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2022 GUIDELINES FOR RISK AND IMPACT ASSESSMENTS OF THE DISCHARGE WATER FROM EXHAUST GAS CLEANING SYSTEMS

1 The Marine Environment Protection Committee, at its seventy-eighth session (6 to 10 June 2022), approved the *2022 Guidelines for risk and impact assessments of the discharge water from exhaust gas cleaning systems*, as set out in the annex.

2 Member Governments are invited to bring the annexed Guidelines to the attention of Administrations, port State control authorities, industry, relevant shipping organizations, shipping companies and other stakeholders concerned.

3 The Committee agreed to keep these Guidelines under review in light of experience gained.

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ANNEX

2022 GUIDELINES FOR RISK AND IMPACT ASSESSMENTS OF THE DISCHARGE WATER FROM EXHAUST GAS CLEANING SYSTEMS

CONTENTS

1 INTRODUCTION

1.1 These guidelines provide information on recommended methodology for risk and impact assessments that Member States should follow when considering local or regional regulations to protect the sensitive waters/environment from the discharge water from EGCS that complies with the Convention. These guidelines include assessments of the risks from a long-term perspective, with respect to aquatic quality, aquatic organism, and/or human health, and the impact assessment approach which may be applied to the specific receiving environment.

1.2 Member States are recommended to conduct an environmental risk assessment according to these guidelines when considering local or regional regulations.

1.3 The purpose of these guidelines is to provide a unified approach containing procedures that would support Member States to judge whether the introduction of restrictions/conditions of discharge water from EGCS would be needed and justifiable or not. In all aspects of risk and impact assessments the need for evidence-based decision-making should be balanced with the precautionary approach as set out in resolution MEPC.67(37).[1]

2 DEFINITIONS AND ABBREVIATIONS

2.1 Definitions

2.1.1 For the purpose of these guidelines,

.1 "Discharge water" means any water from an EGCS to be discharged overboard;

.2 "Washwater" means cleaning medium brought into contact with the exhaust gas stream for the reduction of SO_X;

.3 "Bleed-off water" means an amount of aqueous solution removed from the washwater of an EGCS operating in closed-loop mode to keep its required operating properties and efficiency;

.4 "EGCS residue" means material removed from the washwater or the bleed-off water by a treatment system or discharge water that does not meet the discharge criterion, or other residue material removed from the EGCS;

.5 "Emissions" means any release of substances, subject to control by this annex, from ships into the atmosphere or sea according to regulation 2.1.12 of MARPOL Annex VI[2];

.6 "Aggregated exposure approach" in relation to human exposure scenarios means the assessment of the total exposure to one substance resulting from more than one exposure pathway (inhalation, dermal and oral) and/or from more than one exposure scenario;

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[1] *Guidelines on Incorporation of the precautionary approach in the context of specific IMO activities.*

[2] The regulation numbers in these Guidelines refer to the 2021 Revised MARPOL Annex VI, as adopted by resolution MEPC.328(76), which was accepted on 1 May 2022 in accordance with article 16(2)(f)(iii) of MARPOL and which will enter into force on 1 November 2022.

.7 "Area to be assessed" means sea area where discharge water from EGCS is intended to be restricted under certain conditions;

.8 "Emission factor" means the concentration of the product of individual substance in discharge water from EGCS per the typical flow rate, expressed as mg/MWh; and

.9 "Sea Area for calculating PEC (SAP)" means sea area selected for simulation to estimate Predicted Environmental Concentrations (PECs) of the targeted chemicals, which should be a part of the area to be assessed.

2.1.2 Furthermore, the definitions in *2021 Guidelines for exhaust gas cleaning systems* adopted by resolution MEPC.340(77) apply.

2.2 Abbreviations

2.2.1 For the purpose of these guidelines, the following abbreviations apply.

2021 EGCS Guidelines	*2021 Guidelines for Exhaust Gas Cleaning Systems* adopted by resolution MEPC.340(77)
AIS	Automatic Identification System
AIST	National Institute of Advanced Industrial Science and Technology of Japan
BCF	Bioconcentration Factor
BMD	Benchmark Dose
$BMDL_{10}$	Benchmark Dose Lower Confidence Limit 10%
CFD	Computational Fluid Dynamics
CMR	Carcinogenicity, Mutagenicity and Reproductive Toxicity
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EFSA	European Food Safety Authority
EQS	Environmental Quality Standards
ERA	Environmental Risk Assessment
EUSES	European Union System for The Evaluation of Substances
GESAMP	IMO/FAO/UNESCOIOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
JECFA	Joint FAO/WHO Expert Committee on Food Additives
GESAMP EGCS TT	GESAMP Task Team on Exhaust Gas Cleaning Systems
K_{oc}	Organic Carbon-Water Partition Coefficient
K_p	Permeability Coefficient
MAMPEC	Marine Anti-Foulant Model for PEC Calculation
MOE	Margin of Exposure
NOAEL	No Observed Adverse Effect Level
PBT	Persistence, Bioaccumulation and Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PTMI	Provisional Tolerable Monthly Intake
PTWI	Provisional Tolerable Weekly Intake
(Q)SAR	(Quantitative) Structure-Activity Relationship
RCR	Risk Characterization Ratio
RO	Reverse Osmosis
SAP	Sea Area For Calculating PEC
SOG	Speed Over Ground

TDI	Tolerable Daily Intake
US EPA	The United States Environmental Protection Agency
WET	Whole Effluent Toxicity Test
WHO	World Health Organization
WHO/IPCS	World Health Organization/International Programme on Chemical Safety

3 PRINCIPLES

3.1 The use of EGCS in the area to be assessed should not cause unacceptable risks, especially from a long-term perspective with respect to marine organisms, aquatic quality and/or human health, as assessed in accordance with these Guidelines.

4 APPLICATION

4.1 These Guidelines can be used by Member States when undertaking risk and impact assessments to ascertain whether EGCS discharge water can be discharged in their ports, harbours, estuaries, or coastal and other territorial waters.

4.2 The risk and impact assessments can be done at local, national or regional level (e.g. regional sea conventions) and be conducted at least in cooperation with neighbouring States. Alternatively, Member States can take into consideration risk and impact assessments undertaken by another Party.

5 GENERAL REQUIREMENTS

5.1 Targeted chemical substances and their data-set

5.1.1 The targeted chemical substances for environmental risk assessment (ERA)

5.1.1.1 The targeted chemical substances for ERA should at least include the following "priority hazardous substances":

.1 cadmium;
.2 lead;
.3 mercury;
.4 nickel;
.5 vanadium;
.6 chromium;
.7 copper;
.8 zinc;
.9 acenaphthene;
.10 acenaphthylene;
.11 anthracene;
.12 benzo(a)anthracene;
.13 benzo(a)pyrene;
.14 benzo(b)fluoranthene;
.15 benzo(k)fluoranthene;
.16 benzo(g,h,i)perylene;
.17 chrysene;
.18 fluoranthene;
.19 fluorene;
.20 indeno(1,2,3cd)pyrene;
.21 naphthalene;

.22 pyrene;
.23 phenanthrene; and
.24 dibenzo(a,h)anthracene.

5.1.1.2 The targeted chemical substances for ERA are not limited to the above priority hazardous substances. Other contaminants found in EGCS discharge waters may be added, taking into account the domestic regulations and specific factors from the sensitivity of the area to be assessed.

5.1.1.3 Also, for the area where the administration has concerns on eutrophication, relevant substances (e.g. nitrate, nitrite, ammonia and/or phosphate), which may dissolve into EGCS discharge waters, may be added.

5.1.2 Data-set for ERA

5.1.2.1 The Database of priority hazardous substances developed by the Organization, including physico-chemical data, ecotoxicological data and toxicological data, should be used for ERA.

5.1.2.2 Furthermore, the worst-case emission factors of the priority hazardous substances listed in paragraph 5.1.1.1 should be used for reasonable worst-case scenarios (see paragraph 6.2.2).

.1 Emission Factors for the chemical substances are needed for ERA. In addition, the flow rate of the discharge water against exhaust flow may vary among EGCSs type and the load of engines connected to the EGCSs. However, such information does not depend on the location of the area to be assessed. Therefore, it is recommended that unified and representative Emission Factors (mg/MWh) based on the data for discharge water concentration and flow rate collected by the Organization be utilized.

.2 If the Member States propose to use their original Emission Factors with a scientific reasoning based on their original measurement of EGCS discharge water, all the measurements should be analysed in accordance with the 2021 EGCS Guidelines.

5.1.2.3 The database will be placed to the IMO GISIS under a separate new item titled "Chemicals in EGCS Discharge Water".

5.1.2.4 For the targeted chemical substances for ERA, which are not included in the list of priority hazardous substances, the Member States should prepare the information as in paragraphs 5.1.2.1 and 5.1.2.2.

5.2 Information of the area to be assessed

5.2.1 Data stated in paragraph 5.2.2 should be collected by the Member States implementing the risk assessment in accordance with these guidelines.

5.2.2 Information of the area to be assessed

5.2.2.1 The following information of the area to be assessed is required:

.1 geographical designation of the area to be assessed;

.2 representative water and sediment quality of the area to be assessed;

.3 the meteorographic/oceanographic information in table 1 on each Sea Area for calculating PECs (SAP);

.4 existing threshold concentrations (PNEC, Predicted No Effect Concentration or EQS, Environmental Quality Standards) for each substance (in water, sediment and/or biota) indicating the level in the environment below which there should be no harm (lethal or sub-lethal) to the aquatic ecosystem or human health, taking account of the likely bioavailability of the substances where relevant; and

.5 information on how chemical, biological and physical characteristics of the receiving environments, including their pH and salinity, could affect the level of risk.

Table 1: Parameters used for long-term environmental assessment

Parameter	Unit	Remarks
Current	m/s	Representative value of each SAP.
Wind speed	m/s	Representative value of each SAP.
Wind direction	-	Consider the direction that affects the inflow to the mouth of each SAP.
Temperature	In Celsius	Annual average value of each SAP.
Salinity	PSU (Practical Salinity Unit)*	Representative value of each SAP.
pH	-	Representative value of each SAP.
Tidal difference	m	Representative value of each SAP.
Tidal period	hours	Representative value of each SAP.
Suspended particulate matter (SPM)	mg/L	Representative value of each SAP.
Depth of sediment layer	m	Representative value of each SAP.
Alkalinity	mg/l $CaCO_3$	Representative value of each SAP.

* PSU $\approx$ Salinity concentration in ppt (absolute salinity)

5.2.2.2 It is recommended that the information of the area to be assessed be collected by actual measurements, while representative values from literature can be used in case actual measurements are difficult. For parameters that change according to the season/time of the year, the changes of such parameters should be all-inclusively taken into account to ensure the representativeness of values.

6 RISK CHARACTERIZATION

6.1 Introduction

6.1.1 In this chapter, the methodology to assess the quantitative risks is described. Related international standards and/or existing guidance may be taken into account for risk characterization.

6.1.2 First, the daily loads (g/day) of all the chemical substances, which are discharged from EGCS, should be delivered based on the actual ship activities. Secondly, the PECs (ppt) of the chemical substances should be determined, taking into account the physico-chemical characteristics and the geographical and meteorographical/oceanographical conditions.

Also, the human exposure amount (g/kg-BW/day) may be delivered from the PECs. Finally, for risk characterization, the PEC and/or exposure amount, as predicted risk, is compared with the acceptance criteria. In general, if the ratios of PEC and PNEC, i.e. Risk Characterization Ratios (RCR) are less than 1, then the potential risks in the area to be assessed are acceptable. The cumulative effects of mixtures should be taken into account and a PEC/PNEC summation approach is recommended where PEC/PNEC ratios of all mixture components (PAHs and metals) are summed up to a final Risk Quotient. In addition, the Whole Effluent Toxicity testing may also be used to assess the cumulative effects of the targeted substances.

6.2 Emission scenarios

6.2.1 Activities

6.2.1.1 The actual activities (in total power output) of all ships operating in the SAP should be estimated, using received AIS data by satellites and/or local stations. The same methods described in the Fourth IMO GHG Study 2020 should be applied to calculate the hourly outputs of the main engine as kWh for each ship when operating in the SAP, using the information of SOG in the AIS signal. More simplified methodology may be used, such as utilising the averaged fuel consumption by ship types and sizes reported in the study and adjusting them by applying power curve between the actual power needed and speed obtained from AIS data.

6.2.1.2 The activities should include the power consumed in the auxiliary engines with the assumption that those would be all connected to EGCS, as far as corresponding data is available. To estimate the activities when the ships are stopped (mooring loading or unloading), relevant data from the ship or statistic data of ships[3] should be used to assume the hourly outputs of the auxiliary engines as kWh for each ship when actual ship data is not available. Use of shore power or compliant fuel should be accounted for and excluded.

6.2.2 Reasonable worst-case scenarios

6.2.2.1 For Reasonable worst-case scenarios, the following assumptions should be applied:

.1 the maximum ratio of ships using EGCS in the SAP should be set by the Member States, taking into account the current situation in the SAP and future increase;

.2 all EGCSs installed onboard will be operated under open-loop operation, unless information to the contrary is available; and

.3 the increase of the numbers of ships may be assumed taking into account the future growth of transportation amount and possible infrastructure expansion, as far as corresponding data is available.

6.2.3 The load of the targeted substances in discharge water

6.2.3.1 By multiplying the emission factors to the total activities, the load of each targeted substance in discharge water will be provided (g/day as the input for MAMPEC calculations).

[3] Annex G to the Fourth IMO GHG Study 2020 shows auxiliary engine and boiler power demand assumptions in KW.

6.3 Exposure assessment for PEC

6.3.1 Introduction

6.3.1.1 To assess the risk of EGCS discharge water, in principle, the worst PEC in the area to be assessed should be identified. However, when designating a wide area to be assessed with complex geographical conditions, it may be difficult to simulate the total area with a single SAP with simplified assumption. In this case, multiple SAPs may be set, and PECs should be estimated for all SAPs.

6.3.1.2 It should be noted that PECs from the long-term viewpoint should be estimated. The tools for PECs should be appropriately selected for the purpose or time scale (the exposure time experienced by an organism) of PNEC, DNEL and/or DMEL.

6.3.2 Tools for long-term PEC of substances

6.3.2.1 The environmental concentrations of each substance after 10 years should be predicted using MAMPEC (see appendix 1). The MAMPEC model can take into account the fate of pollutants (e.g. accumulation and persistency) when predicting the concentrations that may be influenced by the hydrodynamical properties of local situations.

6.3.2.2 Although MAMPEC provides default geographical parameters for each "typical" marine environment (e.g. open sea, shipping lane, estuary, commercial harbour, yachting marina and open harbour), the actual geographical parameters collected for each SAP should be applied. Also, if the SAP(s) are too complicated to apply MAMPEC because of complex geography and/or more discharge points than MAMPEC model allows, the other simulation using 3D CFD may be used.

6.3.2.3 As a first assessment, the maximum value in the surroundings from the MAMPEC-BW calculations (e.g. the maximum PEC in the surroundings area outside the harbour. See section 6.8 of the MAMPEC 3.1 HANDBOOK) should be used as a representative concentration. If the result of the first assessment indicates potential risks comparing with the acceptance criteria, the average value from the MAMPEC-BW calculations may be used.

6.3.2.4 When calculating PECs in the SAP(s), the background concentrations of chemical substances should be added.

6.3.3 Selection of SAP for long-term calculation

6.3.3.1 It is recommended that SAP(s) for long-term calculation using a representative area in the area to be assessed including consideration of highest-risk area where the pollutants tend to accumulate, taking into account the geography, oceanic currents and tides, and/or the area with a higher traffic density compared to other areas.

6.3.3.2 To avoid insufficient risk assessment, an SAP should not be too small compared to the area to be assessed, and all SAPs for long-term calculation should, at least, cover the size of typical marinas. In addition, to ensure that SAPs appropriately represent the area to be assessed, SAPs for long-term calculation should cover a large part of the area to be assessed. Though SAPs for long-term calculation will be selected by the Member States, taking into account geographical conditions, in case of simple shape of the area to be assessed, it is recommended that the total SAP(s) cover more than 50% of the area to be assessed or that the ship activities in the total SAP(s) are more than 50% of those in the area to be assessed. The risk assessment for at least half of the area or the ship activities would prevent the arbitrary consequences of the assessment that result from specific small SAP(s).

6.4 Human exposure scenarios

6.4.1 Exposure scenarios involving the general public

6.4.1.1 In addition to the PECs of the targeted chemical substances, the human exposure amount of these substances may be assessed by applying exposure scenarios.

6.4.1.2 Exposure may occur indirectly, as is the case for the general public who may swim in water in areas where EGCS discharge water has been discharged, who eat seafood that has been caught in (the vicinity of) a discharge area, and/or who drink water prepared from the receiving water that may have been exposed to the EGCS discharge water. The following situations have been identified as probable exposure scenarios for the general public. It is recognized that there will be situations when the risk of human exposure is greater, such as amongst subsistence harvesters, and in these instances additional consideration should be given. Each exposure scenario should take into account concentrations in the water (PECs) estimated, as described in paragraph 6.3:

.1 recreational activities in the sea (swimming);

.2 eating seafood exposed to EGCS discharge water; and

.3 drinking water prepared from receiving water that may have been contaminated by the EGCS discharge water.

6.4.1.3 For each scenario, exposure amount may be calculated based on the PEC. An aggregated exposure approach may be applied (see appendix 2).

6.5 Risk assessment

6.5.1 Introduction

6.5.1.1 Prior to the comparison between exposure levels and acceptance criteria, screening on PBT and CMR for each targeted chemical substance should be performed. The ratio of the estimated exposure to the acceptance criteria defines the risk assessment quotient: PEC/PNEC for the aquatic quality and aquatic organism and/or exposure/DNEL or exposure/DMEL for the human health risk assessment.

6.5.1.2 In addition to the PEC/PNEC ratio approach, a whole effluent assessment taking into account the EGCS discharge water may be performed. More details are stated in paragraph 6.7.

6.5.2 Environmental risk assessment

6.5.2.1 Screening for potential Persistence (i.e. poor degradation in the environment), Bioaccumulation (i.e. accumulation in organisms and food chains) and Toxicity (PBT) are necessary, taking into account the following elements:

.1 Persistence:

Persistence should preferably be assessed in simulation test systems that determine the half-life under relevant conditions. Biodegradation screening tests may be used to show that the substances are readily biodegradable.

.2 Bioaccumulation:

The assessment of the (potential for) bioaccumulation should use measured bioconcentration factors in marine (or freshwater) organisms. Where these tests are not applicable, or if logPow <3, Bioconcentration Factor (BCF) values may be estimated using (Quantitative) Structure-Activity Relationship ((Q)SAR) models.

.3 Toxicity:

Acute and chronic ecotoxicity data, ideally covering the sensitive life stages, should in principle be used for the assessment of the toxicity criterion.

6.5.2.2 When assessing the environmental risk, discharge of pollutants from other sources impacting the area assessed should be taken into account.

6.5.3 Human health risk assessment

6.5.3.1 Screening for Carcinogenicity, Mutagenicity and Reproductive toxicity (CMR) properties for the chemicals is necessary.

6.6 Risk characterization and analysis

6.6.1 The ratio between the resulting PEC from the MAMPEC and PNEC is calculated, and where the result is below 1, the assumption is that no unacceptable risk will result from exposure to that chemical. In case that a background concentration of a chemical substance exceeds PNEC, it is assumed that unacceptable risk already exists from exposure to that chemical.

6.6.2 In addition to paragraph 6.6.1, the pH drops delivered from the additional PECs of sulfate/sulfite (i.e. sulphuric/sulphurous acid) should be assessed from the viewpoint of marine acidification. The pH drops can be estimated using the identified concentration (PEC) of sulfate/sulfite and the current and future alkalinity of seawater.

6.6.3 An assessment of secondary poisoning is redundant if the substance of concern demonstrates a lack of bioaccumulation potential (e.g. BCF <500 L/kg wet weight for the whole organism at 6% fat).

6.6.4 An assessment of sediment species is redundant if the potential of the substance of concern to partition into the sediment is low (e.g. K_{oc} <500 L/kg).

6.6.5 Accumulation of priority hazardous substances in sediments should be assessed in the port area

6.7 Whole Effluent Toxicity

6.7.1 Whole Effluent Toxicity (WET) testing using the actual discharge water from EGCS may be performed by the Member States.

6.7.2 The advantage of conducting a WET testing on the EGCS discharge water is that it aggregates and addresses the potential for interactions (i.e. cocktail effects) of the contents of the discharge water.

6.7.3 The Member States should provide both acute and chronic toxicity test data using internationally accepted test procedures to determine the toxicity of the EGCS discharge water when conducting WET testing.

6.7.4 To assess the adverse effects of the discharge water, either the use of pH buffer or filtration process should be avoided.

6.7.5 These toxicity tests should include chronic test methods with multiple test species (a fish, an invertebrate and a plant) that address the sensitive life-stage. The preference is to include both a sub-lethal endpoint (growth) and a survival endpoint.

6.7.6 The test results to be provided include: acute 24-hour, 48-hour, 72-hour and 96-hour Lethal (or Effect) Concentration at which 50% of the test organisms die (or effect) ($L(E)C_{50}$), chronic No Observed Effect Concentration (NOEC) and/or Effect Concentration at which 10% of test organisms show effect (EC_{10}), as appropriate based on the experimental design.

6.7.7 A dilution series including a 100% EGCS discharge water would be tested to determine the 50% of the test organisms die (or effect) using the statistical endpoints for acute ecotoxicity (EC_{50}).

6.7.8 Applying the assessment factor (see paragraph 6.3.3.1 and Table 5 in the Annex to BWM.2/Circ.13/Rev.4 on *Methodology for information gathering and conduct of work of the GESAMP-BWWG*) on the results of WET, $PNEC_{general}$ expressed as dilution ratio should be determined both for short term and long term, the former delivered from the results of acute WET tests and the latter from chronic WET tests.

6.7.9 For the risk characterization applying the WET approach, the comparison between the risk thresholds and PEC will be needed.

6.7.10 From the short-term viewpoints, the ratio between the resulting dilution ratio from the short-term calculation of PECs and the $PNEC_{general}$ from acute WET tests should be calculated, and where the result is below 1, the assumption is that no unacceptable risk will result from exposure to the aggregated ecotoxicity among the discharge water from EGCS.

6.7.11 An initial analysis could use a conservative approach where the dilution capacity would not be taken into consideration (no modelling or plumes analysis would be used). The rationale for taking a conservative approach is that there could be multiple discharges into one location (even though this is not necessarily the case).

6.7.12 From the long-term viewpoints, the ratio between the resulting dilution ratio from the long-term calculation of PECs and the $PNEC_{general}$ from chronic WET tests should be calculated, and where the result is below 1, the assumption is that no unacceptable risk will result from exposure to the aggregated ecotoxicity of the discharge water from EGCS.

6.7.13 As the WET testing will cost, and should be performed at the laboratory with quality assessment and quality control (QA/QC) and with high expertise, the Member States may utilize the data collected by the Organization. NOTE: the results of WET both for acute and chronic may be included in the database developed by the Organization.

7 IMPACT ASSESSMENT

7.1 The impact assessment approach may be applied to the specific receiving environment that is being assessed, at the relevant geographical levels, taking account of the type of water body, i.e. marine (open water), coastal and other territorial waters (within 12 nm from the coastline), estuarine, large harbour and small enclosed harbour environments and areas in the vicinity of dense shipping routes. In addition, saltwater, brackish water and freshwater situations and the effect of tides or their absence may be considered, as appropriate.

7.2 Application of impact assessment approach to the specific receiving environment by identifying and defining:

.1 the existing status (ecological, chemical, environmental, cultural) of the receiving water bodies;

.2 the likely effect on status of the discharge water discharges, in particular whether the discharge could result in failure to meet the objectives of the applicable environmental legislation;

.3 the specific environmental stressors that may be affected by discharge water discharges;

.4 the adverse effects arising from these stressors; and

.5 the presence of priority hazardous substances on sediments affecting dredging operations in port areas.

7.3 Incorporation of the following steps for the specific receiving environment:

.1 a systematic review of the impacts of the discharge water;

.2 specific modelling for physical distribution and fate of the components in discharge water and comparing the PNEC and PEC considering the cumulative effects of the mixture, i.e. use the PEC/PNEC summation approach;

.3 identification of the overall vulnerability of and potential damage to the environment, habitats or organisms that may be impacted, and the potential cost of restoration;

.4 the identification of any direct or indirect socio-economic, cultural and human health impacts of the discharge water discharge;

.5 whether there are any seasonal or temporal impacts that need to be considered;

.6 identification of any practical mitigation measures that could minimise the potential impacts identified at this stage; and

.7 water exchange rate in water bodies that may be affected by the presence of port infrastructures.

7.4 The adoption of restrictions or a ban on discharge water from EGCSs should be considered in areas where any of the following indicative criteria are fulfilled:

.1 environmental objectives in the areas are not met, e.g. good chemical status, good ecological status or good environmental status are not achieved under applicable legislation;

.2 the discharge of EGCS effluents represents an additional risk of deteriorating the environment and the resiliency of the climate system;

.3 the EGCS discharge water conflicts with the conventions and regulations formulated to protect the marine environment (see UNCLOS Article 195, etc.); and

.4 the EGCS discharge effluent represents an increase in the costs of management of dredged materials in ports.

7.5 An uncertainty analysis can be undertaken by identifying whether the potential adverse effects from discharge water discharges are well understood. This may include the effects on the immediate and downstream environment taking into account both spatial and temporal factors.

7.6 When restricting EGCS discharges, consideration should be given to investments already made by industry to comply with regulation 14 of MARPOL Annex VI and other relevant legislation, also taking, however, into account that the choice of EGCS as an alternative compliance option under regulation 4 of MARPOL Annex VI was primarily based on considerations of favourable economic competitiveness. In any case, not restricting EGCS discharges could also lead to the economic burden on governments (for example in relation to management of dredged materials), due to their need to restore environmental degradation, protect human health and impacts on the fishing or tourisms sector deriving from. These impacts should also be overall taken into account. The sooner such measures are taken, the lower the consequent impact will be on industry on Member States.

8 NOTIFICATION TO THE ORGANIZATION

8.1 The Member States that have undertaken risk and impact assessments should notify the Organization of the result of the assessments together with the notification of local regulations on the discharges of discharge water from EGCSs.

APPENDIX 1

GENERAL INFORMATION ON MAMPEC

1 MAMPEC was originally developed to calculate Predicted Environmental Concentrations (PECs) for the exposure assessment of antifoulants (i.e. marine paints on the hull below waterline of ships) leached out in harbours, rivers, estuaries and open water. MAMPEC is a steady-state, 2D-integrated hydrodynamic and chemical fate model.

2 The MAMPEC-BW model was adapted for exposure assessment of chemicals discharged by the use of ballast water treatment systems and has the extended features from the original MAMPEC. On the request of the GESAMP-BWWG and IMO, a special standardised version of MAMPEC-BW for ballast water was developed in 2011, with a dedicated environment, a compound and an emission scenario for the use of BWMS.

3 The MAMPEC calculation for Ballast Water (MAMPEC-BW 3.1) model or the latest available version can be downloaded from the website of Deltares in the Netherlands. The website is as provided below:

https://download.deltares.nl/en/download/mampec/

4 The model and supporting documents have been distributed freely via the internet (https://www.deltares.nl/en/software/mampec/). The model predicts concentrations of targeted chemical substances in generalised "typical" marine environment (e.g. open sea, shipping lane, estuary, commercial harbour, yachting marina and open harbour). For ballast water, a representative harbour model has been defined. Users can specify emission factors (e.g. daily loads), compound-related properties and processes (e.g. K_d, K_{ow}, K_{oc}, volatilisation, speciation, hydrolysis, photolysis, biodegradation) and properties and hydrodynamics related to the specific environment (e.g. currents, tides, salinity, DOC, suspended matter load, port dimensions). MAMPEC includes options for advanced photolysis modelling, incorporation of wind-driven hydrodynamic exchange and other non-tidal exchange processes important for areas without tidal action or inland freshwater environments. MAMPEC can calculate concentrations of targeted chemical substances for individual grids specified by users.

5 In MAMPEC calculation, the total calculation will be located automatically depending on the feature of sea-area.

APPENDIX 2

HOW TO ESTIMATE HUMAN EXPOSURE

1 Introduction

Appendix 2 presents the various steps in human health risk assessment associated with the discharge water from EGCS.

2 The steps in the human health risk assessment

2.1 Hazard characterization

2.1.1 Establishing guidance levels (DNELs and DMELs) for the general public

2.1.1.1 Derivation of guidance levels

The derivation of guidance levels involves the following steps:

- Hazard identification;
- Hazard characterization;
    - Definition of dose descriptor; and
    - Definition of assessment factor.

As part of the hazard identification the type and nature of adverse health effects to humans are identified. The data may consist of information from epidemiological studies and animal-based toxicology studies.

The hazard characterization includes establishing guidance levels (DNELs and DMELs).

The guidance levels are levels, for chemicals with a threshold effect, below which no adverse health effects to humans are expected to occur.

However, for chemicals with a non-threshold effect, such as genotoxic carcinogens, where no lower safe limit exists, the guidance levels are associated with a low, possibly hypothetical, acceptable risk.

2.1.1.2 Dose descriptor

For all chemicals, an effect level, or reference dose, linked to potential adverse effects has to be defined. The Benchmark Dose (BMD) approach is regarded to represent a scientifically more advanced method compared to the NOAEL approach for deriving a reference dose (sometimes referred to as point-of-departure (EFSA, 2017)). The BMD_{10} is defined as the dose for a predetermined level of response, 10% increase or decrease, compared with the background response. It is recommended to use the lower bound of a BMD_{10}, i.e. the $BMDL_{10}$ (US EPA, 2012).

2.1.1.3 Assessment factor or adjustment factor

When results from animal-based studies are extrapolated to the general public, one or more assessment factors are used to reduce the likelihood that the actual risks to humans are underestimated. When results from human are used, adjustment factors may be used to account for human variability.

2.1.2 Guidance values for the general public (threshold effects)

Guidance values based on epidemiological studies, when available, are always preferred (WHO, 2000), and may be retrieved from internationally recognized bodies. These include guidance values established by, for example, JECFA or EFSA for food contaminants, such as TDI, and by WHO for chemicals in drinking water.

Guideline values for chemicals in drinking-water have been established for chemicals that cause adverse health effects after prolonged periods of time. A guideline value normally represents the concentration of a chemical that does not result in any significant risk to health over a lifetime of consumption. The guideline values assume a water consumption of 2 litres per day, and a body weight of 60 kg.

A number of provisional guideline values have, however, been established based on the practical level of treatment performance or analytical achievability. In these cases, the guideline value is higher than the calculated health-based value.

Table 1: Summary of examples of guidance values used for the general public

Type of outcome	Term (units)	Abbreviation	Definition
Non-cancer, including laboratory animal carcinogens not relevant to humans	Tolerable daily intake (mg/kg bw/day)	TDI	An estimate of the amount of a substance in air, food, soil or drinking-water that can be taken in daily, weekly or monthly per unit body weight over a lifetime without appreciable health risk.
	Provisional tolerable weekly intake (mg/kg bw/week)	PTWI	
	Provisional tolerable monthly intake (mg/kg bw/month)	PTMI	
	Derived No Effect Level (mg/kg bw/day)	DNEL	

2.1.3 Guidance values for the general public (non-threshold effects)

2.1.3.1 Approaches to risk assessment

Carcinogens can have a threshold or non-threshold mode of action. As a general rule, a risk for the general public from secondary exposure to a non-threshold carcinogenic substance is unacceptable. When it comes to the threshold carcinogens, these can be assessed by using a DNEL approach. In the case of the non-threshold carcinogens (i.e. with mutagenic potential), a different approach to risk assessment is recommended. In this guideline, the lifetime excess cancer risk level of 10^{-5} is used where possible (in accordance with the WHO Drinking Water Methodology, (WHO, 2001)).

2.1.3.2 Derived Minimal Effect Level

Calculation of an exposure level corresponding to a defined low risk, a Derived Minimal Effect Level (DMEL) is possible based on a semi quantitative approach. In contrast to a DNEL, a DMEL does not represent a "safe" level of exposure. It is a risk related reference value that could be used to better target risk management measures.

2.1.3.3 The large assessment factor approach

The "large assessment factor" approach results in DMEL values represents a low concern from a public health point of view. The basis for this assessment factor is that for substances that are both genotoxic and carcinogenic, an MOE of 10,000 or higher, based on a $BMDL_{10}$ from an animal study, is regarded to be of low concern (EFSA, 2017).

When a $BMDL_{10}$ from an animal study (oral rat carcinogenicity study) is used the assessment factors shown in table 2 should be used.

Table 2: Default assessment factors in the "large assessment factor approach" (modified from ECHA, 2012)

Assessment factor	Default value systemic tumours
Interspecies	10
Intraspecies	10
Nature of the carcinogenic process	10
The point of comparison	10
Total assessment factor	10,000

$$DMEL = \frac{BMDL_{10}}{total\ assessment\ factor} \qquad \text{(Equation 1)}$$

A DMEL derived according to this approach represents an excess cancer risk of 10^{-5}.

2.1.3.4 The slope factor approach

A slope factor is an estimate of the life-time cancer risk associated with a unit dose of a chemical through ingestion (or inhalation). The slope factor is defined as increased cancer risk from lifetime exposure to a substance by ingestion (or inhalation). It is expressed as an estimate of cancer risk associated with a unit concentration (mg/kg bw/d) or risk per mg/kg bw/d (US EPA, 2005). The slope factor may be used to derive the dose (mg/kg bw/d) associated with cancer at a specified risk level, for instance 10^{-5} (or 1 in 100 000). This dose may then be used as a DMEL.

2.1.3.5 Drinking-water guideline values

Drinking-water guideline values are normally determined using a mathematical model (the linearised multistage model) for chemicals considered to be genotoxic carcinogens. These guideline values are presented as concentrations in drinking-water associated with an estimated upper-bound excess lifetime cancer risk of 10^{-5}.

2.2 Exposure assessment

2.2.1 How and where humans may be exposed to EGCS discharge water

Humans may be exposed to EGCS discharge water when swimming in the water where the EGCS discharge water has been discharged, or when consuming seafood that has been caught in the vicinity of the area where the EGCS discharge water has been discharged. In some areas of the world, desalinated seawater is used as drinking water which will add another way of probable exposure. In this guideline, the aggregate exposure approach, as defined by WHO/IPCS (WHO/IPCS, 2009), is applied, that is the combined exposure applicable to each scenario. The term "aggregated exposure" (or "combined exposure"), as defined by the WHO/IPCS, takes into account all relevant pathways (e.g. food, water and residential uses) as well as all relevant routes (oral, dermal and inhalation).

2.2.2 Human exposure scenario

The exposure assessment is carried out through an evaluation of different exposure scenarios. An exposure scenario is a set of information and/or assumptions that describes the situations associated with the potential exposure.

2.2.3 Situations in which the general public might be exposed to EGCS discharge water

2.2.3.1 Exposure scenarios for the general public

Indirect exposure of humans via the environment associated with EGCS discharge water may occur by consumption of seafood and swimming in the receiving water. As a general principle, consumer exposure is normally assessed as being chronic and thus taking place throughout the whole lifetime in order to protect the most vulnerable population groups.

The following situations, as shown in table 3, have been identified as likely exposure scenarios for the general public, and have been regarded as a worst-case exposure.

As the human activities listed in table 3 are not performed near the discharge points for MAMPEC calculations, the maximum PECs in the surroundings should be used as representative concentration in a worst-case exposure.

Table 3: Summary of exposure scenarios for the general public

Situations in which the general public may be exposed to EGCS discharge water containing chemicals		
Situation	**Exposure**	**Duration/quantity**
Recreational activities in the sea	Inhalation of chemicals partitioning into the air above the sea	2 events of 0.5 hours/day
	Dermal exposure to chemicals whilst swimming in the sea	2 events of 0.5 hours/day
	Swallowing of seawater contaminated with EGCS discharge water	2 events of 0.5 hours/day
Eating seafood exposed to EGCS discharge water	Oral consumption	Once or twice/day equivalent to 0.107 kg/day
Drinking water prepared from receiving water that may have been contaminated by the EGCS discharge water	Inhalation of chemicals volatilising from drinking water while showering	0.75 hours/day
	Dermal exposure to chemicals in drinking water while showering	0.75 hours/day
	Ingestion exposure to chemicals in drinking water	Daily total drinking water intake of 2 L/day
Aggregated exposure (through swimming, consumption of seafood and using drinking water)		

A number of assumptions are being used in the human exposure scenarios for the general public. These assumptions are listed in table 4. In all scenarios, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of men is assumed, but the body weight of women (60 kg) is applied. The whole-body surface area for men is 1.94 m^2. One parameter, ingestion rate of water while swimming, is taken from the Swimodel (US EPA, 2003).

Table 4: Summary of physiological parameters in human exposure scenarios for the general public

Parameter	Value	Reference
Body weight	60 kg	WHO (2017)
Whole body, surface area	1.94 m2	US EPA (1997)
Ventilation rate (light activity)	1.25 m3/h	ECHA (2012)
Ingestion rate of water while swimming	0.025 L/h	Swimodel, US EPA (2003)
Ingestion rate of drinking water	2 L/d	WHO (2017)
Showering	0.75 h/d	US EPA (2011)
Quantity of fish consumed	0.107 kg/d	AIST, Japan (2007)
Temperature	293 K	GESAMP assumption
Dilution factor, swimming	100	EUSES (2016)
Reduction rate of chemicals through the desalination process for making up drinking water	10	Average reduction rate of chemicals through the RO treatment: 90% (Smol, M. and Włodarczyk-Makuła, M., 2017)

2.2.3.2 Recreational activities (swimming) in the sea

.1 Inhalation of chemicals partitioning into the air above the sea

Exposure in this scenario is through inhalation of air above the sea while swimming. The concentration of chemicals in the air may be calculated while using the Henry's law constant as described below.

The worst concentration of chemicals in the air may theoretically be calculated using the Henry's law constant. This physical law states that, the mass of gas dissolved by a given volume of solvent, is proportional to the pressure of the gas with which it is in equilibrium. The relative constant quantifies the partitioning of chemicals between the aqueous phase and the gas phase such as rivers, lakes and seas with respect to the atmosphere (gas phase). While making use of the concentration in the water phase, the concentration in the air phase is calculated accordingly:

$$C_{air} = \frac{H}{R \cdot T} \cdot C_{water} \qquad \text{(Equation 2)}$$

where:

C_{air} = concentration in air (mg/m3);
H = Henry's law constant (Pa m3/mole);
R = gas constant (8.314 Pa m3/mole K);
T = absolute temperature (K) (default = 293 K); and
C_{water} = concentration in the water, i.e. maximum PECMAMPEC in surroundings (μg/L).

The concentration in water is the maximum predicted environmental concentration (PEC) value in surroundings as calculated by MAMPEC, and taking into account a dilution factor of 100 (due to wind, turbulence and insufficient time for the chemical to reach equilibrium) (EUSES, 2016). The inhaled dose may be estimated using the equation below, while taking into account various assumptions (number of swims, etc.).

$$Dose_{Inh} = \frac{C_{air} \cdot VR \cdot n \cdot Dur_{swim} \cdot Bio_{inh} \cdot 1000}{BW} \quad \text{(Equation 3)}$$

where:
$Dose_{Inh}$ = inhalation intake of chemical during swimming (µg/kg bw/d);
C_{air} = concentration in air (mg/m3);
VR = ventilation rate – light activity assumed (1.25 m3/h);
n = number of swims per day (2/d);
Dur_{swim} = duration of each swim (0.5 h);
Bio_{inh} = fraction of chemical absorbed through the lungs (default = 1); and
BW = body weight (default = 60 kg).

.2 Dermal exposure to chemicals while swimming in the sea

Option 1.

Exposure in this scenario is via dermal uptake of chemicals when swimming and where the permeability coefficient (Kp) is known, using the following equation,

$$Dose_{der} = \frac{C_{water} \cdot K_p \cdot Dur_{swim} \cdot n \cdot A_{skin} \cdot Bio_{der} \cdot 1000}{BW} \quad \text{(Equation 4.1)}$$

where:
$Dose_{der}$ = dermal uptake per day during swimming (µg/kg bw/d);
C_{water} = concentration in the water, i.e. maximum PECMAMPEC in surroundings (µg/L);
K_p = dermal permeability coefficient (cm/h);
Dur_{swim} = duration of each swim (0.5 h);
n = number of swims per day (2/d);
A_{skin} = surface area of whole body being exposed to water (1.94 m2);
Bio_{der} = bioavailability for dermal intake (default = 1); and
BW = body weight (60 kg).

Option 2

If the Kp value is unknown, the following equation may be used as a conservative approach (ECHA, 2016),

$$Dose_{Der} = \frac{C_{water} \cdot TH_{der} \cdot n \cdot A_{skin} \cdot Bio_{der} \cdot 1000}{BW} \quad \text{(Equation 4.2)}$$

where:
$Dose_{Der}$ = dermal uptake per day during swimming (µg/kg bw/d);
C_{water} = concentration in the water, i.e. maximum PECMAMPEC in surroundings (µg/L);
TH_{der} = thickness of the product layer on the skin (0.0001 m);
N = number of swims per day (2/d);
A_{skin} = surface area of whole body being exposed to water (1.94 m2);
Bio_{der} = bioavailability for dermal intake (default = 1); and
BW = body weight (default = 60 kg).

.3 Swallowing of water contaminated with EGCS discharge water
The oral uptake via swimming is calculated according to the following:

$$Dose_{Oral} = \frac{C_{water} \cdot IR_{swim} \cdot n \cdot Dur_{swim} \cdot Bio_{oral}}{BW} \quad \text{(Equation 5)}$$

where:
$Dose_{Oral}$ = amount of chemical swallowed (µg/kg bw/d);
C_{water} = concentration in the water, i.e. maximum PECMAMPEC in surroundings (µg/L);
IR_{swim} = ingestion rate of water while swimming (0.025 L/h);
N = number of swims per day (2/d);
Dur_{swim} = duration of each swim (0.5 h);
Bio_{oral} = bioavailability for oral intake (default = 1); and
BW = body weight (default = 60 kg).

2.2.3.3 Eating seafood exposed to EGCS discharge water

The concentration of chemicals in the seafood that is being consumed is calculated in this way:

$$C_{fish} = BCF \cdot C_{water} \quad \text{(Equation 6)}$$

where:
C_{fish} = concentration in fish (µg/kg);
BCF = bioconcentration factor (L/kg); and
C_{water} = concentration in the water, i.e. maximum PECMAMPEC in surroundings (µg/L).

The calculation of concentrations in seafood has to be carried out for all chemicals. The cut-off value for the bioconcentration factor as described for the environmental risk assessment (paragraph 6.6.3) is not applicable in the risk assessment for human health. Making the assumption that people in the area only consume fish that is being caught locally (worst-case scenario), the daily intake may be calculated in the following way:

$$Dose_{fish} = \frac{QFC \cdot C_{fish} \cdot Bio_{oral}}{BW} \quad \text{(Equation 7)}$$

where:
$Dose_{fish}$ = uptake of chemical from eating fish (µg/kg bw/d);
QFC = quantity of fish consumed/day (= 0.107 kg/d (AIST, Japan (2007)));
C_{fish} = maximum concentration of chemical in fish (µg/kg);
Bio_{oral} = bioavailability for oral intake (default = 1); and
BW = body weight (default = 60 kg).

2.2.3.4 Drinking water made from receiving water that may have been contaminated by EGCS discharge water:

.1 Inhalation of chemicals volatilisation from drinking water while showering

Exposure in this scenario is through inhalation of chemicals volatilising from drinking water while showering. The concentration of chemicals in the air may be calculated while using the Henry's law constant as already described in equation 1. The concentration in the drinking water is the same as in the scenario 2.2.3.2 and 2.2.3.3, while also taking into consideration a removal ratio of 10 in Reverse Osmosis (RO) desalination process (Smol, M. and

Włodarczyk-Makuła, M., 2017), based on the concentration in the receiving water (i.e. the maximum PECs in the surroundings of MAMPEC calculation).

$$C_{air} = \frac{H}{R \cdot T} \cdot C_{DW} \qquad \text{(Equation 8)}$$

where:
C_{air} = concentration in air (mg/m3);
H = Henry's law constant (Pa m3/mole);
R = gas constant (8.314 Pa m3/mole K);
T = absolute temperature (K) (default = 293 K); and
C_{DW} = concentration in the drinking water, i.e. maximum PECMAMPEC in surroundings (µg/L)·0.9 (µg/L).

The inhaled dose, while showering, may be estimated using the equation below, while taking into account various assumptions,

$$Dose_{Inh} = \frac{C_{air} \cdot VR \cdot n \cdot Dur_{show} \cdot Bio_{inh} \cdot 1000}{BW} \qquad \text{(Equation 9)}$$

where:
$Dose_{Inh}$ = inhalation intake of chemical while showering (µg/kg bw/d);
C_{air} = concentration in air (mg/m3);
VR = ventilation rate – light activity assumed (1.25 m3/h);
N = number of showers per day (1/d);
Dur_{show} = duration of each shower (0.75 h);
Bio_{inh} = fraction of chemical absorbed through the lungs (default = 1); and
BW = body weight (default = 60 kg).

.2 Dermal exposure to chemicals while showering

Option 1

Exposure in this scenario is via dermal uptake of chemicals when taking a shower, and where the dermal permeability coefficient (Kp) is known, is calculated using the following equation,

$$Dose_{der} = \frac{C_{DW} \cdot K_p \cdot Dur_{show} \cdot n \cdot A_{skin} \cdot Bio_{der} \cdot 1000}{BW} \qquad \text{(Equation 10.1)}$$

where:
$Dose_{der}$ = dermal uptake per day during showering (µg/kg bw/d);
C_{DW} = concentration in the drinking water, i.e. maximum PECMAMPEC in surroundings (µg/L)·0.9 (µg/L);
K_p = dermal permeability coefficient (cm/h);
Dur_{show} = duration of each shower (0.75 h);
N = number of showers per day (1/d);
A_{skin} = surface area of whole body being exposed to water (1.94 m2);
Bio_{der} = bioavailability for dermal intake (default = 1); and
BW = body weight (60 kg).

Option 2

If the K_p value is unknown, the following equation may be used as a conservative approach,

$$Dose_{Der} = \frac{C_{DW} \cdot TH_{der} \cdot n \cdot A_{skin} \cdot Bio_{der} \cdot 1000}{BW} \qquad \text{(Equation 10.2)}$$

where:
$Dose_{Der}$ = dermal uptake per day during showering (µg/kg bw/d);
C_{DW} = concentration in the drinking water, i.e. maximum PECMAMPEC in surroundings (µg/L)·0.9 (µg/L);
TH_{der} = thickness of the product layer on the skin (0.0001 m);
N = number of showers per day (1/d);
A_{skin} = surface area of whole body being exposed to water (1.94 m2);
Bio_{der} = bioavailability for dermal intake (default = 1); and
BW = body weight (default = 60 kg).

.3 Ingestion exposure to chemicals in drinking water

The oral uptake via drinking water is calculated according to the following,

$$Dose_{Oral} = \frac{C_{DW} \cdot IR_{drink} \cdot Bio_{oral}}{BW} \qquad \text{(Equation 11)}$$

where:
$Dose_{Oral}$ = amount of chemical swallowed (µg/kg bw/d);
C_{DW} = concentration in the drinking water. i.e. maximum PECMAMPEC in surroundings (µg/L)·0.9 (µg/L);
IR_{drink} = ingestion rate of drinking water (2 L/d);
Bio_{oral} = bioavailability for oral intake (default = 1); and
BW = body weight (default = 60 kg).

2.2.4 Concluding remarks

It should be noted that while the above situations have been identified as typical worst-case exposure scenarios, it is recognized that there will be other situations when exposure of the general public may be greater or less, and consideration should be given to such situations. In addition, the consumer exposure (general public) is normally assessed as chronic/lifetime risk in order to protect the most vulnerable population groups.

2.3 Risk characterization and acceptance criteria

2.3.1 General approach

The Risk Characterization Ratios (RCR) compares the exposure estimates to various DNELs or DMELs. The RCR is calculated according to the following formulae:

$$RCR = \frac{Exposure}{DNEL} \qquad \text{(Equation 12)}$$

or

$$RCR = \frac{Exposure}{DMEL} \qquad \text{(Equation 13)}$$

In both cases, RCR should be used as acceptance criteria. If the RCR < 1, the exposure will lead to no unacceptable risk. However, risks are regarded to be controlled when the estimated exposure levels exceed the DNEL and/or the DMEL, that is, if the RCR ≥ 1.

2.3.2 Health risks for the general public

In the three scenarios applicable for the general public, swimming in seawater contaminated with EGCS discharge water, ingestion of seafood which has been exposed to EGCS discharge water and ingestion of drinking water prepared from receiving water that may have been contaminated by the EGCS discharge water, are taken into consideration.

Aggregated exposure (through swimming, consumption of seafood and drinking water prepared from receiving water that may have been contaminated by the EGCS discharge water), that is the combined exposure applicable to each scenario, is estimated.

The total amount of chemicals that is absorbed as a result of the exposure to the general public, whilst swimming in the sea, eating fish and being exposed to drinking water through showering and drinking water consumption, may be summarised as in table 5.

Table 5: General public scenario – DNEL approach

Chemical Name	Scenario (μg/kg bw/d)							Aggregated exposure (μg/kg bw/d)	DNEL (μg/kg bw/d)	RCR
	Swimming			Consumption of seafood	Drinking water					
	Inhalation	Dermal	Oral	Oral	Inhalation	Dermal	Oral			
A										
B										
C										

The risk-related reference value (DMEL) may be used to calculate an indicative RCR regarding potential cancer risk. DMELs can be used to estimate a risk dose based on the probability of increased cancer incidence over a lifetime (10^{-5}) for the general public (table 6).

Table 6: General public scenario – DMEL approach

Chemical name	Aggregated exposure (μg/kg bw/d)	DMEL (μg/kg bw/d)	Indicative RCR
A			
B			
C			

2.3.3 Mixture toxicity (including dose addition approach)

EGCS discharge water frequently contains mixtures of several chemicals which lead similar mechanism in human systems. One possible way to deal with this situation is to adopt an established international risk assessment approach (known as "grouping" or "dose addition"; Kortenkamp, et al., 2009), which entails a summation of the Risk Characterization Ratios (RCRs) of all substances with recognized carcinogenic potential. This approach had, for example, been used previously for carcinogens by the US EPA (US EPA, 1989), where it is based on the assumption that for carcinogens no dose threshold exists, and that the dose-response function is therefore essentially linear. Thus, if the EGCS discharge water contains two or more chemicals with the same toxicological effect, these could be evaluated as an "assessment group". The RCR for an assessment group is calculated by the addition of all RCRs of the individual components,

$$RCR_{group} = RCR_A + RCR_B + RCR_C + \cdots + RCR_n \qquad \text{(Equation 14)}$$

where:
RCRn = the Risk Characterization Ratios shown in table 5 or table 6.
For the group RCR, the same conclusions apply as described above, that is, if the RCR < 1 using the RCRs in table 6, the exposure is deemed to represent no unacceptable risk. If still an unacceptable risk is identified, further refinement of the exposure assessment and/or the assessment factors might be performed giving special attention to route-specific contributions and additional RMM.

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