithmic procedure (including 17 activity stages and 5 decision nodes) for developing a KB improving (and eventually optimizing) BST while correcting any fault during onboard operations. Although the case example used for implementing this methodology refers to a method well established from the physical/chemical point of view, we have suggested uncertainties that may appear, especially when the aspect of economics is involved.

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Part 4: Investigating Ship Maintenance Dependence On Hull Corrosion/Fouling By Means Of Fuzzy Fault Tree Analysis

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Abstract. In this part, the number N of drydockings of a ship during its lifetime is estimated as an equilibrium point in the trade off between maintenance and energy/environmental cost due to hull fouling promoted/accelerated by electrochemical corrosion and chemical/mechanical erosion. Sensitivity analysis of optimal number N_{opt} corresponding to minimum total cost at equilibrium point is performed to investigate the influence of higher price new antifouling/anticorrosive paints with lower environmental impact. The factors contributing to 'increased maintenance expenditure' (set as 'top event' to be examined) are determined/identified by means of Fault Tree Analysis (FTA) in its fuzzy version to count for uncertainty. A case example is presented, where (i) replacement of previous chemically active agents with more expensive ones and (ii) addition of new active agents within the antifouling/anticorrosive paint at dry docking are the independent/explanatory variables taken into account in FTA. The impact on the 'top event' is estimated as a crisp numerical index (after defuzzification) and the intermediate results, obtained in the bottom-up procedure, are discussed.

4.1 INTRODUCTION

The colonization of submerged surfaces in seawater by fouling organisms (barnacles, algae, mussels, etc.) is a significant problem for the shipping industry. Fouling on ship's hulls promoted/accelerated by electrochemical corrosion and chemical/mechanical erosion is estimated to be responsible for up to 87% of the structural problems recorded in ship maintenance sheets [1], and is translated to higher transport and maintenance costs as well as increased environmental impact [2]. Attached organisms increase drag, reducing a ship's speed under any given set of conditions and raising fuel consumption [3]. Currently, the method for fouling prevention is the use of paints containing various kinds of biocides, as silyl acrylate. As a consequence, high concentrations of the most frequently used biocides have been found in marinas worldwide (e.g. see [4, 5]) and in sediments along shipping lanes [6].

In recent decades the paint systems used in shipbuilding have undergone enormous development in correspondence with emerging regulations and legislation. Notwithstanding, the cost of antifouling, including some time off hire, loss of operating profit, costs of diversion, etc. is extremely high, especially when considering that the frequency of the necessary drydockings increases with the age of the vessel [7]. Once the antifoulant coating fails, fouling happens quickly, increasing maintenance expenditures to 77%. Note, however, that the cost of antifouling

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is also high, approximately equivalent to 1-2 months' operating profit of the ship; on one hand, antifouling is good value, but on the other, is not an operation to be undertaken profligately.

We can investigate the impact of new antifouling paints on the optimal number of drydockings N_{opt}, by splitting the total Expenditure E during the ship's lifetime, into two parts:

E_1 for maintenance (including all economic costs, mainly due to inconvenience in voyage arrangements and drydocking wastewater treatment/disposal) and E_2 for energy consumption (including environmental cost). Evidently, E_1 is an increasing function of N with an increasing rate since inconvenience is disproportionally increased when the time interval between successive drydockings is decreased (i.e., $dE_1/dN>0$, $d^2E_1/dN^2>0$). On the other hand, E_2 is a decreasing function of N with an increasing algebraic or a decreasing absolute rate (i.e., $dE_2/dN<0$, $d^2E_2/dN^2>0$ or $d|dE_2/dN|/dN<0$), due to the validity of the Law of diminishing returns. Obviously, N_{opt} is determined at $E_{min}=(E_1+E_2)_{min} \Rightarrow d(E_1+E_2)/dN=0$ or $ME_1=ME_2$, where $ME_1=dE_1/dN$, $ME_2=|dE_2/dN|$ are the corresponding marginal expenditures. When a new antifouling/anticorrosive paint is applied, the E_1-curve moves upwards to its new position E´1 by a constant increment resulting to unchanged

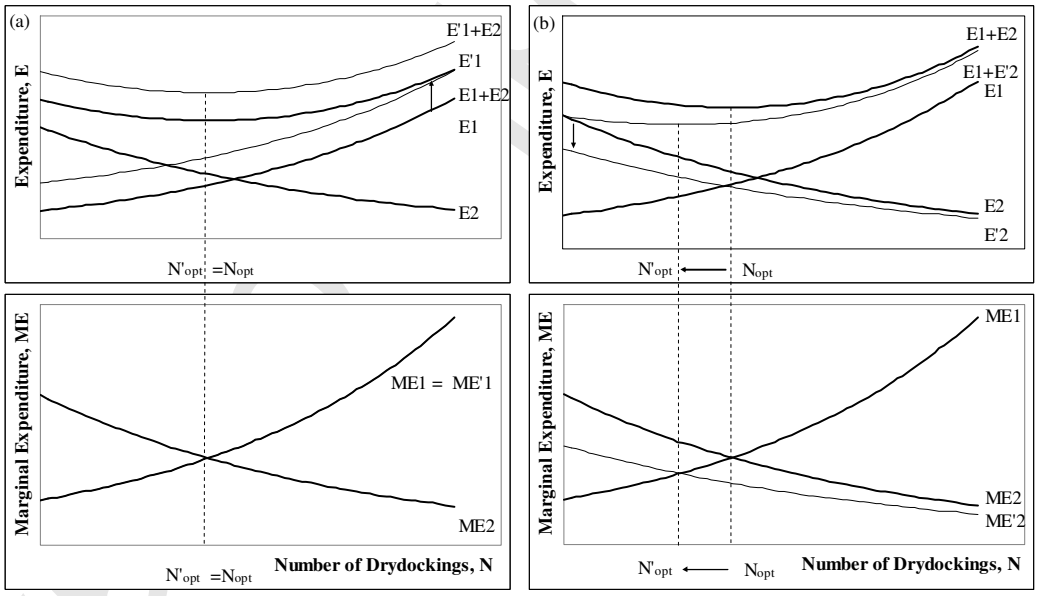

FIGURE 1. Determination of optimal number of drydockings N_{opt} as an equilibrium point of the trade-off between the partial expenditures during the ship's lifetime due to maintenance (E_1) and energy consumption (E_2); the influence of applying a new antifouling paint on the position of N_{opt}, because of the impact on each partial expenditure, is also shown.

N_{opt}, since the corresponding marginal expenditure remains the same (Fig. 1a). On the contrary, the E_2-curve moves downwards to its new position E'_2, becoming more flat, since expenditure decrease in the region of small N-values is more expressed in comparison with the previous situation where the relatively small number of drydockings was causing excessive energy consumption; as a result, N_{opt} is shifting to N'_{opt}, where $N'_{opt}<N_{opt}$ (Fig. 1b).

4.2 METHODOLOGY

The methodology adopted relies mainly on the design and the development of a hierarchical structure capable to perform Fault Tree Analysis (FTA) within a framework incorporating (a) the trunk of the fault tree (i.e., the content part of the fault analysis), (b) a mechanism of (i) assigning fuzzy partition of the space of the variables represented by each tree node and (ii) setting/revising of fuzzy rules used as an inference engine (i.e., the formal part of the fault analysis), and (c) a procedure for testing the node(s) depicted by the inference engine as most probable causes (final or intermediate events) responsible for the fault in order to verify/clarify the main source(s) of error and apply the appropriate remedial activities on *a priori* or *a posteriori* basis [8]. The tree is structured in a top-down direction by deduction; conversely, a revision can be made by induction, after proper information has been collected.

4.3 IMPLEMENTATION AND DISCUSSION

Part of the trunk of the fault tree referring to 'increased maintenance expenditure' (top event) is presented in Fig. 2, whereas the description of the included nodes is provided here below:

1. Increased maintenance expenditure.
  1.1. Higher cost before applying new coating
    1.1.1 Sealer coating needed
      1.1.1.1 Local electrochemical corrosion.
      1.1.1.2 Stress corrosion cracking.
    1.1.2 Additional anticorrosive layer is required.
      1.1.2.1 General pitting corrosion.
      1.1.2.2 Extended exfoliation.
        1.1.2.2.1 Corrosive action of fouling organisms.

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1.1.2.2.2 Surface inhomogeneity of metallic substrate.
1.1.2.2.2.1 Non-uniform distribution of alloying elements.
1.1.2.2.2.2 Surface dislocations
1.2. Higher cost on applying new coating.
1.2.1 Higher price of antifouling/anticorrosive paint.
1.2.1.1 Addition of new active agents.
1.2.1.2 Replacement of previous active agents with more expensive ones.
1.2.2. Higher expenditures for application on the pre-processed surface.
1.2.2.1 Stricter specifications for safety and occupational health.
1.2.2.2 Stricter specifications for waste treatment/disposal.
1.3 Decrease of coating lifetime.

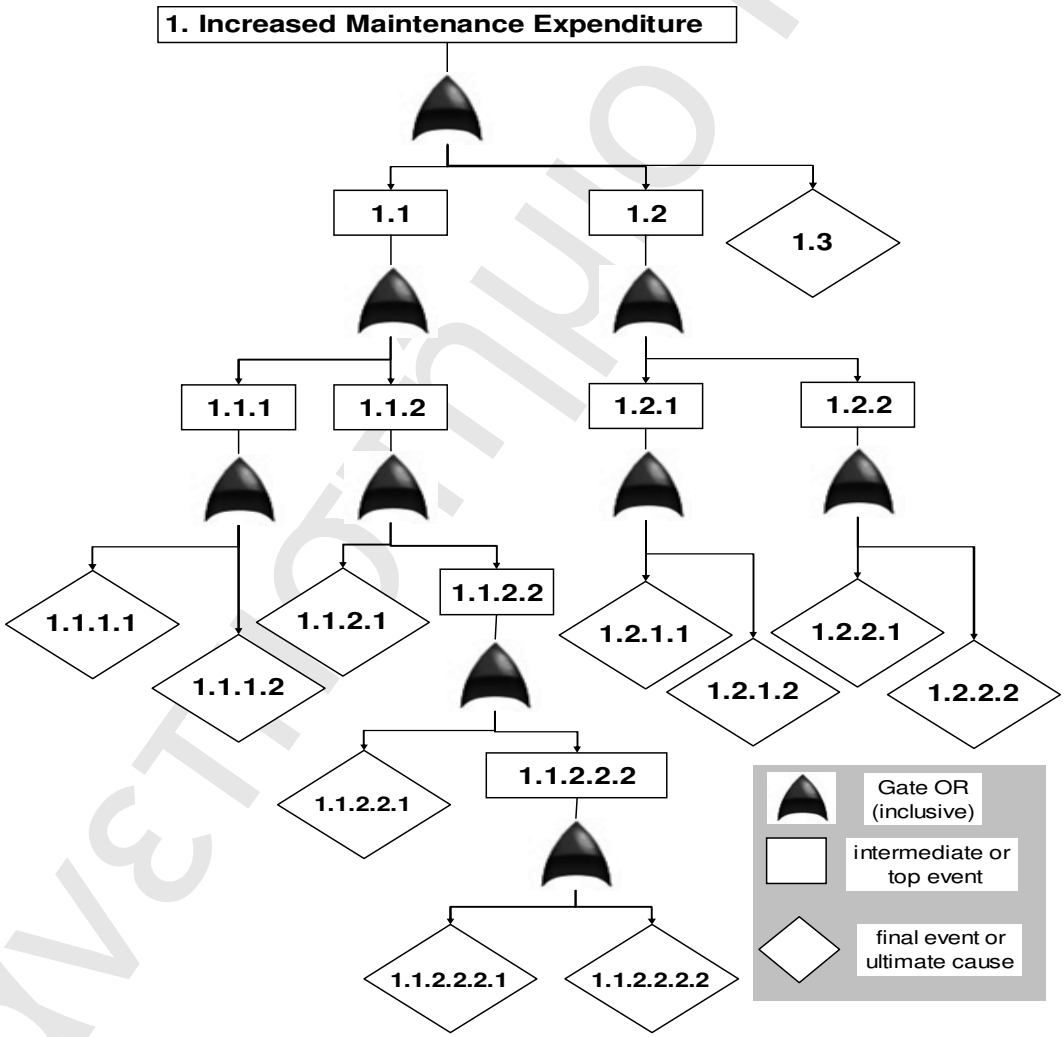

FIGURE 2. Part of the trunk of the 'Increased Maintenance Expenditure' fault tree, constituting the corresponding content part of the methodological framework (the formal being the mechanism of setting/revising the fuzzy rules).

An illustration of the inference achieved is given in Fig. 3, presenting the membership function (MFJ, J=L,M,H for Low, Medium, High level, respectively) for each variable participating within the fuzzy rules chain leading from the final events 1.2.1.1 and 1.2.1.2 (i.e., addition and replacement of agents, respectively) to the top event.

It is worthwhile noting that all values are expressed as means (within a time interval between two successive drydockings), since antifouling paints are subjected to intense chemical attach within the sea environment, almost 1 hour after hull's submersion: ions, pH, and temperature favor bioaccumulation at the surface of the paint, which after 15-20 days (depending on the antifoulant used) manages to establish a small viable colony [6]. The microorganisms secret polysaccharides which insulate the colony/paint border and protect the colony which, then, structures a biofilm with oxygen-flowing channels that promote electrochemical corrosion. The latter spreads across the steel structure of the hull below the antifoulant and beyond the colony/paint border, favoring paint exfoliation (from the inside out) and, thus, helping the spreading of the colony, which in its turn, by the secretion of secondary metabolites, dissolves the adhesives and favor the spreading of electrochemical corrosion (from the outside in). Thereby, a vicious cycle settles that is speeding up at each iteration resulting in failure after 12-20 months in water service life [1].

In order to prevent biofilm formation, current state-of-the-art paints utilize a controlled release mechanism, that allows the continuous feed of the outer paint surface with antifouling molecules for a period of six months, resulting in extending the ship's service life to 28-36 months [4]. Impregnation of paints with nanofibers has been also proposed; while a range of relevant products are already marketed, their high cost prevents application. After the application of an epoxy adhesive, the nanofibres (50-100nm in length and 2-10μm average thickness) are electrostatically charged and applied by spraying [5], in order to assure their orientation

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perpendicular to the surface before the drying of the adhesive. When the coating is submerged, the fibres move with the action of the current, giving rise to a movement on the coating surface which prevents the attachment of marine organisms. In combination with a suitable binder, as methacrylate, the fibres form a three-dimensional structure which originates an extremely strong and flexible coating, while at the same time maintaining the characteristic smoothness of a self-polishing antifouling paint. This technology has been proven quite effective in protecting the antifoulant surface in direct contact with the seawater, extending the ship's service lifetime to 48 months and decreasing maintenance expenditure, according to the FTA presented qualitatively in Fig. 2 and quantitatively in Fig. 3, by means of fuzzy set exogenous inputs and endogenous intermediate estimates.

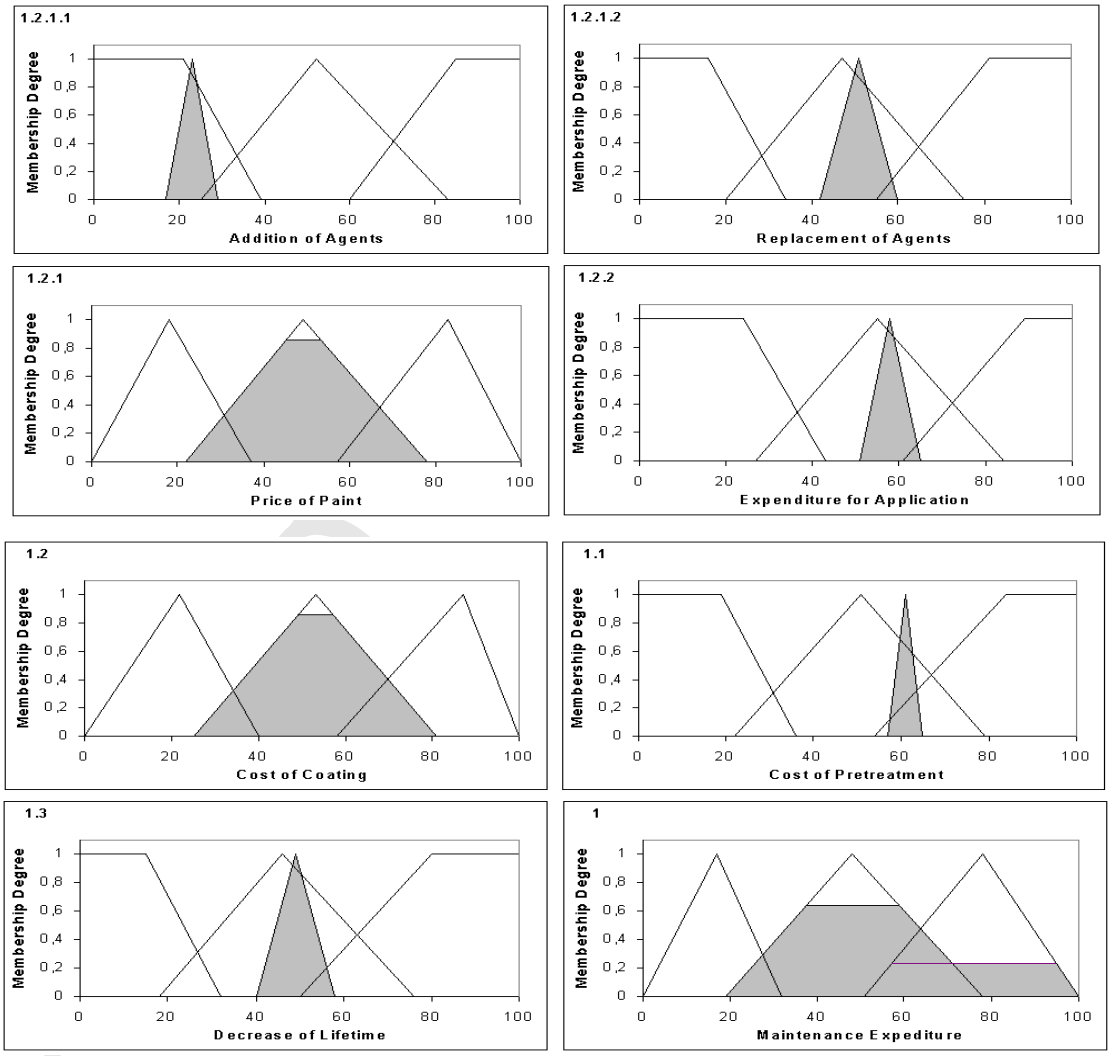

FIGURE 3. MFs for all variables participating within the fuzzy rules chain leading from the final event 1.2.1.1 to the top event (maintenance expenditure). The crisp results for each event (in bold) are: **1.2.1**: 49.68, MFM=0.86; **1.2**: 53.00, MFM=0.86; **1**:56.09, MFM=0.64, MFH=0.23.

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Conclusions

Multicriteria Choice of Ballast Seawater Treatment Method for Shipboard Installations in Bulk Carriers carried out with determination of optimal values of independent variables, based on the tradeoff between environmental/technical and economic partial conflict dependent variables. We have proved, by means of a case example referring to ranking ballast seawater treatment methods for shipboard installations in bulk carriers, that multicriteria analysis can be successfully applied in this discipline giving realistic results.

The employment of an especially designed biocide mixture for use on onboard ballast water treatment was studied by developing a methodological framework, and has been proved by means of Fault Tree Analysis. We set as top event the 'pathogen detection at the coastal area that ships deballast, while the final events, standing for the final causes, included faults due to both, design and operation. We suggested corresponding factors (namely predators or/and biocides) that should be added to a Lotka-Volera type model in order to present the simulated ecosystem more realistically. Such a suggestion can be also used for extending the KB already in service, functioning along with an Intelligent Agent, as shown in the algorithmic procedure that realizes the proposed methodological framework.

During the development of a knowledge base for optimizing ballast seawater processing, we have indicated the functionality of the methodological framework presented herein under the form of an algorithmic procedure (including 17 activity stages and 5 decision nodes) for developing a KB improving (and eventually optimizing) BST while correcting any fault during onboard operations. Although the case example used for implementing this methodology refers to a method well established from the physical/chemical point of view, we have suggested uncertainties that may appear, especially when the aspect of economics is involved.

Finally, we examined, the factors contributing to 'increased maintenance expenditure' (set as 'top event' to be examined) are determined/identified by means of Fault Tree Analysis (FTA) in its fuzzy version to count for uncertainty. We presented a case example, where replacement of previous chemically active agents with more expensive ones and addition of new active

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agents within the antifouling/anticorrosive paint at dry docking are the independent/explanatory variables taken into account in FTA. The impact on the 'top event' is estimated as a crisp numerical index (after defuzzification) and the intermediate results, obtained in the bottom-up procedure.

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i. Appendix

Ballast water treatment methods

Types of Treatment Technologies

The technologies currently available or being developed can generally be grouped under three broad categories based on their primary mechanism for rendering the organism inactive: mechanical, physical and chemical. These groups and the more promising technologies related to each are shown in Figure 1 and described briefly in the following text.

Mechanical Systems

• Filtration – sediment and particles are removed with disk and screen fi lters during ballast intake. They are often self-cleaning with a back-flushing cycle. The waste stream is directed overboard back to the water source. These filtration systems create pressure drops and a reduced flow rate due to resistance in the filter elements and the self-cleaning procedures.

• Cyclonic separation – solid particles are separated from the water due to centrifugal forces. Only those particles with a specific gravity greater than that of water can be separated.

• Electro-mechanical separation – a flocculent is injected that attaches to organisms and sediment. Magnetic separation and filtration is used to remove the solid particles.

Physical Disinfection

• Ultraviolet light – UV radiation is used to attack and break down the cell membrane killing the organism outright or destroying its ability to reproduce. The effectiveness depends on the turbidity of the ballast water (i.e. the concentration of sediments) as this could limit the transmission of the UV radiation. UV lights are required to be maintained and power consumption needs to be considered.

• Cavitation/ultrasounds – venturi pipes or slit plates are used to generate cavitation bubbles and this high energy bubble creation and collapse results in hydrodynamic forces and ultrasonic oscillations, or high frequency noise, which disrupts the cell walls of organisms effectively killing them.

• De-oxygenation – various methods are used to remove the dissolved oxygen in the ballast water and replace it with inactive gases, such as nitrogen or other inert gas. Removing the oxygen not only kills the aerobic organisms but it can also have benefits for corrosion prevention provided that the oxygen content is maintained at the correct levels. De-oxygenation can require a prolonged period in order to render the organisms and pathogens harmless to the receiving waters.

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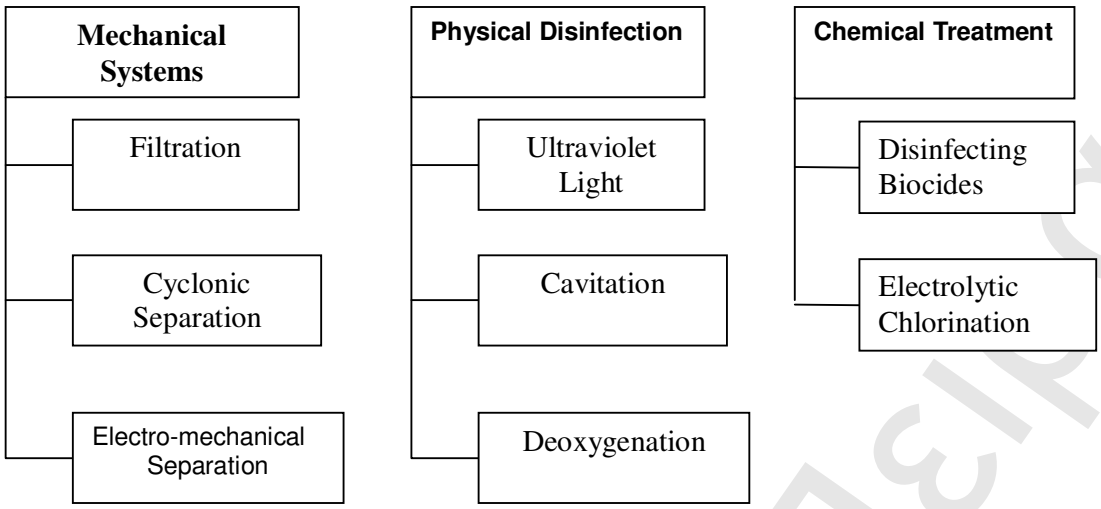

Figure 1: Treatment Technology Types

Chemical Treatment

• Chemical biocides – pre-prepared or packaged disinfectants designed to be dosed into the ballast flow and kill the living organisms by chemical poisoning or oxidation.
Typical biocides include chlorine, chloride ions, chlorine dioxide, sodium hypochlorite and ozone. Residual biocides in the ballast water must meet ballast discharge standards which may necessitate neutralization techniques.

• Electrolytic chlorination – electrical current is applied directly to the ballast water flow in an electrolytic chamber, generating free chlorine, sodium hypochlorite and hydroxyl radicals, causing electrochemical oxidation through the creation of ozone and hydrogen peroxide. This method is limited in effectiveness to seawater having a certain level of dissolved salt and, could also create unwanted residuals. Types of chemical treatments include Active Substances or Preparations. The official definitions given in the BWM Convention are as follows:

• Active substance – a substance or organism, including a virus or a fungus that has a general or specific action on or against harmful aquatic organisms and pathogens.

• Preparation – any commercial formulation containing one or more active substances including any additives. This term also includes any active substances generated on board for the purpose of ballast water treatment and any relevant chemicals formed in the ballast water treatment system that make use of active substances to comply with the BWM Convention.

Technical Challenges & System Combinations

The treatment technologies differ in method and rate of application, scalability, holding time (required for kill rates and safe discharge), power requirements, effects on other ship systems or structure (corrosion), inherent safety and costs of operation. In many cases their efficacy varies with conditions of the ballast water, flow rates, volume of water treated and holding time. There are also issues of whether treatment is done at intake, while being held on board, at discharge, or a combination of the three times.

For instance, filtration, separation and UV radiation are done during ballast loading and discharge and are sized for the maximum flow rate in the ballast system. Conversely chemical biocides and deoxygenation are usually applied to attain a certain concentration in the water in the ballast tanks. The efficacies of these systems do not depend so much on the flow rate of the pumps as the time the ballast is allowed to remain in the tanks to achieve the desired kill rate. Short voyages can be a problem

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for these technologies.

Matching the treatment technology to the ship type, or more accurately the ballast system type, and vessel service is the key to designing a successful ballast water treatment system.

To overcome the limitations of a particular technology many proposed treatment systems are based on a combination of two or more technologies. Although there are approved chemical disinfection only treatments, these are also combined with some form of pre-treatment to make them more effective for certain vessel or ballast conditions.

The most prevalent system types are ones that combine mechanical separation/filtration with UV radiation or chemical disinfection. The initial mechanical separation/filtration is used to remove the larger organisms in order to increase the effectiveness of the secondary treatments.

Considerations for Selection of Treatment Systems

Overview

Ballast water treatment is still an evolving technology with an ever-growing number of manufacturers developing systems to meet the anticipated regulatory requirements. Readers are urged to contact ABS or review the latest IMO information to determine the current status of treatment system approvals. This current situation means that there is limited in-service experience for the systems being offered and there is a general understanding that no single system is suitable for all ship types or service. The owner/operator must make a considered choice for the ballast water treatment that best suits the demands of the ship and service taking into account vendor specifi cations and the extent of shore side and shipboard testing carried out during the type approval process. A careful engineering analysis of the following factors bring order to the decision-making process. These issues are discussed in some detail as follows.

Ship and Vessel Service Characteristics that Impact BWT Selection

• Ship type and capacity

• Ballast water handling practices including NOBOBS (no ballast on board ships)

• Ballast water characteristics

• Vessel service characteristics

• Ballast system characteristics

Treatment Technology Factors

• Treatment method

• Treatment system pressure drops

• Equipment size and space requirements

• Materials, equipment protection (IP rating) and hazardous spaces

• Power requirements

• Impacts on ballast tank and pipe corrosion

• Health and safety (handling, operation and maintenance)

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General Treatment System Considerations

• Proven efficacy and official approvals

• Vendor qualifications and reputation

• Maintenance requirements and system reliability

• Simple operation (control and monitoring)

• Life cycle costs

Challenges for Installation Engineering

• Intake/discharge isolation (cross-contamination)

• Sampling and in-service testing

• Maintaining ballasting flexibility

Ship Type & Capacity

In most instances, the ship type will be the largest single determinant in selecting a suitable treatment system. For this purpose it is convenient to consider two groups of ship types: high ballast dependent ships such as tankers and bulkers; and low ballast dependent ships such as containerships, general cargo ships, and cruise ships. These groupings are based on differences in total ballast capacity, amount of discharge at any one port and ballast flow rates.

As the data in Table 8 indicates, there is a wide range of ballast capacities and pumping rates common to the commercial ship sector. Notably, the high ballast-dependent vessels regularly sail in ballast only conditions (without cargo). Their pump rates are designed to allow full load or discharge in a fixed period of time to facilitate rapid port turnaround times (typically 12, 18 or 24 hours for ballast operations). The low ballast dependent vessels generally have smaller ballast capacities and also may rarely undertake a ballast only voyage. Their pumps do not typically have to handle a full load of ballast on a regular basis. Movement of ballast is more limited and often is a shift (one tank to another to adjust trim or heel) rather than a simple full ballast load/discharge operation.

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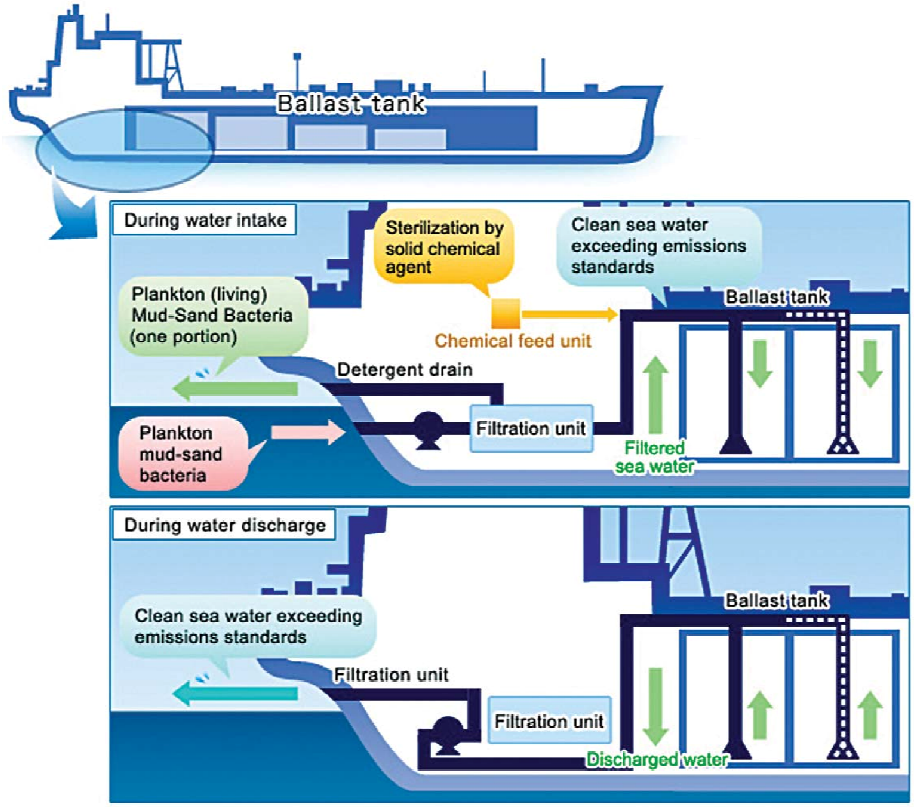

Diagram of Ballast Water Management System

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Ballast Water Handling Practices

The proper sizing of a treatment system depends on the amount of ballast that has to be treated at any given port, more so than the total ballast capacity or maximum flow rate. If, through active ballast management, discharge can be reduced or eliminated then treatment demands decrease. For example, most containerships rarely need to discharge a full ballast load at any one time.

It also should be noted that a large amount of the treatment system prototype testing is done on moderately sized systems (< 250 m3/hour) or is scaled up from other industries and not all systems scale up well to the sizes required for the high ballast capacity pumping rates or volumes of several thousand m^3/hour.

Another ballast practice issue that impacts treatment selection is how accumulated mud and silt in the ballast tanks is addressed. This residue itself can contain invasive species even when the tank is empty of water (a NOBOB – no ballast on board condition). Even if ballast is loaded locally it can become contaminated by the residue in the tank. This may necessitate the treatment of ballast water on discharge as well as loading. If there is little mud accumulation and the tanks are cleaned regularly, this may be less of a concern and the treatment system can be selected accordingly.
For those ships constructed in or after 2009, compliance with G12 guideline is to be applied.

Table 8: Ballast Water Capacity & Ballast Pump Rates by Vessel Type

Vessel Category	Vessel Type	Representative Ballast Capacity (m^3)	Representative Pump Rate (m^3/hr)
High Ballast Dependent Vessels	**Bulk Carriers**		
	Handy	18,000	1,300
	Panamax	35,000	1,800
	Capesize	65,000	3,000
	Tankers		
	Handy	6,500	1,100
	Handymax-Aframax	31,000	2,500
	Suezmax	54,000	3,125
	VLCC	90,000	5,000
	ULCC	95,000	5,800
Low Ballast Dependent Vessels	**Containerships**		
	Feeder	3,000	250
	Feedermax	3,500	400
	Handy	8,000	400
	Subpanamax	14,000	500
	Panamax	17,000	500
	Postpanamax	20,000	750
	***Other* Vessels**		
	Chemical Carriers	11,000	600
	Passenger Ships	3,000	250
	General Cargo	4,500	400
	Ro/Ro	8,000	400
	Combination Vessels	7,000	400

Vessel Service Characteristics

The vessel service or trade route may also be critical for treatment system selection. For example, certain ship types may not be discharging ballast in the US so there will be no concern for US regulations other than the reporting and recordkeeping requirements.

The key regulatory requirement and efficacy standards will be those from IMO. If treatment options for local requirements are too expensive, then operators that trade in those areas only occasionally may opt to forego shipboard installation of additional treatment capability. Instead they may adjust their ballast management to avoid discharge or pay high use costs for a shore/port based system (where available).

Common Ballast System Characteristics

There are also a number of other vessel features related to ship type that are not exclusive to the high/low ballast dependent categorization defined above yet have an impact on treatment system selection. These include the number of separate ballast systems (e.g., oil tankers often have two, one in way of the cargo area and one aft of the cargo), whether eductors are used to supplement ballast discharge, small or crowded engine rooms, or explosion proof ballast equipment requirements. How these features represent design challenges for treatment systems are discussed in the following sections.

Treatment Technology Factors

The second most important set of factors in selecting a suitable treatment system, after ship type and service, are the operating characteristics and requirements of the individual treatment technologies. As noted in Section 2 of this
Advisory, BWT Technologies, there are several type approved technologies that have satisfied the IMO D-2 standard and numerous technologies being actively researched and implemented that should
be able to meet the IMO discharge standards. These technologies differ in method and rate of application, scalability, required holding time, power and related system requirements, impacts on corrosion and inherent safety. Each ship's design,
as well as an owner's particular operating practices and internal risk assessments, will determine how important each of these factors is in the selection process. Taken together, these factors and how the treatment systems address them, indicate the level of analysis required for effective implementation of the particular treatment system.

The following describes treatment factors that should be considered.

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Treatment Method

The methods and technologies being considered
for ballast water treatment can be grouped by basic approach as follows:

- Mechanical systems (filtration or separation)
- Physical disinfection (UV radiation, cavitation, de-oxygenation, etc.)
- Chemical treatment (biocides and electro- chlorination)

Each system has a few fundamental characteristics that impact its suitability for certain ship types, service or flow rates. Most of the treatment systems use a combination of two or more of these technologies to overcome an individual technology's shortcomings.

Mechanical Systems
These require redirecting the full ballast flow through filters, hydrocyclones or other separators. For high volume applications, the size of the equipment required can be problematic. If they
are used during ballast discharge, the filtrate must be maintained on board. High sediment loads can cause problems for filters.

Physical Disinfection

Ultraviolet radiation and cavitation require processing of the entire ballast flow but holding time is not required as treatment is complete once the water passes through the equipment. UV exposure is usually done at both intake and discharge. Its effectiveness degrades with cloudy or turbid water that restricts light penetration.

De-oxygenation can be done at intake to the full ballast flow or directly in the ballast tanks with bubblers. However, the full kill rates may take several days to achieve so the ballast tanks must also have a closed vent system and be fully inerted.

Chemical Treatment

These treatments are dosed into the existing ballast piping during intake or directly into the ballast tanks. The dosage rates must be adjusted to provide the desired kill rate. The chemicals are
usually lethal within several hours of treatment so long holding times are not required. However, the chemicals must be neutralized or be allowed to become biologically ineffective before the ballast water can be considered safe for discharge.

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Table 9: Important Treatment Method Characteristics

Treatment Process	Method of Treatment	When Applied	Time for Lethality	Corrosion Potential
Chlorine Generation	Use electrolytic cell to generate chlorine and bromine that act as biocides. Next, sodium sulfate neutralizes the ballast water prior to discharge. As long as free chlorine exists in the tank, biocide will be active so dosage can be adjusted to keep biocide always active.	At uptake and neutralize at discharge	Hours	High dosage levels promote steel corrosion
Chemical Application	Mix proprietary chemicals with the ballast water in metered dosage rates at intake to kill living organisms. Chemicals degrade over time so ballast will be safe to discharge.	At uptake via eductor	24 hours	High dosage levels promote steel corrosion
Filtration & Radiation	Filtration of the incoming water, usually with self-cleaning 50 micron filters, in parallel with discharge of filtrate to the waters where intake takes place. Ballast water is exposed to a form of radiation, such as UV energy or other hydroxyl radical generator, to kill smaller organisms and bacteria.	At uptake for filter and UV and at discharge for UV	At treatment	No effect
De-oxygenation	Mix inert gas generated on board with the ballast water, either by a venturi eductor or by bubbling from pipes in the tanks. This removes oxygen from the water and lowers pH, therefore killing the living organisms. This process requires the atmosphere in the ballast tank be maintained in an inert condition.	At uptake for some systems and in tanks for others	4 to 6 days	Relatively less corrosive
Ozone Generation	Ozone is generated on board and acts as a biocide. It is applied during the ballast pumping process by eductor either at uptake or discharge. It can be combined with filtration or other methods of treatment.	At uptake for some systems and at discharge for others	Up to 15 hours	Limited effect as ozone has short life. If treated at discharge, no effect.

Treatment System Pressure Drops

The treatment systems that process the full ballast flow through filters, separation systems or venturi's, create added resistance to ballast flow. The pressure drops for such elements vary, with most systemsclaiming from less than 1 bar to about 2 bar. In some cases, back pressure valves may need to be added to the system after a separator to provide sufficient backpressure for clearing out sludge and/or self-cleaning. If the installation requires significant lengths of new ballast piping and valving then some additional pressure drops will be introduced that could prove significant.

The self cleaning or back-flushing operation will redirect some of the ballast flow directly overboard and reduce the flow rate into the tank further. Some hydrocyclones redirect between 5 percent to 10 percent of the flow stream for sludge removal.

The pressure drops and self cleaning process will impact in-service flow rates and system design pressure. For most ships it is not expected that ballast pumps will need to be upgraded. However, the actual flow rates of ballast delivered to the tanks achievable with the selected system must be used when evaluating ballasting times and operation of the treatment system. It could be that ballasting with some treatment systems with high pressure

drops and self-cleaning systems could take 20 percent longer than ballasting without treatment.

It should also be noted that at some level of additional system resistance, gravity ballasting may no longer be feasible because the pressure differentials with the sea water are reduced and acceptable flow rates cannot be maintained. Some separation equipment simply cannot run without sufficient system pressure drop. This will ultimately increase the total power required for the ballasting operation because the main pumps will have to be operated for a longer period.

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ii. APPENDIX

REGULATIONS

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 May 2012

concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

(2) Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation.

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

(4) To ensure a high level of protection for human health, animal health and the environment, this Regulation should apply without prejudice to Union legislation on safety in the workplace and environmental and consumer protection.

(5) Rules concerning the making available on the market of biocidal products within the Community were established by Directive 98/8/EC of the European Parliament and of the Council [3]. It is necessary to adapt those rules in the light of experience and in particular the report on the first seven years of the implementation submitted by the Commission to the European Parliament and the Council, which analyses problems with and weaknesses of that Directive.

[1] OJ C 347, 18.12.2010, p. 62.

[2] Position of the European Parliament of 22 September 2010 (OJ C 50 E, 21.2.2012, p. 73) and position of the Council at first reading of 21 June 2011 (OJ C 320 E, 1.11.2011, p. 1). Position of the European Parliament of 19 January 2012 (not yet published in the Official Journal) and decision of the Council of 10 May 2012.

[3] OJ L 123, 24.4.1998, p. 1.

(6) Taking into account the main changes that should be made to the existing rules, a regulation is the appropriate legal instrument to replace Directive 98/8/EC to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.

(7) A distinction should be drawn between existing active substances which were on the market in biocidal products on the transposition date set in Directive 98/8/EC and new active substances which were not yet on the market in biocidal products on that date. During the ongoing review of existing active substances, Member States should continue to allow biocidal products containing such substances to be made available on the market according to their national rules until a decision is taken on approval of those active substances. Following such a decision Member States, or, where appropriate, the Commission, should grant, cancel or modify authorisations as appropriate. New active substances should be reviewed before biocidal products containing them are placed on the market, so as to ensure that new products that are placed on the market comply with the requirements of this Regulation. However, to encourage the development of new active substances, the evaluation procedure for new active substances should not prevent Member States or the Commission from authorising, for a limited period of time, biocidal products containing an active substance before it is approved, provided that a full dossier has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set out in this Regulation.

(8) To ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier, or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products. Biocidal products containing active substances for which the relevant person does not comply with that obligation should no longer be made available on the market. In such cases, there should be appropriate phase-out periods for disposal and use of existing stocks of biocidal products.

(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.

(10) In order to ensure legal certainty, it is necessary to establish a Union list of active substances approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.

(11) This Regulation applies without prejudice to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency ([1]). Under certain conditions, biocidal active substances are exempt from the relevant provisions of that Regulation.

(12) With a view to achieving a high level of protection of human health, animal health and the environment, active substances with the worst hazard profiles should not be approved for use in biocidal products except in specific situations. These should include situations when approval is justified because of the negligible risk from exposure to the substance, human health, animal health or environmental reasons or the disproportionate negative impact for society of non-approval. When deciding if such active substances may be approved, the availability of suitable and sufficient alternative substances or technologies should also be taken into account.

(13) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are significant indications that an active substance used in biocidal products or treated articles does not meet the requirements of this Regulation, the Commission should be able to review the approval of the active substance.

(14) Active substances should be designated as candidates for substitution if they have certain intrinsic hazardous properties. In order to allow for a regular examination of substances identified as candidates for substitution, the approval period for those substances should not, even in the case of renewal, exceed seven years.

(15) In the course of granting or renewing the authorisation of a biocidal product that contains an active substance that is a candidate for substitution, it should be possible to compare the biocidal product with other authorised biocidal products, non-chemical means of control and prevention methods with regard to risks they pose and benefits from their use. As a result of such a comparative assessment, a biocidal product containing active substances identified as candidates for substitution should be prohibited or restricted where it is demonstrated that other authorised biocidal products or non-chemical control or prevention methods that present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages. Appropriate phase-out periods should be provided for in such cases.

([1]) OJ L 396, 30.12.2006, p. 1.

(16) In order to avoid unnecessary administrative and financial burdens for industry and competent authorities, a full in-depth evaluation of an application to renew the approval of an active substance or the authorisation of a biocidal product should be carried out only if the competent authority that was responsible for the initial evaluation decides that this is necessary on the basis of the available information.

(17) There is a need to ensure effective coordination and management of the technical, scientific and administrative aspects of this Regulation at Union level. The European Chemicals Agency set up under Regulation (EC) No 1907/2006 ('the Agency') should carry out specified tasks with regard to the evaluation of active substances as well as the Union authorisation of certain categories of biocidal products and related tasks. Consequently, a Biocidal Products Committee should be established within the Agency to carry out certain tasks conferred on the Agency by this Regulation.

(18) Certain biocidal products and treated articles as defined in the Regulation are also regulated by other Union legislation. It is therefore necessary to draw clear borderlines in order to ensure legal certainty. A list of product-types covered by this Regulation with an indicative set of descriptions within each type should be set out in an Annex to this Regulation.

(19) Biocidal products intended to be used not only for the purposes of this Regulation, but also in connection with medical devices, such as disinfectants used to disinfect surfaces in hospitals and medical devices, may pose risks other than those with which this Regulation is concerned. Therefore, such biocidal products should comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements set out in Annex I to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [2] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [3].

(20) Where a product has a biocidal function that is inherent to its cosmetic function, or where that biocidal function is considered to be a secondary claim of a cosmetic product and is therefore regulated under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [4], that function and the product should remain outside the scope of this Regulation.

(21) The safety of food and feed is subject to Union legislation, in particular Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [5]. Therefore, the present Regulation should not apply to food and feed used as repellents or attractants.

(22) Processing aids are covered by existing Union legislation, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [6] and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [7]. Therefore, it is appropriate to exclude them from the scope of this Regulation.

(23) As products used for the preservation of food or feed by the control of harmful organisms, previously covered by product-type 20, are covered by Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008, it is not appropriate to maintain that product-type.

(24) As the International Convention for the Control and Management of Ships' Ballast Water and Sediments provides for an effective assessment of the risks posed by ballast water management systems, the final approval and subsequent type-approval of such systems should be considered equivalent to the product authorisation required under this Regulation.

(25) To avoid possible negative effects on the environment, biocidal products that can no longer lawfully be made available on the market should be dealt with in accordance with Union legislation on waste, in particular Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste [8], as well as national legislation implementing that legislation.

(26) To facilitate the making available on the market throughout the Union of certain biocidal products with similar conditions of use in all Member States, it is appropriate to provide for Union authorisation of those products. In order to allow some time for the Agency to build up the necessary capacity and to gain experience with this procedure, the possibility to apply for Union authorisation should be extended through a step-wise approach to further categories of biocidal products with similar conditions of use in all Member States.

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, p. 1.
[3] OJ L 331, 7.12.1998, p. 1.
[4] OJ L 342, 22.12.2009, p. 59.
[5] OJ L 31, 1.2.2002, p. 1.
[6] OJ L 268, 18.10.2003, p. 29.
[7] OJ L 354, 31.12.2008, p. 16.
[8] OJ L 312, 22.11.2008, p. 3.

(27) The Commission should review experience with the provisions on Union authorisations and report to the European Parliament and the Council by 31 December 2017, accompanying its report with proposals for changes if appropriate.

(28) To ensure that only biocidal products that comply with the relevant provisions of this Regulation are made available on the market, biocidal products should be subject to authorisation either by competent authorities for making available on the market and use within the territory of a Member State or part of it, or by the Commission for making available on the market and use within the Union.

(29) To encourage the use of products with a more favourable environmental or human or animal health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products. Once authorised in at least one Member State, those products should be allowed to be made available on the market in all Member States without the need for mutual recognition, under certain conditions.

(30) To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

(31) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.

(32) To evaluate the risks that would arise from proposed uses of biocidal products, it is appropriate that applicants submit dossiers which contain the necessary information. Defining a data set for active substances and for biocidal products in which they are contained is necessary so as to assist both applicants seeking authorisation and competent authorities carrying out an evaluation to decide on authorisation.

(33) In the light of the diversity of both active substances and biocidal products not subject to the simplified authorisation procedure, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request the adaptation of the data requirements, as appropriate, including the waiving of data requirements which are not necessary or are impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide appropriate technical and scientific justification to support their requests.

(34) In order to help applicants, and in particular small and medium-sized enterprises (SMEs), to comply with the requirements of this Regulation, Member States should provide advice, for example by establishing helpdesks. This advice should be in addition to the operational guidance documents and other advice and assistance provided by the Agency.

(35) In particular, to ensure that applicants can effectively exercise the right to request the adaptation of data requirements, Member States should provide advice on this possibility and the grounds on which such requests could be made.

(36) To facilitate access to the market it should be possible to authorise a group of biocidal products as a biocidal product family. Biocidal products within a biocidal product family should have similar uses and the same active substances. Variations in the composition or the replacement of non-active substances should be specified, but may not adversely affect the level of risk or significantly reduce the efficacy of the products.

(37) When authorising biocidal products it is necessary to ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, or, in the case of vertebrates, unnecessary suffering and pain. Furthermore, they may not have, in the light of current scientific and technical knowledge, any unacceptable effect on human health, animal health or on the environment. Where appropriate, maximum residue limits for food and feed should be established with respect to active substances contained in a biocidal product to protect human and animal health. When these requirements are not met, biocidal products shall not be authorised unless their authorisation is justified because of the disproportionate negative impact for society of not authorising them when compared to the risks arising from their use.

(38) Where possible, the presence of harmful organisms should be avoided by means of suitable precautionary steps, such as proper warehousing of goods, compliance with relevant hygiene standards and immediate disposal of waste. As far as possible, biocidal products that pose lower risks for humans, animals and the environment should be used whenever they provide an effective remedy, and biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used only as a last resort.

(39) Some authorised biocidal products may present certain risks if used by the general public. It is therefore appropriate to provide that certain biocidal products should not generally be authorised for making available on the market for use by the general public.

Texto orientativo principios

(40) To avoid duplication of the evaluation procedures and to ensure free movement of biocidal products within the Union, procedures should be established to ensure that product authorisations granted in one Member State are recognised in other Member States.

(41) To enable closer cooperation between Member States in the evaluation of biocidal products and to facilitate biocidal products' market access, it should be possible to launch the mutual recognition procedure when applying for the first national authorisation.

(42) It is appropriate to lay down procedures for the mutual recognition of national authorisations and, in particular, to resolve any disagreements without undue delay. If a competent authority refuses mutual recognition of an authorisation or proposes to restrict it, a coordination group should try to reach an agreement on the action to be taken. If the coordination group does not succeed in finding an agreement within a specified time limit, the Commission should be empowered to take a decision. In case of technical or scientific questions, the Commission may consult the Agency before preparing its decision.

(43) However, considerations related to public policy or public security, environmental and human and animal health protection, the protection of national treasures and the absence of the target organisms might justify, following agreement with the applicant, Member States' refusal to grant an authorisation or decision to adjust the terms and conditions of the authorisation to be granted. If no agreement with the applicant can be found, the Commission should be empowered to take a decision.

(44) The use of biocidal products of certain product-types might give rise to animal welfare concerns. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products falling under such product-types, in so far as such derogations are justified and do not jeopardise the purpose of this Regulation regarding an appropriate level of protection of the internal market.

(45) In order to facilitate the functioning of the authorisation and mutual recognition procedures, it is appropriate to establish a system for the mutual exchange of information. To accomplish this, a Register for Biocidal Products should be established. Member States, the Commission and the Agency should use this Register to make available to each other the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.

(46) If the use of a biocidal product is in the interests of a Member State, but there is no applicant interested in making available on the market such a product in the

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Member State, official or scientific bodies should be able to apply for an authorisation. If they are granted an authorisation, they should have the same rights and obligations as any other authorisation holder.

(47) To take account of scientific and technical developments as well as the needs of authorisation holders, it is appropriate to specify under which conditions authorisations can be cancelled, reviewed or amended. The notification and exchange of information which may affect authorisations is also necessary to enable competent authorities and the Commission to take appropriate action.

(48) In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to permit, for a limited period of time, the making available on the market of biocidal products which do not comply with the requirements of this Regulation.

(49) To encourage research and development in active substances and biocidal products, it is necessary to establish rules concerning the making available on the market and use of unauthorised biocidal products and non-approved active substances for the purposes of research and development.

(50) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade in identical biocidal products authorised in different Member States.

(51) To determine, where necessary, the similarity of active substances, it is appropriate to lay down rules concerning technical equivalence.

(52) To protect human health, animal health and the environment, and to avoid discrimination between treated articles originating in the Union and treated articles imported from third countries, all treated articles placed on the internal market should contain only approved active substances.

(53) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled.

(54) Applicants that have invested in supporting the approval of an active substance or the authorisation of a biocidal product in accordance with this Regulation or Directive 98/8/EC should be able to recover part of their investment by receiving equitable compensation whenever use of proprietary information which they submitted in support of such approval or authorisation is made for the benefit of subsequent applicants.

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(55) With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

(56) To encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the approval of such active substances or the authorisation of biocidal products containing them which is longer than the period of protection for information concerning existing active substances and biocidal products containing them.

(57) It is essential to minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products, to be carried out only when the purpose and use of a product so requires. Applicants should share, and not duplicate, studies on vertebrates in exchange for equitable compensation. In the absence of an agreement on sharing of studies on vertebrates between the data owner and the prospective applicant, the Agency should allow the use of the studies by the prospective applicant without prejudice to any decision on compensation made by national courts. Competent authorities and the Agency should have access to the contact details of the owners of such studies via a Union register so as to inform prospective applicants.

(58) A level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of equitable compensation of the costs borne by data owners.

(59) The generation of information by alternative means not involving tests on animals which are equivalent to prescribed tests and test methods should also be encouraged. In addition, the adaptation of data requirements should be used to prevent unnecessary costs related to testing.

(60) To ensure that the requirements laid down with respect to the safety and quality of authorised biocidal products are satisfied when they are made available on the market, Member States should take measures for appropriate control and inspection arrangements and manufacturers should maintain a suitable and proportionate quality control system. To this end, it may be appropriate for Member States to take action together.

(61) Effective communication of information on risks resulting from biocidal products and risk management measures is an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful to the commercial interests of the person concerned, except where it is necessary for the protection of human health, safety or the environment or for other reasons of overriding public interest.

(62) To increase the efficiency of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, authorisation holders should keep records of the products they place on the market.

(63) It is necessary to specify that provisions concerning the Agency laid down in Regulation (EC) No 1907/2006 should apply accordingly in the context of biocidal active substances and products. Where separate provisions need to be made with respect to the tasks and functioning of the Agency under this Regulation, they should be specified in this Regulation.

(64) The costs of the procedures associated with the operation of this Regulation need to be recovered from those making biocidal products available on the market and those seeking to do so in addition to those supporting the approval of active substances. To promote the smooth operation of the internal market, it is appropriate to establish certain common principles applicable both to fees payable to the Agency and to Member States' competent authorities, including the need to take into account, as appropriate, the specific needs of SMEs.

(65) It is necessary to provide for the possibility of an appeal against certain decisions of the Agency. The Board of Appeal set up within the Agency by Regulation (EC) No 1907/2006 should also process appeals against decisions adopted by the Agency under this Regulation.

(66) There is scientific uncertainty about the safety of nanomaterials for human health, animal health and the environment. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials, if possible based on the work of appropriate international forums and to specify that the approval of an active substance does not include the nanomaterial form unless explicitly mentioned. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(67) To ensure a smooth transition, it is appropriate to provide for a deferred application of this Regulation and to provide for specific measures concerning the assessment of applications for the approval of active substances and authorisation of biocidal products submitted before the application of this Regulation.

(68) The Agency should take over the coordination and facilitation tasks for new submissions for approval of active substances as of the date of applicability of this Regulation. However, in view of the high number of historical dossiers it is appropriate to allow some time for the Agency to prepare for the new tasks related to dossiers submitted under Directive 98/8/EC.

(69) To respect the legitimate expectations of companies with respect to the placing on the market and use of low-risk biocidal products covered by Directive 98/8/EC, those companies should be allowed to make such products available on the market if they comply with the rules on the registration of low-risk biocidal products under that Directive. However, this Regulation should apply after the expiry of the first registration.

(70) Taking into consideration that some products were not covered by Community legislation on biocidal products, it is appropriate to provide for transitional periods for such products and treated articles.

(71) This Regulation should take account, as appropriate, of other work programmes concerned with the review or authorisation of substances and products, or relevant international Conventions. In particular, it should contribute to the fulfilment of the Strategic Approach to International Chemicals Management adopted on 6 February 2006 in Dubai.

(72) In order to supplement or amend this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of certain non-essential elements of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(73) The Commission should adopt immediately applicable delegated acts where, in duly justified cases relating to the restriction of an active substance in Annex I or to the removal of an active substance from that Annex, imperative grounds of urgency so require.

(74) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers [1].

(75) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the approval of an active substance or to the cancelling of an approval, imperative grounds of urgency so require.

(76) Since the objective of this Regulation, namely, to improve the functioning of the internal market for biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment cannot be sufficiently achieved by the Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Purpose and subject matter

1. The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

2. This Regulation lays down rules for:

(a) the establishment at Union level of a list of active substances which may be used in biocidal products;

(b) the authorisation of biocidal products;

[1] OJ L 55, 28.2.2011, p. 13.

(c) the mutual recognition of authorisations within the Union;

(d) the making available on the market and the use of biocidal products within one or more Member States or the Union;

(e) the placing on the market of treated articles.

Article 2

Scope

1. This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2. Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:

(a) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community [1];

(b) Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC;

(c) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [4];

(d) Regulation (EC) No 1831/2003;

(e) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [5] and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [6];

(f) Regulation (EC) No 1333/2008;

(g) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods [7];

(h) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed [8];

(i) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market [9];

(j) Regulation (EC) No 1223/2009;

(k) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys [10].

Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.

3. Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the following instruments:

(a) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [11];

(b) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work [12];

(c) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work [13];

(d) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [14];

[1] OJ L 92, 7.4.1990, p. 42.
[2] OJ L 311, 28.11.2001, p. 1.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 136, 30.4.2004, p. 1.
[5] OJ L 139, 30.4.2004, p. 1.
[6] OJ L 139, 30.4.2004, p. 55.
[7] OJ L 354, 31.12.2008, p. 34.
[8] OJ L 229, 1.9.2009, p. 1.
[9] OJ L 309, 24.11.2009, p. 1.
[10] OJ L 170, 30.6.2009, p. 1.
[11] OJ 196, 16.8.1967, p. 1.
[12] OJ L 183, 29.6.1989, p. 1.
[13] OJ L 131, 5.5.1998, p. 11.
[14] OJ L 330, 5.12.1998, p. 32.

(e) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ([1]);

(f) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ([2]);

(g) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([3]);

(h) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ([4]);

(i) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants ([5]);

(j) Regulation (EC) No 1907/2006;

(k) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising ([6]);

(l) Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals ([7]);

(m) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ([8]);

(n) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides ([9]);

(o) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer ([10]);

(p) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes ([11]);

(q) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions ([12]).

4. Article 69 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5. This Regulation shall not apply to:

(a) food or feed used as repellents or attractants;

(b) biocidal products when used as processing aids.

6. Biocidal products which obtained final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VIII of this Regulation. Articles 47 and 68 shall apply accordingly.

7. Nothing in this Regulation shall prevent Member States from restricting or banning the use of biocidal products in the public supply of drinking water.

8. Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.

9. The disposal of active substances and biocidal products shall be carried out in accordance with the Union and national waste legislation in force.

Article 3

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'biocidal product' means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

([1]) OJ L 200, 30.7.1999, p. 1.
([2]) OJ L 262, 17.10.2000, p. 21.
([3]) OJ L 327, 22.12.2000, p. 1.
([4]) OJ L 158, 30.4.2004, p. 50.
([5]) OJ L 158, 30.4.2004, p. 7.
([6]) OJ L 376, 27.12.2006, p. 21.
([7]) OJ L 204, 31.7.2008, p. 1.
([8]) OJ L 353, 31.12.2008, p. 1.
([9]) OJ L 309, 24.11.2009, p. 71.
([10]) OJ L 286, 31.10.2009, p. 1.
([11]) OJ L 276, 20.10.2010, p. 33.
([12]) OJ L 334, 17.12.2010, p. 17.

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

(b) 'micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

(c) 'active substance' means a substance or a micro-organism that has an action on or against harmful organisms;

(d) 'existing active substance' means a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

(e) 'new active substance' means a substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

(f) 'substance of concern' means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

Such a substance would, unless there are other grounds for concern, normally be:

— a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

— a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,

— a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;

(g) 'harmful organism' means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

(h) 'residue' means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

(i) 'making available on the market' means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

(j) 'placing on the market' means the first making available on the market of a biocidal product or of a treated article;

(k) 'use' means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;

(l) 'treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

(m) 'national authorisation' means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;

(n) 'Union authorisation' means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;

(o) 'authorisation' means national authorisation, Union authorisation or authorisation in accordance with Article 26;

(p) 'authorisation holder' means the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation;

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(q) 'product-type' means one of the product-types specified in Annex V;

(r) 'single biocidal product' means a biocidal product with no intended variations as to the percentage of the active or non-active substances it contains;

(s) 'biocidal product family' means a group of biocidal products having similar uses, the active substances of which have the same specifications, and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products;

(t) 'letter of access' means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation;

(u) 'food' and 'feed' mean food as defined in Article 2 of Regulation (EC) No 178/2002 and feed as defined in Article 3(4) of that Regulation;

(v) 'processing aid' means any substance falling within the definition of point (b) of Article 3(2) of Regulation (EC) No 1333/2008 or point (h) of Article 2(2) of Regulation (EC) No 1831/2003;

(w) 'technical equivalence' means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;

(x) 'Agency' means the European Chemicals Agency established by Regulation (EC) No 1907/2006;

(y) 'advertisement' means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

(z) 'nanomaterial' means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

— 'particle' means a minute piece of matter with defined physical boundaries,

— 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

— 'aggregate' means a particle comprising strongly bound or fused particles;

(aa) 'administrative change' means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

(ab) 'minor change' means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;

(ac) 'major change' means an amendment of an existing authorisation which is neither an administrative change nor a minor change;

(ad) 'vulnerable groups' means persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents;

(ae) 'small and medium-sized enterprises' or 'SMEs' means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ([1]).

2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:

(a) 'substance';

(b) 'mixture';

(c) 'article';

(d) 'product and process-orientated research and development';

(e) 'scientific research and development'.

([1]) OJ L 124, 20.5.2003, p. 36.

3. The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial [1], and whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 in order to adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress and taking into account the Recommendation 2011/696/EU.

CHAPTER II

APPROVAL OF ACTIVE SUBSTANCES

Article 4

Conditions for approval

1. An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.

2. The approval of an active substance shall be restricted to those product-types for which relevant data have been submitted in accordance with Article 6.

3. The approval shall specify the following conditions, as appropriate:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) the product-type;

(d) manner and area of use including, where relevant, use in treated articles;

(e) designation of categories of users;

(f) where relevant, characterisation of the chemical identity with regard to stereoisomers;

(g) other particular conditions based on the evaluation of the information related to that active substance;

(h) the date of approval and the expiry date of the approval of the active substance.

[1] OJ L 275, 20.10.2011, p. 38.

4. The approval of an active substance shall not cover nanomaterials except where explicitly mentioned.

Article 5

Exclusion criteria

1. Subject to paragraph 2, the following active substances shall not be approved:

(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;

(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;

(c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;

(d) active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;

(e) active substances which meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006.

2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:

(a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

(b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

(c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.

The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. The use of the biocidal product with the active substances concerned shall be restricted to Member States in which at least one of the conditions set out in this paragraph is met.

3. No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties.

Pending the adoption of those criteria, active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.

Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.

Article 6

Data requirements for an application

1. An application for approval of an active substance shall contain at least the following elements:

(a) a dossier for the active substance satisfying the requirements set out in Annex II;

(b) a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and

(c) if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

2. Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:

(a) the data are not necessary owing to the exposure associated with the proposed uses;

(b) it is not scientifically necessary to supply the data; or

(c) it is not technically possible to generate the data.

However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1), if required by the evaluating competent authority under Article 8(2).

3. An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for determining what constitutes adequate justification to adapt the data requirements under paragraph 1 of this Article on the grounds referred to in point (a) of paragraph 2 of this Article.

Article 7

Submission and validation of applications

1. The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance of the application and its unique identification code.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1), and any justifications for the adaptation of data requirements, have been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

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4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

5. On validating an application in accordance with paragraph 3 or 4, the evaluating competent authority shall without delay inform the applicant, the Agency and other competent authorities accordingly, indicating the date of the validation.

6. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 8

Evaluation of applications

1. The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. As specified in the second subparagraph of Article 6(2), the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

3. Where the evaluating competent authority considers that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

4. Within 270 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the approval of the active substance having regard to the conclusions of the evaluating competent authority.

Article 9

Approval of an active substance

1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either:

(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or

(b) in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

2. Approved active substances shall be included in a Union list of approved active substances. The Commission shall keep the list up to date and make it electronically available to the public.

Article 10

Active substances which are candidates for substitution

1. An active substance shall be considered a candidate for substitution if any of the following conditions are met:

(a) it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);

(b) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

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(c) its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;

(d) it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006;

(e) there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;

(f) it contains a significant proportion of non-active isomers or impurities.

2. When preparing its opinion on the approval or renewal of the approval of an active substance, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

3. Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 66 and 67, information on potential candidates for substitution during a period of no more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

4. By way of derogation from Article 4(1) and Article 12(3), the approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.

5. Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in the relevant Regulation adopted in accordance with Article 9.

Article 11

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter, in particular Article 5(2) and Article 10(1).

CHAPTER III

RENEWAL AND REVIEW OF APPROVAL OF AN ACTIVE SUBSTANCE

Article 12

Conditions for renewal

1. The Commission shall renew the approval of an active substance if the active substance still meets the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

2. In the light of scientific and technical progress, the Commission shall review and, where appropriate, amend the conditions specified for the active substance referred to in Article 4(3).

3. The renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation adopted in accordance with point (a) of Article 14(4) renewing such an approval.

Article 13

Submission and acceptance of applications

1. Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

2. When applying for the renewal of the approval of the active substance, the applicant shall submit:

(a) without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial approval or, as appropriate, previous renewal; and

(b) its assessment of whether the conclusions of the initial or previous assessment of the active substance remain valid and any supporting information.

3. The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance.

4. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 14

Evaluation of applications for renewal

1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating competent authority shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

2. Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1, 2 and 3 of Article 8.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application in accordance with Article 13(3), prepare and submit to the Agency a recommendation on the renewal of the approval of the active substance. It shall provide the applicant with a copy of its recommendation.

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, notify the applicant of the fees payable under Article 80(2). The evaluating competent authority shall reject the application if the applicant fails to pay the fees within 30 days of the notification and shall inform the applicant accordingly.

3. Within 270 days of receipt of a recommendation from the evaluating competent authority, if it has carried out a full evaluation of the application, or 90 days otherwise, the Agency shall prepare and submit to the Commission an opinion on renewal of the approval of the active substance.

4. The Commission shall, on receipt of the opinion of the Agency, adopt:

(a) an implementing regulation providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or

(b) an implementing decision that the approval of an active substance is not renewed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 9(2) shall apply.

5. Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Commission shall, by means of implementing acts, adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

6. Where the Commission decides not to renew or decides to amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 15

Review of approval of an active substance

1. The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. The Commission shall make publicly available the information that it is carrying out a review and shall provide an opportunity for applicant to submit comments. The Commission shall take due account of those comments in its review.

Where those indications are confirmed, the Commission shall adopt an implementing Regulation amending the conditions of approval of an active substance or cancelling its approval. That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 82(3). Article 9(2) shall apply. The Commission shall inform the initial applicants for the approval accordingly.

On duly justified imperative grounds of urgency the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 82(4).

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of approval of an active substance. The Agency shall, within 270 days of the request, prepare an opinion and submit it to the Commission.

3. Where the Commission decides to cancel or amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 16

Implementing measures

The Commission may adopt, by means of implementing acts, detailed measures for the implementation of Articles 12 to 15, further specifying the procedures for the renewal and review of the approval of an active substance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

1. Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.

2. Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder.

Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State ('the receiving competent authority').

Applications for Union authorisation shall be submitted to the Agency.

3. An authorisation may be granted for a single biocidal product or a biocidal product family.

4. An authorisation shall be granted for a maximum period of 10 years.

5. Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.

Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.

Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

7. The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 18

Measures geared to the sustainable use of biocidal products

By 18 July 2015 the Commission shall, on the basis of experience gained with the application of this Regulation, submit to the European Parliament and the Council a report on how this Regulation is contributing to the sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human health, animal health and the environment by biocidal products. That report shall, inter alia, examine:

(a) the promotion of best practices as a means of reducing the use of biocidal products to a minimum;

(b) the most effective approaches for monitoring the use of biocidal products;

(c) the development and application of integrated pest management principles with respect to the use of biocidal products;

(d) the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater and whether additional measures are needed to address those risks;

(e) the role that improved performance of the equipment used for applying biocidal products could play in sustainable use.

On basis of that report, the Commission shall, if appropriate, submit a proposal for adoption in accordance with the ordinary legislative procedure.

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Article 19

Conditions for granting an authorisation

1. A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

(a) the active substances are approved for the relevant product-type and any conditions specified for those active substances are met;

(b) it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;

(ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

(iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— the fate and distribution of the biocidal product in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— the impact of the biocidal product on non-target organisms,

— the impact of the biocidal product on biodiversity and the ecosystem;

(c) the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

(d) the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product;

(e) where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1], Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food [2], Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [3], Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [4] or Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed [5];

(f) where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

2. The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

(a) realistic worst case conditions under which the biocidal product may be used;

(b) the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

(c) the consequences of use and disposal of the biocidal product;

(d) cumulative effects;

(e) synergistic effects.

3. A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20.

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[1] OJ L 37, 13.2.1993, p. 1.
[2] OJ L 338, 13.11.2004, p. 4.
[3] OJ L 70, 16.3.2005, p. 1.
[4] OJ L 152, 16.6.2009, p. 11.
[5] OJ L 140, 30.5.2002, p. 10.

4. A biocidal product shall not be authorised for making available on the market for use by the general public where:

(a) it meets the criteria according to Directive 1999/45/EC for classification as:

— toxic or very toxic,

— a category 1 or 2 carcinogen,

— a category 1 or 2 mutagen, or

— toxic for reproduction category 1 or 2;

(b) it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:

— acute oral toxicity category 1 or 2 or 3,

— acute dermal toxicity category 1 or 2 or 3,

— acute inhalation toxicity (gases and dust/mist) category 1 or 2 or 3,

— acute inhalation toxicity (vapours) category 1 or 2,

— a category 1A or 1B carcinogen,

— a category 1A or 1B mutagen, or

— toxic for reproduction category 1A or 1B;

(c) it meets the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;

(d) it has endocrine-disrupting properties; or

(e) it has developmental neurotoxic or immunotoxic effects.

5. Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.

6. In the case of a biocidal product family, a reduction in the percentage of one or more active substances may be allowed, and/or a variation in percentage of one or more non-active substances, and/or the replacement of one or more non-active substances by other specified substances presenting the same or lower risk. The classification, hazard and precautionary statements for each product within the biocidal product family shall be the same (with the exception of a biocidal product family comprising a concentrate for professional use and ready-for-use products obtained through dilution of that concentrate).

A biocidal product family shall be authorised only if all the biocidal products within it, taking into account the permitted variations referred to in the first subparagraph, are expected to comply with the conditions set out in paragraph 1.

7. Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of maximum residue limits with respect to active substances contained in a biocidal product in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 1935/2004, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 or Directive 2002/32/EC.

8. Where, for active substances covered by Article 10(1)(a) of Regulation (EC) No 470/2009, no maximum residue limit has been established in accordance with Article 9 of that Regulation at the time of the approval of the active substance, or where a limit established in accordance with Article 9 of that Regulation needs to be amended, the maximum residue limit shall be established or amended in accordance with the procedure referred to in Article 10(1)(b) of that Regulation.

9. Where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009.

Article 20

Requirements for applications for authorisation

1. The applicant for an authorisation shall submit the following documents together with the application:

(a) for biocidal products other than biocidal products meeting the conditions laid down in Article 25:

(i) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;

(ii) a summary of the biocidal product characteristics including the information referred to in points (a), (b) and (e) to (q) of Article 22(2), as applicable;

(iii) a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product;

(b) for biocidal products that the applicant considers meet the conditions laid down in Article 25:

(i) a summary of the biocidal product characteristics as referred to in point (a)(ii) of this paragraph;

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

2. The receiving competent authority may require that applications for national authorisation be submitted in one or more of the official languages of the Member State where that competent authority is situated.

3. For applications for Union authorisations submitted under Article 43, the applicant shall submit the summary of the biocidal product characteristics referred to in point (ii) of paragraph (1)(a) of this Article in one of the official languages of the Union accepted by the evaluating competent authority at the time of application and in all official languages of the Union before the authorisation of the biocidal product.

Article 21

Waiving of data requirements

1. By way of derogation from Article 20, the applicant need not provide data required under that Article where any of the following applies:

(a) the data are not necessary owing to the exposure associated with the proposed uses;

(b) it is not scientifically necessary to supply the data; or

(c) it is not technically possible to generate the data.

2. The applicant may propose to adapt the data requirements of Article 20 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

3. In order to ensure the harmonised application of paragraph 1(a) of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for defining when the exposure associated with the proposed uses would justify adapting the data requirements of Article 20.

Article 22

Content of authorisation

1. An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.

2. Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:

(a) trade name of the biocidal product;

(b) name and address of the authorisation holder;

(c) date of the authorisation and its date of expiry;

(d) authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %;

(f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites);

(g) manufacturers of the active substances (names and addresses including location of manufacturing sites);

(h) type of formulation of the biocidal product;

(i) hazard and precautionary statements;

(j) product-type and, where relevant, an exact description of the authorised use;

(k) target harmful organisms;

(l) application doses and instructions for use;

(m) categories of users;

(n) particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;

(o) instructions for safe disposal of the product and its packaging;

(p) conditions of storage and shelf-life of the biocidal product under normal conditions of storage;

(q) where relevant, other information about the biocidal product.

Article 23

Comparative assessment of biocidal products

1. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).

2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.

3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI ('comparative assessment') demonstrates that both of the following criteria are met:

(a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;

(b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.

5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying the criteria for determining when comparative assessments involve questions better addressed at Union level and the procedures for such comparative assessments.

6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years.

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect four years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

Article 24

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Article 22(2) and Article 23(3).

CHAPTER V

SIMPLIFIED AUTHORISATION PROCEDURE

Article 25

Eligibility for the simplified authorisation procedure

For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible if all the following conditions are met:

(a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;

(b) the biocidal product does not contain any substance of concern;

(c) the biocidal product does not contain any nanomaterials;

(d) the biocidal product is sufficiently effective; and

(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Article 26

Applicable procedure

1. Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The evaluating competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the evaluating competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

3. Within 90 days of accepting an application, the evaluating competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees paid in accordance with Article 80(2) shall be reimbursed.

Article 27

Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure

1. A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product's labelling, unless that Member State provides otherwise.

2. Where a Member State other than that of the evaluating competent authority considers that a biocidal product authorised in accordance with Article 26 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Article 25, it may refer that matter to the coordination group established in accordance with Article 35(1). Article 35(3) and Article 36 shall apply *mutatis mutandis*.

Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that Member State may provisionally restrict or prohibit making available on the market or use of that product on its territory.

Article 28

Amendment of Annex I

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article.

2. Active substances give rise to concern where:

(a) they meet the criteria for classification according to Regulation (EC) No 1272/2008 as:

— explosive/highly flammable,

— organic peroxide,

— acutely toxic of category 1, 2 or 3,

— corrosive of category 1A, 1B or 1C,

— respiratory sensitiser,

— skin sensitiser,

— germ cell mutagen of category 1 or 2;

— carcinogen of category 1 or 2,

— human reproductive toxicant of category 1 or 2 or with effects on or via lactation,

— specific target organ toxicant by single or repeated exposure, or

— toxic to aquatic life of acute category 1;

(b) they fulfil any of the substitution criteria set out in Article 10(1); or

(c) they have neurotoxic or immunotoxic properties.

Active substances also give rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

3. The Commission shall also be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 25. Where imperative grounds of urgency so require, the procedure provided for in Article 84 shall apply to delegated acts adopted pursuant to this paragraph.

4. The Commission shall apply paragraph 1 or 3 at its own initiative or at the request of an economic operator or a Member State providing the necessary evidence as referred to in those paragraphs.

Whenever the Commission amends Annex I it shall adopt a separate delegated act in respect of each substance.

5. The Commission may adopt implementing acts further specifying the procedures to be followed with respect to an amendment of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

CHAPTER VI

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 29

Submission and validation of applications

1. Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the receiving competent authority. The receiving competent authority shall inform the applicant of the fees payable under Article 80(2), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 80(2), the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

2. Within 30 days of acceptance, the receiving competent authority shall validate the application if it complies with the following requirements:

(a) the relevant information referred to in Article 20 has been submitted; and

(b) the applicant states that it has not applied to any other competent authority for a national authorisation for the same biocidal product for the same use(s).

In the context of the validation referred to in the first subparagraph, the receiving competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

3. Where the receiving competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The receiving competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in paragraph 2.

The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly.

4. Where the Register for Biocidal Products referred to in Article 71 shows that a competent authority other than the receiving competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving competent authority shall decline to evaluate the application. In that event, the receiving competent authority shall inform the applicant of the possibility of seeking mutual recognition in accordance with Article 33 or 34.

5. If paragraph 3 does not apply and the receiving competent authority considers that the application is complete, it shall validate the application and without delay inform the applicant accordingly, indicating the date of the validation.

Article 30

Evaluation of applications

1. The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

2. Where it appears that additional information is necessary to carry out the evaluation, the receiving competent authority shall ask the applicant to submit such information within a specified time limit. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly.

3. Within the 365-day period referred to in paragraph 1, the receiving competent authority shall:

(a) draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the 'assessment report');

(b) send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and

(c) take due account of those comments when finalising its assessment.

Article 31

Renewal of a national authorisation

1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving competent authority at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date.

2. The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

3. When applying for renewal, the applicant shall submit:

(a) without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

(b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

4. The receiving competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

5. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

6. Where the receiving competent authority decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 30.

Where the receiving competent authority decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of this Article.

7. Where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the receiving competent authority shall grant a renewal for the period necessary to complete the evaluation.

CHAPTER VII

MUTUAL RECOGNITION PROCEDURES

Article 32

Authorisation through mutual recognition

1. Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).

2. Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.

Προς διανομή

Article 33

Mutual recognition in sequence

1. Applicants wishing to seek the mutual recognition in sequence, in one or more Member States ('the Member States concerned'), of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ('the reference Member State') shall submit an application to each of the competent authorities of the Member States concerned containing, in each case, a translation of the national authorisation granted by the reference Member State into such official languages of the Member State concerned as it may require.

The competent authorities of the Member States concerned shall inform the applicant of the fees payable under Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the competent authorities of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

2. Within 30 days of acceptance referred to in paragraph 1, the Member States concerned shall validate the application and inform the applicant accordingly, indicating the date of the validation.

Within 90 days of validating the application, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics referred to in Article 22(2) and shall record their agreement in the Register for Biocidal Products.

3. Within 30 days of reaching agreement, each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

4. Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in the second subparagraph of paragraph 2, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 2, may authorise the product accordingly.

Article 34

Mutual recognition in parallel

1. Applicants wishing to seek the mutual recognition in parallel of a biocidal product which has not yet been authorised in accordance with Article 17 in any Member State shall submit to the competent authority of the Member State of its choice ('the reference Member State') an application containing:

(a) the information referred to in Article 20;

(b) a list of all other Member States where a national authorisation is sought ('the Member States concerned').

The reference Member State shall be responsible for the evaluation of the application.

2. The applicant shall, at the same time as submitting the application to the reference Member State in accordance with paragraph 1, submit to the competent authorities of each of the Member States concerned an application for mutual recognition of the authorisation for which it has applied to the reference Member State. This application shall contain:

(a) the names of the reference Member State and of the Member States concerned;

(b) the summary of biocidal product characteristics referred to in Article 20(1)(a)(ii) in such official languages of the Member States concerned as they may require.

3. The competent authorities of the reference Member State and of the Member States concerned shall inform the applicant of the fees payable in accordance with Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the competent authorities of the reference Member State and of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

4. The reference Member State shall validate the application in accordance with Article 29(2) and (3) and inform the applicant and the Member States concerned accordingly.

Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 30(3) and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.

5. Within 90 days of receipt of the documents referred to in paragraph 4, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics, and shall record their agreement in the Register for Biocidal Products. The reference Member State shall enter the agreed summary of biocidal product characteristics and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product.

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6. Within 30 days of reaching agreement, the reference Member State and each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

7. Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in paragraph 5, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 5 may authorise the product accordingly.

Article 35

Referral of objections to the coordination group

1. A coordination group shall be set up to examine any question, other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19.

All Member States and the Commission shall be entitled to participate in the work of the coordination group. The Agency shall provide the secretariat of the coordination group.

The coordination group shall establish its rules of procedure.

2. If any of the Member States concerned considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

3. Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(4) or Article 34(6) as appropriate.

Article 36

Referral of unresolved objections to the Commission

1. If the Member States referred to in Article 35(2) fail to reach agreement within the 60-day period laid down in Article 35(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.

2. The Commission may ask the Agency for an opinion on scientific or technical questions raised by Member States. Where the Commission does not ask the Agency for an opinion it shall provide the applicant and, where applicable, the authorisation holder with the opportunity to provide written comments within 30 days.

3. The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4. The decision referred to in paragraph 3 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification of the decision, either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.

Article 37

Derogations from mutual recognition

1. By way of derogation from Article 32(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

(a) the protection of the environment;

(b) public policy or public security;

(c) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;

(d) the protection of national treasures possessing artistic, historic or archaeological value; or

(e) the target organisms not being present in harmful quantities.

Any of the Member States concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or Article 10(1) applies.

2. The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the proposed derogation.

If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. In that case, the Commission:

(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;

(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 82(3).

The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.

The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.

3. If the Commission has not adopted a decision pursuant to paragraph 2 within 90 days of being informed in accordance with the second subparagraph of paragraph 2, the Member State concerned may implement the derogation proposed pursuant to paragraph 1.

While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within two years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended.

4. By way of derogation from Article 32(2), a Member State may refuse to grant authorisations for product-types 15, 17 and 20 on grounds of animal welfare. Member States shall without delay inform other Member States and the Commission of any decision taken in this respect and its justification.

Article 38

Opinion of the Agency

1. If so requested by the Commission pursuant to Article 36(2) or Article 37(2), the Agency shall issue an opinion within 120 days from the date on which the matter in question was referred to it.

2. Before issuing its opinion, the Agency shall provide the applicant and, where applicable, the authorisation holder with an opportunity to provide written comments within a specified time limit not exceeding 30 days.

The Agency may suspend the time limit referred to in paragraph 1 to allow the applicant or the authorisation holder to prepare the comments.

Article 39

Application for mutual recognition by official or scientific bodies

1. Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or the protection of public health may apply, under the mutual recognition procedure provided for in Article 33 and with the consent of the authorisation holder in that other Member State, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that Member State.

The applicant shall demonstrate that the use of such a biocidal product is of general interest for that Member State.

The application shall be accompanied by the fees payable under Article 80.

2. Where the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 19 and the conditions under this Article are met, the competent authority shall authorise the making available on the market and use of the biocidal product. In that case, the body that made the application shall have the same rights and obligations as other authorisation holders.

Article 40

Supplementary rules and technical guidance notes

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the renewal of authorisations subject to mutual recognition.

The Commission shall also draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 37 and 39.

CHAPTER VIII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

SECTION 1

Granting of Union authorisations

Article 41

Union authorisation

A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation. For those categories of biocidal products referred to in Article 42(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.

Article 42

Biocidal products for which Union authorisation may be granted

1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 and those of product-types 14, 15, 17, 20 and 21. The Union authorisation may be granted:

(a) from 1 September 2013, to biocidal products containing one or more new active substances and biocidal products of product-types 1, 3, 4, 5, 18 and 19;

(b) from 1 January 2017, to biocidal products of product-types 2, 6 and 13; and

(c) from 1 January 2020, to biocidal products of all remaining product-types.

2. The Commission shall by 1 September 2013 draw up guidance documents on the definition of 'similar conditions of use across the Union'.

3. The Commission shall submit a report to the European Parliament and the Council on the application of this Article by 31 December 2017. That report shall contain an assessment of the exclusion of product-types 14, 15, 17, 20 and 21 from the Union authorisation.

The report shall, if appropriate, be accompanied by relevant proposals for adoption in accordance with the ordinary legislative procedure.

Article 43

Submission and validation of applications

1. Applicants wishing to apply for Union authorisation in accordance with Article 42(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have similar conditions of use across the Union, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the relevant information referred to in Article 20 has been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the evaluation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

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5. On validating the application in accordance with paragraph 3 or 4, the evaluating competent authority shall, without delay, inform the applicant, the Agency and other competent authorities accordingly, indicating the date of the validation.

6. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 44

Evaluation of applications

1. The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Article 19, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the information requested.

3. Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements:

(a) a statement on whether the conditions laid down in Article 19(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 22(2);

(b) where relevant, details of any terms or conditions which should be imposed on the making available on the market or use of the biocidal product;

(c) the final assessment report on the biocidal product.

4. Within 30 days of submitting its opinion to the Commission, the Agency shall transmit to the Commission, in all the official languages of the Union, the draft summary of the biocidal product characteristics, as referred to in Article 22(2), where applicable.

5. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).

SECTION 2

Renewal of Union authorisations

Article 45

Submission and acceptance of applications

1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 80(1).

2. When applying for renewal, the applicant shall submit:

(a) without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

(b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

3. The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall inform the applicant of the fees payable to it under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

4. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 46

Evaluation of applications for renewal

1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

2. Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 and 2 of Article 44.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application, prepare and submit to the Agency a recommendation on the renewal of the authorisation. It shall provide the applicant with a copy of its recommendation.

The evaluating competent authority shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

3. Within 180 days of receipt of a recommendation from the evaluating competent authority, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation.

4. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied.

5. Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

CHAPTER IX

CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

Article 47

Obligation for notification of unexpected or adverse effects

1. On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, that may affect the authorisation, the holder of an authorisation shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:

(a) new data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, animals or the environment;

(b) any data indicating the potential of the active substance for the development of resistance;

(c) new data or information indicating that the biocidal product is not sufficiently effective.

2. The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

3. The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such data or information it receives.

Competent authorities of Member States that have issued a national authorisation for the same biocidal product under the mutual recognition procedure shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

Article 48

Cancellation or amendment of an authorisation

1. Without prejudice to Article 23, the competent authority of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that:

(a) the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;

(b) the authorisation was granted on the basis of false or misleading information; or

(c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

2. Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision.

3. Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

Competent authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 35 and 36 shall apply *mutatis mutandis*.

Article 49

Cancellation of an authorisation at the request of the authorisation holder

At the reasoned request of an authorisation holder, the competent authority that granted the national authorisation or, in the case of Union authorisation, the Commission shall cancel the authorisation. Where such a request concerns a Union authorisation, it shall be submitted to the Agency.

Article 50

Amendment of an authorisation at the request of the authorisation holder

1. Amendments to the terms and conditions of an authorisation shall be made only by the competent authority that authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.

2. An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 19 or, where relevant, Article 25 are still met and whether the terms and conditions of the authorisation need to be amended.

The application shall be accompanied by the fees payable under Article 80(1) and (2).

3. An amendment to an existing authorisation shall fall under one of the following categories of changes:

(a) administrative change;

(b) minor change; or

(c) major change.

Article 51

Detailed rules

In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay down detailed rules for the application of Articles 47 to 50 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The rules referred to in the first paragraph of this Article shall be based, inter alia, on the following principles:

(a) a simplified notification procedure shall be applied for administrative changes;

(b) a reduced evaluation period shall be established for minor changes;

(c) in the case of major changes, the evaluation period shall be proportionate to the extent of the proposed change.

Article 52

Period of grace

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the disposal and use of existing stocks of the biocidal products concerned.

CHAPTER X

PARALLEL TRADE

Article 53

Parallel trade

1. A competent authority of a Member State ('Member State of introduction') shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ('Member State of origin') to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ('the reference product').

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The application shall be accompanied by the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

2. Where the competent authority of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 80(2). The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within 30 days of receiving the request.

3. A biocidal product shall be considered as identical to the reference product only if all the following conditions are met:

(a) they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process;

(b) they are identical in specification and content in respect of the active substances and the type of formulation;

(c) they are the same in respect of the non-active substances present; and

(d) they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

4. An application for a parallel trade permit shall include the following information and items:

(a) name and authorisation number of the biocidal product in the Member State of origin;

(b) name and address of the competent authority of the Member State of origin;

(c) name and address of the authorisation holder in the Member State of origin;

(d) original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;

(e) name and address of the applicant;

(f) name to be given to the biocidal product to be distributed in the Member State of introduction;

(g) a draft label for the biocidal product intended to be made available on the market in the Member State of introduction in the official language or languages of the Member State of introduction, unless that Member State provides otherwise;

(h) a sample of the biocidal product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(i) name and authorisation number of the reference product in the Member State of introduction.

The competent authority of the Member State of introduction may require a translation of the relevant parts of the original instructions for the use referred to in point (d).

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5. The parallel trade permit shall prescribe the same conditions for making available on the market and use as the authorisation of the reference product.

6. The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 49 and the requirements of Article 19 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired.

7. Without prejudice to specific provisions in this Article, Articles 47 to 50 and Chapter XV shall apply *mutatis mutandis* to biocidal products made available on the market under a parallel trade permit.

8. The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

CHAPTER XI **TECHNICAL EQUIVALENCE** *Article 54*

Assessment of technical equivalence

1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency and pay the applicable fees in accordance with Article 80(1).

2. The applicant shall submit all data that the Agency requires to assess technical equivalence.

3. The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

4. After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it to Member States and to the applicant.

5. Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

6. Where appropriate, the Agency may consult the competent authority of the Member State which acted as the evaluating competent authority for the evaluation of the active substance.

7. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraphs 3, 4 and 5 of this Article.

8. The Agency shall draw up technical guidance notes to facilitate the implementation of this Article.

CHAPTER XII

DEROGATIONS

Article 55

Derogation from the requirements

1. By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

The competent authority referred to in the first subparagraph shall, without delay, inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall, without delay, inform the other competent authorities and the Commission of the revocation of such action.

On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

2. By way of derogation from point (a) of Article 19(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

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Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2). Competent authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

3. By way of derogation from point (a) of Article 19(1), the Commission may, by means of implementing acts, allow a Member State to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). A Member State wishing to obtain such a derogation shall apply to the Commission, providing due justification.

Article 56

Research and development

1. By way of derogation from Article 17, an experiment or a test for the purposes of research or development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ('experiment' or 'test') may take place only under the conditions laid down in this Article.

Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.

2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the competent authorities.

In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.

3. If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall, without delay, inform the Commission and other competent authorities of its decision.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying detailed rules supplementing this Article.

Article 57

Exemption from registration under Regulation (EC) No 1907/2006

In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products authorised for placing on the market in accordance with Article 27, 55 or 56 shall be regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of Regulation (EC) No 1907/2006.

CHAPTER XIII

TREATED ARTICLES

Article 58

Placing on the market of treated articles

1. This Article shall apply exclusively to treated articles that are not biocidal products. It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

2. A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.

3. The person responsible for the placing on the market of such a treated article shall ensure that the label provides the information listed in the second subparagraph, where:

— in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or

— in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.

The label referred to in the first subparagraph shall provide the following information:

(a) a statement that the treated article incorporates biocidal products;

(b) where substantiated, the biocidal property attributed to the treated article;

(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;

(e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.

4. Notwithstanding the labelling requirements set out in paragraph 3, the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment.

5. Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article.

6. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise. In the case of treated articles that are not produced as part of a series but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

7. The Commission may adopt implementing acts for the application of paragraph 2 of this Article, including appropriate notification procedures, possibly involving the Agency, and further specifying the labelling requirements under paragraphs 3, 4 and 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

8. Where there are significant indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), Article 5(2) or Article 25, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or Article 28(2).

CHAPTER XIV

DATA PROTECTION AND DATA-SHARING

Article 59

Protection of data held by competent authorities or the Agency

1. Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:

(a) the subsequent applicant submits a letter of access; or

(b) the relevant time limit for data protection has expired.

2. When submitting data to a competent authority or to the Agency for the purposes of this Regulation the applicant shall, where relevant, indicate the name and contact details of the data owner for all data submitted. The applicant shall also specify whether it is the data owner or holds a letter of access.

3. The applicant shall, without delay, inform the competent authority or the Agency about any changes to the ownership of the data.

4. The advisory scientific committees set up under Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment [1] shall also have access to the data referred to in paragraph 1 of this Article.

Article 60

Data protection periods

1. Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.

Data protected under this Article or for which the protection period under this Article has expired shall not be protected again.

2. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end five years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

3. The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).

The protection period for new data submitted with a view to the renewal or amendment of the authorisation of a biocidal product shall end five years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.

Article 61

Letter of access

1. A letter of access shall contain at least the following information:

(a) the name and contact details of the data owner and the beneficiary;

(b) the name of the active substance or biocidal product for which access to the data is authorised;

(c) the date on which the letter of access takes effect;

(d) a list of the submitted data to which the letter of access grants citation rights.

2. Revocation of a letter of access shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

Article 62

Data sharing

1. In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation.

2. Any person intending to perform tests or studies ('the prospective applicant')

(a) shall, in the case of data involving tests on vertebrates; and

(b) may, in the case of data not involving tests on vertebrates,

submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant.

[1] OJ L 66, 4.3.2004, p. 45.

The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner.

Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant:

(a) shall, in the case of data involving tests on vertebrates; and

(b) may, in the case of data not involving tests on vertebrates,

request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.

Article 63

Compensation for data sharing

1. Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.

2. Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation.

3. Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof, at the earliest one month after the prospective applicant receives the name and address of the data submitter from the Agency.

Within 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.

The data owner shall not refuse to accept any payment offered pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court, in accordance with the second subparagraph.

4. Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner, having regard to the guidance established by the Agency [1]. The prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of this Regulation.

5. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 64

Use of data for subsequent applications

1. Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.

Where the relevant data protection period according to Article 60 has expired in relation to a biocidal product, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.

An appeal may be brought, in accordance with Article 77, against decisions of the Agency under the first and second subparagraphs of this paragraph.

2. Notwithstanding paragraph 1, subsequent applicants shall provide the following data accordingly to the receiving competent authority or the Agency, as applicable:

(a) all necessary data for the identification of the biocidal product, including its composition;

(b) the data needed to identify the active substance and to establish technical equivalence of the active substance;

(c) the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of the authorised biocidal product.

[1] Guidance on data sharing established in accordance with Regulation (EC) No 1907/2006.

ΠΟΥΤΙΤΟ ΕΠΙΣΗΜΟ

CHAPTER XV **INFORMATION AND COMMUNICATION** *SECTION 1*

Monitoring and reporting

Article 65

Compliance with requirements

1. Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [1] shall apply accordingly.

2. Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.

In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

(a) safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

(b) records of the various manufacturing operations performed;

(c) results of internal quality controls;

(d) identification of production batches.

Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3).

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and Member States.

3. Every five years, from 1 September 2015, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular:

(a) information on the results of official controls carried out in accordance with paragraph 2;

(b) information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases;

(c) any available information on adverse environmental effects experienced through using biocidal products;

(d) information on the use of nanomaterials in biocidal products and the potential risks thereof.

Reports shall be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission.

The reports shall be published on the relevant website of the Commission.

4. On the basis of the reports received in accordance with paragraph 3, and within 12 months from the date referred to in the second subparagraph of that paragraph, the Commission shall draw up a composite report on the implementation of this Regulation, in particular Article 58. The Commission shall submit the report to the European Parliament and to the Council.

Article 66

Confidentiality

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2] and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

2. The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned:

(a) details of the full composition of a biocidal product;

(b) the precise tonnage of the active substance or biocidal product manufactured or made available on the market;

[1] OJ L 218, 13.8.2008, p. 30.

[2] OJ L 145, 31.5.2001, p. 43.

(c) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

(d) names and addresses of persons involved in testing on vertebrates.

However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.

3. Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

(a) the name and address of the authorisation holder;

(b) the name and address of the biocidal product manufacturer;

(c) the name and address of the active substance manufacturer;

(d) the content of the active substance or substances in the biocidal product and the name of the biocidal product;

(e) physical and chemical data concerning the biocidal product;

(f) any methods for rendering the active substance or biocidal product harmless;

(g) a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

(h) recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;

(i) safety data sheets;

(j) methods of analysis referred to in Article 19(1)(c);

(k) methods of disposal of the product and of its packaging; (l) procedures to be followed and measures to be taken in the case of spillage or leakage;

(m) first aid and medical advice to be given in the case of injury to persons.

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4. Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 67(3) shall not be made available, including a justification as to why the disclosure of the information could be harmful for their commercial interests or those of any other party concerned.

Article 67

Electronic public access

1. From the date on which an active substance is approved, the following up-to-date information held by the Agency or the Commission on active substances shall be made publicly and easily available free of charge:

(a) where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;

(b) if applicable, the name as given in the European Inventory of Existing Commercial Chemical Substances;

(c) the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);

(d) physicochemical endpoints and data on pathways and environmental fate and behaviour;

(e) the result of each toxicological and ecotoxicological study;

(f) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;

(g) the guidance on safe use provided in accordance with Annexes II and III;

(h) analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.

2. From the date on which a biocidal product is authorised, the Agency shall make publicly and easily available free of charge the following up-to-date information:

(a) the terms and conditions of the authorisation;

(b) the summary of the biocidal product characteristics; and

(c) analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.

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3. From the date on which an active substance is approved, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on active substances:

(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;

(b) the study summaries or robust study summaries of studies submitted to support the approval of the active substance;

(c) information, other than that listed in paragraph 1 of this Article, contained in the safety data sheet;

(d) the trade name(s) of the substance;

(e) the assessment report.

4. From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information:

(a) study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and

(b) the assessment report.

Article 68

Record-keeping and reporting

1. Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall make available the relevant information contained in these records to the competent authority on request.

2. To ensure the uniform application of paragraph 1 of this Article, the Commission shall adopt implementing acts to specify the form and content of the information in records. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

SECTION 2

Information about biocidal products

Article 69

Classification, packaging and labelling of biocidal products

1. Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008.

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

2. In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information:

(a) the identity of every active substance and its concentration in metric units;

(b) the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

(c) the authorisation number allocated to the biocidal product by the competent authority or the Commission;

(d) the name and address of the authorisation holder;

(e) the type of formulation;

(f) the uses for which the biocidal product is authorised;

(g) directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorisation;

(h) particulars of likely direct or indirect adverse side effects and any directions for first aid;

(i) if accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups;

(j) directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;

(k) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

(l) where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

(m) where applicable, the categories of users to which the biocidal product is restricted;

(n) where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;

(o) for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC.

By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (e), (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3. Member States may require:

(a) the provision of models or drafts of the packaging, labelling and leaflets;

(b) that biocidal products made available on the market in their territories be labelled in their official language or languages.

Article 70

Safety data sheets

Safety data sheets for active substances and biocidal products shall be prepared and made available in accordance with Article 31 of Regulation (EC) No 1907/2006, where applicable.

Article 71

Register for Biocidal Products

1. The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products.

2. The Register for Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission and between applicants and competent authorities, the Agency and the Commission.

3. Applicants shall use the Register for Biocidal Products to submit applications and data for all procedures covered by this Regulation.

4. Upon submission of applications and data by applicants, the Agency shall check that these have been submitted in the correct format and notify the relevant competent authority accordingly without delay.

Where the Agency decides that the application has not been submitted in the correct format, it shall reject the application and inform the applicant accordingly.

5. Once the relevant competent authority has validated or accepted an application, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency.

6. The competent authorities and the Commission shall use the Register for Biocidal Products to record and communicate the decisions they have taken in relation to the authorisations of biocidal products and shall update the information in the Register for Biocidal Products at the time such decisions are taken. The competent authorities shall, in particular, update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled, or for which a parallel trade permit has been granted, refused or cancelled. The Commission shall, in particular, update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

The information to be introduced into the Register for Biocidal Products shall include, as appropriate:

(a) the terms and conditions of the authorisation;

(b) the summary of the biocidal product characteristics referred to in Article 22(2);

(c) the assessment report of the biocidal product.

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The information referred to in this paragraph shall also be made available to the applicant through the Register for Biocidal Products.

7. In the event that the Register for Biocidal Products is not fully operational by 1 September 2013 or ceases to be operational after that date, all obligations in relation to submissions and communication placed upon Member States, competent authorities, the Commission and applicants by this Regulation shall continue to apply. With a view to ensuring the uniform application of this paragraph, particularly with regard to the format in which information may be submitted and exchanged, the Commission shall adopt the necessary measures in accordance with the examination procedure referred to in Article 82(3). Those measures shall be limited in time to the period strictly necessary for the Register for Biocidal Products to become fully operational.

8. The Commission may adopt implementing acts laying down detailed rules on the types of information to be entered in the Register for Biocidal Products. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

9. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the use of the Register.

Article 72

Advertising

1. Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences 'Use biocides safely. Always read the label and product information before use.'. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2. Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type being advertised.

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

Article 73

Poison control

Article 45 of Regulation (EC) No 1272/2008 shall apply for the purposes of this Regulation.

CHAPTER XVI

THE AGENCY

Article 74

Role of the Agency

1. The Agency shall carry out the tasks conferred on it by this Regulation.

2. Articles 78 to 84, 89 and 90 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* taking into account the role of the Agency with respect to this Regulation.

Article 75

Biocidal Products Committee

1. A Biocidal Products Committee is hereby established within the Agency.

The Biocidal Products Committee shall be responsible for preparing the opinion of the Agency on the following issues:

(a) applications for approval and renewal of approval of active substances;

(b) review of approval of active substances;

(c) applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 and review of the inclusion of such active substances in Annex I;

(d) identification of active substances which are candidates for substitution;

(e) applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes;

(f) scientific and technical matters concerning mutual recognition in accordance with Article 38;

(g) at the request of the Commission or of Member States' competent authorities, any other questions that arise from the operation of this Regulation relating to technical guidance or risks to human health, animal health or the environment.

2. Each Member State shall be entitled to appoint a member of the Biocidal Products Committee. Member States may also appoint an alternate member.

In order to facilitate its work, the Committee may, by a decision of the Management Board of the Agency in agreement with the Commission, be divided into two or more parallel committees. Each parallel committee shall be responsible for the tasks of the Biocidal Products Committee assigned to it. Each Member State shall be entitled to appoint one Member for each of the parallel committees. The same person may be appointed to more than one parallel committee.

3. Committee members shall be appointed on the basis of their experience relevant to performing the tasks specified in paragraph 1 and may work within a competent authority. They shall be supported by the scientific and technical resources available to Member States. To this end, Member States shall provide adequate scientific and technical resources to Committee members that they have nominated.

4. Article 85, paragraphs 4, 5, 8 and 9, and Articles 87 and 88 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* to the Biocidal Products Committee.

Article 76

Secretariat of the Agency

1. The Secretariat of the Agency referred to in point (g) of Article 76(1) of Regulation (EC) No 1907/2006 shall undertake the following tasks:

(a) establishing and maintaining the Register for Biocidal Products;

(b) performing the tasks relating to the acceptance of the applications covered by this Regulation;

(c) establishing technical equivalence;

(d) providing technical and scientific guidance and tools for the application of this Regulation by the Commission and Member States' competent authorities and providing support to national helpdesks;

(e) providing advice and assistance to applicants, in particular to SMEs, for the approval of an active substance or its inclusion in Annex I to this Regulation or for a Union authorisation;

(f) preparing explanatory information on this Regulation;

(g) establishing and maintaining database(s) with information on active substances and biocidal products;

(h) at the request of the Commission, providing technical and scientific support to improve cooperation between the Union competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products;

(i) notification of decisions taken by the Agency;

(j) specification of formats and software packages for the submission of information to the Agency;

(k) providing support and assistance to Member States in order to avoid the parallel assessment of applications relating to the same or similar biocidal products referred to in Article 29(4);

2. The Secretariat shall make the information identified in Article 67 publicly available, free of charge, over the internet, except where a request made under Article 66(4) is considered justified. The Agency shall make other information available on request in accordance with Article 66.

Article 77

Appeal

1. Appeals against decisions of the Agency taken pursuant to Article 7(2), Article 13(3), Article 26(2), Article 43(2), Article 45(3), Article 54(3), (4) and (5), Article 63(3) and Article 64(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006.

Article 92(1) and (2) and Articles 93 and 94 of Regulation (EC) No 1907/2006 shall apply to appeal procedures lodged under this Regulation.

Fees may be payable, in accordance with Article 80(1) of this Regulation, by the person bringing an appeal.

2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

Article 78

The budget of the Agency

1. For the purposes of this Regulation, the revenues of the Agency shall consist of:

(a) a subsidy from the Union, entered in the general budget of the European Union (Commission Section);

(b) the fees paid to the Agency in accordance with this Regulation;

(c) any charges paid to the Agency for services that it provides under this Regulation;

(d) any voluntary contributions from Member States.

2. Revenue and expenditure for activities related to this Regulation and to Regulation (EC) No 1907/2006 shall be dealt with separately in the Agency's budget and shall have separate budgetary and accounting reporting.

Revenue of the Agency referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation. Revenue of the Agency referred to in paragraph 1 of this Article shall not be used for carrying out tasks under Regulation (EC) No 1907/2006.

Article 79

Formats and software for submission of information to the Agency

The Agency shall specify formats and software packages and make them available free of charge on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions pursuant to this Regulation.

The technical dossier referred to in Article 6(1) and Article 20 shall be submitted using the IUCLID software package.

CHAPTER XVII **FINAL PROVISIONS** *Article 80*

Fees and charges

1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, an implementing Regulation specifying:

(a) the fees payable to the Agency, including an annual fee for products granted a Union authorisation in accordance with Chapter VIII and a fee for applications for mutual recognition in accordance with Chapter VII;

(b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and

(c) conditions of payment.

That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 82(3). It shall apply only with respect to fees paid to the Agency.

The Agency may collect charges for other services it provides.

The fees payable to the Agency shall be set at such a level as to ensure that the revenue derived from the fees, when combined with other sources of the Agency's revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered. The fees payable shall be published by the Agency.

2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.

Based on the principles set out in paragraph 3, the Commission shall issue guidance concerning a harmonised structure of fees.

Member States may levy annual fees with respect to biocidal products made available on their markets.

Member States may collect charges for other services they provide.

Member States shall set and publish the amount of fees payable to their competent authorities.

3. Both the implementing Regulation referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:

(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs;

(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;

(c) the specific needs of SMEs shall be taken into account, as appropriate, including the possibility of splitting payments into several instalments and phases;

(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;

(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and

(f) the deadlines for the payment of fees shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.

Article 81

Competent authorities

1. Member States shall designate a competent authority or competent authorities responsible for the application of this Regulation.

Member States shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation can be carried out efficiently and effectively.

Δημοσίευση προς διαβούλευση

2. Competent authorities shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Regulation. That shall include the provision of advice about the possibility of adapting the data requirements of Articles 6 and 20, the grounds on which such an adaptation can be made, and on how to prepare a proposal. It shall be in addition to the advice and assistance that the Secretariat of the Agency shall provide in accordance with Article 76(1)(d).

Competent authorities may in particular provide advice by establishing helpdesks. Helpdesks already established under Regulation (EC) No 1907/2006 may act as helpdesks under this Regulation.

3. Member States shall inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesks by 1 September 2013. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesks.

The Commission shall make publicly available a list of competent authorities and helpdesks.

Article 82

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Biocidal Products ('the committee'). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 shall apply.

Article 83

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) shall be conferred on the Commission for a period of five years from 17 July 2012. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 84

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 83(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 85

Adaptation to scientific and technical progress

In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the adaptation of Annexes II, III and IV to such scientific and technical progress.

Προσωρινή Μετάφραση

Article 86

Active substances included in Annex I to Directive 98/8/EC

The active substances included in Annex I to Directive 98/8/EC shall be deemed to have been approved under this Regulation and shall be included in the list referred to in Article 9(2).

Article 87

Penalties

Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 September 2013 and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 88

Safeguard clause

Where, on the basis of new evidence, a Member State has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment, it may take appropriate provisional measures. The Member State shall, without delay, inform the Commission and the other Member States accordingly and give reasons for its decision based on the new evidence.

The Commission shall, by means of implementing acts, either permit the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 89

Transitional measures

1. The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 14 May 2014. To that end, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme.

Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period.

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt either implementing regulations providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.

2. By way of derogation from Article 17(1), Article 19(1) and Article 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until two years after the date of approval of the last of the active substances to be approved in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing existing active substances which have been or are being evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC [1], but which have not yet been approved for that product-type.

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1.

3. Following a decision to approve a particular active substance for a specific product-type Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years of the date of approval.

To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.

[1] OJ L 325, 11.12.2007, p. 3.

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

(a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and

(b) disposal and use of existing stocks of the biocidal product may continue until 365 days after the date of approval of the active substance(s).

4. Where a Member State's competent authority rejects the application for authorisation of a biocidal product submitted under paragraph 3 or decides not to grant authorisation, that biocidal product shall no longer be made available on the market 180 days after the date of such rejection or decision. Disposal and use of existing stocks of such biocidal products may continue until 365 days after the date of such rejection or decision.

Article 90

Transitional measures concerning active substances evaluated under Directive 98/8/EC

1. The Agency shall be responsible for coordinating the process of evaluation of dossiers submitted after 1 September 2012 and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission.

2. Applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No 1451/2007.

That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Every effort shall be made to avoid additional testing on vertebrates and to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements.

Notwithstanding paragraph 1, the Agency shall also be responsible for coordinating the evaluation process of dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission from 1 January 2014.

Article 91

Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC

Applications for biocidal product authorisations submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with that Directive.

Notwithstanding the first paragraph, the following shall apply:

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5(1) is met, the biocidal product shall be authorised in accordance with Article 19,

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Article 92

Transitional measures concerning biocidal products authorised/registered under Directive 98/8/EC

1. Biocidal products for which an authorisation or registration in accordance with Article 3, 4, 15 or 17 of Directive 98/8/EC was granted before 1 September 2013 can continue to be made available on the market and used subject, where applicable, to any conditions of authorisation or registration stipulated under that Directive until the expiry date of the authorisation or registration or its cancellation.

2. Notwithstanding paragraph 1, this Regulation shall apply to biocidal products referred to in that paragraph from 1 September 2013.

Article 93

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

1. Without prejudice to Article 89, applications for authorisation of biocidal products not covered by the scope of Directive 98/8/EC and falling within the scope of this Regulation and which were available on the market on 1 September 2013 shall be submitted at the latest by 1 September 2017.

2. By way of derogation from Article 17(1), biocidal products referred to in paragraph 1 of this Article for which an application was submitted in accordance with paragraph 1 of this Article may continue to be made available on the market or used until the date of the decision granting the authorisation. In the case of a decision refusing to grant the authorisation, the biocidal product shall no longer be made available on the market 180 days after such a decision.

By way of derogation from Article 17(1), biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article may continue to be made available on the market or used until 180 days after 1 September 2017.

Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the first subparagraph or 12 months after the date referred to in the second subparagraph, whichever is the later.

Article 94

Transitional measures concerning treated articles

1. By way of derogation from Article 58 and without prejudice to Article 89, treated articles that were available on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product-type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the application for the approval of the active substance(s) for the relevant product-type is submitted at the latest by 1 September 2016.

2. In the case of a decision not to approve an active substance for the relevant product-type, treated articles which were treated with, or which incorporate, biocidal product(s) containing that active substance shall no longer be placed on the market 180 days after such a decision or as of 1 September 2016, whichever is the later, unless an application for the approval has been submitted in accordance with paragraph 1.

Article 95

Transitional measures concerning access to the active substance dossier

1. As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the 'relevant person') shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

(a) a dossier complying with the requirements of Annex II or, where appropriate, with Annex IIA to Directive 98/8/EC; or

(b) a letter of access to a dossier as referred to under point (a); or

(c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph.

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrates.

The relevant person to whom a letter of access to a dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1).

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

2. The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1) or have taken over the role of the participant.

3. Without prejudice to Article 93, as of 1 September 2015, a biocidal product shall not be made available on the market if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product, is not included in the list referred to in paragraph 2.

Without prejudice to Articles 52 and 89, disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until 1 September 2016.

4. This Article shall not apply to active substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such active substances.

Δοκιμαστικό Τεύχος

Article 96

Repeal

Without prejudice to Articles 86, 89, 90, 91 and 92 of this Regulation, Directive 98/8/EC is hereby repealed with effect from 1 September 2013.

References to the repealed Directive shall be construed as references to this Regulation and read in accordance with the correlation table in Annex VII.

Article 97

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 22 May 2012.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	N. WAMMEN

Πανεπιστήμιο Πειραιώς

ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 25(a)

EC number	Name/group	Restriction	Comment
Category 1 — Substances authorised as food additives according to Regulation (EC) No 1333/2008			
200-018-0	Lactic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 270
204-823-8	Sodium acetate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 262
208-534-8	Sodium benzoate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 211
201-766-0	(+)-Tartaric acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 334
200-580-7	Acetic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 260
201-176-3	Propionic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 280
Category 2 — Substances included in Annex IV to Regulation (EC) No 1907/2006			
200-066-2	Ascorbic acid		
232-278-6	Linseed oil		
Category 3 — Weak acids			
Category 4 — Traditionally used substances of natural origin			
Natural oil	Lavender oil		CAS 8000-28-0
Natural oil	Peppermint oil		CAS 8006-90-4
Category 5 — Pheromones			
222-226-0	Oct-1-en-3-ol		
Mixture	Webbing clothes moths pheromone		
Category 6 — Substances included in Annex I or IA to Directive 98/8/EC			
204-696-9	Carbon dioxide	Only for use in ready-for-use gas canisters functioning together with a trapping device	
231-783-9	Nitrogen	Only for use in limited quantities in ready-for-use canisters	
250-753-6	(Z,E)-Tetradec-9,12-dienyl acetate		

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EC number	Name/group	Restriction	Comment
Category 7 — Other			
	Baculovirus		
215-108-5	Bentonite		
203-376-6	Citronellal		
231-753-5	Iron sulphate		

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ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation of the dossier referred to in point (a) of Article 6(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all active substances. However, in some cases the physical or chemical properties of the substance may mean that it is impossible or unnecessary to provide specific data elements belonging to the CDS.

   With regard to the ADS, the data elements to be provided for a specific active substance shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the substance, existing data, information which is part of the CDS and the types of products in which the active substance will be used and the exposure patterns related to these uses.

   Specific indications for the inclusion of some data elements are provided in column 1 of the Annex II table. The general considerations regarding adaptation of information requirements as set out in Annex IV shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the Annex II table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates. The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in Article 4(1) are met.

   The applicant should consult the detailed technical guidance regarding the application of this Annex and the preparation of the dossier referred to in point (a) of Article 6(1), which is available on the website of the Agency.

   The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

   Additional information may need to be submitted if it is necessary to carry out the evaluation as indicated in Article 8(2).

3. A detailed and full description of the studies conducted or referred to and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements. Evidence should also be provided to demonstrate that the active substance upon which the tests have been carried out is the same as the substance for which the application has been submitted.

4. The formats made available by the Agency must be used for submission of the dossiers. In addition, IUCLID must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the website of the Agency.

5. Tests submitted for the purpose of the approval of an active substance shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ([1]). However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes ([2]) and in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances ([3]) or other international standards recognised as being equivalent by the Commission or the Agency. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

([1]) OJ L 142, 31.5.2008, p. 1.
([2]) OJ L 276, 20.10.2010, p. 33.
([3]) OJ L 50, 20.2.2004, p. 44.

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7. Where testing is done, a detailed description (specification) of the active substance used and its impurities must be provided. Testing should be performed with the active substance as manufactured or, in the case of some of the physical and chemical properties (see indications given in column I of the table), with a purified form of the active substance.

8. Where test data exist that have been generated before 1 September 2013 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State concerned, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrates.

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In-vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

TITLE 1

CHEMICAL SUBSTANCES

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 and are not repeated in column 3, also apply.

	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
1.	APPLICANT		
1.1.	Name and address		
1.2.	Contact person		
1.3.	Active substance manufacturer (name, address and location of manufacturing plant(s))		
2.	IDENTITY OF THE ACTIVE SUBSTANCE For the active substance, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated		
2.1.	Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)		
2.2.	Chemical name (IUPAC and CA nomenclature or other international chemical name(s))		
2.3.	Manufacturer's development code number(s)		
2.4.	CAS number plus EC, INDEX and CIPAC numbers		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
2.5.	Molecular and structural formula (including SMILES notation, if available and appropriate)		
2.6.	Information on optical activity and full details of any isomeric composition (if applicable and appropriate)		
2.7.	Molar mass		
2.8.	Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability		
2.9.	Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit		
2.10.	The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances		
2.11.	Analytical profile of at least five representative batches (g/kg active substance) including information on content of the impurities referred to in 2.10.		
2.12.	The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower		
3.	PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE		
3.1.	Appearance (1)		
3.1.1.	Aggregate state (at 20 °C and 101,3 kPa)		
3.1.2.	Physical state (i.e. viscous, crystalline, powder) (at 20 °C and 101,3 kPa)		
3.1.3.	Colour (at 20 °C and 101,3 kPa)		
3.1.4.	Odour (at 20 °C and 101,3 kPa)		
3.2.	Melting/freezing point (2)		
3.3.	Acidity, alkalinity		
3.4.	Boiling point (2)		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
3.5.	Relative Density (2)		
3.6.	Absorption spectra data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient at relevant wavelengths, where relevant (2)		
3.7.	Vapour pressure (2)		
3.7.1.	Henry's law constant must always be stated for solids and liquids if it can be calculated		
3.8.	Surface tension (2)		
3.9.	Water solubility (2)		
3.10.	Partition coefficient (n-octanol/water) and its pH dependency (2)		
3.11.	Thermal stability, identity of breakdown products (2)		
3.12.	Reactivity towards container material		
3.13.	Dissociation constant	ADS	
3.14.	Granulometry		
3.15.	Viscosity	ADS	
3.16.	Solubility in organic solvents, including effect of temperature on solubility (2)	ADS	
3.17.	Stability in organic solvents used in biocidal products and identity of relevant breakdown products (1)	ADS	
4.	PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS		
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Self-reactive substances and mixtures		
4.9.	Pyrophoric liquids		
4.10.	Pyrophoric solids		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
4.11.	Self-heating substances and mixtures		
4.12.	Substances and mixtures which in contact with water emit flammable gases		
4.13.	Oxidising liquids		
4.14.	Oxidising solids		
4.15.	Organic peroxides		
4.16.	Corrosive to metals		
4.17.	Additional physical indicators for hazards		
4.17.1.	Auto-ignition temperature (liquids and gases)		
4.17.2.	Relative self ignition temperature for solids		
4.17.3.	Dust explosion hazard		
5.	METHODS OF DETECTION AND IDENTIFICATION		
5.1.	Analytical methods including validation parameters for the determination of active substance as manufactured and where appropriate, for relevant residues, isomers and impurities of the active substance and additives (e.g. stabilisers) For impurities other than relevant impurities this only applies if they are present at ≥ 1 g/kg		
5.2.	Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in/on the following where relevant		
5.2.1.	Soil		
5.2.2.	Air		
5.2.3.	Water (surface, drinking etc.) and sediment		
5.2.4.	Animal and human body fluids and tissues		
5.3.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
	products where relevant (not necessary if neither the active substance nor articles treated with it come into contact with food-producing animals, food of plant or animal origin or feeding stuffs)		
6.	EFFECTIVENESS AGAINST TARGET ORGANISMS		
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organism(s)		
6.4.	Likely concentration at which the active substance will be used in products and, where appropriate, in treated articles		
6.5.	Mode of action (including time delay)		
6.6.	Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate		
6.7.	Any known limitations on efficacy		
6.7.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.7.2.	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms		
7.	INTENDED USES AND EXPOSURE		
7.1.	Field of use(s) envisaged for biocidal products and, where appropriate, treated articles		
7.2.	Product-type(s)		
7.3.	Detailed description of the intended use pattern(s) including in treated articles		
7.4.	Users e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Likely tonnage to be placed on the market per year and, where relevant, for the envisaged major use categories		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
7.6.	Exposure data in conformity with Annex VI to this Regulation		
7.6.1.	Information on human exposure associated with the intended uses and disposal of the active substance		
7.6.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance		
7.6.3.	Information on exposure of food- producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.6.4.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
8.	TOXICOLOGICAL PROFILE FOR HUMAN AND ANIMAL INCLUDING METABOLISM		
8.1.	Skin irritation or skin corrosion The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		
8.2.	Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		
8.3.	Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided		Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)
8.4.	Respiratory sensitisation	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.5.	Mutagenicity The assessment of this endpoint shall comprise the following consecutive steps: — an assessment of the available in vivo genotoxicity data — an in vitro test for gene mutations in bacteria, an in vitro cytogenicity test in mammalian cells and an in vitro gene mutation test in mammalian cells are required — appropriate in vivo genotoxicity studies shall be considered in case of a positive result in any of the in vitro genotoxicity studies		
8.5.1.	In vitro gene mutation study in bacteria		
8.5.2.	In vitro cytogenicity study in mammalian cells		
8.5.3.	In vitro gene mutation study in mammalian cells		
8.6.	In vivo genotoxicity study The assessment of this endpoint shall comprise the following consecutive steps: — If there is a positive result in any of the in vitro genotoxicity studies and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed/conducted by the applicant — If either of the in vitro gene mutation tests is positive, an in vivo test to investigate unscheduled DNA synthesis shall be conducted — A second in vivo somatic cell test may be necessary, depending on the results, quality and relevance of all the available data — If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered	ADS	The study/ies do(es) not generally need to be conducted if: — the results are negative for the three in vitro tests and if no metabolites of concern are formed in mammals or — valid in vivo micronucleus data is generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.
8.7.	Acute toxicity In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 shall be provided for at least one other route of administration		The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
	— The choice for the second route will depend on the nature of the substance and the likely route of human exposure — Gases and volatile liquids should be administered by the inhalation route — If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered. Before a new dermal acute toxicity study is carried out, an in vitro dermal penetration study (OECD 428) should be conducted to assess the likely magnitude and rate of dermal bioavailability — There may be exceptional circumstances where all routes of administration are deemed necessary		
8.7.1.	By oral route The Acute Toxic Class Method is the preferred method for the determination of this endpoint		The study need not be conducted if: — the substance is a gas or a highly volatile substance
8.7.2.	By inhalation Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account: — the vapour pressure of the substance (a volatile substance has vapour pressure $> 1 \times 10^{-2}$ Pa at 20 °C) and/or — the active substance is a powder containing a significant proportion (e.g. 1 % on a weight basis) of particles with particle size MMAD < 50 micrometers or — the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometers) — the Acute Toxic Class Method is the preferred method for the determination of this endpoint		
8.7.3.	By dermal route Testing by the dermal route is necessary only if: — inhalation of the substance is unlikely, or — skin contact in production and/or use is likely, and either		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
	— the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin, or — the results of an in vitro dermal penetration study (OECD 428) demonstrate high dermal absorption and bioavailability		
8.8.	Toxicokinetics and metabolism studies in mammals The toxicokinetics and metabolism studies should provide basic data about the rate and extent of absorption, the tissue distribution and the relevant metabolic pathway including the degree of metabolism, the routes and rate of excretion and the relevant metabolites		
8.8.1.	Further toxicokinetic and metabolism studies in mammals Additional studies might be required based on the outcome of the toxicokinetic and metabolism study conducted in rat. These further studies shall be required if: — there is evidence that metabolism in the rat is not relevant for human exposure — route-to-route extrapolation from oral to dermal/inhalation exposure is not feasible Where it is considered appropriate to obtain information on dermal absorption, the assessment of this endpoint shall proceed using a tiered approach for assessment of dermal absorption	ADS	
8.9.	Repeated dose toxicity In general, only one route of administration is necessary and the oral route is the preferred route. However, in some cases it may be necessary to evaluate more than one route of exposure. For the evaluation of the safety of consumers in relation to active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route Testing by the dermal route shall be considered if: — skin contact in production and/or use is likely, and — inhalation of the substance is unlikely, and		The repeated dose toxicity study (28 or 90 days) does not need to be conducted if: — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products for systemic and local effects and no synergistic effects are expected, or — relevant human exposure can be excluded in accordance with Section 3 of Annex IV In order to reduce testing carried out on vertebrates and in particular the need for free-standing single-endpoint studies, the design of the repeated dose toxicity studies shall take account of the possibility to explore several endpoints within the framework of one study

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Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
— one of the following conditions is met: (i) toxicity is observed in an acute dermal toxicity test at lower doses than in the oral toxicity test, or (ii) information or test data indicate dermal absorption is comparable or higher than oral absorption, or (iii) dermal toxicity is recognised for structurally related substances and for example is observed at lower doses than in the oral toxicity test or dermal absorption is comparable or higher than oral absorption Testing by the inhalation route shall be considered if: — exposure of humans via inhalation is likely taking into account the vapour pressure of the substance (volatile substances and gases have vapour pressure > 1×10^{-2} Pa at 20 °C), and/or — there is the possibility of exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometers)		
8.9.1. Short-term repeated dose toxicity study (28 days), preferred species is rat		The short-term toxicity study (28 days) does not need to be conducted if: (i) a reliable sub-chronic (90 day) study is available, provided that the most appropriate species, dosage, solvent and route of administration were used, (ii) the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: — other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or — appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short term toxicity study but which are liable to result in adverse effects after prolonged exposure

	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.9.2.	Sub-chronic repeated dose toxicity study (90 days), preferred species is rat		The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as H372 and H373 (Regulation (EC) No 1272/2008), for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor allows the extrapolation towards the NOAEL-90 days for the same route of exposure, and — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — the substance is unreactive, insoluble, not bioaccumulative and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure
8.9.3.	Long-term repeated dose toxicity (≥ 12 months)		The long-term toxicity study (≥ 12 months) does not need to be conducted if: — Long-term exposure can be excluded and no effects have been seen at the limit dose in the 90-day study or — a combined long-term repeated dose/carcinogenicity study (8.11.1) is undertaken
8.9.4.	Further repeat dose studies Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of administration shall be undertaken in case of: — no other information on toxicity for a second non-rodent species is provided for, or — failure to identify a no observed adverse effect level (NOAEL) in the 28- or the 90-day study, unless the reason is that no effects have been observed at the limit dose, or — substances bearing positive structural alerts for effects for which the rat or mouse is an inappropriate or insensitive model, or	ADS	

Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
— toxicity of particular concern (e.g. serious/ severe effects), or — indications of an effect for which the available data is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, hormonal activity), or — concern regarding local effects for which a risk characterisation cannot be performed by route-to route extrapolation, or — particular concern regarding exposure (e.g. use in biocidal products leading to exposure levels which are close to the toxicologically relevant dose levels), or — effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28- or the 90-day study, or — the route of administration used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made.		
8.10. Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies need not be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
			— If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered — If a substance is known to cause developmental toxicity, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered
8.10.1.	Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route. The study shall be initially performed on one species		
8.10.2.	Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route. If another reproductive toxicity test is used justification shall be provided. The extended one-generation reproductive toxicity study adopted at OECD level shall be considered as an alternative approach to the multi-generation study		
8.10.3.	Further pre-natal developmental toxicity study. A decision on the need to perform additional studies on a second species or mechanistic studies should be based on the outcome of the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration	ADS	
8.11.	Carcinogenicity See 8.11.1 for new study requirements		A carcinogenicity study does not need to be conducted if: — the substance is classified as mutagen category 1A or 1B. The default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required
8.11.1.	Combined carcinogenicity study and long-term repeated dose toxicity Rat, oral route of administration is the preferred route. If an alternative route is proposed a justification must be provided.		

	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
	For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.11.2.	Carcinogenicity testing in a second species — A second carcinogenicity study should normally be conducted using the mouse as test species — For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.12.	Relevant health data, observations and treatments Justification should be provided if data is not available		
8.12.1.	Medical surveillance data on manufacturing plant personnel		
8.12.2.	Direct observation, e.g. clinical cases, poisoning incidents		
8.12.3.	Health records, both from industry and any other available sources		
8.12.4.	Epidemiological studies on the general population		
8.12.5.	Diagnosis of poisoning including specific signs of poisoning and clinical tests		
8.12.6.	Sensitisation/allergenicity observations		
8.12.7.	Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
8.12.8.	Prognosis following poisoning		
8.13.	Additional studies Additional data which may be required depending on the characteristics and intended use of the active substance Other available data: Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic' (genomic, proteomic, metabolomic, etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel	ADS	
8.13.1.	Phototoxicity	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.13.2.	Neurotoxicity including developmental neurotoxicity — The preferred test species is the rat unless another test species is justified to be more appropriate — For delayed neurotoxicity tests the preferred species will be the adult hen — If anticholinesterase activity is detected a test for response to reactivating agents should be considered If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties then additional information or specific studies will be required. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS	
8.13.3.	Endocrine disruption If there is any evidence from in vitro, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required to: — elucidate the mode/mechanism of action — provide sufficient evidence for relevant adverse effects For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS	
8.13.4.	Immunotoxicity including developmental immunotoxicity If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required to: — elucidate the mode/mechanism of action — provide sufficient evidence for relevant adverse effects in humans For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.13.5.	Mechanistic data — any studies necessary to clarify effects reported in toxicity studies	ADS	
8.14.	Studies related to the exposure of humans to the active substance	ADS	
8.15.	Toxic effects on livestock and pets	ADS	
8.16.	Food and feeding stuffs studies including for food-producing animals and their products (milk, eggs and honey) Additional information related to the exposure of humans to the active substance contained in biocidal products	ADS	
8.16.1.	Proposed acceptable residue levels i.e. maximum residue limits (MRL) and the justification of their acceptability	ADS	
8.16.2.	Behaviour of the residue of the active substance on the treated or contaminated food or feeding stuffs including the kinetics of disappearance Residue definitions should be provided where relevant. It is also important to compare residues found in toxicity studies with residues formed in food-producing animals and their products, as well as food and feed	ADS	
8.16.3.	Overall material balance for the active substance Sufficient residue data from supervised trials on food- producing animals and their products, as well as food and feed, to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	ADS	
8.16.4.	Estimation of potential or actual exposure of humans to the active substance and residues through diet and other means	ADS	
8.16.5.	If residues of the active substance occur in or on feeding stuffs for a significant period of time or are found in food of animal origin after treatment on or around food-producing animals (e.g. direct treatment on animals or indirect treatment of animal houses or surroundings) then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	ADS	
8.16.6.	Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance	ADS	
8.16.7.	Any other available information that is relevant It may be appropriate to include information on migration into food, especially in the case of treatment of food contact materials	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.16.8.	Summary and evaluation of data submitted under 8.16.1 to 8.16.8 It is important to establish whether the metabolites found in food (from animals or plants) are the same as those tested in toxicity studies. Otherwise values for risk assessment (e.g. ADI) are not valid for the residues found	ADS	
8.17.	If the active substance is to be used in products for action against plants including algae then tests shall be required to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals	ADS	
8.18.	Summary of mammalian toxicology Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL		
9.	ECOTOXICOLOGICAL STUDIES		
9.1.	Toxicity to Aquatic Organisms		
9.1.1.	Short-term toxicity testing on fish When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied		The study does not need to be conducted if: — a valid long-term aquatic toxicity study on fish is available
9.1.2.	Short-term toxicity testing on aquatic invertebrates		
9.1.2.1.	Daphnia magna		
9.1.2.2.	Other species	ADS	
9.1.3.	Growth inhibition study on algae		
9.1.3.1.	Effects on growth rate of green algae		
9.1.3.2.	Effects on growth rate of cyanobacteria or diatoms		
9.1.4. 9.1.4.1. 9.1.4.2.	Bioconcentration Estimation methods Experimental determination		The experimental determination may not need to be carried out if: — it can be demonstrated on the basis of physico-chemical properties (e.g. log Kow < 3) or other evidence that the substance has a low potential for bioconcentration
9.1.5.	Inhibition of microbial activity The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria		

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Column 1 Information required		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
9.1.6.	Further Toxicity Studies on Aquatic Organisms If the results of the ecotoxicological studies, studies on fate and behaviour and/or the intended use(s) of the active substance indicate a risk for the aquatic environment, or if long-term exposure is expected, then one or more of the tests described in this Section shall be conducted	ADS	
9.1.6.1.	Long term toxicity testing on Fish (a) Fish Early Life Stage (FELS) Test (b) Fish short term toxicity test on embryo and sack fry stages (c) Fish juvenile growth test (d) Fish full life cycle test	ADS	
9.1.6.2.	Long term toxicity testing on invertebrates (a) Daphnia growth and reproduction study (b) Other species reproduction and growth (e.g. Mysid) (c) Other species development and emergence (e.g. Chironomus)	ADS	
9.1.7.	Bioaccumulation in an appropriate aquatic species	ADS	
9.1.8.	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	
9.1.9.	Studies on sediment- dwelling organisms	ADS	
9.1.10.	Effects on aquatic macrophytes	ADS	
9.2. 9.2.1. 9.2.2. 9.2.3.	Terrestrial toxicity, initial tests Effects on soil micro-organisms Effects on earthworms or other soil- dwelling non-target invertebrates Acute toxicity to plants	ADS	
9.3. 9.3.1.	Terrestrial tests, long term Reproduction study with earthworms or other soil-dwelling non-target invertebrates	ADS	
9.4. 9.4.1. 9.4.2.	Effects on birds Acute oral toxicity Short-term toxicity — eight-day dietary study in at least one species (other than chickens, ducks and geese)	ADS	For endpoint 9.4.3 the study does not need to be conducted if: — the dietary toxicity study shows that the LC_{50} is above 2 000 mg/kg

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Column 1 Information required		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
9.4.3.	Effects on reproduction		
9.5.	Effects on arthropods	ADS	
9.5.1.	Effects on honeybees		
9.5.2.	Other non-target terrestrial arthropods, e.g. predators		
9.6.	Bioconcentration, terrestrial	ADS	
9.7.	Bioaccumulation, terrestrial	ADS	
9.8.	Effects on other non-target, non-aquatic organisms	ADS	
9.9.	Effects on mammals	ADS	Data are derived from the mammalian toxicological assessment. The most sensitive relevant mammalian long-term toxicological endpoint (NOAEL) expressed as mg test compound/kg bw/day shall be reported
9.9.1.	Acute oral toxicity		
9.9.2.	Short term toxicity		
9.9.3.	Long term toxicity		
9.9.4.	Effects on reproduction		
9.10.	Identification of endocrine activity	ADS	
10.	ENVIRONMENTAL FATE AND BEHAVIOUR		
10.1.	Fate and behaviour in water and sediment		
10.1.1.	Degradation, initial studies If the assessment performed indicates the need to investigate further the degradation of the substance and its degradation products or the active substance has an overall low or absent abiotic degradation, then the tests described in 10.1.3 and 10.3.2 and where appropriate — in 10.4 shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed		
10.1.1.1.	Abiotic		
	(a) Hydrolysis as a function of pH and identification of breakdown products — The identification of breakdown products is required when the breakdown products at any sampling time are present at ≥ 10 % (b) Phototransformation in water, including identification of transformation products		

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Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
10.1.1.2. Biotic		
(a) Ready biodegradability		
(b) Inherent biodegradability (where appropriate)		
10.1.2. Adsorption/desorption		
10.1.3. Rate and route of degradation including identification of metabolites and degradation products		
10.1.3.1. Biological sewage treatment		
(a) Aerobic biodegradation	ADS	
(b) Anaerobic biodegradation	ADS	
(c) STP simulation test	ADS	
10.1.3.2. Biodegradation in freshwater		
(a) Aerobic aquatic degradation study	ADS	
(b) Water/sediment degradation test	ADS	
10.1.3.3. Biodegradation in sea water	ADS	
10.1.3.4. Biodegradation during manure storage	ADS	
10.1.4. Adsorption and desorption in water/aquatic sediment systems and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.1.5. Field study on accumulation in sediment	ADS	
10.1.6. Inorganic substances: information on fate and behaviour in water	ADS	
10.2. Fate and behaviour in soil	ADS	
10.2.1. Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions Laboratory studies on rate of degradation in three additional soil types	ADS	
10.2.2. Field studies, two soil types	ADS	
10.2.3. Soil accumulation studies	ADS	

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
10.2.4.	Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.2.5.	Further studies on sorption		
10.2.6.	Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	ADS	
10.2.6.1.	Column leaching studies		
10.2.6.2.	Lysimeter studies		
10.2.6.3.	Field leaching studies		
10.2.7.	Extent and nature of bound residues The determination and characteristics of bound residues is recommended to be combined with a soil simulation study	ADS	
10.2.8.	Other soil degradation studies	ADS	
10.2.9.	Inorganic substances: information on fate and behaviour in soil		
10.3.	Fate and behaviour in air		
10.3.1.	Phototransformation in air (estimation method) Identification of transformation products		
10.3.2.	Fate and behaviour in air, further studies	ADS	
10.4.	Additional studies on fate and behaviour in the environment	ADS	
10.5. 10.5.1.	Definition of the residue Definition of the residue for risk assessment	ADS	
10.5.2.	Definition of the residue for monitoring		
10.6.	Monitoring data	ADS	
10.6.1.	Identification of all degradation products (> 10 %) must be included in the studies on degradation in soil, water and sediments		
11.	MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
11.1.	Recommended methods and precautions concerning handling, use, storage, transport or fire		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
11.2.	In case of fire, nature of reaction products, combustion gases etc.		
11.3.	Emergency measures in case of accident		
11.4.	Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil		
11.5.	Procedures for waste management of the active substance for industry or professional users		
11.6.	Possibility of reuse or recycling		
11.7.	Possibility of neutralisation of effects		
11.8.	Conditions for controlled discharge including leachate qualities on disposal		
11.9.	Conditions for controlled incineration		
11.10.	Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances ([3]), of Annexes I and II to Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration ([4]), of Annex I to Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy ([5]), of Part B of Annex I to Directive 98/83/EC or Annexes VIII and X to Directive 2000/60/EC		
12.	CLASSIFICATION, LABELLING AND PACKAGING		
12.1.	State any existing classification and labelling		
12.2.	The hazard classification of the substance resulting from the application of Regulation (EC) No 1272/2008 In addition, for each entry, the reasons why no classification is given for an endpoint should be provided		
12.2.1.	Hazard classification		
12.2.2.	Hazard pictogram		
12.2.3.	Signal word		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
12.2.4.	Hazard statements		
12.2.5.	Precautionary statements including prevention, response, storage and disposal		
12.3.	Specific concentration limits, where applicable, resulting from the application of Regulation (EC) No 1272/2008		
13.	SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

(1) The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
(2) The information provided should be for the purified active substance of stated specification.
(3) OJ L 20, 26.1.1980, p. 43.
(4) OJ L 372, 27.12.2006, p. 19.
(5) OJ L 348, 24.12.2008, p. 84.

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TITLE 2

MICRO-ORGANISMS

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in Regulation (EC) No 440/2008 that are not repeated in column 3, also apply.

Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Manufacturer (name, address and location of manufacturing plant)		
2. IDENTITY OF THE MICRO-ORGANISM		
2.1. Common name of the micro-organism (including alternative and superseded names)		
2.2. Taxonomic name and strain		
2.3. Collection and culture reference number where the culture is deposited		
2.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
2.5. Specification of the technical grade active ingredient		
2.6. Method of production and quality control		
2.7. Content of the micro-organism		
2.8. Identity and content of impurities, additives, contaminating micro-organisms		
2.9. Analytical profile of batches		
3. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM		
3.1. General information on the micro-organism		
3.1.1. Historical background		
3.1.2. Historical uses		
3.1.3. Origin, natural occurrence and geographical distribution		

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	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
3.2.	Development stages/life cycle of the micro-organism		
3.3.	Relationships to known plant or animal or human pathogens		
3.4.	Genetic stability and factors affecting it		
3.5.	Information on the production of metabolites (especially toxins)		
3.6.	Production and resistance to antibiotics and other anti-microbial agents		
3.7.	Robustness to environmental factors		
3.8.	Further information on the micro-organism		
4.	METHODS OF DETECTION AND IDENTIFICATION		
4.1.	Analytical methods for the analysis of the micro-organism as manufactured		
4.2.	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)		
5.	EFFECTIVENESS AGAINST TARGET ORGANISM		
5.1.	Function and mode of control e.g. attracting, killing, inhibiting		
5.2.	Infectiveness, dispersal and colonisation ability		
5.3.	Representative organism(s) controlled and products, organisms or objects to be protected		
5.4.	Effects on representative target organism(s) Effects on materials, substances and products		
5.5.	Likely concentration at which the micro-organism will be used		
5.6.	Mode of action (including time delay)		
5.7.	Efficacy data		
5.8.	Any known limitations on efficacy		
5.8.1.	Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and appropriate management strategies		
5.8.2.	Observations on undesirable or unintended side effects		
5.8.3.	Host specificity, range and effects on species other than the target organism		

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Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
5.9. Methods to prevent loss of virulence of seed stock of the micro-organism		
6. INTENDED USES AND EXPOSURE		
6.1. Field of use(s) envisaged		
6.2. Product-type(s)		
6.3. Detailed description of the use pattern(s)		
6.4. Category of users for which the micro-organism should be approved		
6.5. Exposure data applying, as appropriate, the methodologies described in Section 5 of Annex I to Regulation (EC) No 1907/2006		
6.5.1. Information on human exposure associated with the intended uses and disposal of the active substance		
6.5.2. Information on environmental exposure associated with the intended uses and disposal of the active substance		
6.5.3. Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7. EFFECT ON HUMAN AND ANIMAL HEALTH		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
7.1. Basic information		
7.1.1. Medical data		
7.1.2. Medical surveillance on manufacturing plant personnel		
7.1.3. Sensitisation/allergenicity observations		
7.1.4. Direct observation, e.g. clinical cases Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression		
7.2. Basic studies		
7.2.1. Sensitisation		
7.2.2. Acute toxicity, pathogenicity, and infectiveness		
7.2.2.1. Acute oral toxicity, pathogenicity and infectiveness		
7.2.2.2. Acute inhalatory toxicity, pathogenicity and infectiveness	ADS	
7.2.2.3. Intraperitoneal/subcutaneous single dose	ADS	

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Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
7.2.3. In vitro genotoxicity testing		
7.2.4. Cell culture study		
7.2.5. Information on short-term toxicity and pathogenicity	ADS	
7.2.5.1. Health effects after repeated inhalatory exposure	ADS	
7.2.6. Proposed treatment: first aid measures, medical treatment		
7.3. Specific toxicity, pathogenicity and infectiveness studies	ADS	
7.4. Genotoxicity — in vivo studies in somatic cells	ADS	
7.5. Genotoxicity — in vivo studies in germ cells	ADS	
7.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation		
7.7. Residues in or on treated articles, food and feedingstuffs	ADS	
7.7.1. Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs	ADS	
7.7.2. Further information required	ADS	
7.7.2.1. Non-viable residues	ADS	
7.7.2.2. Viable residues	ADS	
7.8. Summary and evaluation of residues in or on treated articles, food and feedingstuffs	ADS	
8. EFFECTS ON NON-TARGET ORGANISMS		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
8.1. Effects on aquatic organisms		
8.1.1. Effects on fish		
8.1.2. Effects on freshwater invertebrates		
8.1.3. Effects on algae growth		
8.1.4. Effects on plants other than algae	ADS	
8.2. Effects on earthworms		
8.3. Effects on soil micro-organisms		
8.4. Effects on birds		
8.5. Effects on bees		
8.6. Effects on arthropods other than bees		

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Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.7. Further studies	ADS	
8.7.1. Terrestrial plants	ADS	
8.7.2. Mammals	ADS	
8.7.3. Other relevant species and processes	ADS	
8.8. Summary and evaluation of effects on non-target organisms		
9. ENVIRONMENTAL FATE AND BEHAVIOUR		
9.1. Persistence and multiplication		
9.1.1. Soil		
9.1.2. Water		
9.1.3. Air		
9.1.4. Mobility		
9.1.5. Summary and evaluation of fate and behaviour in the environment		
10. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
10.1. Recommended methods and precautions concerning handling, storage, transport or fire		
10.2. Emergency measures in case of an accident		
10.3. Procedures for destruction or decontamination		
10.4. Procedures for waste management		
10.5. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use		
11. CLASSIFICATION, LABELLING AND PACKAGING OF THE MICRO-ORGANISM		
11.1. Relevant risk group specified in Article 2 of Directive 2000/54/EC		
12. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

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ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with point (b) of Article 6(1) and the dossier accompanying an application for the authorisation of a biocidal product in accordance with point (a) of Article 20(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

   With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

   Specific indications for the inclusion of some data elements are provided in column 1 of the Annex III table. The general considerations regarding adaptation of information requirements as set out in Annex IV to this Regulation shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates.

   For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation.

   The relevant calculation methods used for the classification of mixtures as laid down in Regulation (EC) No 1272/2008 shall, where appropriate, be applied in the hazard assessment of the biocidal product. Such calculation methods shall not be used if, in relation to a particular hazard, synergistic and antagonistic effects between the different substances contained in the product are considered likely.

   Detailed technical guidance regarding the application of this Annex and the preparation of the dossier is available on the website of the Agency.

   The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

   Additional information may need to be submitted if necessary to carry out the evaluation as indicated in Article 29(3) or Article 44(2).

   The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria in Article 19(1)(b) are met.

3. A detailed and full description of studies conducted and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements.

4. The formats made available by the Agency shall be used for submission of the dossiers. In addition, IUCLID shall be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

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6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

7. Where testing is done, a detailed quantitative and qualitative description (specification) of the product used for each test and its impurities must be provided.

8. Where test data exist that have been generated before 17 July 2012 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State, on a case-by-case basis, taking into account, among other factors, the need to avoid unnecessary testing.

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

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TITLE 1

CHEMICAL PRODUCTS

Core data set and additional data set for chemical products

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
1. APPLICANT		
1.1. Name and address, etc.		
1.2. Contact person		
1.3. Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCT		
2.1. Trade name or proposed trade name		
2.2. Manufacturer's development code and number of the product, if appropriate		
2.3. Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and non-active substances (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of the biocidal product shall be given		
2.4. Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution		
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES		
3.1. Appearance (at 20 °C and 101,3 kPa)		
3.1.1. Physical state (at 20 °C and 101,3 kPa)		
3.1.2. Colour (at 20 °C and 101,3 kPa)		
3.1.3. Odour (at 20 °C and 101,3 kPa)		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10		
3.3. Relative density (liquids) and bulk, tap density (solids)		
3.4. Storage stability, stability and shelf-life		
3.4.1. Storage stability tests		
3.4.1.1. Accelerated storage test		
3.4.1.2. Long term storage test at ambient temperature		
3.4.1.3. Low temperature stability test (liquids)		
3.4.2. Effects on content of the active substance and technical characteristics of the biocidal product		
3.4.2.1. Light		
3.4.2.2. Temperature and humidity		
3.4.2.3. Reactivity towards container material		
3.5. Technical characteristics of the biocidal product		
3.5.1. Wettability		
3.5.2. Suspensibility, spontaneity and dispersion stability		
3.5.3. Wet sieve analysis and dry sieve test		
3.5.4. Emulsifiability, re-emulsifiability and emulsion stability		
3.5.5. Disintegration time		
3.5.6. Particle size distribution, content of dust/fines, attrition, friability		
3.5.7. Persistent foaming		
3.5.8. Flowability/Pourability/Dustability		
3.5.9. Burning rate — smoke generators		
3.5.10. Burning completeness — smoke generators		
3.5.11. Composition of smoke — smoke generators		
3.5.12. Spraying pattern — aerosols		
3.5.13. Other technical characteristics		
3.6. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised		
3.6.1. Physical compatibility		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
3.6.2. Chemical compatibility		
3.7. Degree of dissolution and dilution stability		
3.8. Surface tension		
3.9. Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS		
4.1. Explosives		
4.2. Flammable gases		
4.3. Flammable aerosols		
4.4. Oxidising gases		
4.5. Gases under pressure		
4.6. Flammable liquids		
4.7. Flammable solids		
4.8. Self-reactive substances and mixtures		
4.9. Pyrophoric liquids		
4.10. Pyrophoric solids		
4.11. Self-heating substances and mixtures		
4.12. Substances and mixtures which in contact with water emit flammable gases		
4.13. Oxidising liquids		
4.14. Oxidising solids		
4.15. Organic peroxides		
4.16. Corrosive to metals		
4.17. Additional physical indications of hazard		
4.17.1. Auto-ignition temperatures of products (liquids and gases)		
4.17.2. Relative self-ignition temperature for solids		
4.17.3. Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION		
5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product		

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	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
5.2.	In so far as not covered by Annex II 5.2 and 5.3, analytical methods for monitoring purposes including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:	ADS	
5.2.1.	Soil	ADS	
5.2.2.	Air	ADS	
5.2.3.	Water (including drinking water) and sediment	ADS	
5.2.4.	Animal and human body fluids and tissues	ADS	
5.3.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6.	EFFECTIVENESS AGAINST TARGET ORGANISMS		
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which the active substance will be used		
6.5.	Mode of action (including time delay)		
6.6.	The proposed label claims for the product and, where label claims are made, for treated articles		
6.7.	Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		
6.8.	Any known limitations on efficacy		
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2.	Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
6.9. Summary and evaluation		
7. INTENDED USES AND EXPOSURE		
7.1. Field(s) of use envisaged for biocidal products and, where appropriate, treated articles		
7.2. Product-type		
7.3. Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles		
7.4. User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5. Likely tonnage to be placed on the market per year and, where relevant, for different use categories		
7.6. Method of application and a description of this method		
7.7. Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes		
7.8. Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal health and the environment		
7.9. Proposed instructions for use		
7.10. Exposure data in conformity with Annex VI to this Regulation		
7.10.1. Information on human exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.2. Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.3. Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
7.10.4. Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		
8.1. Skin corrosion or skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected
8.2. Eye irritation (1) The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ECand Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.3. Skin sensitisationThe assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected — the available information indicates that the product should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)
8.4. Respiratory sensitisation	ADS	Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.5. Acute toxicity — Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.5.1. By oral route		
8.5.2. By inhalation		
8.5.3. By dermal route		
8.5.4. For biocidal products that are intended to be authorised for use with other biocidal products, the risks to human health, animal health and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried out using combinations of the products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.6. Information on dermal absorption Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach		
8.7. Available toxicological data relating to: — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP)
8.8. Food and feedingstuffs studies	ADS	
8.8.1. If residues of the biocidal product remain in or on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	ADS	

	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.9.	Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product	ADS	
8.10.	Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required for the biocidal product In addition, for certain biocides which are applied directly or around livestock (including horses) residue studies might be needed	ADS	
9.	ECOTOXICOLOGICAL STUDIES		
9.1.	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary		
9.2.	Further Ecotoxicological studies Further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3.	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4.	If the biocidal product is in the form of bait or granules the following studies may be required:		
9.4.1.	Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2.	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk		
9.5.	Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
10. ENVIRONMENTAL FATE AND BEHAVIOUR The test requirements below are applicable only to the relevant components of the biocidal product		
10.1. Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2. Further studies on fate and behaviour in the environment Further studies chosen from among the endpoints referred to in Section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required. For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3. Leaching behaviour	ADS	
10.4. Testing for distribution and dissipation in the following:	ADS	
10.4.1. Soil	ADS	
10.4.2. Water and sediment	ADS	
10.4.3. Air	ADS	
10.5. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions	ADS	
10.6. If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
11.1. Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire		
11.2. Identity of relevant combustion products in cases of fire		
11.3. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
11.4. Possibility of destruction or decontamination following release in or on the following:		
11.4.1. Air		
11.4.2. Water, including drinking water		
11.4.3. Soil		
11.5. Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)		
11.6. Procedures for cleaning application equipment where relevant		
11.7. Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms		
12. CLASSIFICATION, LABELLING, AND PACKAGING As established in point (b) of Article 20(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted. Example labels, instructions for use and safety data sheets shall be provided		
12.1. Hazard classification		
12.2. Hazard pictogram		
12.3. Signal word		
12.4. Hazard statements		
12.5. Precautionary statements including prevention, response, storage and disposal		
12.6. Proposals for safety-data sheets should be provided, where appropriate		
12.7. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. EVALUATION AND SUMMARY The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

(1) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

Πανεπιστήμιο Πειραιώς

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Manufacturer and formulator of the biocidal product and the micro-organism(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCTS		
2.1. Trade name or proposed trade name		
2.2. Manufacturer's development code and number of the biocidal product, if appropriate		
2.3. Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given		
2.4. Formulation type and nature of the biocidal product		
3. BIOLOGICAL, PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT		
3.1. Biological properties of the micro-organism in the biocidal product		
3.2. Appearance (at 20 °C and 101,3 kPa)		
3.2.1. Colour (at 20 °C and 101,3 kPa)		
3.2.2. Odour (at 20 °C and 101,3 kPa)		
3.3. Acidity, alkalinity and pH value		
3.4. Relative density		
3.5. Storage stability, stability and shelf-life		
3.5.1. Effects of light		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
3.5.2. Effects of temperature and humidity		
3.5.3. Reactivity towards the container		
3.5.4. Other factors affecting stability		
3.6. Technical characteristics of the biocidal product		
3.6.1. Wettability		
3.6.2. Suspensibility and suspension stability		
3.6.3. Wet sieve analysis and dry sieve test		
3.6.4. Emulsifiability, re-emulsifiability, emulsion stability		
3.6.5. Particle size distribution content of dust/fines, attrition and friability		
3.6.6. Persistent foaming		
3.6.7. Flowability/Pourability/Dustability		
3.6.8. Burning rate — smoke generators		
3.6.9. Burning completeness — smoke generators		
3.6.10. Composition of smoke — smoke generators		
3.6.11. Spraying patterns — aerosols		
3.6.12. Other technical characteristics		
3.7. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered		
3.7.1. Physical compatibility		
3.7.2. Chemical compatibility		
3.7.3. Biological compatibility		
3.8. Surface tension		
3.9. Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS		
4.1. Explosives		
4.2. Flammable gases		
4.3. Flammable aerosols		
4.4. Oxidising gases		
4.5. Gases under pressure		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
4.6. Flammable liquids		
4.7. Flammable solids		
4.8. Oxidising liquids		
4.9. Oxidising solids		
4.10. Organic peroxides		
4.11. Corrosive to metals		
4.12. Other physical indications of hazard		
4.12.1. Auto-ignition temperatures of products (liquids and gases)		
4.12.2. Relative self-ignition temperature for solids		
4.12.3. Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION		
5.1. Analytical method for determining the concentration of the micro-organism(s) and substances of concern in the biocidal product		
5.2. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the article treated with it does not come into contact with food-producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISM		
6.1. Function and mode of control		
6.2. Representative pest organism(s) to be controlled and products, organisms or objects to be protected		
6.3. Effects on representative target organisms		
6.4. Likely concentration at which micro-organism will be used		
6.5. Mode of action		
6.6. The proposed label claims for the product		
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests, or field trials used including performance standards, where appropriate and relevant		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
6.8. Any other known limitations on efficacy including resistance		
6.8.1. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2. Observations on undesirable or unintended side effects		
7. INTENDED USES AND EXPOSURE		
7.1. Field of use envisaged		
7.2. Product-type		
7.3. Detailed description of intended use		
7.4. User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5. Method of application and a description of this method		
7.6. Application rate and if appropriate the final concentration of the biocidal product or the micro-organism active substance in a treated article or the system in which the product is to be used (e.g. in the application device or bait)		
7.7. Number and timing of applications and duration of protection Any particular information relating to the geographical location or climatic variations including necessary waiting periods for re-entry or necessary withdrawal period or other precautions to protect human health, animal health and the environment		
7.8. Proposed instructions for use		
7.9. Exposure data		
7.9.1. Information on human exposure associated with the proposed/expected uses and disposal		
7.9.2. Information on environmental exposure associated with the proposed/expected uses and disposal		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.1. Skin corrosion or irritation		
8.2. Eye irritation		
8.3. Skin sensitisation		
8.4. Respiratory sensitisation	ADS	
8.5. Acute toxicity — Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		
8.5.1. Oral		
8.5.2. Inhalation		
8.5.3. Dermal		
8.5.4. Additional acute toxicity studies		
8.6. Information on dermal absorption if required		
8.7. Available toxicological data relating to: — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.8. Supplementary studies for combinations of biocidal products For biocidal products that are intended to be authorised for use with other biocidal products, the risks to humans, animals and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried using combinations of the products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
8.9. Residues in or on treated articles, food and feedingstuffs	ADS	
9. ECOTOXICOLOGICAL STUDIES		
9.1. Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary		
9.2. Further ecotoxicological studies Further studies chosen from among the endpoints referred to in Section 8 of Annex II 'Micro-organisms' for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3. Effects on any other specific non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4. If the biocidal product is in the form of bait or granules 9.4.1. Supervised trials to assess risks to non-target organisms under field conditions 9.4.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk	ADS	
9.5. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR		
10.1. Foreseeable routes of entry into the environment on the basis of the use envisaged		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
10.2. Further studies on fate and behaviour in the environment Where relevant, all the information required in Section 9 of Annex II 'Micro-organisms' may be required for the product For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3. Leaching behaviour	ADS	
10.4. If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
11.1. Recommended methods and precautions concerning: handling, storage, transport or fire		
11.2. Measures in the case of an accident		
11.3. Procedures for destruction or decontamination of the biocidal product and its packaging		
11.3.1. Controlled incineration		
11.3.2. Others		
11.4. Packaging and compatibility of the biocidal product with proposed packaging materials		
11.5. Procedures for cleaning application equipment where relevant		
11.6. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use		
12. CLASSIFICATION, LABELLING AND PACKAGING Example labels, instructions for use and safety data sheets shall be provided		
12.1. Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC		

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Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates
12.2. Precautionary statements including prevention, response, storage and disposal		
12.3. Proposals for safety-data sheets should be provided, where appropriate		
12.4. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

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ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This Annex sets out rules to be followed when the applicant proposes to adapt the data requirements set out in Annexes II and III in accordance with Article 6(2) and (3) or Article 21(1) and (2), without prejudice to the specific rules set out in Annex III on the use of the calculation methods for classification of mixtures to avoid testing on vertebrates.

The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) sufficient adequate and reliable documentation is provided to assess the equivalency of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters/endpoints foreseen to be investigated in the corresponding test methods;

(3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter;

(4) adequate and reliable documentation of the study is provided; and

(5) the study is performed using a system of quality assurance.

1.1.3. Historical human data

As a general rule, in accordance with Article 7(3) of Regulation (EC) No 1272/2008, tests on humans shall not be performed for the purposes of this Regulation. However, existing historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered.

Data collected on humans shall not be used to lower the safety margins resulting from tests or studies on animals.

The strength of the data for a specific human health effect depends, among other things, on the type of analysis and the parameters covered, and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

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(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or does not have a particular dangerous property, while the information from each single source alone is considered insufficient to support this notion. There may be sufficient weight of evidence from the use of positive results of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the Commission as being equivalent, leading to the conclusion that a substance has a particular dangerous property. However, if the newly developed test method has been approved by the Commission, but has not yet been published, its results may be taken into account even where this leads to the conclusion that a substance does not have a particular dangerous property.

Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property:

— further testing on vertebrates for that property shall not be undertaken,

— further testing not involving vertebrates may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence, but not the absence of a given dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— the results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— the results are adequate for the purpose of classification and labelling and risk assessment, and

— adequate and reliable documentation of the applied method is provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on the use of (Q)SARs.

1.4. In vitro methods

Results obtained from suitable in vitro methods may indicate the presence of a given dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well-developed according to internationally agreed test development criteria.

Where such in vitro tests are positive, it is necessary to confirm the dangerous property by adequate *in vivo* tests. However, such confirmation may be waived if the following conditions are met:

(1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

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(2) results are adequate for the purpose of classification and labelling and risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

In the case of negative results, these exemptions do not apply. A confirmation test may be requested on a case-by-case basis.

1.5. Grouping of substances and read-across approach

Substances whose physico-chemical, toxicological and ecotoxicological properties are similar or follow a regular pattern as a result of structural similarity may be considered as a group or 'category' of substances. Application of the group concept requires that physico-chemical properties, human and animal health effects, and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based on:

(1) a common functional group indicating the presence of dangerous properties;

(2) common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results shall:

— be adequate for the purpose of classification and labelling and risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method, and

— cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter.

In all cases, adequate and reliable documentation of the applied method shall be provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on technically and scientifically justified methodology for the grouping of substances.

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion, or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with some endpoints in Sections 8 and 9 of Annexes II and III, notwithstanding Article 6(2), may be omitted based on exposure considerations, where exposure data in accordance with Annex II or III are available.

In that case, the following conditions shall be met:

— An exposure assessment shall be performed, covering primary and secondary exposure under realistic worst case for all intended uses of the biocidal product that contains the active substance for which approval is applied, or of the biocidal product for which the authorisation is sought.

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— If a new exposure scenario is introduced at a later stage, during the product authorisation process, additional data shall be submitted to assess whether the justification for data adaptation still applies.

— The reasons why the outcome of the exposure assessment justifies waiving of data requirements shall be clearly and transparently explained.

However, testing cannot be omitted for non-threshold effects. As a consequence, certain core data shall always be obligatory, e.g. genotoxicity testing.

If relevant, the Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the criteria established in accordance with Article 6(4) and Article 21(3).

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment, in accordance with the relevant Technical Notes for Guidance where available.

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ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1: Disinfectants

These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 3: Veterinary hygiene

Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

Products used to impregnate materials which may enter into contact with food.

Product-type 5: Drinking water

Products used for the disinfection of drinking water for both humans and animals.

MAIN GROUP 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

Product-type 6: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

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Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects.

This product-type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.

Product-type 10: Construction material preservatives

Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product-type 15: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.

Product-type 17: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.

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Product-type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.

MAIN GROUP 4: Other biocidal products

Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

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ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

TERMS AND DEFINITIONS

Correspondence with the criteria set out in Article 19(1)(b)

The subheadings 'Effects on human and animal health', 'Effects on the Environment', 'Effects on Target Organisms' and 'Efficacy' used in the Sections 'Assessment' and 'Conclusions' correspond to the four criteria set out in Article 19(1)(b) as follows:

'Efficacy' corresponds to criterion (i): 'is sufficiently effective'.

'Effects on target organisms' corresponds to criterion (ii): 'has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross resistance or unnecessary suffering and pain for vertebrates'.

'Effects on human and animal health' corresponds to criterion (iii): 'has no immediate or delayed unacceptable effects itself, or as a result of its residues, on human health, including that of vulnerable groups [1], or animal health, directly or through drinking water, food, feed, air, or through other indirect effects'.

'Effects on the environment' corresponds to criterion iv: 'has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment,

[1] See definition of vulnerable groups in Article 3.

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— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— its impact on non-target organisms,

— its impact on biodiversity and the ecosystem'.

Technical definitions

(a) Hazard identification

The identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) Dose (concentration) — response (effect) assessment

The estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) Exposure assessment

The determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) Risk characterisation

The estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation', i.e. the quantification of that likelihood.

(e) Environment

Water, including sediment, air, soil, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex sets out the common principles for the evaluation of dossiers for biocidal products referred to in Article 19(1)(b). A decision by a Member State or the Commission to authorise a biocidal product shall be taken on the basis of the conditions set down in Article 19, taking account of the evaluation carried out according to this Annex. Detailed technical guidance regarding the application of this Annex is available on the website of the Agency.

2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials, the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.

3. In order to ensure a high and harmonised level of protection of human health, animal health and the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product, taking into account any cumulative and synergistic effects.

4. A risk assessment on the active substance(s) present in the biocidal product is always required. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

5. Additional risk assessments shall be carried out, in the same manner as described above, on any substance of concern present in the biocidal product. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

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6. In order to carry out a risk assessment, data are required. These data are detailed in Annexes II and III and take account of the fact that there are a wide variety of applications as well as different product-types and that this has an impact on the associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. The evaluating body shall take due consideration of the requirements of Articles 6, 21 and 62 in order to avoid duplication of data submissions. Data may also be required on a substance of concern present in a biocidal product. For in-situ generated active substances, the risk assessment includes also the possible risks from the precursor(s).

7. The results of the risk assessments carried out on the active substance and on the substances of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

8. When making evaluations of a biocidal product the evaluating body shall:

   (a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

   (b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

9. The application of these common principles shall, when taken together with the other conditions set out in Article 19, lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised. Such authorisation may include restrictions on use or other conditions. In certain cases the competent authorities may conclude that more data are required before an authorisation decision can be made.

10. In the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent authorities or the Commission shall also evaluate whether the conditions of Article 5(2) can be satisfied.

11. During the process of evaluation, applicants and the evaluating bodies shall cooperate in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

12. The judgments made by the evaluating body during the evaluation must be based on scientific principles, preferably recognised at international level, and must be made with the benefit of expert advice.

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be validated by the evaluating or receiving competent authority in accordance with the relevant articles of the Regulation. After validation of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.

15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the scientific definitions and methodologies for the assessment of cumulative and synergistic effects.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail hazard identification and the establishment of appropriate reference values for dose or effect concentrations such as NOAEL or Predicted No Effect Concentrations (PNEC), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the appropriate reference values for each of the active substances and for any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

(a) the hazards due to the physico-chemical properties,

(b) the risk to humans and animals,

(c) the risk to the environment,

(d) the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

20. The information provided on the biocidal product family shall permit the evaluating body to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 19(1)(b).

21. Where relevant the technical equivalence for every active substance contained in the biocidal product shall be established with reference to active substances already included in the list of approved active substances.

Effects on human and animal health

Effects on human health

22. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

23. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute toxicity,

— irritation,

— corrosivity,

— sensitisation,

— repeated dose toxicity,

— mutagenicity,

— carcinogenicity,

— reproductive toxicity,

— neurotoxicity,

— immunotoxicity,

— disruption of the endocrine system,

— any other special properties of the active substance or substance of concern,

— other effects due to physico-chemical properties.

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24. The populations previously mentioned are:

— professional users,

— non-professional users,

— humans exposed directly or indirectly via the environment.

In considering these populations, particular attention should be given to the need to protect vulnerable groups within these populations.

25. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

26. The evaluating body shall apply points 27 to 30 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

27. For repeated dose toxicity and reproductive toxicity the dose-response relationship shall be assessed for each active substance or substance of concern and, where possible, a NOAEL identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

28. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or another appropriate dose-effect descriptor shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

29. For mutagenicity and carcinogenicity, a non-threshold assessment should be carried out if the active substance or substance of concern is genotoxic and carcinogenic. If the active substance or a substance of concern is not genotoxic a threshold assessment shall be carried out.

30. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur, particularly in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects as a result of the use of the biocidal product.

31. When carrying out the risk assessment special consideration shall be given to toxicity data derived from observations of human exposure where such data are available, e.g. information gained from manufacture, from poison centres or epidemiology surveys.

32. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed directly or indirectly via the environment), for which exposure to a biocidal product occurs or can reasonably be foreseen, with particular attention paid to the pathways of exposure relevant for vulnerable groups. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern, including relevant metabolites and degradation products to which a population is, or may be exposed during use of the biocidal product and articles treated with that product.

33. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Articles 6 and 21 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,

— the form in which the biocidal product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties of the biocidal product,

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— the likely routes of exposure and potential for absorption,

— the frequency and duration of exposure,

— maximum residue levels,

— the type and size of specific exposed populations, where such information is available.

34. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,

— be subjected to an analysis taking into account possible elements of uncertainty,

— be reliably validated with measurements carried out under circumstances relevant for the use of the model,

— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

35. Where, for any of the effects set out in point 23 a reference value has been identified, the risk characterisation shall entail comparison of the reference value with the evaluation of the dose/concentration to which the population will be exposed. Where a reference value cannot be established a qualitative approach shall be used.

Assessment factors account for the extrapolation from animal toxicity to the exposed human population. The setting of an overall assessment factor considers the degree of uncertainty in inter-species and intra-species extrapolation. In the absence of suitable chemical-specific data, a default assessment factor of 100 is applied to the relevant reference value. Additional elements can also be considered for assessment factors, including toxicokinetics and toxicodynamics, the nature and severity of the effect, human (sub-)populations, exposure deviations between study results and human exposure with regard to frequency and duration, study duration extrapolation (e.g. sub-chronic to chronic), dose-response relationship and the overall quality of the toxicity data package.

Effects on animal health

36. Using the same relevant principles as described in the section dealing with effects on humans, the evaluating body shall consider the risks posed to animals from the biocidal product.

Effects on the environment

37. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota, following the use of the biocidal product.

38. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as PNEC. However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Articles 6 and 20. It shall be calculated by applying an assessment factor to the reference values resulting from tests on organisms, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)). Where appropriate, other dose-effect descriptors may be used as reference values.

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41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller the degree of uncertainty and the size of the assessment factor.

42. For each environmental compartment, an exposure assessment shall be carried out in order to predict the likely concentration of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However, in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions (including any relevant contribution from articles treated with biocidal products) are known or are reasonably foreseeable.

44. The PEC, or the qualitative estimation of exposure, shall be determined taking account of, in particular and where appropriate:

— adequately measured exposure data,

— the form in which the product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties,

— breakdown/transformation products,

— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

— the frequency and duration of exposure,

— long range environmental transportation.

45. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 34. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

48. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) if it contains any substance of concern or relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006, or if it has endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on target organisms

49. An assessment shall be made to demonstrate that the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate, the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

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50. The evaluating body shall, where relevant, evaluate the possibility of the development by the target organism of resistance or cross-resistance to an active substance in the biocidal product.

Efficacy

51. Data submitted by the applicant shall be sufficient to substantiate the efficacy claims for the product. Data submitted by the applicant or held by the evaluating body must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Union guidelines where these are available and applicable. Where appropriate, other methods from the list below can be used. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method

— national standard method

— industry standard method (if accepted by the evaluating body)

— individual producer standard method (if accepted by the evaluating body)

— data from the actual development of the biocidal product (if accepted by the evaluating body).

Summary

53. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects.

54. For biocidal product containing more than one active substance, any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

CONCLUSIONS

General principles

55. The purpose of the evaluation is to establish whether or not the product complies with the criteria set down in point (b) of Article 19(1). The evaluating body shall reach its conclusion as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product, based on the assessment carried out in accordance with points 13 to 54 of this Annex.

56. In establishing compliance with the criteria set out in point (b) of Article 19(1), the evaluating body shall arrive at one of the following conclusions for each product-type and each area of use of the biocidal product for which application has been made:

(1) that the biocidal product complies with the criteria;

(2) that, subject to specific conditions/restrictions, the biocidal product can comply with the criteria;

(3) that it is not possible, without additional data, to establish if the biocidal product complies with the criteria;

(4) that the biocidal product does not comply with the criteria.

57. The evaluating body shall, when seeking to establish whether a biocidal product complies with the criteria in point (b) of Article 19(1), take into account uncertainty arising from the variability in the data used in the evaluation process.

58. If the conclusion arrived at by the evaluating body is that additional information or data are required, then the evaluating body shall justify the need for any such information or data. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

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Effects on human and animal health

Effects on human health

59. The evaluating body shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment. In reaching these conclusions, particular attention shall be paid to vulnerable groups among the different populations.

60. The evaluating body shall examine the relationship between exposure and effect. A number of factors need to be considered when examining this relationship. One of the most important factors is the nature of the adverse effect of the substance under consideration. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, immunotoxicity, reproductive toxicity, disruption of the endocrine system together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern, or of their relevant metabolites or degradation products.

61. Typically, the margin of exposure (MOE_{ref}) — the ratio between the dose descriptor and the exposure concentration — is in the region of 100, but a MOE_{ref} that is higher or lower than this may also be appropriate depending on, among other things, the nature of the critical effects and the sensitivity of the population.

62. The evaluating body shall, where appropriate, conclude that criterion (iii) under point (b) of Article 19(1) can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.

63. If, for non-professional users, the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population, the product shall not normally be considered as complying with criterion (iii) under point (b) of Article 19(1) for this population.

Effects on animal health

64. Using the same relevant criteria as described in the section dealing with effects on human health, the evaluating body shall consider whether criterion (iii) under point (b) of Article 19(1) is complied with for animal health.

Effects on the environment

65. The basic tool used in the decision-making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC, the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

66. For any given environmental compartment, if the PEC/PNEC ratio is equal to or less than 1, the risk characterisation shall be that no further information and/or testing is necessary. If the PEC/PNEC ratio is greater than 1, the evaluating body shall judge, on the basis of the size of that ratio and on other relevant factors, whether further information and/or testing is required to clarify the concern or appropriate risk reduction measures are necessary, or whether the biocidal product cannot comply with criterion (iv) under point (b) of Article 19(1).

Water

67. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target organisms in the aquatic, marine or estuarine environment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. In particular, the evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1), where under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments), would undermine the achievement of compliance with the standards laid down in:

— Directive 2000/60/EC,

— Directive 2006/118/EC,

— Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy [1],

— Directive 2008/105/EC, or

— international agreements on the protection of river systems or marine waters from pollution.

68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in groundwater, exceeds the lower of the following concentrations:

— the maximum permissible concentration laid down by Directive 98/83/EC, or

— the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological data,

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

69. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where the foreseeable concentration of the active substance or a substance of concern, or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by:

— Directive 2000/60/EC,

— Directive 98/83/EC, or

— has an impact deemed unacceptable on non-target organisms,

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

70. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that, if followed, they minimise the likelihood of accidental contamination of water or its sediments.

Soil

71. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in soil, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Air

72. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) of point (b) of Article 19(1) where there is a reasonably foreseeable possibility of unacceptable effect on the air compartment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Non-target organisms

73. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product, if for any active substance or substance of concern:

— the PEC/PNEC is above 1, or

— the concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

[1] OJ L 164, 25.6.2008, p. 19.

74. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product, if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1, unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Effects on target organisms

75. Where the development of resistance or cross-resistance to the active substance in the biocidal product is likely, the evaluating body shall consider actions to minimise the consequences of this resistance. This may involve modification of the conditions under which an authorisation is given. However, where the development of resistance or cross-resistance cannot be reduced sufficiently, the evaluating authority shall conclude that the biocidal product does not satisfy criterion (ii) under point (b) of Article 19(1).

76. A biocidal product intended to control vertebrates shall not normally be regarded as satisfying criterion (ii) under point (b) of Article 19(1) unless:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

77. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State or, where appropriate, in the Union, except where the biocidal product is intended for use in specific circumstances. The evaluating body shall evaluate dose-response data generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

78. In relation to the criteria set out in points (iii) and (iv) of Article 19(1)(b), the evaluating body shall combine the conclusions arrived at for the active substance(s) and the substances of concern to produce overall summary conclusions for the biocidal product itself. A summary of the conclusions in relation to the criteria set out in points (i) and (ii) of Article 19(1)(b) shall also be made.

OVERALL INTEGRATION OF CONCLUSIONS

The evaluating body shall, on the basis of the evaluation carried out in accordance with the principles set down in this Annex, come to a conclusion as to whether or not it is established that the biocidal product complies with the criteria laid down under point (b) of Article 19(1).

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International Association of Drilling Contractors

Guideline for Mobile Offshore Drilling Units

Subject to the U.S. EPA NPDES Permit Requirements For Discharges Incidental to Normal Vessel Operations

PURPOSE

The purpose of this document is to provide guidance to the owners and operators of Mobile Offshore Drilling Units (MODUs), including inland barge units, regarding implementation of, and compliance with, the provisions of the recently-issued U.S. Environmental Protection Agency (EPA) National Pollutant Discharge Elimination System (NPDES) General Permit for Discharges Incidental to the Normal Operation of a Vessel (the VGP).

EPA's issuance of the VGP responds to a District Court ruling that vacated a longstanding EPA regulation that had excluded discharges incidental to the normal operation of a vessel from the need to obtain an NPDES permit. This regulation provided an exemption to the prohibition against discharge-without-a-permit under section 301 of the Clean Water Act (CWA).

The VGP and its requirements apply to 26 different discharges incidental to the normal operation of all commercial vessels 79 feet or greater in length when operating as a means of transportation within the 3 mile territorial sea of the United States (Permit Waters) commencing on 6 February 2009. The VGP would typically be applicable to a MODU that:

- Is moving between drilling locations within Permit Waters;
- At dockside, laid-up or stacked[1] within Permit Waters; or
- Enters Permit Waters from overseas or from a location on the OCS.

Because the drilling industry routinely experiences large swings in business activity, it is normal industry practice for MODUs to be laid-up (*i.e.*, warm stacked or cold stacked) for prolonged periods when business activity is low. Thus, it is IADC's view that stacked units remain both eligible for, and subject to, the provisions of the VGP. Nonetheless, MODU owners with large numbers of stacked units within Permit Waters may find it advantageous to explore obtaining coverage under an alternative permit where inspections, etc. could be better tailored to the conditions on board stacked units.

1 EPA has indicated that the issue of precisely when vessels that are laid-up or stacked cease operating in a capacity as a means of transportation will necessarily depend upon the specific facts presented. This would include factors such as the duration the vessel is out of service, normal industry practices with respect to vessel lay-up, and the ability of the vessel to return to transportation service without major renovations.

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COMPLIANCE APPROACHES

MODUs that routinely operate in Permit Waters should establish an internal program to address compliance with the permit requirements on an ongoing basis.

MODUs that do not routinely, but may or only occasionally, enter Permit Waters (*e.g.*, deepwater units that would typically only enter Permit Waters to transit to a shipyard) need not establish a continuous program for compliance, but should establish a program to assure that appropriate inspections have been completed and documented so as to assure compliance with all NPDES Permit requirements prior to entry into Permit Waters.

Because of the possible need to enter Permit Waters for repairs, it is recommended that all MODUs operating on the U.S. Outer Continental Shelf establish programs to assure compliance with the VGP and that a Notice of Intent (NOI) be submitted for such vessels once enrollment is available.

EPA Region 6 has confirmed that it is not necessary for MODUs to repeatedly apply for and terminate coverage under the VGP as these vessels move in and out of Permit Waters or when they become subject to an O&G Permit.[2] IADC has not sought similar confirmation from other EPA Regions.

EPA has stated that vessels when in drydock do not operate "in a capacity as a means of transportation" and thus are not subject to (or eligible for coverage under) the VGP. With respect to vessels under construction, EPA has stated that when the vessel is engaged in sea trials which result in operational discharges, because testing is a critical part of vessel operation, such discharges would be incidental to the normal operation of a vessel, and thus eligible for coverage under the VGP. However, any discharges resulting from construction activities are not covered by the VGP as they are incidental to vessel construction, not vessel operation. Accordingly, MODU owner/operators should take steps to assure that any discharges not covered by the VGP are covered by the shipyard's NPDES permit or are otherwise disposed of in accordance with applicable regulatory requirements.

Considering their unit's exposure to operations in Permit Waters, MODU owner/operators should give consideration to developing a unit-specific VGP Compliance Plan that takes into account the MODU's anticipated operations within Permit Waters, the specific equipment installed on the unit, and the EPA-required Best Management Practices (BMPs) applicable to the unit.

2 MODU owners/operators should document when a MODU enters into or exits from Permit Waters and when coverage under an O&P Permit commences or terminates.

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IMPORTANT DATES

19 December 2008: Effective date of the VGP. Provisions of the VGP that require compliance in an explicit amount of time are based on this date.

6 February 2009: As of this date, discharges of certain effluents incidental to normal vessel operations in Permit Waters were required to be in conformance with the VGP. Noncompliance with the permit terms became subject to civil and criminal enforcement actions under the CWA.

19 February 2009: MODUs to which the VGP applied were required to meet the VGP's inspection, training, recordkeeping and reporting requirements.

19 June 2009: Electronic submissions of a NOI for a VGP will be available and required on, but not later than 90 days, after this date.[3] (19 September 2009)

19 December 2009: MODUs must comply with the VGP's requirements to take corrective actions requiring major renovations in drydock. The first annual report of non-compliances should be submitted to EPA no later than this date.

VGP REQUIREMENTS

An NPDES Permit authorizes the discharge of a specified amount of a pollutant(s) into U.S waters under certain specified conditions.

The VGP addresses potential vessel discharges by establishing numerical effluent limits for some discharge streams and imposing required Best Management Practices (BMPs) for others where numerical limits are not practicable. Although all discharges covered by the VGP will be covered for the MODU, a MODU owner/operator is required to comply with only those requirements for the effluents that the vessel actually produces, not the entire list of potential discharges.

The VGP has been modified since it was first issued in December 2008, and can be expected to be further modified during its term. It is recommended that MODU

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3 MODUs operating in Permit Waters or which may operate in Permit Waters should file an NOI on or after 19 June 2009 by using EPA's e-NOI system at: www.epa.gov/npdes/eNOI; or sending the completed form to:
EPA Vessel Notice Processing Center Mail Code 4203M
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Questions regarding the form may be directed to the NOI Center after 19 June 2009 at: +1 866 352-7755.
Based on an NOI review, EPA may delay the discharge authorization date for further review, or may deny coverage under the permit and require submission of an application for an individual NPDES permit. EPA will provide a written determination if VGP coverage is denied and indicates it will allow reasonable time to obtain individual permit coverage before general permit coverage terminates.
All NOIs received will be posted at www.epa.gov/npdes/noisearch. Late NOIs will be accepted, but authorization to discharge is not retroactive.

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owners/operators periodically check to ensure that they are using the most recent VGP. The VGP can be found on EPA website at: http://cfpub.epa.gov/npdes/home.cfm?program_id=350.

The VGP contains specific requirements that are applicable to specific vessel types. Barges are one vessel type for which such requirements are provided. While the EPA does not define "barge" for purposes of the permit, IADC recommends that MODU owner/operators treat any non-propelled MODU as a "barge" for purposes of the permit.

In addition to the requirements for specific vessel types, the permit imposes requirements for individual States or Indian Country Lands. As of the date of issue of this Guideline the States and Indian Country Lands which have imposed additional requirements are not areas where MODUs normally operate.

RELATIONSHIP TO OIL AND GAS PERMITS

MODUs not only operate as vessels subject to the VGP, but also conduct operations in a non-transportation capacity (*i.e.*, oil and gas drilling). As a result, MODUs are expected to transition between coverage under the VGP and coverage under a permit for oil and gas operations (O&G Permit). The exact timing of the transition between permits will depend upon the specific circumstances. This is a potential source of confusion and adds to the complexity of assuring compliance with the VGP, particularly for MODUs conducting drilling operations within Permit Waters.

The oil company operator will seek O&G Permit coverage under an Oil and Gas General Permit[4] or may obtain coverage under an individual permit, depending upon the location and the oil company's business decisions.

At no time are the VGP and an O&G Permit simultaneously in effect for a MODU. Nonetheless, in order to assure compliance with the VGP, certain inspections and tests under the VGP must be completed while under the coverage of the O&G Permit. There can be significant differences between discharges authorized by (and discharge limitations under) an O&P Permit and those authorized by the VGP. An individual

4 O&G General Permits applicable to drilling operations in the territorial sea or internal waters include:
- LAG29000 – NPDES General Permit for the Territorial Seas of Louisiana.
- CWOGF-G – Water Discharge Permit: Oil & Gas Exploration, Development, and Production Facilities in Coastal Waters.
- TXG260000 – NPDES General Permit for Discharges from the Offshore Subcategory of the Oil and Gas Extraction Point Source Category to the Territorial Seas off Texas.
- TXG330000 – NPDES General Permit for Discharges from the Oil and Gas Extraction Point Source Category to Coastal Waters in Texas.
- AKG280000 – Authorization to Discharge under the National Pollutant Discharge Elimination System (NPDES) for Oil and Gas Extraction Facilities on the Outer Continental Shelf and Contiguous State Waters.
- AKG-31-5000 – Authorization to Discharge under the National Pollutant Discharge Elimination System (NPDES) for Oil and Gas Extraction Facilities in Federal and State Waters in Cook Inlet.

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MODU's operations should be controlled to comply with (and where appropriate, take advantage of) the permit in effect at the time.

While this guideline makes recommendations with respect to activities that should be undertaken while a MODU may be subject to an O&G Permit, these recommendations relate to the VGP. This guideline is not intended to provide any recommendations regarding implementation of, or compliance with, any O&G Permit.

BEST MANAGEMENT PRACTICES (BMPs)

The VGP addresses 26 different effluent streams (not all of which are relevant to MODUs). Because of the nature of vessel discharges, the EPA has determined that it is not practicable to rely on numeric effluent limits for the large majority discharge types until greater information is available. In the VGP, the EPA has included many non-numeric effluent limits and requires permittees to engage in specific behaviors or BMPs.

Annex 1 summarizes the EPA required BMPs and provides additional IADC recommended practices and commentary.

VOYAGE PLANNING

Certain provisions of the VGP limit permissible discharges depending on the location of the vessel, *e.g.,* nutrient impaired waters, hypoxic waters, or within waters that are federally protected wholly or in part for conservation purposes. In planning for relocation of a unit, consideration should be given to:

- The list of Federally Protected Waters found in Part 12 of the VGP: http://www.epa.gov/npdes/pubs/vessel_vgp_permit.pdf.
- Also each operator should review the list of nutrient-impaired waters found at: http://www.epa.gov/npdes/pubs/vessel_impair_nutrient.pdf; and http://www.epa.gov/npdes/pubs/vessel_impair_copper.pdf.; and
- The information provided regarding hypoxic waters found at: http://www.ncddc.noaa.gov/interactivemaps/hypoxia-watch.

TRAINING

For MODUs that routinely operate in Permit Waters basic VGP and BMP training should be provided to all personnel, including contractors and visitors. Such basic training should include an introduction to the Vessel General Permit and the MODU BMPs, as well as company/unit specific policies and best management practices. This training may be incorporated into the new employee orientation or on board induction.

For MODUs that do not routinely, but may or only occasionally, enter Permit Waters, basic VGP and BMP training should be provided to all personnel on board, including contractors and visitors prior to entry into Permit Waters through employee orientation or on board induction. When possible, it is recommended that such training be provided one week prior to entry into permit waters.

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BMP training should be given to appropriate facility supervisors and contractor supervisors for the purpose of informing these personnel of the components and objectives of the VGP. The training should address the requirements of each BMP for the MODU, goals for continuous improvement, reporting and recordkeeping requirements, and potential penalties for non-compliance. Training is done on an as needed basis in the event that there is a change in facility or contractor personnel, or a significant BMP Plan modification. Records of training should be maintained for three years.

EVALUATION AND RE-EVALUATION

The operational guidance and instructions should be re-evaluated and appropriately revised when the VGP is amended or re-issued. Other circumstances that will trigger modification of the operational guidance and instructions include, but are not limited to, the following:

- In response to identified shortcomings in the operational guidance and instructions (*e.g.*, following a near-miss, when new equipment is installed, or operating procedures are changed).

- Whenever inspections or incidents reveal a need to modify procedures or equipment to further reduce the potential to release contaminants to the receiving water.

RECORDKEEPING

For recordkeeping purposes each MODU must keep written records on the unit. A summary of the required records is contained in Appendix 1 of this guideline. (A more detailed description is available in section 4.2 of the VGP.) Owners and operators may choose how these records will be maintained, but must retain them on the unit for a period of three years.

SIGNATORIES

EPA regulations and the VGP require that certain records be signed by a person that is a 'signatory' in accordance with 40 CFR 122.22. The VGP, specifically recognizes that a signatory includes the person in charge (*e.g.* the Master), or their duly authorized representative. Accordingly, no designation letter is required for the person in charge (Offshore Installation Manager or Master) for most MODUs, but a designation letter would be required to assign or delegate signatory authority to others on the unit or to shore based personnel, who are not a 'responsible corporate officer' under 40 CFR 122.22, in order to serve as a duly authorized representative. Generic examples are provided in Appendix 7. Any duly authorized representative must be designated in writing with notification provided to the EPA Regional office. Rather than naming an individual, it is recommended that any designations refer to an assigned job position.

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INSPECTIONS

Routine

Visual inspections (walk-throughs) should be performed daily and any potential non-conformity, non-compliance, or violation of the VGP should be documented and corrected as necessary. The visual inspection should include:

- Checking for leaks and spills.
- Examination of areas which have been identified of special concern (*.e.g.*, recently-repaired equipment).
- Identify equipment and materials that are not properly stored or positioned.
- Initiating corrective actions as necessary.

The person conducting the routine weekly inspection must be a signatory per 40 CFR Part 122.22.

The records of routine weekly inspections must be made available to the EPA or their authorized representative upon request. Unit operators must initiate corrective actions for problems noted in their inspections in the time allotted period. (The next section describes corrective actions.)

The routine weekly inspection should follow a checklist, developed for the individual unit on the basis of a review of its equipment and operations and should focus on stored materials (new and spent), equipment, and work areas with the potential to pollute. You must document the date and time of this inspection, locations on board the unit inspected, personnel conducting the inspection, location of any visual sampling and observations, note any potential problems and sources of contamination found, and it must be signed by the person conducting the inspection, if not the person in charge. While the weekly checklist must reflect the individual unit, a generic example report is provided in Appendix 2.

The person conducting the inspection is required to sign the weekly inspection form and completed inspection forms are to be maintained on board the unit for a period of three years.

Quarterly

At least once per quarter samples must be taken of any discharge stream that is not readily able to be visually inspected, such as those discharged below the waterline (*e.g.*, bilgewater or graywater). The sample should be inspected for any signs of visible pollutants or constituents of concern, such as: discoloration, visible sheen, suspended solids, floating solids, foam, or changes in clarity. You must document the date and time of this inspection, ship locations inspected, personnel conducting the inspection, location of any visual sampling and observations, note any potential problems and

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sources of contamination found, and it must be signed by the person conducting the inspection, if not the person in charge. While the form used for this quarterly inspection must reflect the individual unit, a generic example report for this inspection is provided in Appendix 3.

Annual

A comprehensive annual vessel inspection must be conducted by qualified personnel at least once every twelve (12) months. Qualified personnel include the person in charge or the owner/operator of the vessel, if appropriately trained, or appropriately trained marine or environmental engineers or technicians, or an appropriately trained class society representative acting on behalf of the owner/operator. While the annual checklist must reflect the individual unit, a generic example report for this inspection is provided in Appendix 4.

Drydock

A drydock report, prepared by the classification society or their flag administrations must be made available to the EPA or an authorized representative of the EPA upon request. In lieu of, or in addition to the classification society or flag report, the owner/operator must prepare their own report and make it available for the EPA. The VGP requirements for the drydock report are specific and may not be addressed in the routine drydock reports provided by classification societies or flag administrations. While the drydock checklist must reflect the individual unit, a generic example report is provided in Appendix 5.

CORRECTIVE ACTIONS

Deadlines for eliminating a problem(s) or violation(s) are determined by the complexity of the corrective action and/or the impact of the problem(s) / violation(s). Compliance with many permit or VGP requirements can be accomplished immediately.

Corrective Action types:	**Must be completed by:**
Housekeeping or operational and maintenance requirements	Immediate Compliance
Corrective actions that can be accomplished with relatively simple adjustments to your control measures, using existing personnel and resources, and not requiring the MODU to be in drydock.	**As soon as possible but no later than 2 weeks** after the discovery of the problem/violation, or if leaving waters subject to this permit, before expiration of the 2 week period or before re-entering the waters subject to the VGP, whichever is later.

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Corrective Action types:	Must be completed by:
Corrective actions that require new parts or the installation of new equipment, not requiring the MODU to be in drydock: MODU must address the underlying cause of the noncompliance and return to compliance and/or complete necessary repairs.	**No later than 3 months after the discovery of the problem,** or, if leaving waters subject to the VGP, before expiration of the 3 month period or before re-entering waters subject to the VGP, whichever is later. However, if completing repairs within 3 months is impracticable, you must complete the repairs as soon as possible after 3 months and document the reason why more time is needed as part of your corrective action assessment.
For corrective actions that require large or comprehensive renovations, alterations or repairs to the MODU that can only be achieved while the vessel is in drydock: MODU must address the underlying cause of the noncompliance and return to compliance and/or complete necessary renovations or repairs prior to re-launching the MODU from drydock.	**Complete necessary renovations or repairs prior to re-launching the MODU from drydock**.

Any inspection or observation that results in a problem, non-conformance, noncompliance, or violation will require a corrective action assessment within the above time frames listed.

Corrective Action Assessment Record- A generic example of the information required by this type of record can be found in Appendix 6 and is further explained in section 3.2 of the VGP.

PERMIT COMPLIANCE RECORDS [5]

The VGP contains no specific requirements with respect to the form of documentation required to or for demonstration of permit compliance. To assist MODU owners/operators in meeting these requirements, some of the below listed records have generic examples provided in an appendix to this guideline. Those without an example provided in the appendix should already be available within one of the company's current policies or procedures manual(s).

- MODU Relocation / Voyage Record (Company policy),
- Effluent Limit Violations Record (Company policy),
- Routine Weekly Inspection Record (See Appendix 2),

5 A Record developed to achieve and/or demonstrate compliance with the VGP is subject to inspection by the EPA and, once provided to the agency may be subject to public view. If the records maintained for VGP compliance are intertwined (and not extractable) with other records, it may be difficult to produce the required records without disclosing non-required ones. You should be aware of this as you consider the systems (*e.g.*, records) that you will use to comply with the recordkeeping requirements of the VGP.

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- Cargo Operations Record (Company policy, if required),
- Quarterly Sampling Record (See Appendix 3),
- Annual Inspection Record (See Appendix 4),
- Additional Maintenance and Discharge Information Record (Company policy),
- Drydock Inspection Record (See Appendix 5),
- Corrective Action Assessment Record (See Appendix 6), and
- Training Record (Company policy)

Alternative forms of recordkeeping, so long as the permit requirements are met, are perfectly acceptable.

The VGP requires that all documentation (except the Notice of Intent, Notice of Termination, and reports submitted to EPA) required under the permit is signed and dated by the person preparing the documentation. The Notice of Intent, Notice of Termination, and reports (including monitoring data) submitted to EPA must include a signed certification in a form specified in the permit. (See example in Appendix 7).

REPORTING

Annual

A report must be submitted to the EPA Regional office that documents all instances of non compliance at least once per year. This report should be submitted to the Regional office responsible for the waters in which the non compliance occurred (VGP section 8). For multiple occurrences in various locations, the report should go to the regional office with the most number of occurrences or, if an even number, then to the regional office where the unit spent the most time. Since no specific format is specified, you may use company letterhead and include the information contained in your inspection and/or assessment reports (*i.e.*, date, time, location, requirement, cause, corrective action, etc) for each of the non compliances.

24-hour + 5-day Additional Reporting

Owners/operators must report any non compliance which may endanger health or the environment to the EPA regional office. The information must be provided orally within 24 hours from the time you become aware of the circumstances. Additionally, a 5-day written follow up report must also be provided within five days of your awareness.

Reportable Quantities of Hazardous Substances or Oil

Owners/operators should, in addition to the above 24-hour/5-day reporting, follow their standard procedures for this type of discharge, which should require them to report it to the National Response Center (1-800-424-8802 or 202-267-2675). Additionally, the VGP recordkeeping requirement (VGP section 4.4.2) indicates that within 14 calendar days of knowledge of the release that the on board records should indicate:

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a) The discovery date and description of the discharge or release;
b) The circumstances leading up to it;
c) The responses employed to handle it; and
d) The measures taken to prevent re-occurrence of it.

One Time Permit Report

The vessel owner/operator is required to submit a one time report between 30 to 36 months after obtaining permit coverage. The report form, which is available in section 13 of the VGP, is needed to assist the EPA in development of the next version of the VGP.

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Recordkeeping - Appendix 1

Written records must be kept on the MODU that include the following information:

- Vessel information: Vessel Name, International Maritime Organization (IMO) number and/or Official number and vessel type.
- Voyage Log: Date and port of arrival, last port of call, next port of call.
- Violation of effluent limits: Description of violation, date, name of person identifying the violation, and name of person recording violation, and location where corrective action assessment is stored.
- Log of deficiencies or problems: Routine inspection non-compliance issues, corrective actions planned or taken, and the inspector's name.
- Results of all monitoring conducted: Analytical results, which include sample documentation, results, and laboratory documentation.
- Annual inspection report: Findings from annual inspection, corrective actions taken or planned, and the inspector's name.
- Imposed requirements and actions taken: Written requirements given to the vessel by the EPA or an authorized state agency and how these requirements were met.
- Maintenance and discharge information for the following:
    - Deck maintenance;
    - Bilgewater disposal;
    - Paint application;
    - AFFF discharges;
    - Chain locker inspection;
    - Controllable pitch propellers, stern tube and other oil-to-sea interfaces;
    - Emergencies requiring discharges into prohibited waters;
    - Gas turbine water wash; and
    - Graywater discharges

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Routine Weekly Inspection Report- Appendix 2

To be completed at least once weekly or whenever a problem, non-conformance, noncompliance or violation is observed.

_____ _____

Person in charge or duly authorized representative's printed name

MODU / Vessel Name

Signature _____ Date & Time_____

Latitude _____ Longitude _____

Note any problem, non-conformance, noncompliance or violation that was observed while performing the visual inspection. Note any areas which not able to be inspected and reason why.

Area	**Observed problem, non-conformance, noncompliance or violation**

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Quarterly Inspection Report- Appendix 3

To be completed at least once per quarter and taken from any discharge stream that is not readily able to be visually inspected, such as those discharged below the waterline (*e.g.*, bilgewater or graywater).

_____ _____

Person in charge or duly authorized representative's printed name

MODU / Vessel Name

Signature _____ Date & Time _____

Latitude _____ Longitude _____

Year _____ Quarter _____

Type of Sample & Location:
Results:
Type of Sample & Location
Results:
Type of Sample & Location
Results:
Type of Sample & Location
Results:

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Annual Inspection Report- Appendix 4

To be completed at least once every 12 month period and conducted by a qualified personnel.

NOTE: A classification society or flag State report may be used if it contains all the required information and is completed by an appropriately trained surveyor. Full explanations are required any time a section of the inspection cannot be performed.

AREAS THAT MUST **BE EXAMINED**	**RESULTS**
Vessel hull for attached living organisms, flaking anti-fouling paint, exposed TBT or other organotin surfaces	SAT / UNSAT
Ballast water tanks, as applicable	SAT / UNSAT
Bilges, pumps and oily water separator (OWS) sensors, as applicable.	SAT / UNSAT
Protective seals for lubrication and hydraulic leaks	SAT / UNSAT
Oil and chemical storage areas, cargo areas, and waste storage areas	SAT / UNSAT
All visible pollution control measures to ensure that they are functioning properly	SAT / UNSAT

_____ _____

Person in charge or duly authorized representative's printed name

MODU / Vessel Name

Signature _____ Date & Time_____

Call Sign_____ Official Number_____

Gross Tonnage _____ Port of Registry _____

Remarks: _____

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Drydock Inspection Report- Appendix 5

To be completed after final completion of a DRYDOCK period.

NOTE: Not all items will be applicable to every MODU. Full explanations are required any time a section of the inspection cannot be performed

Inspection criteria	**Performed**
The chain locker has been cleaned for both sediment and living organisms	Yes N/A
The MODU hull, thrusters, gratings, sea chest, and other surface areas of the MODU have been inspected for attached living organism and those organisms have been removed OR neutralized.	Yes No
Any antifouling hull coatings have been applied, maintained and removed consistent with the FIFRA label if applicable: any exposed existing or new coating does not contain biocides or toxics that are banned for use in the United States.	Yes No
All cathodic protection, anodes or dialectic coatings have been inspected, cleaned and/or replaced to reduce flaking	Yes No
All pollution control equipment is properly functioning.	Yes No

_____ _____

Person in charge or duly authorized representative's printed name

MODU / Vessel Name

Signature _____ Date & Time_____

Call Sign_____ Official Number_____

Gross Tonnage _____ Port of Registry _____

Remarks: _____

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Corrective Action Assessment - Appendix 6

Vessel Name- _____ Date: _____

Description of the problem:

Explanation of the cause:

Description of Corrective actions planned: Drydock required: Yes__ No__

Date and time corrective action implemented:

Summary of Corrected Actions taken:

Recorder name and title Signature

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Designation Letter - Appendix 7.1

ADHOC Drilling Company, Inc.

Director, Water Division
EPA Region

Date:_____

Subj: NDPES Vessel General Permit – Corporate Designation of Duly Authorized Representatives

In accordance with 40 CFR 122.22 and Section 4.2 of the NPDES Vessel General Permit, ADHOC Drilling Company, Inc. delegates the authority to sign documents associated with the Vessel General Permit within its corporate structure as follows:

- Vice President of Regional Operations (responsible corporate officer) designates General Manager(s)
- General Manager(s) designates Operations Manager(s)
- Operations Manager(s) designates Rig Manager(s)
- Rig Manager(s) designates vessel Person(s) in Charge / Offshore Installation Manager(s)
- Person(s) in Charge / Offshore Installation Manager(s) may delegate to senior crewmembers via a duly authorized representative designation letter
  [Note: Use position titles appropriate to the company.]

Name _____

Signature _____

Title _____

(Must be a responsible corporate officer identified in 40 CFR122.22 (a)(1)(i))
"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information contained therein. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information contained is, to the best of my knowledge and belief, true, accurate, and complete. I have no personal knowledge that the information submitted is other than true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

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Designation Letter - Appendix 7.2

ADHOC Drilling Company, Inc.

Director, Water Division
EPA Region

Date:_____

Subj: DRILLUNIT XX (Identifying number)
NDPES Vessel General Permit – Designation of Duly Authorized Representatives

In accordance with 40 CFR 122.22 and Section 4.2 of the NPDES Vessel General Permit, authority to sign documents associated with the Vessel General Permit related to the DILLLUNIT XX is delegated to the following corporate positions:

- Maintenance Supervisor
- Barge Engineer

[Note: Use position titles appropriate to the company and unit.]

Name _____

Signature _____

Title _____

(Must be a responsible corporate officer identified in 40 CFR122.22(a)(1)(i)) or identified corporate delegate.)

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information contained therein. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information contained is, to the best of my knowledge and belief, true, accurate, and complete. I have no personal knowledge that the information submitted is other than true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

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1. Deck Washdown and Runoff and Above Water line Hull Cleaning

EPA required BMPs

Vessel owner/operators must minimize the introduction of on-deck debris, garbage, residue and spill into deck washdown and runoff discharges. When required by their class societies (e.g., oil tankers), their flag Administrations, or the U.S. Coast Guard, vessels must be fitted with and use perimeter spill rails and scuppers to collect the runoff for treatment. Where feasible, machinery on deck must have coamings or drip pans to collect any oily water from machinery and prevent spills. The drip pans must be drained to a waste container for proper disposal and/or periodically wiped and cleaned. The presence of floating solids, visible foam, halogenated phenol compounds, and dispersants, or surfactants in deck washdowns must be minimized. Vessel operators must minimize deck washdowns while in port.

Vessel operators must maintain their topside surface and other above water line portions of the vessel to minimize the discharge of rust (and other corrosion by-products), cleaning compounds, paint chips, non-skid material fragments, and other materials associated with exterior topside surface preservation. Furthermore, vessel owner/operators must minimize residual paint droplets from entering waters subject to this permit whenever they are conducting maintenance painting. Possible minimization techniques include, but are not limited to, avoiding paint spraying in windy conditions or avoiding over-application of paint. This permit does not authorize the disposal of unused paint into waters subject to this permit.

If deck washdowns or above water line hull cleaning will result in a discharge, they must be conducted with non-toxic and phosphate free cleaners and detergents. Furthermore, cleaners and detergents should not be caustic or only minimally caustic and should be biodegradable.

Note: EPA provides the following definitions:

"Non-toxic" soaps, cleaners, and detergents means these materials which do not exhibit potentially harmful characteristics as defined by the Consumer Product Safety Commission regulations found at 16 CFR Chapter II, Subchapter C, Part 1500.

"Phosphate Free" soaps, cleaners, and detergents means these materials which contain, by weight, 0.5% or less of phosphates or derivatives of phosphates.

Commentary: None

Additional recommended practices:

- If possible, deck washdowns should be postponed until the unit is outside Permit Waters.
- When washdowns are necessary within Permit Waters, collect all debris, garbage and residues for disposal prior to conducting washdowns.
- A procurement process should be established which reviews soaps, cleaners and detergents that are intended for use for deck washdowns or above the water line hull cleaning will meet the VGP requirements.
- Machinery containment/drip pans and containment wells around fuel oil and bulk lubricating oil tank vents, overflows and fill pipes should be routinely maintained and any oily waste disposed of properly or retained on board for discharge in accordance with applicable regulations.

- For MODUs completing drilling operations, consideration should be given to conducting washdowns of the drill floor and drilling fluid processing areas while the O&G Permit remains in effect.

Πανεπιστήμιο Πειραιώς

2. Bilgewater

EPA required BMPs

All bilgewater discharges must be in compliance with the regulations in 40 CFR Parts 110 (Discharge of Oil), 116 (Designation of Hazardous Substances), and 117 (Determination of Reportable Quantities for Hazardous Substances) and 33 CFR §151.10 (Control of Oil Discharges). In addition:

- Vessel operators may not use dispersants, detergents, emulsifiers, chemicals or other substances to remove the appearance of a visible sheen in their bilgewater discharges.
- Except in the case of flocculants or other required additives (excluding any dispersants or surfactants) used to enhance oil/water separation during processing (after bilgewater has been removed from the bilge), vessel operators may not add substances that drain to the bilgewater that are not produced in the normal operation of a vessel. The use of oil solidifiers, flocculants, or other required additives are allowed only as part of an oil water separation system provided they do not alter the chemical make-up of the oils being discharged and they are not discharged into waters subject to this permit. Routine cleaning and maintenance activities associated with vessel equipment and structures are considered to be normal operation of a vessel if those practices fall within normal marine practice.
- All vessels must minimize the discharge of bilgewater into waters subject to this permit. This can be done by minimizing the production of bilgewater, disposing of bilgewater on shore where adequate facilities exist, or discharging into waters not subject to this permit (i.e., more than 3 nautical miles (nm) from shore) for vessels that regularly travel into such waters. Though not regulated under this permit, EPA notes that discharges of bilgewater outside waters subject to this permit (i.e. more than 3 nm from shore) are regulated under Annex I of the International Convention for the Prevention of Pollution from Ships as implemented by the Act to Prevent Pollution from Ships and U.S. Coast Guard regulations found in 33 CFR 151.09.
- Vessels greater than 400 gross tons shall not discharge untreated oily bilgewater into waters subject to this permit.
- Vessels greater than 400 gross tons that regularly sail outside the territorial sea (at least once per month) shall not discharge treated bilgewater within 1 nm of shore if technologically feasible (e.g. holding would not impact safety and stability, would not contaminate other holds or cargo, would not interfere with essential operations of the vessel). Any discharge which is not technologically feasible to avoid must be documented as part of the requirements in Part 4.2.
- Vessels greater than 400 gross tons shall not discharge treated bilgewater into waters referenced in Part 12.1 unless the discharge is necessary to maintain the safety and stability of the ship. Any discharge of bilgewater into these waters must be documented as part of the recordkeeping requirements in Part 4.2 and vessel operators must document whether this bilgewater discharge was made for safety reasons.
- For vessels greater than 400 gross tons that regularly sail outside the territorial sea (at least once per month), if treated bilgewater is discharged into waters subject to this permit, it must be discharged when vessels are underway (sailing at speeds greater than 6 knots), unless doing so would threaten the safety and stability of the ship. EPA notes that vessel operators may also choose to dispose of bilgewater on shore where adequate facilities exist. Any discharge which is made for safety reasons must be documented as part of the requirements in Part 4.2.

Commentary:

(1) All MODUs presently in service are greater than 400 gross tons.

(2) The provisions of 33 CFR 151.10 applicable to a MODU within Permit Waters are as follows:

Πανεπιστήμιο Πειραιώς

§ 151.10 Control of oil discharges.

* * * * *

(b) When within 12 nautical miles of the nearest land, any discharge of oil or oily mixtures into the sea from a ship other than an oil tanker or from machinery space bilges of an oil tanker is prohibited except when all of the following conditions are satisfied—
  (1) The oil or oily mixture does not originate from cargo pump room bilges;
  (2) The oil or oily mixture is not mixed with oil cargo residues;
  (3) The oil content of the effluent without dilution does not exceed 15 ppm;
  (4) The ship has in operation oily-water separating equipment, a bilge monitor, bilge alarm, or combination thereof as required by Part 155 Subpart B of this chapter; and
  (5) The oily-water separating equipment is equipped with a 15 ppm bilge alarm; for U.S. inspected ships, approved under 46 CFR 162.050 and for U.S. uninspected ships and foreign ships, either approved under 46 CFR 162.050 or listed in the current International Maritime Organization (IMO) Marine Environment Protection Committee (MEPC) Circular summary of MARPOL 73/78 approved equipment.

Note: In the navigable waters of the United States, the Federal Water Pollution Control Act (FWPCA), section 311(b)(3) and 40 CFR Part 110 govern all discharges of oil or oily-mixtures.

* * * * *

(e) The provisions of paragraphs (a), (b), (c) and (d) of this section do not apply to the discharge of clean or segregated ballast.

(f) The person in charge of an oceangoing ship that cannot discharge oily mixtures into the sea in compliance with paragraphs (a), (b), (c), or (d) of this section must ensure that those oily mixtures are—
  (1) Retained on board; or
  (2) Discharged to a reception facility. If the reception facility is in a port or terminal in the United States, each person who is in charge of each oceangoing tanker or any other oceangoing ship of 400 gross tons or more shall notify the port or terminal, at least 24 hours before entering the port or terminal, of—
    (i) The estimated time of day the ship will discharge oily mixtures;
    (ii) The type of oily mixtures to be discharged; and
    (iii) The volume of oily mixtures to be discharged.

Note: There are Federal, state, or local laws or regulations that could require a written description of the oil residues and oily mixtures to be discharged. For example, a residue or mixture containing oil might have a flashpoint less than 60 °C (140 °F) and thus have the characteristic of ignitability under 40 CFR 261.21, which might require a description of the waste for a manifest under 40 CFR Part 262, Subpart B. Occupational safety and health concerns may be covered, as well as environmental ones.

The notice required in this section is in addition to those required by other Federal, state, and local laws and regulations. Affected persons should contact the appropriate Federal, state, or local agency to determine whether other notice and information requirements, including 40 CFR Parts 262 and 263, apply to them.

(g) No discharge into the sea shall contain chemicals or other substances introduced for the purpose of circumventing the conditions of discharge specified in this regulation.

(h) This section does not apply to a fixed or floating drilling rig or other platform that is operating under a National Pollutant Discharge Elimination System (NPDES) permit.[6]

The provisions of 33 CFR 155 applicable to MODUs[7] within Permit Waters are as follows:

6 Note: 33 CFR 151 and 155 pre-date the issuance of the VGP. The NPDES permit referred to in these regulations is the O&G Permit.

Προσχέδιο προς Παράδοση

§ 155.400 Platform machinery space drainage on oceangoing fixed and floating drilling rigs and other platforms.

(a) No person may operate an oceangoing fixed or floating drilling rig or other platform unless it either—
  (1) Complies with the oily-water separating equipment requirements of a valid National Pollutant Discharge Elimination System (NPDES) permit issued in accordance with section 402 of the Clean Water Act and 40 CFR Chapter I;
  (2) Complies with the oily-water separating equipment requirements for oceangoing ships of 400 gross tons and above as set forth in either §155.360 or §155.370; or
  (3) Is not equipped with an installed bilge pumping system for discharge of oily mixtures from platform machinery spaces into the sea and has the capacity to retain on board all of these oily mixtures and is equipped to discharge these mixtures for transport to a reception facility.

(b) When an oceangoing fixed or floating drilling rig or other platform is in a special area, is not proceeding en route, or is within 12 nautical miles of the nearest land; it must either—
  (1) Have the capacity to retain on board all machinery space oily mixtures from platform machinery space drainage and be equipped to discharge these mixtures for transport to a reception facility; or
  (2) Discharge in accordance with §151.10 (b)(3), (b)(4), and (b)(5) of this chapter, provided the drilling rig or platform is not within a special area.

(c) Paragraph (b) of this section does not apply to a fixed or floating drilling rig or other platform that is operating under an NPDES permit.

(4) Prior to the effective date of the VGP, the net effect of these regulations is that MODU had the following options for handling machinery spaced drainage when within what are now Permit Waters:

- They could retain on board all machinery space oily mixtures from machinery space drainage and be equipped to discharge these mixtures for transport to a reception facility.
- They could handle them in accordance with an O&G Permit when such a permit was in force; or
- They could be discharged when all of the following conditions were satisfied–
  (3) The oil content of the effluent without dilution does not exceed 15 ppm;
  (4) The ship has in operation oily-water separating equipment, a bilge monitor, bilge alarm, or combination thereof as required by Part 155 Subpart B of this chapter; and
  (5) The oily-water separating equipment is equipped with a 15 ppm bilge alarm; for U.S. inspected ships, approved under 46 CFR 162.050 and for U.S. uninspected ships and foreign ships, either approved under 46 CFR 162.050 or listed in the current International Maritime Organization (IMO) Marine Environment Protection Committee (MEPC) Circular summary of MARPOL 73/78 approved equipment.

(5) Amendments to MARPOL Annex I entered into force on 1 January 2007 imposed further restrictions on the discharge into the sea of oil or oily mixtures. Regulation 15/2 of the amended regulations reads:

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7 33 CFR 151 contains no provisions that are directly applicable to fixed and floating drilling rigs that are not "oceangoing". 33 CFR 151.05 provides the following definition:
Oceangoing ship means a ship that--
(1) Is operated under the authority of the United States and engages in international voyages;
(2) Is operated under the authority of the United States and is certificated for ocean service;
(3) Is operated under the authority of the United States and is certificated for coastwise service beyond three miles from land;
(4) Is operated under the authority of the United States and operates at any time seaward of the outermost boundary of the territorial sea of the United States as defined in Sec. 2.22of this chapter; or
(5) Is operated under the authority of a country other than the United States.

Πρόγραμμα Παράκτιος

2 Any discharge into the sea of oil or oily mixtures from ships of 400 gross tonnage and above shall be prohibited except when all the following conditions are satisfied:

.1 the ship is proceeding en route;

.2 the oily mixture is processed through an oil filtering equipment meeting the requirements of regulation 14 of this Annex;

.3 the oil content of the effluent without dilution does not exceed 15 parts per million;

.4 the oily mixture does not originate from cargo pump-room bilges on oil tankers; and

.5 the oily mixture, in case of oil tankers, is not mixed with oil cargo residues.

Additional guidance regarding handling of oily wastes in machinery spaces was provided in November 2008.[8]

These amendments have yet been reflected in 33 CFR 151, which makes their enforceability with respect to ships operated under the authority of the United States; however, they should generally be considered applicable to any State party to MARPOL Annex I.

(6) The following BMPs of the VGP place new restrictions on permitted discharges:

- Vessels greater than 400 gross tons that regularly sail outside the territorial sea (at least once per month) shall not discharge treated bilgewater within 1 nm of shore if technologically feasible (e.g. holding would not impact safety and stability, would not contaminate other holds or cargo, would not interfere with essential operations of the vessel). Any discharge which is not technologically feasible to avoid must be documented as part of the requirements in Part 4.2.
- Vessels greater than 400 gross tons shall not discharge treated bilgewater into waters referenced in Part 12.1 unless the discharge is necessary to maintain the safety and stability of the ship. Any discharge of bilgewater into these waters must be documented as part of the recordkeeping requirements in Part 4.2 and vessel operators must document whether this bilgewater discharge was made for safety reasons.
- For vessels greater than 400 gross tons that regularly sail outside the territorial sea (at least once per month), if treated bilgewater is discharged into waters subject to this permit, it must be discharged when vessels are underway (sailing at speeds greater than 6 knots), unless doing so would threaten the safety and stability of the ship. EPA notes that vessel operators may also choose to dispose of bilgewater on shore where adequate facilities exist. Any discharge which is made for safety reasons must be documented as part of the requirements in Part 4.2.

Additional recommended practices:

- Where fitted, oily-water separators (OWS) should be included in the unit's planned maintenance program.

- There have been significant amendments to the IMO standards for oily-water separating equipment [3.9]. Owners of units where oily-water separating equipment is routinely used may wish to consider replacement of existing oily-water separators, particularly if costly repairs to existing systems are needed.

8 IMO Circular MEPC.1/Circ.641, Supplementary Guidelines for approval of bilge and sludge handling systems, and IMO Circular MEPC.1/Circ. 642, 2008 Revised Guidelines for systems for handling oily wastes in machinery spaces of ships incorporating guidance notes fro an integrated bilge water treatment system (IBTS).

9 IMO Resolution MEPC.107(49), Revised Guidelines on specification for pollution prevention equipment for machinery space bilges of ships.

Πανεπιστήμιο Πειραιώς

3. Ballast Water

EPA required BMPs

All discharges of ballast water must comply with the Coast Guard regulations found in 33 CFR Part 151. Vessels that operate solely within one Captain of the Port (COTP) zone are exempt from certain requirements, as described in 33 CFR 151.2010(b). Additionally, owner/operators of all vessels subject to coverage under this permit which are equipped with Ballast Tanks must comply with any additional BMPs in this section.

All discharges of ballast water may not contain oil, noxious liquid substances (NLSs), or hazardous substances in a manner prohibited by U.S. laws, including section 311 of the Clean Water Act.

All owner/operators of vessels equipped with ballast water tanks must maintain a ballast water management plan that has been developed specifically for the vessel that will allow those responsible for the plan's implementation to understand and follow the vessel's ballast water management strategy. Owner/operators must make that plan available upon request to any EPA representative. Vessel owner/operators must assure that the master and crew members who actively take part in the management of the discharge or who may affect the discharge understand and follow the management strategy laid out in the plan.

EPA notes that these plans are being imposed as "conditions to assure compliance" with effluent limitations under CWA 402(a)(2) and 40 CFR 122.43(a).

Masters, owners, operators, or persons-in-charge of all vessels equipped with ballast water tanks that operate in waters of the U.S. must:

- Avoid the discharge of ballast water into waters subject to this permit that are within or that may directly affect marine sanctuaries, marine preserves, marine parks, shellfish beds, or coral reefs or other waters listed in Part 12.1.
- Minimize or avoid uptake of ballast water in the following areas and situations:
  - Areas known to have infestations or populations of harmful organisms and pathogens (e.g., algal blooms).
  - Areas near sewage outfalls.
  - Areas near dredging operations.
  - Areas where tidal flushing is poor or when a tidal stream is known to be more turbid.
  - In darkness when bottom dwelling organisms may rise up in the water column.
  - In shallow water or where propellers may stir up the sediment.
  - Areas with pods of whales, convergence zones and boundaries of major currents
- Clean ballast tanks regularly to remove sediments in mid-ocean or under controlled arrangements in port, or at dry dock.
- No sediment discharge from cleaning of ballast tanks is authorized in waters subject to this permit.

Discharge only the minimal amount of ballast water essential for vessel operations while in the waters subject to this permit.

2.2.3.4 On-shore Treatment of Ballast Water

For those vessels whose design and construction safely allows for the transfer of ballast water to shore, if compatible onshore treatment for ballast water is available and economically practicable and achievable, the vessel owner/operator must use this treatment for any ballast water discharges, unless they use an onboard ballast water treatment system approved by the Commandant of the Coast Guard. If vessels use on-shore treatment at one port, and they will not discharge ballast water into any other waters subject to this permit for their entire duration in waters subject to this permit, then it is not necessary to meet the requirements of 2.2.3.5, 2.2.3.6, 2.2.3.7, and 2.2.3.8.

2.2.3.5 Requirements for Ocean Going Voyages While Carrying Ballast Water

Any vessels that carry ballast water that was taken on in areas less than 200 nautical miles from any shore that will subsequently operate beyond the Exclusive Economic Zone (EEZ) and more than 200 nm from any shore must carry out an exchange of ballast water for any tanks that will discharge ballast water into waters subject to this permit unless the vessel meets one of the exemptions in Part 2.2.3.11.

This exchange must be conducted in compliance with the following standards prior to discharging ballast water into waters subject to this permit:

- The exchange must occur in waters beyond the U.S. EEZ;
- The exchange must occur in an area more than 200 nautical miles from any shore;

The exchange must be commenced as early in the vessel voyage as possible, as long as the vessel is more than 200 nm from any shore.

EPA suggested BMPs

Suggested control measures to minimize the discharge of ballast water include, but are not limited to, transferring ballast water between tanks within the vessel in lieu of ballast water discharge. Another option for minimizing the potential for spread of aquatic nuisance species (ANS) via ballast water discharges might be using treated graywater (only in areas where treated graywater may be discharged) for those vessels that generate substantial quantities of graywater (e.g. cruise ships). Yet another option is to use potable water for ballast.

Commentary:

(1) The International Convention for the Control and Management of Ships' Ballast Water.

The International Convention for the Control and Management of Ships' Ballast Water and Sediments will enter into force 12 months after ratification by 30 States, representing 35 % of world merchant shipping tonnage. As of 31 March 2009, the Convention had been ratified by 18 States representing approximately 15% of the world merchant shipping tonnage. Countries party to the Convention are: Albania, Antigua & Barbuda, Barbados, Egypt, France, Kenya, Liberia, Maldives, Mexico, Nigeria, Norway, Saint Kitts and Nevis, Sierra Leone, South Africa, Spain, Syrian Arab Republic, and Tuvalu.

MODUs are treated as 'ships' for the purposes of the Convention, and only the provisions regarding surveys contain any exemptions. Under the Convention, ships are required to have on board and implement a Ballast Water Management Plan approved by the Administration (Regulation B-1). The Ballast Water Management Plan is specific to each ship and includes a detailed description of the actions to be taken to implement the Ballast Water Management requirements and supplemental Ballast Water Management practices.

Ships must have a Ballast Water Record Book to record when ballast water is taken on board; circulated or treated for ballast water management purposes; and discharged into the sea. It should also record when ballast water is discharged to a reception facility and accidental or other exceptional discharges of ballast water.

The Convention contains specific requirements for ballast water management.

- Ships constructed before 2009 with a ballast water capacity of between 1500 and 5000 cubic metres must conduct ballast water management that at least meets the ballast water exchange standards or the ballast water performance standards (which requires the installation and use of an approved Ballast Water Management System (BWMS)) until 2014, after which time it shall at least meet the ballast water performance standard.
- Ships constructed before 2009 with a ballast water capacity of less than 1500 or greater than 5000 cubic metres must conduct ballast water management that at least meets the ballast water exchange standards or the ballast water performance standards until 2016, after which time it shall at least meet the ballast water performance standard.

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- Ships constructed in or after 2009 with ballast water capacity of less than 5000 cubic metres must conduct ballast water management that at least meets the ballast water performance standard.
- Ships constructed in or after 2009 but before 2012, with a ballast water capacity of 5000 cubic metres or more shall conduct ballast water management that at least meets the ballast water exchange standard until 2016 and at least the ballast water performance standard after 2016.
- Ships constructed in or after 2012, with a ballast water capacity of 5000 cubic metres or more shall conduct ballast water management that at least meets the ballast water performance standard.

BWMS must be approved by the Administration in accordance with IMO Guidelines. As of 31 March 2009, there are a limited number of BWMS which have obtained final approval.
All ships using ballast water exchange should:

- whenever possible, conduct ballast water exchange at least 200 nautical miles from the nearest land and in water at least 200 m in depth, taking into account Guidelines developed by IMO;
- be as far from the nearest land as possible, and in all cases at least 50 nautical miles from the nearest land and in water at least 200 m in depth, in cases where the ship is unable to conduct ballast water exchange listed as above.

The ballast water exchange standard requires that ships performing ballast water exchange do so with an efficiency of 95 % volumetric exchange of ballast water. For ships exchanging ballast water by the pumping-through method, pumping through three times the volume of each ballast water tank shall be considered to meet the standard described. Pumping through less than three times the volume may be accepted provided the ship can demonstrate that at least 95 percent volumetric exchange is met.

The ballast water performance standards requires that ships conducting ballast water management discharge less than 10 viable organisms per cubic meter greater than or equal to 50 μm in minimum dimension and less than 10 viable organisms per ml less than 50 μm in minimum dimension and greater than or equal to 10 μm in minimum dimension; and discharge of the indicator microbes shall not exceed the specified concentrations.

The indicator microbes, as a human health standard, include, but are not be limited to:
a. Toxicogenic Vibrio cholerae with less than 1 colony forming unit (cfu) per 100 ml or less than 1 cfu per 1 gram (wet weight) zooplankton samples ;
b. Escherichia coli less than 250 cfu per 100 milliliters;
c. Intestinal Enterococci less than 100 cfu per 100 milliliters.

It is not clear at this time if either EPA or the U.S. Coast Guard will accept flag-State approval of BWMS or operation of such systems as meeting the requirements of the VGP or Coast Guard regulations.

(2) It is perceived that MODUs, which meet all of the IMO and USCG requirements with regards to ballast water management, would also meet all of the VGP requirements too.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

4. Anti-Fouling Hull Coatings

EPA required BMPs

- All anti-fouling hull coatings subject to registration under FIFRA*(see 40 CFR 152.15) must be registered, sold or distributed, applied, maintained, and removed in a manner consistent with applicable requirements on the coatings' FIFRA label.
- For anti-fouling hull coatings not subject to FIFRA registration (i.e. not produced for sale and distribution in the United States), hull coatings must not contain any biocides or toxic materials banned for use in the United States (including those on EPA's List of Banned or Severely Restricted Pesticides). This requirement applies to all vessels, including those registered and painted outside the United States.

At the time of initial application or scheduled reapplication of anti-fouling coatings, you must give consideration, as appropriate for vessel class and vessel operations, to the use of hull coatings with the lowest effective biocide release rates, rapidly biodegradable components (once separated from the hull surface), or non-biocidal alternatives, such as silicone coatings.

Some ports and harbors are impaired by copper. These waters include Shelter Island Yacht Basin in San Diego, California and waters in and around the ports of Los Angeles/Long Beach. A complete list of such waters may be found at www.epa.gov/npdes/vessels. When vessels spend considerable time in these waters (defined as spending more than 30 days per year), or use these waters as their home port (i.e. house boats, ferries or rescue vessels), vessel owner/operators shall consider using antifouling coatings that rely on a rapidly biodegradable biocide or another alternative rather than copper based coatings. If after consideration of alternative biocides, vessel operators continue to use copper based antifoulant paints, they must document in their recordkeeping documentation how this decision was reached.

The discharge of Tributyltin (TBT) or any other organotin compound is prohibited by this permit. Therefore, vessel operators covered by this permit have a zero discharge standard for TBT or any other organotin compound. You may not use an antifoulant coating containing TBT or any other organotin compound. If the vessel has previously been covered with a hull coating containing TBT or any other organotin compound, vessels must be effectively over-coated so that no TBT or other organotin leaches from the vessel hull or the TBT or other organotin coating must have been removed from the vessel's hull.

* Federal Insecticide, Fungicide, and Rodenticide Act

Commentary:

(1) An International Anti-fouling System Certificate pursuant to the Convention on the Control of Harmful Anti-fouling Systems on Ships, 2001, may be useful in demonstrating compliance with the VGP with regard to the presence of TBT coatings. The Convention entered into force on 17 September 2008. As of 31 March 2009, States party to the Convention are: Antigua & Barbuda, Australia, Bahamas, Bulgaria, Cook Islands, Croatia, Cyprus, Denmark, Estonia, France, Greece, Hungary, Japan, Kiribati, Latvia, Liberia, Lithuania, Malta, Marshall Islands, Mexico, Netherlands, Nigeria, Norway, Panama, Poland, Republic of Korea, Romania, Saint Kitts and Nevis, Sierra Leone, Slovenia, Spain, Sweden, Tuvalu and Vanuatu.

(2) The following table provides a list of copper-impaired waters in areas where MODUs currently operate. The list may change, so reference should be made to the EPA website at www.epa.gov/npdes/vessels.

Προσχέδιο

Name/Location	Waterbody Type
Bayou Barataria/Barataria Waterway, LA	Stream/creek/river
Bayou Cane, LA	Wetland
Bayou Trepagnier – NORCO to Bayou Labranche, LA	Stream/creek/river
Cross Lake, LA	Lake/reservoir/pond
Duncan Canal (Parish Line Canal), LA	Stream/creek/river
Lake Pontchartrain, LA	Lake/reservoir/pond
James' Bayou, TX	Lake/reservoir/pond

Additional recommended practices:

- If not already completed, a survey should be undertaken to determine the characteristics of any existing hull coatings. IMO Resolutions MEPC.102(48) and MEPC.104(49) the Organization has developed "Guidelines for Survey and Certification of Anti-fouling Systems on Ships" and "Guidelines for Brief Sampling of Anti-Fouling Systems on Ships", respectively.

Πανεπιστήμιο Πειραιώς

5. Aqueous Film Forming Foam (AFFF)

EPA required BMPs

Discharges of AFFF are authorized for emergency purposes when needed to ensure the safety and security of the vessel and her crew.

For all vessels that sail outside of the territorial sea more than once per month, maintenance and training discharges of fluorinated AFFF are not authorized within waters subject to this permit (Any such discharges should be collected and stored for onshore disposal or scheduled when the vessel is outside such waters). Discharge volumes associated with regulatory certification and inspection must be minimized and a substitute foaming agent (i.e. non-fluorinated) must be used if possible within waters subject to this permit.

For vessels that do not leave the territorial sea more than once per month, if maintenance and training discharges are required, AFFF must be collected and stored for onshore disposal if technologically feasible unless the vessel uses non-fluorinated or alternative foaming agent. For those vessels for which it is not technologically feasible to collect and store the fluorinated AFFF foam, vessel owner/operators must limit the discharge to that amount necessary to conduct legally required tests. Training should be conducted as far from shore as is practicable. Maintenance and training discharges are not allowed in port.

For all vessels, AFFF discharges may not occur in or within 1 nm of a water referenced in Part 12.1 unless they are discharged:

-For emergency purposes,
-By rescue vessels such as fireboats for firefighting purposes,
-By vessels owned or under contract to do business exclusively in or within 1 nm of those protected areas by the United States government or state or local governments.

If AFFF discharge occurs in waters in Part 12.1 for emergency purposes, a written explanation must be kept in the ship's log or other vessel recordkeeping documentation consistent with Part 4.2 of this permit.

Commentary:

This BMP is not intended to interfere in any way with any essential emergency management operations. If an emergency occurs while in Permit Waters that results in an AFFF discharge an explanation of the emergency and the need to discharge AFFF needs to be documented and reported to the appropriate EPA office.

EPA's BMP states "if maintenance and training discharges are required, AFFF must be collected and stored for onshore disposal if technologically feasible unless the vessel uses non-fluorinated or alternative foaming agent." Published reports are available[10] comparing the acute aquatic toxicity (LC 50) of various AFFF formulations to those of 'fluorine-free' formulations, which show substantially lower LC 50 values for the 'fluorine-free' formulations. It should be permissible to discharge these 'fluorine-free' formulations as 'non-fluorinated' foaming agents in accordance with the BMP. EPA provides no guidance on which to base the selection of any other 'alternative' foaming agent.

Additional Recommended Practices:

- AFFF fire extinguishing systems, if installed, should be included in the unit's planned maintenance system.

10 E.g., reports by the Fire Fighting Foam Coalition and the U.K. Fire Industry Association.

Πανεπιστήμιο Πειραιώς

- When possible, units that are equipped with AFFF should conduct any inspection, maintenance or training that may result in the discharge of AFFF while outside Permit Waters.

- Where testing of existing AFFF systems must be undertaken within Permit Waters, the possibility of conducting the tests with a non-fluorinated agent, while maintaining the existing inventory of AFFF, should be investigated with the system manufacturer and regulatory authorities.

- When installing a new fire extinguishing system, or it becomes necessary to replace an existing AFFF fire extinguishing system, consideration should be given to procuring a system using a non-fluorinated agent.

- Should it be necessary to replace an existing AFFF inventory, consideration should be given to procuring a non-fluorinated agent compatible with the existing system, or modifying the system as may be necessary in order to use a non-fluorinated agent.

Πανεπιστήμιο Πειραιώς

6. Boiler / Econimizer Blowdown

EPA required BMPs

Minimize the discharge of boiler/economizer blowdown in port if chemicals or other additives are used to reduce impurities or prevent scale formation. For vessels greater than 400 gross tons which leave the territorial sea at least once per week, boiler/economizer blowdown may not be discharged in waters subject to this permit, unless:

- The vessel remains within waters subject to this permit for a longer period than the necessary duration between blowdown cycles,
- The vessel needs to conduct blowdown immediately before entering drydock, or
- For safety purposes.

For all vessels, boiler/economizer blowdown may not be discharged in waters referenced in Part 12.1 except for safety purposes. Furthermore, boiler/economizer blowdown should be discharged as far from shore as practical.

Commentary:

MODUs operating in Permit Waters are rarely equipped with boilers or boilers with economizers.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

7. Cathodic Protection

EPA required BMPs

Cathodic protection must be maintained to prevent the corrosion of the ship's hull. The discharge of zinc, magnesium, and aluminum are expected from properly functioning cathodic protection sacrificial electrodes. However, vessel operators must minimize the flaking of large, corroded portions of these anodes. Sacrificial anodes must not be used more than necessary to adequately prevent corrosion of the vessel's hull, sea chest, rudder, and other exposed areas of the vessel. Vessel operators must appropriately clean and/or replace these anodes in periods of maintenance (such as drydocking), so that release of these metals to waters is minimized.

Vessel operators should be cognizant that magnesium is less toxic than aluminum, which is less toxic than zinc. If vessel operators use sacrificial electrodes, they must use the metals that are less toxic to the extent technologically feasible and economically practicable and achievable.

If vessel operators use ICCP, they must maintain dielectric shields to prevent flaking.

EPA suggested BMPs

EPA recommends the use of Impressed Current Cathodic Protection (ICCP) in place of or to reduce the use of sacrificial electrodes when technologically feasible (e.g. adequate power sources, appropriate for vessel hull size and design), safe, and adequate to protect against corrosion, particularly for new vessels.

Commentary:

Cathodic protection systems typically employ sacrificial electrodes or a combination of sacrificial anodes and ICCP. Consideration should be given to the installation of ICCP where such systems may be feasibly installed.

Additional recommended practices:

- An ICCP, if installed, should be included in the unit's planned maintenance program.

Πανεπιστήμιο Πειραιώς

8. Chain Locker Effluent

EPA required BMPs

The anchor chain must be carefully and thoroughly washed down (*i.e.*, more than a cursory rinse) as it is being hauled out of the water to remove sediment and marine organisms. In addition, chain lockers must be cleaned thoroughly during dry docking to eliminate accumulated sediments and any potential accompanying pollutants. For vessels that regularly sail outside waters subject to this permit, if technically feasible, periodically clean, rinse, and/or pump out the space beneath the chain locker prior to entering waters subject to this permit (preferably mid ocean) if the anchor has been lowered into any near-shore waters. Furthermore, for vessels that leave waters subject to this permit at least once per month, chain lockers may not be rinsed or pumped out in waters subject to this permit, unless not emptying them would compromise safety. Such a safety claim must be documented in the vessel's recordkeeping documentation consistent with Part 4.2.

Commentary:

None

Additional recommended practices:

None

Πανεπιστήμιο Πατρών

9. Controllable Pitch Propeller and Thruster Hydraulic Fluid and other Oil to Sea Interfaces, including Lubrication Discharges from Paddle Wheel Propulsion, Stern Tubes, Thruster Bearings, Stabilizers, Rudder Bearings, Azimuth Thrusters, Propulsion Pod Lubrication, and Wire Rope and Mechanical Equipment Subject to Immersion

EPA required BMPs

The protective seals on controllable pitch propellers, azimuth thrusters, propulsion pods, rudder bearings, or any other oil to sea interfaces must be maintained in good operating order to minimize the leaking of hydraulic oil or other oils. The vessel owner/operator must not discharge oil in quantities that may be harmful as defined in 40 CFR Part 110 from any oil to sea interface. If possible, maintenance activities on controllable pitch propellers, thrusters and other oil-to-sea interfaces should be conducted when a vessel is in drydock.

Minimize maintenance activities on stern tube seals when a vessel is outside of drydock. If maintenance or emergency repair must occur on stern tubes or other oil-to sea interfaces which have a potential to release oil in quantities that may be harmful as defined in 40 CFR Part 110, appropriate spill response resources (e.g. oil booms) must be used to contain any oil leakage. Operators of the vessel must have ready access to any spill response resources to clean any potential oil spills.

After applying lubrication to wire rope and mechanical equipment subject to immersion, wire ropes and other equipment must be thoroughly wiped-down to remove excess lubricant.

Owner/operators should use an environmentally preferable lubricant, including vegetable oil, synthetic ester, or polyalkylene glycol as a base for these applications when feasible. Use of an environmentally preferable lubricant does not authorize the discharge of any lubricant in a quantity that may be harmful as defined in 40 CFR Part 110.

Commentary:

None

Additional recommended practices:

- Prepare a unit-specific list of oil-water interfaces subject to the VGP.
- Promptly repair any lubricant seal leaks on equipment subject to immersion.
- Apply only the amount of lubrication necessary for proper maintenance of tow wire, mooring line, or mechanical coupling devices.
- Apply lubrication in a manner that minimizes drips and spills and promptly clean up any drips or spills that occur.
- Establish procurement procedures that give consideration to:
  - The type(s) of lubricants used in new equipment subject to the VGP to assure environmentally preferable lubricants are used, when feasible; and
  - The feasibility of using environmentally preferable lubricants on existing equipment.
- If maintenance or emergency repair of thrusters must be undertaken while afloat in Permit Waters, use an oil boom to contain possible hydraulic oil leakage and have cleanup/response equipment, such as oil absorbent pads, on hand to clean up any spillage/discharge.

Πολιτιστικό Ίδρυμα

10. Distillation and Reverse Osmosis Brine

EPA required BMPs

Brine from the distillation system and reverse osmosis reject water shall not contain or come in contact with machinery or industrial equipment (other than that necessary for the production of potable water), toxic or hazardous materials, or wastes.

Commentary:

None

Additional recommended practices:

- Minimize the production and associated discharges of distillation and reverse osmosis brine while in Permit Waters.

- On units which will operate a distillation or reverse osmosis unit in Permit Waters, consideration should be given to installing a dedicated line to discharge reject water. In order to eliminate the need for quarterly sampling, the discharge should be located above the waterline in a readily visible location.

Πανεπιστήμιο Πειραιώς

11. Elevator Pit Effluent

EPA required BMPs

Discharges of untreated elevator pit effluent are not authorized within waters subject to this permit except in cases of emergency. Elevator pit effluent may be discharged into waters subject to this permit if it is managed with the vessel's bilgewater and meets all the requirements of Part 2.2.2 of this permit or it must otherwise be treated with an oily-water separator and discharged with an oil content below 15 ppm as measured by EPA Method 1664 or other appropriate method for determination of oil content as accepted by the International Maritime Organization (IMO) (e.g. ISO Method 9377) or U.S. Coast Guard. Emergency discharges must be documented in the ship's log or other vessel recordkeeping documentation consistent with Part 4.2.

Commentary:

MODUs operating in Permit Waters are rarely equipped with elevator pits that can be discharged to the sea.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

12. Firemain Systems

EPA required BMPs

Discharges from firemain systems are authorized for emergency purposes when needed to ensure the safety and security of the vessel and her crew, other emergency situations, and for testing and inspection purposes as may be required to assure its operability in an emergency. Firemain systems may be discharged in port for certification, maintenance, and training requirements if the intake comes directly from the surrounding waters or potable water supplies and there are no additions to the discharge. Furthermore, firemain discharges may be discharged for deck washdown or other secondary uses if the intake comes directly from the surrounding waters or potable water supplies and the discharge meets all relevant effluent limitation associated with that activity. When feasible, maintenance and training should be conducted outside port and/or outside waters subject to this permit.

Do not discharge firemain systems in waters listed in Part 12.1 except in emergency situations or when washing down the anchor chain to comply with anchor wash down requirements in Part 2.2.8.

Commentary:

This BMP is not intended to interfere in any way with any essential emergency management operations. If an emergency occurs while in Permit Waters that requires use of the firemain system, an explanation of the emergency and the need to use the firemain system will need to be documented and reported to the appropriate EPA office.

Additional Recommended Practices:

None

Πανεπιστήμιο Πειραιώς

13. Freshwater Layup

EPA required BMPs

Minimize the amount of disinfection agents used in freshwater layup to the minimum required to prevent aquatic growth.

Commentary:

When certain ships are out of service for an extended period and the seawater cooling systems are not circulated, the main condensers are placed in a freshwater layup to prevent the accumulation of biological growth and the resultant loss of condenser efficiency while the seawater cooling system is not in use. The layup is accomplished by blowing the seawater from the main condensers with air and isolating the condensers. The condensers are then filled with potable water to which biocides may be added. Freshwater layup is not generally associated with MODU operations.

Additional Recommended Practices:

None

Πανεπιστήμιο Πειραιώς

14 Gas Turbine Wash Water

EPA required BMPs

Gas turbine wash water must not be directly discharged within waters subject to this permit. Where feasible, such wash water must be prevented from commingling with bilge water that will be discharged in waters subject to this permit, for example by collecting it separately and properly disposing of it on-shore. Under no circumstances may oils, including oily mixtures, from gas turbine wash water be discharged in waters subject to this permit in quantities that may be harmful as determined in accordance with 40 CFR Part 110.

Commentary:

There are no known MODUs operating in Permit Waters equipped with gas turbines.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

15. Graywater

EPA required BMPs

All vessels must minimize the discharge of graywater while in port. For those vessels that cannot store graywater, the owner or operator and their crews should minimize the production of graywater in port. All vessels that have the capacity to store graywater shall not discharge that graywater in waters listed in Part 12.1. For vessels that cannot store graywater, vessel operators must minimize the production of graywater while in waters listed in Part 12.1.

For vessels greater than 400 gross tons that regularly travel more than 1 nm from shore that have the capacity to store graywater for a sufficient period, graywater must be discharged greater than 1 nm from shore while the vessel is underway, unless the vessel meets the treatment standards and other requirements contained under Parts 5.1.1 and 5.1.2 or 5.2.1 and 5.2.2 of this permit. Additional specific requirements for Graywater apply to Cruise Vessels (Parts 5.1 and 5.2) and Large Ferries (Part 5.3).

Vessels that do not travel more than 1 nm from shore shall minimize the discharge of graywater and, provided the vessel has available graywater storage capacity, must dispose of graywater on shore if appropriate facilities are available and such disposal is economically practicable and achievable unless the vessel meets the treatment standards and other requirements contained under Parts 5.1.1 and 5.1.2 or 5.2.1 and 5.2.2 of this permit. Minimize the discharge of graywater when the vessel is not underway.

If graywater will be discharged in waters subject to this permit, the introduction of kitchen oils must be minimized to the graywater system. When cleaning dishes, you must remove as much food and oil residue as practicable before rinsing dishes. Oils used in cooking shall not be added to the graywater system. Oil from the galley and scullery shall not be discharged in quantities that may be harmful as defined in 40 CFR Part 110.

Vessel owner/operators must use phosphate free and non-toxic soaps and detergents for any purpose if they will be discharged into waters subject to this permit. These detergents must be free from toxic or bio-accumulative compounds and not lead to extreme shifts in receiving water pH.

If you are underway in a nutrient impaired water, or a water that is impaired as a result of nutrient enrichment (such as waters listed as impaired for phosphorus, nitrogen, or for hypoxia or anoxia (low dissolved oxygen concentrations)) you must follow these additional steps:

When the vessel has adequate graywater storage capacity, the vessel owner/operator shall not discharge graywater into nutrient impaired waters subject to this permit (e.g., the Chesapeake Bay). A complete list of such waters can be found at www.epa.gov/npdes/vessels. Where the vessel does not have adequate storage capacity to eliminate such discharges, graywater production and discharge must be minimized in such waters. Any such discharge must be conducted while the vessel is underway in areas with significant circulation and depth to the extent feasible. Graywater stored while in such waters can later be disposed of on shore or discharged in accordance with the other requirements of this permit.

Commentary:

The provisions of parts 5.1 and 5.2 referred to in the EPA required BMPs do not apply to MODU operations.

Additional recommended practices:

- Unit managers should ascertain whether unit graywater systems are arranged to discharge through the sewage treatment system and document their findings.
- Procurement procedures should be established to assure that soaps and detergents that could be discharged as graywater (e.g., for galley, laundry, or personal use) will meet the VGP requirements.

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- Where graywater is discharged:
  - Minimize the introduction of kitchen oils to the graywater system.
  - When cleaning dishes, remove as much food and oil residue as practicable before rinsing dishes.
- Consider providing shore-side washrooms, kitchen and laundry facilities when practicable when a MODU is at the dock or in dry-dock.
- Use tie-ins to shore-side treatment facilities when feasible.
- Minimize the production of graywater through:
  - Promptly repairing leaky fixtures.
  - Using sinks, showers, washing machines, etc. in most economic operating condition.
  - Educating crew members on steps to be taken to reduce the production and contamination of graywater; and
  - Posting signs on the MODU to remind crew of the need to minimize production of graywater.

Πανεπιστήμιο Πειραιώς

16. Motor Gasoline and Compensating Discharge

EPA required BMPs

The discharge of motor gasoline and compensating effluent must not have oil in quantities that may be harmful as defined in 40 CFR 110.3, which includes discharges resulting in a visible sheen, or an oil concentration that exceeds 15 ppm. Determination of oil concentration may be measured by EPA Method 1664 or other appropriate method for determination of oil content as accepted by the International Maritime Organization (IMO) (e.g. ISO Method 9377) or U.S. Coast Guard. Compliance with the 15 ppm oil concentration limitation may be established with visual monitoring for an oily sheen. Minimize discharge of motor gasoline and compensating discharge in port. If an oily sheen is observed, the vessel operator must deploy appropriate oil containment practices. Vessels shall not discharge motor gasoline and compensating discharge in waters subject to this permit listed in Part 12.1.

Commentary:

There is no known use of Motor Gasoline and Compensating Discharge by MODUs.

Additional Recommended Practices:

None

Πανεπιστήμιο Πειραιώς

17. Non-Oily Machinery Wastewater

EPA required BMPs

If discharged directly overboard, non-oily machinery wastewater must be free from oils (in quantities that may be harmful pursuant to 40 CFR Part 110) and any additives that are toxic or bio-accumulative in nature. Non-oily machinery wastewater may also be drained to the bilge.

Commentary:

As this discharge stream can be discharged without treatment, it is necessary to review the drainage arrangements to assure that the possibility of contamination with oil or oily mixtures is minimized. Separation of non-oily and oily discharge streams minimizes the need for treatment of discharges.

Alternatively, the drainage may be directed to the discharge stream for discharges of oil, including oily mixtures, or the discharge stream for bilgewater.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

18. Refrigeration and Air Condensate Discharge

EPA required BMPs

You must not allow refrigeration and air condensate discharge to come into contact with oily or toxic materials if it is discharged directly overboard. Refrigeration and air conditioning condensate that is collected and plumbed for internal recycling (e.g. recycled as "technical water") is allowed to commingle with oily water; however, the commingled discharge must meet all requirements of Part 2.1.4 of this permit and Part 2.2.2 of this permit if applicable.

Commentary:

As this discharge stream can be discharged without treatment, it is necessary to review the drainage arrangements to assure that the possibility of contamination with oil or oily mixtures or toxic materials is minimized. Separation from the oily discharge streams minimizes the need for treatment of discharges.

Alternatively, the drainage may be directed to the discharge stream for discharges of oil, including oily mixtures, or the discharge stream for bilgewater.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

19. Seawater Cooling Overboard Discharge

EPA required BMP

When possible, seawater cooling overboard should be discharged when the vessel is underway so that any thermal impacts are dispersed.

Maintenance of all piping and seawater cooling systems must meet the requirements of Part 2.2.20 (Seawater-Piping Biofouling Prevention).

EPA suggested BMP

To reduce the production and discharge of seawater cooling overboard discharge, EPA recommends that vessel owner/operators use shore based power when the vessel is in port if:

- Shore power is readily available for vessel owner/operators from utilities or port authorities,
- Shore based power supply systems are capable of providing all needed electricity required for vessel operations; and
- The vessel is equipped to connect to shore-based power and such systems are compatible with the available shore power.

Commentary:

None

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

20. Seawater Piping Biofouling Prevention

EPA required BMPs

Seawater piping biofouling chemicals subject to FIFRA* registration (see 40 CFR 152.15) must be used in accordance with their FIFRA label. No pesticides or chemicals banned for use in the United States may be discharged into waters subject to this permit.

Vessel owner/operators must use the minimum amount of biofouling chemicals needed to keep fouling under control. Discharges containing active agents must contain as little chlorine as possible.

Vessel owner/operators must remove fouling organisms from seawater piping on a regular basis and dispose of removed substances in accordance with local, State, and federal regulations. Removed fouling organisms shall not be discharged into waters subject to this permit.

* Federal Insecticide, Fungicide, and Rodenticide Act

EPA suggested BMPs

EPA recommends that if removed fouling organisms are discharged into waters, they should be discharged more than 50 nm from shore. Vessel owner/operators should remove any organisms while at sea to reduce the risk of invasive species introduction in ports.

Commentary:

While the suggestion regarding removal and discharge of fouling organism in waters more than 50 nm from shore is noted, it may not be practicable in the case of units that are outside Permit Waters and are undergoing required inspections that necessitate cleaning of sea valves and seachests and strainers.

It should also be noted that many units are not moved between areas having differing ecosystems, so the risk of introduction of an invasive species posed by removal of fouling organisms outside Permit Waters is minimal.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

21. Boat Engine Wet Exhaust

EPA required BMPs

Vessels generating wet exhaust must be maintained in good operating order, well tuned, and functioning according to manufacturer specifications if available to decrease pollutant contributions to wet exhaust.

EPA suggested BMPs

EPA encourages vessel operators to consider four-stroke versus two-stroke engines for vessels generating wet exhaust that are covered under this permit. Use of a four-stroke engine may minimize the discharge of pollutants to US waters. Vessel owner/operators should use low sulfur or alternative fuels for their vessels to reduce the concentration of pollutants in their discharge.

Commentary:

None

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

22. Sonar Dome Discharge

EPA required BMP

The water inside the sonar dome shall not be discharged within waters subject to this permit for maintenance purposes. Vessel operators should not use biofouling chemicals that are bio-accumulative for the exterior of sonar domes when other viable alternatives are available.

Commentary:

MODUs are rarely, if ever, equipped with sonar domes.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

23. Underwater Ship Husbandry

EPA required BMPs

Vessel owner/operators must minimize the transport of attached living organisms when they travel into U.S. waters from outside the U.S. economic zone or when traveling between COTP zones.

Whenever possible, rigorous hull-cleaning activities should take place in drydock, or another land-based facility where the removal of fouling organisms or spent antifouling coatings paint can be contained. If water-pressure based systems are used to clean the hull and remove old paint, use facilities which treat the washwater prior to discharge to remove the antifouling compound(s) and fouling growth from the washwater.

Vessel owner/operators who remove fouling organisms from hulls while the vessel is waterborne must employ methods that minimize the discharge of fouling organisms and antifouling hull coatings. These shall include:

- Selection of appropriate cleaning brush or sponge rigidity to minimize removal of antifouling coatings and biocide releases into the water column.
- Limiting use of hard brushes and surfaces to the removal of hard growth.
- When available and feasible, use of vacuum control technologies to minimize the release or dispersion of antifouling hull coatings and fouling organisms into the water column.

Vessel owner/operators must minimize the release of copper based antifoulant paint into the water column when they clean their vessel. Cleaning of copper based antifoulant paints must not result in any visible cloud or plume of paint in the water: if a visible cloud or plume of paint develops, shift to a softer brush or less abrasive cleaning technique. A plume or cloud of paint can be noted by the presence of discoloration or other visible indication that is distinguishable from hull growth or sediment removal. Production of a plume or cloud of sediment or hull growth is normal in some cases during vessel hull cleaning, but this plume or cloud should be substantially paint free (e.g. paint should not be clearly identifiable in the plume or cloud).

Vessels that use copper based anti-fouling paint must not clean the hull in copper impaired waters within the first 365 days after paint application unless there is a significant visible indication of hull fouling.

Commentary:

None

Additional recommended practices:

- If not already completed, a survey should be undertaken to determine the characteristics of any existing hull coatings. IMO Resolutions MEPC.102(48) and MEPC.104(49) the Organization has developed “Guidelines for Survey and Certification of Anti-fouling Systems on Ships” and “Guidelines for Brief Sampling of Anti-Fouling Systems on Ships”, respectively.

When feasible, extensive hull cleaning shall be conducted when the rig is in drydock or when the byproducts of the cleaning can be contained and disposed of properly, especially when cleaning hulls using water pressure based systems. This BMP encourages all waste to be collected and disposed of properly to ensure that they are not washed into waters subject to the Vessel General Permit (VGP). While these practices do not specifically address the release of antifouling materials from hulls during vessel operations (i.e., hull coating leachate), they are critical to controlling levels of contaminants that result in the same type of environmental degradation. In addition, these same practices will reduce the potential for release of introduced species during hull cleaning and paint preparation activities.

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Vessel owner/operators who remove fouling organisms from hulls while the vessel is waterborne must employ methods that minimize the discharge of fouling organisms and antifouling hull coatings. These shall include:

- Selection of appropriate cleaning brush or sponge rigidity to minimize removal of antifouling coatings and biocide releases into the water column.
- Limiting use of hard brushes and surfaces to the removal of hard growth.
- When available and feasible, use of vacuum control technologies to minimize the release or dispersion of antifouling hull coatings and fouling organisms into the water column.

Πανεπιστήμιο Πειραιώς

24. Welldeck Discharge

EPA required BMPs

Welldeck discharges that contain graywater from smaller vessels should not be discharged within waters subject to this permit except in cases of emergency. Welldeck discharges from washdown of gas turbine engines may not be discharged within waters subject to this permit. Welldeck discharges from equipment and vehicle washdowns must be free from garbage and must not contain oil in quantities that may be harmful as defined in 40 CFR Part 110.

Commentary:

MODUs operating in Permit Waters are rarely, if ever, configured with welldecks.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς

25. Graywater Mixed with Sewage from Vessels

EPA required BMPs

The commingled discharge of graywater mixed with sewage from vessels must comply with the effluent limits for graywater discharge in Part 2 or Part 5 of this permit if applicable. Though not a requirement of this permit, vessel owner/operators are advised that all discharges commingled with sewage must meet the requirements set forth in section 312 of the Clean Water Act and its implementing regulations found at 40 CFR Part 140 and 33 CFR Part 159. Hence, discharges of graywater mixed with sewage must meet both standards to be in compliance with the Clean Water Act.

Commentary

None

Additional recommended practices

Unit managers should ascertain whether their unit graywater systems are arranged to discharge through the sewage treatment system.

Where existing systems on units are combined, consideration should be given to making each system independent in order to avoid commingling sewage with graywater.

Πανεπιστήμιο Πειραιώς

26. Exhaust Gas Scrubber Washwater

EPA required BMPs

Exhaust gas scrubber washwater discharge must not contain oil, including oily mixtures, in quantities that may be harmful as determined in accordance with 40 CFR Part 110. Sludge generated from exhaust gas scrubber washwater discharge must not be discharged in waters subject to this permit.

EPA suggested BMPs

EPA recommends that owner/operators of vessels with exhaust gas cleaning systems that result in washwater discharges follow the guidelines set out in section 10 for Exhaust Gas Cleaning Systems (resolution MEPC.170(57)).

Commentary:

Exhaust gas scrubbers are rarely, if ever, installed on MODUs.

Additional recommended practices:

None

Πανεπιστήμιο Πειραιώς