# Regional strategic approach–

## HELCOM's management framework for hazardous substances

Baltic Marine Environment Protection Commission

Hazardous substances

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# Summary

Baltic Sea Action Plan 2021 identified the need for the development of a regional strategic approach for addressing hazardous substances in HELCOM (action HL1). EG Haz developed the approach and framework described in this document by focusing on the findings and proposals of a background report which had reviewed the previous HELCOM hazardous substances framework (BSEP 182).

The established framework aims to i) promote a truly holistic assessment of hazardous substances, i.e. cover many substances; ii) strongly link actions with the outcomes of the assessment of the situation, i.e. target actions to these substances and issues (including gaps) which matter the most; iii) interact actively with existing policies, by both utilizing data generated by them and influencing them; and ensure that adopted HELCOM actions are of added value to – and function in synergy with – existing policies (implementing also BSAP actions HL9 and HL11).

The scheme of the management framework consists of four steps. At step 1, substances of concern for the Baltic Sea and its ecosystem services are identified and ranked based on three independent but complementary assessments. These focus respectively on marine levels, measured or estimated inputs (along with PBT properties), and analogous evidence such as observed biological effects or expected higher inputs in the near future. At step 2, additional information is gathered, at least for top-ranked substances/groups (regulatory status, areas of poor status, and predominant sources) and horizontal issues are identified. Step 3 generates/updates three 'priority lists', which essentially provide three different perspectives (substances, sources, uncertainties) to support management decisions at Step 4. The lists also aim to convey a message to stakeholders on the main issues with regard to hazardous substances for the Baltic Sea. The DAPSIM causal framework forms the basis for selection of possible mitigation measures and supporting actions at Step 4: for each priority substance or issue to address, information is reorganized, to identify the relevant element(s) in the causal chain (D/A/P/S/I) and gaps of existing measures in properly addressing these elements. Options for new measures may be assessed against criteria such as effectiveness, resource efficiency, secondary impacts, and fairness.

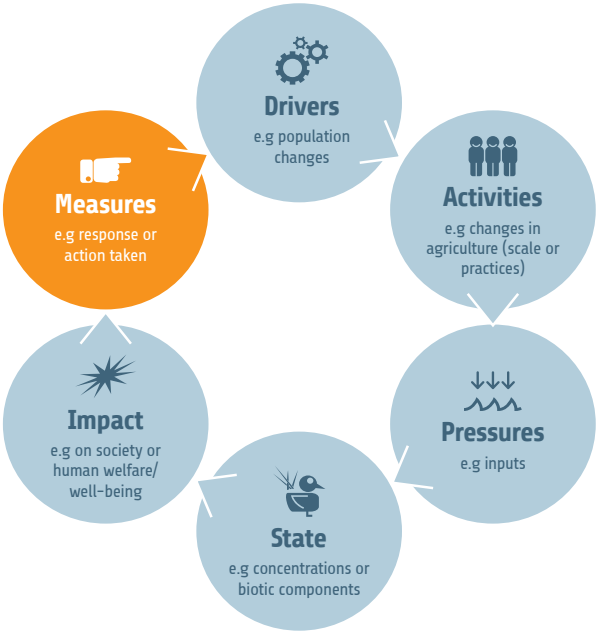
The approach incorporates flexibility in the exact mechanism via which to implement the scheme, depending on resources availability, data availability (substances vary a lot in this respect), and policy aspects. At the same time it is a systematic approach where each piece of data has a concrete place and clear contribution to understanding of the overall case. Special attention has been paid in expressing uncertainties and in balancing the requirement for evidence with the precautionary principle.

Recurring cycles of the framework every 6 years are designed in a way that can be fed by data generated in other HELCOM or regulatory processes (HOLAS, PLC, EU MSFD, EU WFD, etc.) and vice versa can support these processes e.g. by setting the basis for proposing new indicators and promoting increased coordination towards monitoring programmes and programmes of measures.

# A. Need for a hazardous substances framework

Preparatory work leading to the HELCOM Baltic Sea Action Plan (BSAP 2021) recognized that the current HELCOM framework for hazardous substances was mainly based on a limited number of priority contaminants and a list of measures to prevent their input to the marine environment compiled on an ad hoc basis (see Figure 1). Recommendation 31E/1 laid down general principles and recommendations for the work on hazardous substances. However, there was no systematic mechanism for regular updating of the priority list. Furthermore, there was no systematic process to ensure that HELCOM actions and recommendations address the most important needs for the Baltic Sea or that they have added value compared to EU legislation, Russian law, or international conventions. Nor was there clarity about the level of contribution or the scale (spatial, temporal) at which effects of HELCOM actions were expected. The previous approach was therefore rather ad hoc, selective based on issues raised through existing processes, and was not holistic or sufficient.

Thus, BSAP 2021 identified the need for the development of a regional strategic approach (action HL1) or, in other words, a well-defined and functional strategic framework, for addressing hazardous substances in HELCOM. In this context, HELCOM needed to clarify its role in relation to other policies in the Baltic Sea region and identify the synergy and added value of its activities, to establish a structured mechanism for managing the HELCOM list of priority substances (HL10) and to establish procedures to both: utilize information obtained under various policies (HL9) and follow-up and actively influence these processes (HL11).



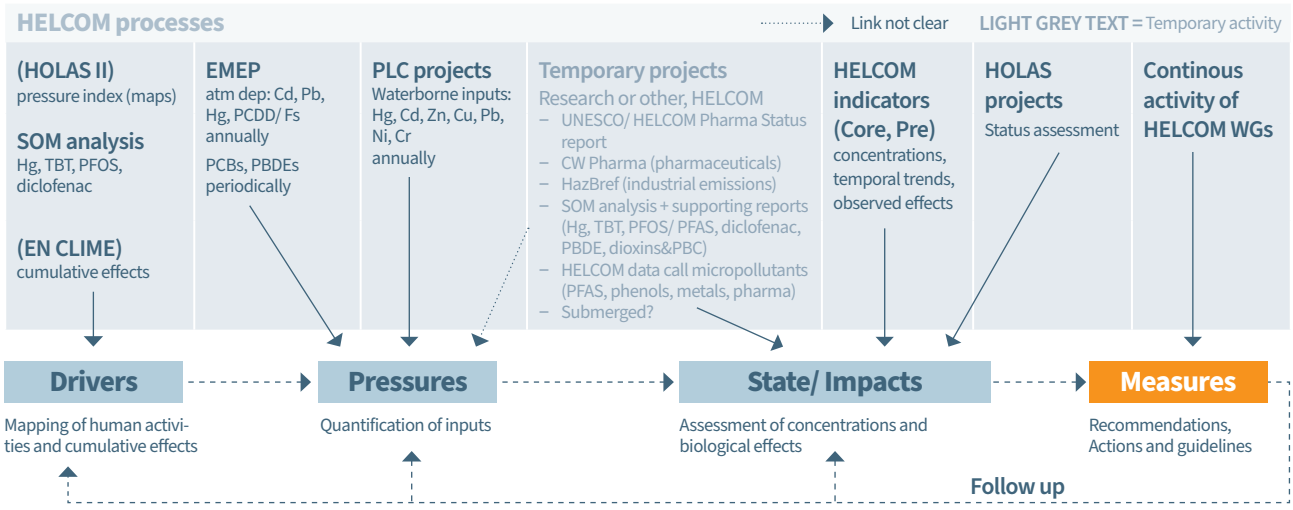



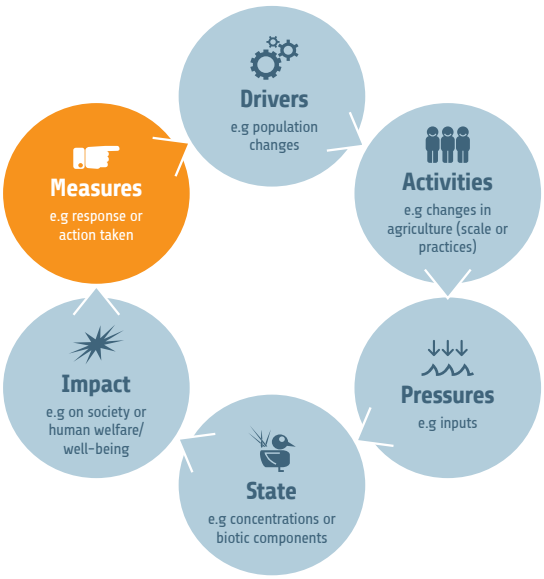

**Figure1.** Overview of the previous HELCOM hazardous substances framework from the regional policy document on hazardous substances (BSEP 182). Dashed lines highlight lack of proper linking between the management steps. Listing of the few individual substances covered e.g. by PLC and HOLAS hazardous substances indicators emphasizes the lack of holisticness. Another weakness (not shown here) related to the lack of a system to ensure added value and synergy (e.g. of HELCOM measures) with existing policies.

# B. Framework's scheme

At the beginning of the development process, BSEP 182[1] was used as basis for deriving requirements for the new regional management framework. Following that, firstly a vision was established (Figure 2).

Main aspects to note:

— Links between the management steps are strong: Adoption of HELCOM measures relies on assessment of the situation. A new step (in yellow) has been introduced to properly link the two steps. Two types of actions are defined. The second type (measures to resolve key gaps in data and methodologies – i.e. to improve assessments) closes the cycle, aiming to improve the quality of the assessments.
— Assessment is now designed to be holistic, e.g. covering many substances. Therefore, prioritization processes are necessary (in the yellow part), to promote focus on what matters most.
— Regular inputs of data from – and influence of – other policies is foreseen.



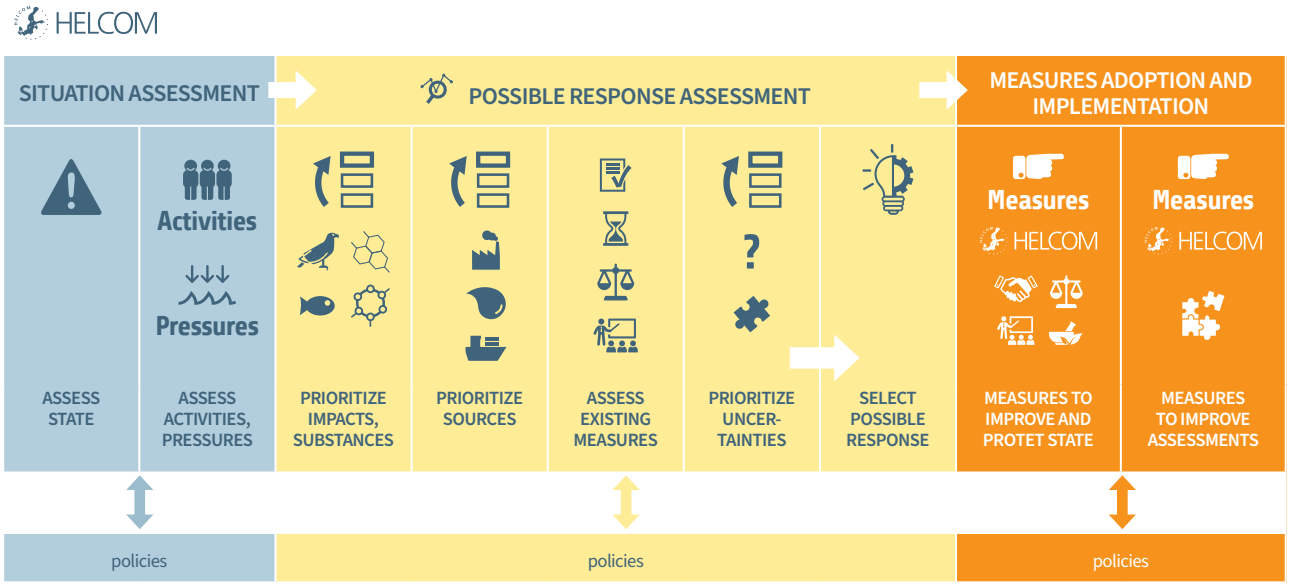




**Figure 2.** Vision created for the new hazardous substances framework.

1 Background report on an update of HELCOM work on hazardous substances in the Baltic Sea (2021)

This vision was then converted to a scheme about how it can be implemented in practice (Figure 3). The proposed scheme for the HELCOM's hazardous substances framework includes 4 steps.

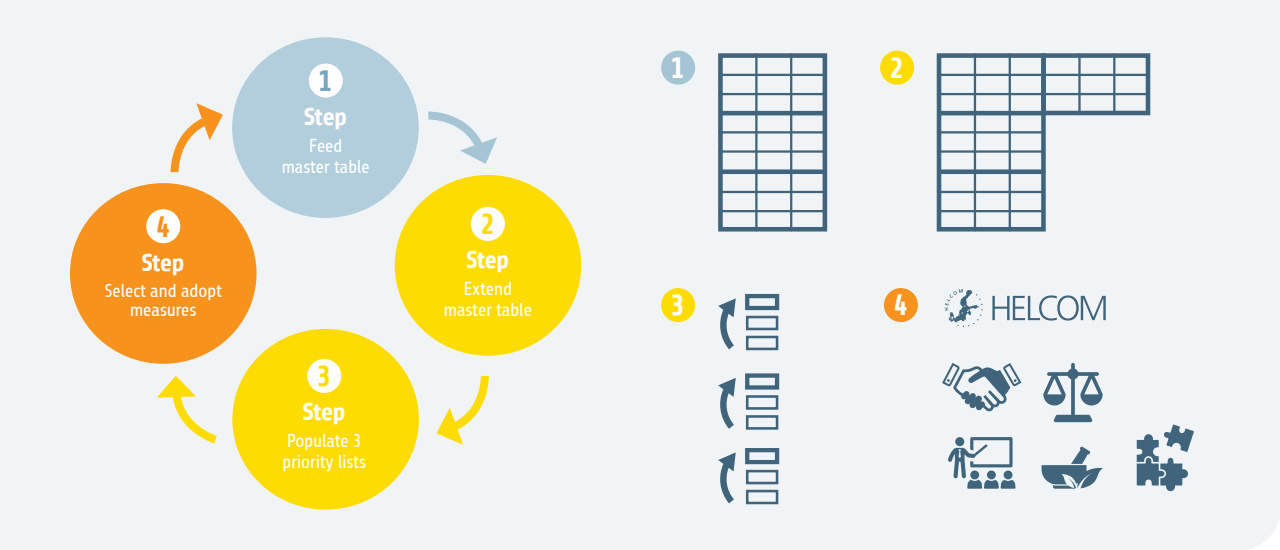



**Figure 3.** Scheme for the new framework: main steps.

## B.1. Step 1

At step 1, substances of concern for the Baltic Sea are listed, scored, and categorized.

This takes place in a working table, the '***Master table of substances of concern for Baltic Sea***'. A substance (or group of substances) is listed in the table if it fulfils the minimum criteria for any of the following concerns: '*critical/significant presence in Baltic Sea*', '*likely significant inputs to Baltic Sea*', or '*analogous concerns*'[2] related to these.

| | ← concerns | | | → | → evaluation ← |
|---|---|---|---|---|---|
| ↑ SUBSTANCE/GROUP | Critical /Significant presence in Baltic Sea | Likely significant inputs in Baltic Sea | Analogous concerns | Hazardous properties | OVERALL SCORE |
| … | … | … | … | … | … |
| … | … | … | … | … | … |
| … | … | … | … | … | … |
| … | … | … | … | … | … |
| … | … | … | … | … | … |
| … | … | … | … | … | … |

**Figure 4.** Illustrative depiction of the 'Master table of substances of concern for Baltic Sea'.

2 Analogous concerns means indirect evidence for the two previous concerns.For-details on what each of the three assessments cover and the respective criteria, see section C.

Note: The 'Master table' is **not** an extensive list of all known chemical compounds / hazardous compounds, but rather a working table with a limited number of substances, selected based on a few specified criteria. The substances that are not included in the current framework run, and belong to the broader 'chemical universe', are not neglected. In later runs of the framework, they may be included in the Master table, if they then fulfil the criteria. Accordingly, substances may be removed from the Master table if they then do not fulfil the criteria anymore (e.g., once better information becomes available to clarify they no longer represent a significant risk).

The three different triggers for listing a substance in the table are complementary. They are assessed based on three parallel, independent assessments. They aim to provide a means for identifying, objectively and holistically, substances and groups that may pose the highest threat for the Baltic Sea. E.g. assessing activities and pressures (under the inputs assessment) reduces bias towards substances which are monitored in the marine environment, or which are easy to detect. This also promotes early identification of emerging (or unrecognized) substances which may not have yet reached critical levels at the Sea.

The total number of substances in the Master table will depend on how strict the criteria for the concerns are. The stricter the criteria, the less the substances listed. The Master table may contain a number of entries in the low 100s, for example.

Note: Using **ranges in scores** is an important feature of the framework. This is because the level of information varies significantly between different substances. Furthermore, recognition and clear reflection of knowledge gaps is important for concluding in later steps of the framework, which knowledge gaps are the most important. In many ways the range component provides a reflection of confidence and can thus support the type or level of action of relevance in the final stages of the framework. For example, measures which aim at filling gaps should then focus on these priority aspects (i.e., where better information is needed to improve confidence and clarity in decision making).

A total score[3] for each listed substance/group of concern may also be calculated. The total score aims to roughly indicate the anticipated magnitude of that substance's/group's impact on the Baltic Sea and its ecosystem services – and accordingly the level of *priority* for adoption of measures towards reducing the inputs (where needed).

Note: Defining also groups of substances in the Master table is a feature that serves many roles. Management of chemicals in the forms of groups allows a more efficient and feasible holistic assessment. For example, groups of substances may be (depending on their definition) easier to monitor, link to biological effects, or addressed via horizontal measures.

3 This overall score is not aimed to be a simple sum of the score for each individual concern. Instead, it may depend on different combination scenarios of positive, negative, and 'uncertain' assessments per individual concern.

## B.2. Step 2

At step 2, top-ranked rows (substances or groups) of the Master table are extended with further information that can support stronger and more detailed evaluations in later steps. Similarly to step 1, the focus will be on using those sources and parameters that provide the best available evidence and can be utilized in an efficient manner.

This means that for top-ranked substances/groups (e.g. 10 or more, dependent on the type of top-ranked substances e.g. regulated or not, regional needs, resources), additional information is gathered and filled in (details about the regulatory status, areas of poor status, main sources of releases) to assist their management in the following steps (steps 3, 4).

Note: The regulatory status of a substance is an important parameter for its categorization to be identified as early in the system as possible.

Thus, the proposal for the scheme is to list such substances coming from Step 1 in the Master table, along with all other ones, to help form a good holistic perspective (as they still fulfill the criteria of a concern for likely impacts to the Baltic Sea, based e.g. on marine levels etc.) but report information about regulatory status as a first task during Step 2. This will allow the flexibility to cease – if deemed relevant – gathering of information and further processing (towards possible HELCOM actions) for such substances, depending on the views of Contracting Parties during implementation of a certain framework run[4]. In practice, for substances of concern which are marked as a 'heavily regulated' at the start of Step 2 may:

— skip gathering of information on areas of poor status and main sources of releases when finalizing Step 2;
— skip scrutiny about whether listing in priority lists is justified during Step 3 (prioritization), as the concern has been identified and scrutinized also by other organizations and there is clearly solid basis for including it in priority list;
— be dedicated limited assessment during Step 4 (actions), as there might be relatively little space for HELCOM actions of added value to the existing policy landscape.

4 Whether HELCOM actions are best to focus only on less/non-regulated substances or can also consider effectiveness improvements for regulated substances, may depend on the case. As already proposed in the regional policy document on hazardous substances (BSEP 182), a requirement for the framework is that HELCOM actions focus on substances and sources of the highest regional relevance and that the framework helps also identifying the relative contribution of HELCOM actions to addressing hazardous pressures to Baltic Sea (e.g. are actions about the most impactful substances / about the most contributing sources of releases). Of course, where no options are seen for HELCOM further addressing regulated substances (such as interim measures when effect of regulations takes too much time, information campaigns, fostering implementation of regulations, identifying and targeting secondary sources, remediation efforts, actions to reduce exposure from contaminated sea food, etc.), actions will need to focus on substances of lower priority for which there may be higher potential for added value.

Horizontal issues, covering several substances, high-ranked and low-ranked, are also identified. For instance, a common knowledge gap might be identified for a cluster of substances or a type of activity, driver or specific pathway (e.g. via the effluent of wastewater treatment plants) which is the main cause of emission for a cluster of substances. Such issues will be possible to target with collective measures in step 4[5].

| | ← concerns → | | | | ← evaluation → | | ← extra info → | | |
|---|---|---|---|---|---|---|---|---|---|
| SUBSTANCE/ GROUP | Critical / Significant presence in Baltic Sea | Likely significant inputs in Baltic Sea | Analogous concerns | Hazardous properties | OVERALL SCORE | STATUS CATEGORY | Regulatory status | Areas of poor status | Predominant sources |
| … | … | … | … | … | … | … | | | |
| … | … | … | … | … | … | … | | | |
| … | … | … | … | … | … | … | | | |
| … | … | … | … | … | … | … | | | |
| … | … | … | … | … | … | … | | | |
| … | … | … | … | … | … | … | | | |
| | horizontal issues | | | | | | | horizontal issues | |

**Figure 5.** Illustrative depiction of the extended 'Master table of substances of concern for Baltic Sea'.

## B.3. Step 3

At step 3, key information from the extended Master table populates three priority lists, which identify substances and issues from the Master table for priority action.

In practice, this step will generate (*update* in future re-runs of the framework cycle) three 'priority lists':

- Priority substances: typically among the top-ranked substances/ groups in the extended Master table
- Priority sources: key sources of releases (mainly horizontal ones), pathways, and drivers
- Priority uncertainties to address (mainly horizontal ones): key gaps in data and methodologies

These three lists provide, in essence, three different perspectives to help HELCOM management decisions in step 4. They also convey a common understanding and a message about anticipated priority issues to other stakeholders.


**Figure 6.** Illustrative depiction of Steps 3 and 4 of the proposed framework scheme.

For the exact definitions of the three lists, see Section C – STEP 3.

5 For instance, if for a pool of substances scoring high under 'likely significant inputs to Baltic Sea', information on presence in Baltic Sea is not sufficient or not available, this can be identified as a horizontal issue for listing under the list of priority uncertainties. A possible action will be future coverage by monitoring activities, for these substances.

## B.4. Step 4

At step 4, HELCOM actions are adopted for addressing matters selected from the three priority lists.

To achieve the placement and design of appropriate actions, this step includes a process to take into account important factors (e.g. list existing measures, assess the reason that the issue has not yet been addressed) and to list possible HELCOM actions, including influence of other policies. The mechanism (section C) for this Step aims to establish an efficient process for identifying and selecting, where relevant, appropriate actions.

Adaptation or discontinuation of an ongoing action (which HELCOM has control over or can influence) are also possible outcomes of this step to the extent justified, to release resources.

## B.5. Added value and synergies (examples)

Firstly, the new scheme is designed to improve the previous hazardous substances framework of HELCOM. The requirements it was built upon (strengthened management cycle, holisticness, added value of HELCOM actions towards fulfilment of BSAP goals, synergy with other policies, modern tools) were set according to the needs identified in 2021 BSAP and the work that led up to it. In fact, the scheme and respective detailed processes have been to great extent inspired by ideas reflected in the 2021 regional policy document on hazardous substances (BSEP 182) and from elements of relevant paradigms. It is also the result of continuous improvements that have taken into account the experience, expertise, and guidance provided by EG Haz and WG Source to Sea during its development.

More specific examples of the foreseen added value:

### Added value on top of the HOLAS and PLC assessments of hazardous substances

The new management framework will complement these processes significantly, since for example until now the holistic status assessment depended only on a small number of hazardous substances indicators and it did not link to development of actions for improving the state. The same applies for the Pollution Load Compilation (PLC) work, where only releases and inputs of very few selected substances have been addressed. The framework is not only intended to compile (and promote generation of) and process information for more substances but also to be a flexible tool that can and has to utilize much more information and data types on hazardous substances than those for which indicators exist at the time of running it. These not only relate to state (e.g. screening data, Effect-Directed-Analysis, scientific articles, further info on biological effects where relevant), but importantly to activities and pressures, aspects such as regrettable substitution, etc. Of course, although processing of this extra information is intended to be structured and systematic, it will clearly not be as data-rich, systematic, and standardized as for HOLAS.

Looking at the interaction between the management framework and HOLAS, they can act in a synergistic way. Indicator data can feed the framework for the relevant substances. In the opposite direction, running the framework cycles will provide evidence that may hint for the need of creation of new indicators for future HOLAS assessments. Accordingly, data from the new indicators can feed later framework runs in a more harmonized regional manner – and a more direct way.

## Added value and interactions with other policies, such as EU MSFD and WFD

An example of added value in this respect is accounting for the Baltic Sea perspective. Another example is improved coordination of MSFD implementation. These two examples are elaborated below.

European Commission's reports have referred to the need to put regional cooperation at the heart of MSFD implementation. They also emphasize (as also does the Directive itself) Regional Sea Conventions (RSCs) as the forum where cooperation and further coordination at regional or sub-regional level can be stimulated. EU Member States are accordingly encouraged to use RSC information systematically in national implementation processes.

More specifically on hazardous substances, the European Commission and further reviews have identified the need to generally improve identification of marine-relevant contaminants for assessment[6]. It has also been recognized that discussion on the selection of relevant contaminants at RSCs has been ongoing for many years, but the process to agree on the relevant contaminants has been too slow[7].

The added value of advancing the monitoring of biological effects linked to chemicals, and in general using techniques to consider mixture effects, and identify possible drivers of toxicity, has also been emphasized in various reports.

Better coordination will not only contribute to improved identification of marine-relevant contaminants but may well support improved programmes of measures. It will also promote the generation of new key information and, where relevant, more representative environmental data (e.g. higher spatial and temporal resolution).

Similarly to what was stated for the 'in-HELCOM' perspective (two-ways interaction between HOLAS and the framework), interaction between policies also works in both directions: Looking at one direction, the existing MSFD/WFD data are naturally among the data[8] to feed the run of the framework. And vice versa, HELCOM framework's processes are expected to support MSFD's tasks and aims (good environmental status in the marine environment), while focusing on the Baltic Sea perspective and BSAP goals.

For example, running the framework may well:

- support the creation of new indicators for future HOLAS assessments (on state and pressures), which will in turn better support Contracting Parties' reporting of MSFD assessments and environmental targets (Art. 8, 10);
- lead to adoption of HELCOM actions (in particular at regional level), which can support monitoring programmes and programmes of measures reported by Contracting Parties under MSFD Art. 11 and 13[9] - with development of appropriate actions being often a challenge for individual Contracting Parties to develop with resources typically available;
- where relevant and feasible, lead to actions in the form of influencing other policies dealing with hazardous substances (e.g. proposing the inclusion of a substance of concern for the Baltic Sea into the Watch List, Priority list of WFD, or its addressing via one of the REACH regimes or processes, etc.).

6 JRC: MSFD – Review and analysis of EU Member States' 2018 reports – Descriptors 8,9 – Victoria Tornero, Simona Boschetti, Georg Hanke – 2021

7 28th Meeting of the Working Group on Good Environmental Status (EU MSFD CIS: WG GES), 18–19 April 2023

8 Of course further sources of information, in particular those helping in identifying relevant substances beyond those in the WFD priority list (which typically account for a large part of the WFD and MSFD assessments), must also be used. Still, for obtaining the big picture, MSFD and WFD information is very important to take in.

9 See the two types of actions foreseen in the scheme (reduce releases, fill information gaps)

It is also an essential feature of the framework that it provides a structure, in which each type of data (e.g. concentrations in the marine environment or rivers, market information, persistence and bioaccumulativity properties, hazardous mode of action, regulatory status and other existing measures, etc.) has a concrete place and clear contribution to understanding of the overall case. Therefore, it enables a systematic assessment of an overall complex issue still allowing expert opinion to be applied.

The systematic structuring of available information facilitates the identification of key gaps in data or methodologies, which would be priority for resolving towards the consequent run of the framework cycle (priority uncertainties). It helps express uncertainties and it makes it easy to absorb scientific developments and data becoming newly available to the framework.

Beyond the structure (scheme) itself, there is flexibility in the framework to allow adaptability of the exact mechanism via which it is run and the depth and scope of assessment so that it can always be adjusted according to the amount of resources available, availability of synergies and tools, and the particular needs[10].

## B.6. Administrative process /Organizational aspects

### Timeframe of framework cycles

Alignment of timelines with EU MSFD and HOLAS would clearly support synergy and efficiency.

The above would mean a recurrent *cycle performed every 6 years.*

Launching future re-runs of the framework cycle right after completion of HOLAS (e.g., *start the run in the autumn in the year of publication of a HOLAS report cycle*) appeals as the most efficient planning. That would allow the framework to utilize indicator data in the framework run directly. If recurrent screening campaigns (in accordance with BSAP HL28) are planned so that they will have produced an output with the same timelines (e.g. a surveillance indicator for use in HOLAS), taking on board recent screening information will also be facilitated[11].

Further draft information gathered by Contracting Parties which are also members of the EU, towards the (upcoming[12]) update of MSFD assessments (reporting of MSFD Art. 8, for substances beyond the regional HELCOM indicators), can also be utilized if properly planned. Otherwise, relying on reported information under the previous MSFD cycle could be applied, though it risks reducing the meaningfulness of the assessment due to the time lag associated (e.g. it would not allow for a very meaningful assessment of current knowledge gaps).

Such a time-planning would also allow utilizing relevant information from very recent WFD River Basin Management Plans in the framework.

Furthermore, completion of the framework run and adoption of HELCOM actions via standard HELCOM procedures could be targeted within such a timeframe to allow, where deemed relevant by Contracting Parties, contribution of its final outputs in the preparation of Contracting Parties' MSFD monitoring programme updates (HELCOM actions for filling knowledge gaps) and of programmes of measures (HELCOM actions for reducing releases / for improving and protecting the state of Baltic Sea).

It is estimated that the above planning for future runs would mean an available time-window for running the framework and adoption of ***monitoring-related*** HELCOM actions of 1.5 years (to support timely contribution to the national updates of MSFD monitoring programmes). An extra 1.5 years for adopting ***other*** HELCOM actions (actions to protect and improve the state of Baltic Sea; and any actions towards improvement of assessment methodologies) would be available, including those which could contribute to the national updates of MSFD programmes of measures.

Of course, the cycles can be planned to be completed earlier than that. In fact, completing the cycles 1.5 year after launch, and adopting all types of actions at once, is preferable, to avoid an extensive time period between start of the assessment of hazardous substances and adoption of HELCOM actions[13].

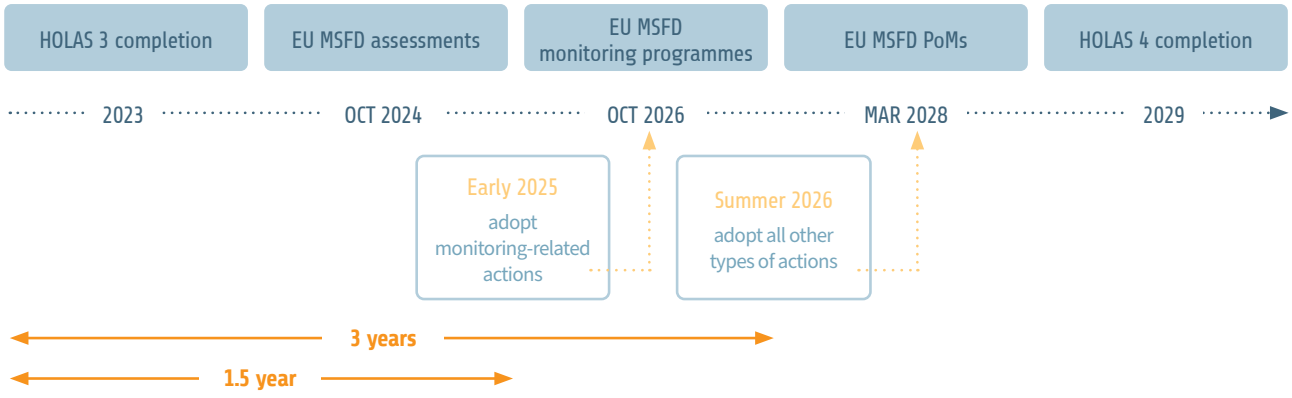



**Figure 7.** Considerations about the timeframe of framework cycles, in relation to HOLAS and EU MSFD timelines.

10 For instance, updating assessments in future cycles of the framework, or assessing where a newly identified substance of concern would rank among already recorded substances would require less resources than the first assessment and it would make use of the experience from the primary run, in terms of key data sources, methodologies, and tools.

11 Furthermore, should future HOLAS assessments contain more information, for example related to drivers, pressures, inputs, biological effects, or sufficiency of measures, then there would be an even stronger basis for the core input into future runs of this framework.

12 For the current MSFD cycle this is due in October 2024.

13 As a concrete example: For the primary framework run that would mean: launched in Autumn 2023, be expected to generate monitoring-related actions latest by early 2025 (to also be possible to contribute to MSFD monitoring programmes which are due in October 2026), and expected to generate other types of actions latest by summer 2026 (to also be possible to contribute to MSFD programmes of measures, which are due in March 2028). The following run would then be launched in Autumn 2029.

In addition, the framework run could also directly contribute to the post-HOLAS review and gap analysis process from which future development priorities are set for the following HOLAS such as a need for new indicators or threshold value revision etc.[14]

Note: Although a 6-year interval is proposed between cycles, should an important issue be recognized between established cycles (e.g. relating to an emerging substance of high concern), there will not be a need to run the whole framework process. Updating the information in the Master table for the specific substance (or including it, if not already included) will promote a perspective on its priority for action in relation to other, already identified substances of concern and if necessary, immediate action.

### Roles (HELCOM Contracting Parties, Groups, Stakeholder organizations)

An overview of the proposed roles is provided in the figure below.

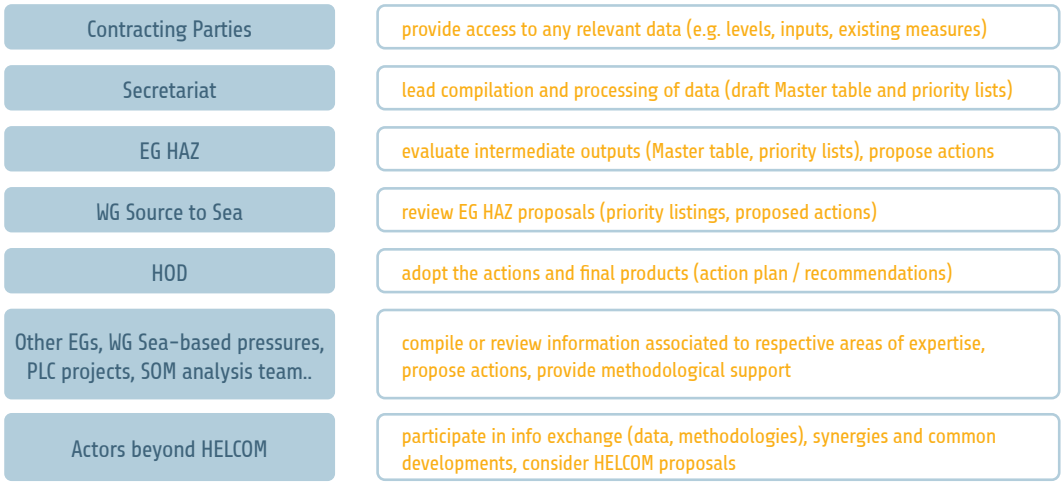



**Figure 8.** Overview of roles proposed in the implementation of framework cycles.

It is noted that the current suggestion foresees that *topic-specific Groups* (WG Maritime etc.) may not only provide support on data and methodologies but they may also make specific proposals for actions, or be responsible for such actions, when relevant to their topic. This is because they would be best placed in terms of knowledge and networking to identify, develop, and monitor those actions.

*'Actors beyond HELCOM'* covers synergies and common developments with stakeholders such as other RSCs and the NORMAN Network, as well as EU organizations and Groups (e.g. ECHA, EMA, EFSA, MSFD Expert Network on Contaminants, etc.) and other organizations (ICES Groups, etc.).

14 The cycles could of course also be planned to be completed earlier, e.g. within 1.5 year. For the above scenario, that would mean adopting all types of actions by Spring 2025. That was eventually the plan made for the primary run, following also the timelines provided in BSAP for implementation of Action HL1, to adopt all types of actions at once

# C. Framework's operational mechanism – key aspects

A step-by-step overview of the proposed process is presented in Figure 9.

While developing the proposal for the mechanism, a review of existing policies and paradigms of similar processes established by other organizations (on substances management, including prioritization), as well as methodologies from guidance and scientific literature, was used to identify those elements which are relevant for HELCOM – and thus, have been taken over in the proposed processes. Accordingly, those elements that were deemed not fit for the purpose of the HELCOM framework or can be implemented in a better way elsewhere – thus, have been proposed to be implemented in a different way in the HELCOM framework.

Key aspects of proposed methodologies, taking into account also experiences from the primary run are summarized further below, for the main tasks.

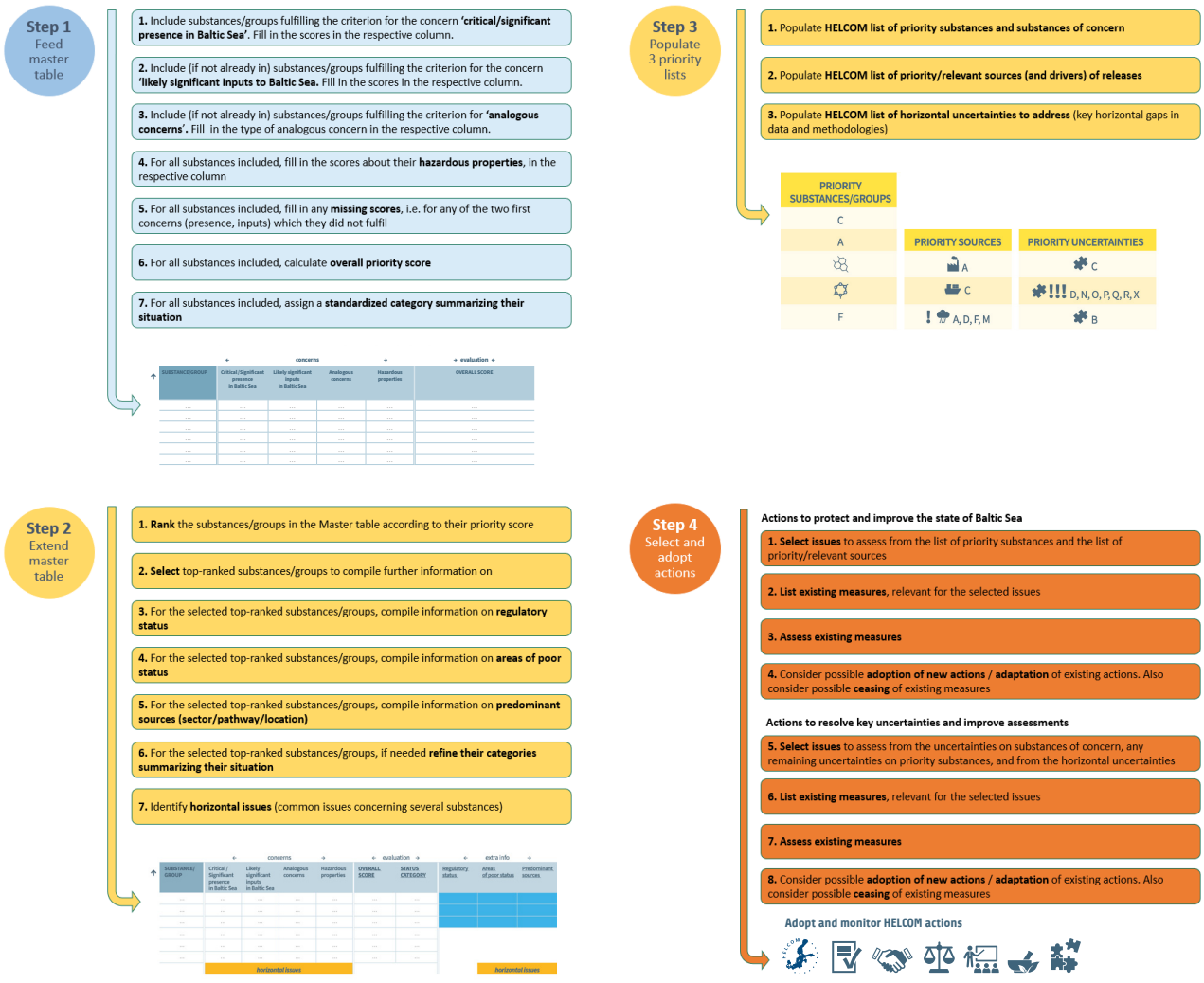



**Figure 9.** Overview of the process foreseen for each step of the framework cycle. The mechanism provides more details about how to implement the individual tasks.

# STEP 1: Feed master table

## *Concern: Critical/ Significant presence in Baltic Sea*

| | |
|---|---|
| **Criterion for a substance/group to enter the table:** | — Threshold Value (TV) is exceeded in 2 assessment units, covering 2 CPs or an off-shore area[16] [SCORE 5-10]<br>— OR TV is exceeded in 1 assessment unit, *with stricter criteria on percentage and number of sites/samples with exceedance, and provided the substance is not known to be used in only 1 CP*[16] [SCORE 5-10]<br>— OR detected with high frequency (>35% of sites) in screening/monitoring campaigns covering it [SCORE <5] |
| **Scoring factors:** | higher score for:<br>— higher spatial/temporal frequency of TV exceedance<br>— higher level of TV exceedance<br>— off-shore exceedance<br>— frequent detection |
| **Range in score if:** | — low reliability/accuracy of data (e.g. screening)<br>— OR low representativeness of data (small number of sites/samples)<br>— OR low reliability of TV<br>— OR the available data does not cover the most relevant matrix for a substance |
| **Possible data sources:** | All types of analyses having identified or explicitly covered (by the protocol) a substance (or group) can be used. E.g. target-monitoring, wide-scope target screening, suspect screening, Effect-Directed Analysis (EDA). Target-analyses will be given higher weight in case both target and non-target data is available for a certain assessment unit unless the latter provide contradictory positive evidence of presence. Focus: last 6 years.<br>Examples: *HOLAS hazardous substances indicators, PreEMPT project and other screening results, EU MSFD data, national and other databases, dedicated data calls, published reports, scientific articles, etc.* |

15 Level 3 scale of assessment is assumed. Measurements considered are those representative of assessment units (no samples from mixing zones adjacent to points of discharge, or from spills). TV exceedance is decided based on the worst matrix per assessment unit, and for the conclusion there are requirements for the minimum percentage and number of sites/samples exceeding TV (≥10%, >2 samples/sites with exceedance). The TV is selected based on an order of priority (e.g. EQS proposals in draft legislation > previous HELCOM/EU agreed TVs > lowest national TVs e.g. in WFD/MSFD assessments or TVs derived during the run based on scientific data > experimental or predicted lowest PNEC from available databases).

16 Based on the experience from the primary run, an additional possibility to fulfil the criterion was added. By making less strict the criteria about the number of samples with exceedances (1 exceedance per assessment unit is also sufficient), but increasing the strictness of percentage and number of such assessment units: 'TV is exceeded in 4 assessment units (with each having exceedance in ≥20% samples even if only 1 sample)'. That was to enable more effective utilization of data from the PreEMPT campaign, which was representative in terms of Baltic Sea (covered many assessment units), but included relatively limited samples per unit.

## *Concern: Likely significant inputs to Baltic Sea*

| | |
|---|---|
| **Criterion for a substance/group to enter the table:** | — Inputs to Baltic Sea (either extrapolated from measurements on the pathways[17] - or estimated based on market and relevant factors such as use pattern, mobility etc.) evaluated together with PBT properties (toxicity, persistence, and bioaccumulation)[18]:<br>• minimum criterion = borderline-PBT substance[19] with inputs of 1 tonne/year *or equivalent (equivalent means that e.g. if $TV_w$ is lower than 10µg/l, inputs <1t/y also qualify for likely significant inputs proportionally - similar considerations for the PB properties)* [SCORE 5-10]<br>— OR Inputs to Baltic Sea converted to PEC (Predicted Environmental Concentration – ideally in Baltic Sea matrices) via modelling using PBT and PHYSCHEM properties<br>• minimum criterion = PEC>TV [SCORE 5-10] |
| **Scoring factors:** | — orders of magnitude of difference (+/-) of inputs,P,B,T versus reference borderline case (reference case = SCORE 5)<br>— or ratio PEC/TV (worst matrix) [SCORE >5 if ratio>1] |
| **Range in score if:** | — conservative estimation based on market is also included in the assessment (this can form the upper end of the range, the lower being based on measurements on pathways)<br>— OR measurement data with:<br>— low representativeness of data (small part of the total catchment flow covered by riverine measurements, only a few countries represented by data, small number of samples)<br>— missing data on pathways expected to be relevant for the substance (e.g. atmospheric deposition, known use in specific off-shore activities without data)<br>— no data on or unreliable P/B/T/PHYSCHEM properties |
| **Possible data sources:** | Available measurement data (*e.g. PLC, other HELCOM reports such as on dredged material deposition, EU WFD, monitoring/screening in rivers / WWTP effluents / atmospheric deposition, E-PRTR, future data from EU UWWTD, spills data, project outputs, scientific articles, etc.*). Available market data from Baltic Sea catchment (or if not available, extrapolated from e.g. EU market data). Estimations on environmental releases based on market data (*e.g. high-scoring substances from modelling-based exercise during the second review of the WFD priority list*). Available reports on use in off-shore activities (*e.g. JRC report on substances released from sea-based activities*). PBT properties from regulatory information or available databases / modelling. |

17 Direct releases from off-shore activities, direct releases from (coastal) land-based activities, riverine, atmospheric deposition.

18 It is considered important that inputs assessment is not only based on the inputs value (and apply a minimum criterion of X tonnes or kilograms /year), but it also takes into account the variable toxicity of substances, when evaluating inputs in terms of likely significance. Similarly, Persistence and Bioaccumulativity are also important factors for the inputs' evaluation, as they will determine the likelihood of high marine levels. A PEC estimation offers an alternative, more exact methodology to evaluate inputs taking into account such properties and should be used, where feasible.

19 Roughly in accordance with REACH criteria, e.g. borderline T means TVw=10µg/l (or CMR properties), borderline P for the marine/estuarine environment means half-life in water ~40–60 days or in sediment ~120–180 days, borderline B means BCF (bioconcentrsation factor for aquatic species) of 2,000.

### *Concern: Analogous concerns*

| | |
|---|---|
| **Criterion for a substance/group/cluster* to enter the table:**<br><br>** biological effects evidence, although may in few cases indicate single substances, will typically indicate clusters of substances having certain toxicological properties (e.g. 'neurotoxicants')*[20]. | — biological effects reliably linked to hazardous substances (groups/clusters/substances)<br>— identification as toxicity drivers (EDA studies)<br>— likely effects of mixtures<br>— very significant presence in analogous sea<br>— likely significant inputs in near future (regrettable substitution, significant emerging use, time-delayed emissions e.g. from dumped material; evolution of drivers/activities)<br>— hazardous degradation products<br>— other as relevant[21] |
| **Scoring factors:** | no score, only flag the concern |
| **Possible data sources:** | Examples: *Data call on biological effects, OSPAR CONnECT, EDA studies in scientific literature, etc.* |

### *Concern: Criticality of hazardous mode of action[22] - only assessed and scored for substances which have entered the Master table due to any of the above concerns*

| | |
|---|---|
| **What is assessed** | modes of action relevant in terms of ecotoxicity or toxicity for human health (latter is relevant e.g. due to consumption of sea food) |
| **Scoring factors:** | — Specific categories of modes of action for the aquatic environment evaluated as more 'critical' than others[23]<br>— CMR properties, Endocrine disruption properties[24] (human health) |
| **Range in score if[25]:** | — classification not official<br>— CMR (2)<br>— REACH substance not yet assessed for regulatory needs<br>— ongoing regulatory process towards establishing hazardous properties<br>— biologically active substance with no specific information on HAZ properties |
| **Possible data sources:** | *Harmonized (EU CLP) or official classifications, self-classifications (CLP), PBT assessments (REACH/Biocides.), data gathered for pharmaceuticals, curated databases on modes of action or PBT properties, PBT modeling results, etc.* |

20 Such broad clusters are not foreseen to be assigned specific scores. However, this is not a reason to omit them in the Master table or the HELCOM list of priority substances/groups. Instead, the message that such an entry would provide is very important in the last steps of the framework cycle (priority listing and adoption of actions for improving status or filling key information gaps). For instance, if biomarkers for neurotoxicity often exceed the relevant threshold in Baltic Sea, such a cluster entry can trigger an investigation for filling the knowledge gap about the substances being neurotoxicity drivers in Baltic Sea.

21 For instance, at the primary run an additional analogous concern assessed was the potential for trophic biomagnification (in particular to predators such as mammals or birds). Although such assessment would normally be included in the presence assessment, during the exercise it was realized that there was hardly any TV available for such species to compare with biota levels with. Instead, there were available studies and data for several substances about biomagnification factors. Therefore, a defined analogous concern was used to allow qualitative utilization of this information and eventual flagging under analogous concerns (which are not scored, but rather used to support expert judgement).

22 Toxicity thresholds are used already in the presence and inputs assessments, therefore this fourth scoring aspect should not take again into account the level of toxicity as such. Instead, the aim here is to assess what types of effects may be expected if thresholds are exceeded – and how critical these would be.

23 General rough evaluation based on aspects such as severity, reversibility, long-term consequences, ecological Impact, synergistic effects, and/or species sensitivity.

24 Endocrine disruption for the environment is included under ecotoxicity above.

25 In the primary run, a range was given for all substances of concern (i.e. these that fulfilled the criteria of TV exceedances etc.): the lower end in the range reflected the known modes of action; and the higher end the max possible score (based on the assumption that modes of action beyond the known ones cannot be excluded). As for the ranking the lower ends of score were eventually used (reasonable best case scenarios), essentially this meant that ranking was based on the known modes of action. Still, the range provided information about the respective uncertainty (smaller if the known mode of action is already critical) and what could be the worst case scenarios in terms of impacts to Baltic Sea and its ecosystem services per substance.

### *Overall priority score*

Translating the information that scores of individual concerns provide (magnitude of each individual concern and level of uncertainty about this) to the likely overall impacts/threats of a substance is not straightforward.

During the primary run, a first version of an algorithm towards an 'overall priority score' was considered, to facilitate selection of priority substances at Step 3. This is illustrated in Figure 10 and is described shortly below. However, it was considered prudent to not select candidate priority substances only based on such a 'combined ranking' but also to add candidate substances from the individual rankings. This is explained further in the mechanism proposals for Step 3 below.

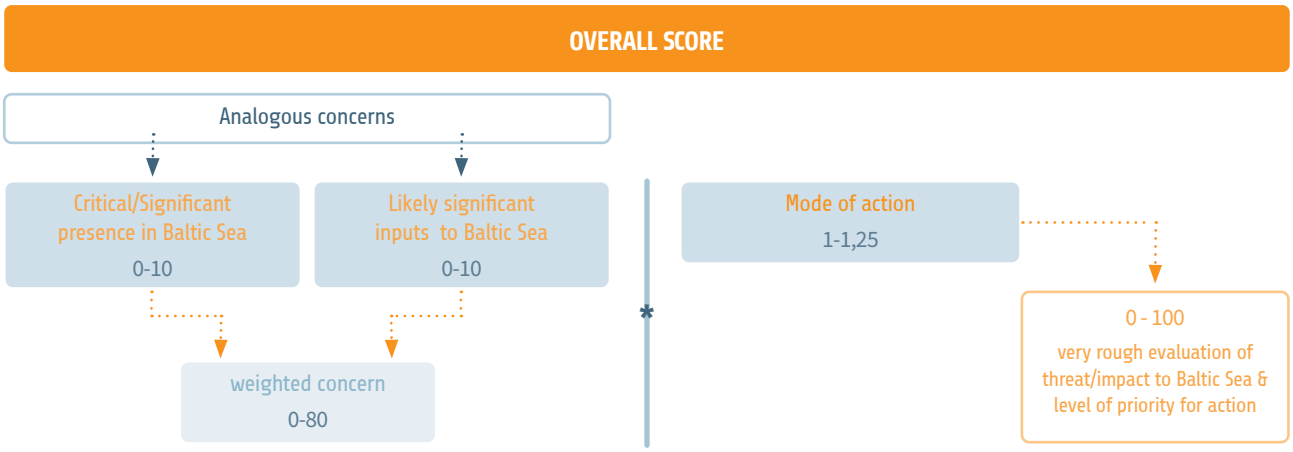



**Figure 10.** The algorithm used during the primary run towards an overall priority score of substances/groups, to support their ranking. Eventually, candidate priority substances were not only taken based on this 'combined ranking', but also from individual (presence/inputs, as well as analogous concerns) rankings.

According to this algorithm:

- The scores about the presence in - and inputs to - the Baltic Sea are to a certain extent complementary in indicating the possible impact or threat of a substance for the Baltic Sea. Furthermore, depending on the case, more reliable information may be available for one or the other. A weighted average can be applied, where more weight is given to the more reliable information from the two, depending on the substance.
- Analogous concerns (for which no scoring was foreseen) could be considered as providing supporting evidence in relation to the other concerns. Therefore, it is suggested to take analogous concerns into account by possibly adapting the score (range) of the concern they are analogous to, via expert judgement. Or, alternatively, to bring forward the respective flag to Step 3 (including any flagged substances not highlighted at all in the presence or inputs assessments) – and utilize it in that step, along with the further expert judgement foreseen there.

# STEP 2: Extend master table

The aim and process for this step has generally been described above (section B2).

Selected aspects on how to perform the two main tasks in this step (gathering extra information for substances among the top-ranked ones and identifying horizontal issues) are highlighted below:

***Gathering of extra information***

- Regulatory status: 'Heavily regulated' and 'regulated' are terms that can be used as part of the updated 'status/situation category' of each substance, after its assessment of regulatory status. Those statuses would need to be defined in the form of a list of legislative regimes assumed as typically addressing respective substances. However, this categorization may be subjective. Furthermore, inclusion under a certain regulatory regime may not be similarly effective for all substances. Therefore, it is important in this step is to at least list the legislative regimes under which it is covered, to allow considerations such as those mentioned in section B2, and also to support assessment of existing measures in Step 4.
- Areas of poor status: As presence assessment criteria typically require the assignment of marine levels information to the established HELCOM Assessment Units (in order to allow counting of 'red' and 'green' Assessment Units etc.), the reflection of the approximate status per Assessment Unit can be derived directly from these data.
- Predominant sources of releases: These may be defined based on the information gathered during the inputs assessment (e.g in terms of predominant pathway from the four assessed or including also 'upstream' pathways such as WWTP effluents – or in terms of apportionment of market or releases to uses/activities). For cluster entries (e.g. in the example given earlier, 'neurotoxicants') and group entries, this field may be filled with information about the substances in that group/cluster with the highest contribution. Such information, apart from substances that are known to trigger such biological effects when exposure occurs, may originate from application of Effect-Directed Analysis to Baltic Sea samples, or from an evaluation of the Master table, or from any existing studies. To the extent known, the respective main sources of releases for these, highest contributing substances to the group/cluster, may be listed as well.

***Identification of horizontal issues***

As explained above, horizontal issues are issues that concern several substances. Four types of horizontal issues are anticipated:

- key uncertainties on priority (i.e. uncertainties about the impact of certain substances on Baltic Sea, i.e. on presence, inputs, thresholds, modes of action, etc.)
- areas of poor status – plus uncertainties in the identification of such areas
- predominant sources of releases – plus uncertainties in the identification of those
- drivers affecting activities and pressures (those will often be identified by expert judgement and not so much by the overview that the Master table provides)

# STEP 3: Populate (update) the three priority lists

As mentioned already, the priority lists aim to provide three different standpoints of the problem of hazardous pollution in the Baltic Sea in order to assist management decisions at the last step of the framework's process. They also aim to convey a common understanding and a message to other stakeholders about the respective anticipated highest priority issues.

The three priority lists have the following definitions:

***HELCOM list of priority substances and substances of concern:***
Substances/groups with the highest anticipated risk (current impact or threat for the near future) for the Baltic Sea and its ecosystem services.

The list can be sub-divided into 'priority substances' and 'substances of concern', on the basis of the level of any remaining uncertainties on the risk.

***HELCOM list of priority/relevant sources (and drivers) of hazardous releases:***
- sectors of human activity (land- or sea-based) or specific activities
- pathways to the Baltic Sea
- (drivers)

anticipated to have the highest contribution to / threat for overall inputs of hazardous substances to the Baltic Sea.

The list may be defined as containing 'relevant' or 'priority' sources, depending on the outcome of the assessment, i.e., on whether the listed sources are limited to a few that were found to be the cause of more significant amount and types of releases than other relevant sources - or all relevant sources listed were found to contribute significantly and could not be differentiated in this respect.

***HELCOM list of horizontal uncertainties to address:***
Key horizontal gaps in data or methodologies hindering:

- assessment of level of priority of substances/groups
- assessment of predominant sources of inputs
- identification of areas of poor status
- assessment of most appropriate actions

Remaining uncertainties associated with priority substances or substances of concern may be reflected as additional information per entry in the first list (HELCOM list of priority substances and substances of concern). Instead, this third list intends to reflect issues encountered during a specific run of the approach, which related to substances other than the ones on the lists of priority or concern. Main examples of substances the horizontal gaps relate to may be provided as additional information per entry in this third list.

***Considerations when selecting candidate substances of priority/ concern***

- Selecting substances from combined vs. individual (presence, inputs) rankings

  If it is assumed that individual assessments (presence, inputs) are sufficiently reliable, it can be considered that:

  - Substances scoring high in PRESENCE assessment can directly be assumed to have current impacts on some species
  - Substances scoring high in INPUTS assessment:
    - in the absence of (reliable) PRESENCE data for these substances, they can be assumed of likely having impacts currently (assumption: this magnitude of inputs has been the same or higher in the past – thus critical levels in Baltic Sea such as steady-state concentrations have likely been reached)
    - regardless of PRESENCE data and what these show, they can be assumed of likely being a threat for impacts in the near future (as when steady-state concentrations are reached, these are predicted to be above toxicity threshold values) – current impacts close to mixing zones cannot be excluded either, especially in case of acutely toxic substances
  - Substances flagged as of ANALOGOUS CONCERNS of type 'likely significant inputs in the near future' (e.g. emerging sectors or dumped materials):
    - regardless of PRESENCE and INPUTS data and what these show, they can be assumed of likely/possibly being a threat for impacts in the near future (as inputs will likely increase significantly in the future)

The above, along with the definition of the HELCOM list of priority **substances and substances of concern, would suggest selecting as candidate substances top-ranked substances from all three assessments.** Also using a combined ranking is possible, where individual scores are summed per substance, and further information such as on criticality of mode of action can be taken into account. How many substances to select from each list or what weights to apply in a combined ranking (or how to interpret the underlying evidence to eventually list top-ranked substances under 'priority' vs 'concern') is a matter of **policy decision.**

Taking further into account that there is typically a certain degree or underlying uncertainty in individual assessments, which is reflected in the respective score ranges (narrow vs. broad), additional considerations include the following:

- Higher weight / Higher number of candidate substances from one list: may be applied in a more flexible way, taking into account (apart from policy aspects) which of the assessments has less uncertainty.
- INPUTS assessment has always, beyond the uncertainty of the data it uses, an additional inherent uncertainty[26], as it is a prediction about the current/future marine state (this is why substances fulfilling INPUTS

26 In particular if it is not expressed as PECs vs TVs.

criteria are expressed as of likely significant inputs). Thus, PRESENCE assessment will normally have a tendency to provide more clear candidates or more weight for the overall evidence (if both presence and inputs data is available for a substance). Still, substances ranking high in INPUTS assessment are very important to include / consider as candidates as well to cover precautionary aspects (we should not wait until a substance reaches critical levels in the Baltic Sea before prioritizing it for action). Input data is also important to use for identifying candidate substances as it may cover the lack of (sufficiently reliable) marine data for many substances.

- *How to assess uncertainty*
  - The actual method to assess uncertainty may be quantitative or qualitative. Factors that can be used to assess it (e.g. to derive the ranges of scores of PRESENE and INPUTS, if this is done in a quantitative manner) were listed in Section C (Step 1). When automation is available, score-ranges may be derived based on concrete rules. For example, the range of inputs reflecting their variation in the time period covered can be translated to a range of inputs score. Or default uncertainty factors may be applied, depending on the percentage of catchment flow covered by riverine measurements or the number of countries covered by the data. Sensitivity analysis may also be run by the tool used to derive the scores based on concrete scenarios. For instance, for substances for which toxicity thresholds are unreliable, alternative scenarios with higher or lower toxicity threshold may be run, to derive reasonable best/worst case scores. Similar scenarios or combined scenarios may be run if there are unreliable marine levels (e.g. based only on screening data), i.e. try lower/higher concentrations. Or scenarios with assumed better/worse state in Assessment Units without data can be tested.
  - Factors not taken into account in quantitative estimations can be taken into account during the expert judgement step, which is always involved to finalize the lists in Step 3[27].
- *How to handle uncertainty and the precautionary principle*
  - Whether quantitative or qualitative, a question will always be how certain or how precautionary to be in the selection. For instance, using as basis 'best case' scenarios or focusing only on substances with very strong evidence in all aspects (measured levels, toxicity thresholds) will promote selecting substances with high certainty on risk. On the other hand, using 'reasonable best case' or even 'reasonable worst case' scenarios for the actual ranking will enable prioritizing also substances with less strong evidence on impacts and will be a more effective preventive approach (especially if it can take a lot of time or even be infeasible to gather sufficient data) but it may mean the need of selecting more substances. Or, if a limited number of substances is selected, there is a higher chance for some false listing and omitting substances with clear risks[28].
  - The regional strategic approach in any case has a place for substances not making it to the sub-list of priority substances as such substances may still be included in the sub-list of 'substances of concern'. For these ones, at least supporting actions to reduce the uncertainties are foreseen. Instead, for substances in the sub-list of priority substances measures will normally aim for the mitigation of risks, i.e. aspects such as promotion of substitution and reduction of releases (or even, where relevant, remediation). Such mitigation actions may be applied also to substances of concern, where (or when/if later) information shows that this is needed.
  - In deciding the most appropriate list, the precautionary principle should be kept in mind. The balance between gathering more and more evidence on risk versus preventing a situation which may be very difficult to reverse if releases continue - as well the added value of HELCOM actions versus existing regulatory measures (substances with proven risk are often already regulated by existing legislation).
  - Policy considerations and how exactly to apply the precautionary principle will affect the decision on listing in one versus the other list. Compromise solutions are possible and should be considered too, such as: applying light mitigation measures for substances of concern; foreseeing relatively short deadlines for supporting actions aiming at collecting further information along perhaps with extended producer responsibility like schemes or other initiatives to support efficient collection of that information or complementary targeted search of extra supporting information during Step 3.

27 For the primary run of the approach, such additional factors applied for some cases included for example: uncertainty on identity for substances detected during suspect screening; cases where presence data may have not covered the relevant matrix for a substance; market information (where this was unavailable and was not taken into account during inputs assessment), check on whether natural background levels have been taken into account in the TV derivation; trends in PRESENCE or INPUTS.

28 This is because the 'reasonable worst case' scenario for a substance with somewhat uncertainty in the underlying data (broad range in priority score) may be of higher concern, evaluated as more impactful for the Baltic Sea, than the 'reasonable worst case' for a substance with very little uncertainty (narrow range in priority score – which is thus almost identical to the base scenario).

# STEP 4: Select and adopt HELCOM actions

Step 4 includes the adoption of:

- Measures to protect and improve the state of Baltic Sea, aiming to address mainly selected issues from
  - the HELCOM list of priority substances
  - and the HELCOM list of priority/relevant sources (and drivers) of releases
- Supporting actions to resolve key uncertainties[29] and improve assessments, aiming to address mainly selected issues from
  - the HELCOM list of substances of concern
  - any remaining uncertainties on the HELCOM list of priority substances
  - the HELCOM list of horizontal uncertainties to address

Certain tasks, methodologies, and tools which could help significantly in establishing an efficient process are the following:

- categorization of existing measures in terms of which element of the causal chain of the issue the measure controls/targets, who has established a measure, who is the target actor, and how the measure controls/targets the issue (mode of action)
- use of an iterative process for identifying and selecting possible HELCOM actions (start with high-level analysis and readily available info; and if needed get into more details)
- use right assignment (assign to the right Group and involve exchange and synergies with relevant stakeholders)
- use management principles and if possible develop decision trees (develop a scheme to limit the options and guide the selection process – apply principles such as the hierarchy of consideration of options, where e.g. actions targeting elements early in the causal chain or utilizing the frames of existing policies or measures may be considered before other actions – assess options for new measures in terms of their expected effectiveness[30] in addressing the issue, resource-efficiency[31], secondary impacts[32], and fairness)

For the purpose of the primary run, the above was translated to a simple excel template. The template utilizes the DAPSIM causal/management framework structure and aims to assist the assessment towards possible actions, for priority substances and issues.

29 Such actions include among many other types, e.g. monitoring activities and adaptation of the frequency and type of existing monitoring.
30 Direct benefits.
31 Need for a small amount of resources to achieve the effect, i.e. low direct costs / low costs–benefits ratio and short time needed for implementation and effect.
32 Impacts beyond the issue in hand (indirect benefits or costs).

# Annex I – List of abbreviations

| | |
|---|---|
| BCF | Bioconcentration factor |
| BSAP | Baltic Sea Action Plan |
| BSEP | Baltic Sea Environment Proceedings |
| CIS | Common Implementation Strategy |
| CLP Regulation | EU Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures |
| CMR | Carcinogenic, mutagenic and reprotoxic |
| CPs | HELCOM Contracting Parties |
| DAPSIM | HELCOM causal framework:<br>Drivers - Activities - Pressures - State - Impact - Measures |
| ECHA | European CHemicals Agency |
| EDA | Effect-Directed Analysis |
| EFSA | European Food Safety Authority |
| EG Haz | HELCOM Expert Group on Hazardous Substances |
| EMA | European Medicines Agency |
| E-PRTR | European Pollutant Release and Transfer Register |
| EQS | Environmental Quality Standard |
| EU MSFD | EU Marine Strategy Framework Directive |
| EU WFD | EU Water Framework Directive |
| GES | Good Environmental Status |
| HAZ properties | Hazardous properties |
| HOLAS | HELCOM Holistic Assessments |
| ICES | International Council for the Exploration of the Sea |
| JRC | Joint Research Centre OF THE European Commission |
| P, B, T properties | Persistence, Bioaccumulation, and Toxicity properties |
| PBT | Persistent, Bioaccumulative and Toxic |
| PEC | Predicted Environmental Concentration |
| PHYSCHEM | Physico-chemical properties |
| PLC | Pollution Load Compilation |
| PoMs | Programmes oif Measures |
| REACH | EU Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RSCs | Regional Sea Conventions |
| SOM | Sufficiency of Measures |
| TV | Threshold Value |
| $TV_w$ | Threshold Value for the water matrix |
| UWWTD | EU's Urban Wastewater Treatment Directive |
| WG | Working Group |
| WWTP | WasteWater Treatment Plant |

# Annex II.
# Data sources used in the primary run of the regional strategic approach

The table below lists the main (types of) data sources identified in the primary run of Step 1 of the draft regional strategic approach. It is reminded that Step 1 includes the identification of substances of possible concern for the Baltic Sea, on the basis of three independent, complementary assessments (marine levels, inputs to Baltic Sea, analogous concerns). It also includes scoring, to support their ranking. Scoring applies to the three respective concerns and also includes a fourth assessment/factor, relating to the mode of action in terms of toxicity.

Certain data sources were utilized in later Steps in the exercise (partially or completely, qualitatively or quantitatively), for instance in the context of additional weight of evidence, along with the expert judgement foreseen in Step 3, where the priority lists are developed. Another example is to support considerations of appropriate actions in Step 4, along with many other data sources used in that Step. Individual scientific articles and reports utilized are typically not listed as such below, but rather indicated as a group, as the aim of this Annex is to indicate the type of data sources used for supporting future runs.

| PRESENCE (marine levels) 2015-2024 | INPUTS (inputs to Baltic Sea) 2015-2024 - main sources - | ANALOGOUS CONCERNS 2015-2024 | MODES OF ACTION |
|---|---|---|---|
| Used at Step 1 | Used at Step 1 | Used at Step 1 | Used at Step 1 |
| **Regional/National monitoring** | **Direct inputs (off-shore activities)** | **Biological Effects** | CMR properties: Harmonized classification (EU CLP Regulation) |
| HELCOM HOLAS indicators for hazardous substances | HELCOM BSEFS on depositing of dredged material | HELCOM data call on Biological Effects, BEACON project (EE, LV, SE) | CMR properties: self classification (C&L notifications of EU CLP Regulation, EU REACH Registrations) |
| DE MUDAB, UPM | HELCOM BSEFS Shipping discharges/emissions | **Presence in analogous sea** | Modes of action: Kramer et al, 2024 (curated data) |
| DK data in ICES DOME | Scientific articles from project EMERGE (shipping emissions) | CONnECT (North-East Atlantic samples) | **Retrieved/Processed, but not used** |
| EE data in ICES DOME | HELCOM indicator: oil spills | **Likely significant inputs in the near future: time-delayed emissions from dumped materials: dumped munitions/explosives** | Modes of action: further data from literature research |
| FI data in ICES DOME | HELCOM Annual report on discharges observed during aerial surveillance | NATO Towards the Monitoring of Dumped Munitions Threat (MODUM) report (2018), HELCOM report on Chemical Munitions Dumped in the Baltic Sea (2016) | |
| LT data in ICES DOME | Aerial surveillance data | **Trophic magnification potential** | |
| LV data in ICES DOME | HELCOM report on Shipping accidents, Shipping accidents in the Baltic Sea | Scientific articles, Dissertations (4) | |
| PL data in ICES DOME | Scientific review on Off-shore Wind Farms emissions (Kirchgeorg et al, 2018) | **Likely significant inputs in the near future: emerging sectors** | |
| SE SGU national data host | UBA report on from offshore energy industry and other sea-based activities (2024) | Consultations | |
| HELCOM data call on pharmaceuticals | JRC report on identification of marine chemical contaminants released from sea-based sources (2016) | **Toxicity drivers in analogous sea (Effect-Directed Analysis studies)** | |
| **Screening projects** | **Riverine inputs, Direct inputs (land-based activities), Industrial emissions** | Scientific review (1) | |
| PreEMPT, CONnECT (Baltic Sea samples) | PLC-8 assessment report | | |
| LifeAPEX | Undeman et al, 2022 (Micropollutants in urban wastewater, data from 650 WWTPs, 2010-2019) | | |
| **Reports, articles, projects** | E-PRTR emissions data | | |
| LifeAPEX (monitoring part) | EEA WATERBASE (2015-2022) riverine data (proximity of river mouths) | | |
| Reports & Scientific articles/reviews (datasets) (8) | Reports & Scientific articles (3) | | |
| Reports & Scientific articles/reviews (statistics) (24) | **Atmospheric deposition** | | |
| **Used only at a later Step** | PLC-8 assessment report / EMEP data | | |
| HELCOM data call on PFAS | Reports & Scientific articles/reviews (2, including from project EMERGE) | | |
| **Retrieved/Processed, but not used** | **P, B properties** | | |

| PRESENCE (marine levels) 2015-2024 | INPUTS (inputs to Baltic Sea) 2015-2024 - main sources - | ANALOGOUS CONCERNS 2015-2024 | MODES OF ACTION |
|---|---|---|---|
| LT WISE SoE | RIVM's PBT/PMT screening tool (BIOWIN3 model, BCFBAF model) | | |
| FI VESLA and KERTY | **Used only at later Step** | | |
| UBA-HELCOM | Market volumes: EU REACH registered tonnage | | |
| DK Miljøportal | Market volumes: REACH applications for authorization, authorizations, Downstream user notifications | | |
| EE KESE | Market volumes and worst-case release factors: SPIN database (SE, DK, ~FI) | | |
| Graphic and statistical overview of temporal trends and spatial variations within the Swedish National Monitoring Programme for Contaminants in Marine Biota (2023) | Market volumes, $PEC_{sw}$: based on sales data from HELCOM data call on pharmaceuticals | | |
| **Identified, but not retrieved** | Riverine/WWTP data from HELCOM data call on pharmaceuticals (to the extent not overlapping with WATERBASE, Undeman study) | | |
| ECHA REACH Registration factsheets (environmental monitoring data) | Riverine/WWTP data from HELCOM data call on PFAS (to the extent not overlapping with WATERBASE, Undeman study) | | |
| NORMAN Digital Freeze Sample Platform (retrospective searches for extra suspects in PreEMPT samples) | Veterinary medicines approved for fish in EU / in active use | | |
| | P, B properties: based on official assessment (REACH Candidate List of SVHC, BPR list of approved active substances, llist of approved active subtsances for use in plant protection products in accordance with EU Regulation Regulation 1107/2009) | | |
| | P, B properties: ECHA PACT | | |
| | P, B properties: EU REACH registrations | | |
| | P, B properties: identified scientific articles and databases | | |
| | **Retrieved/Processed, but not used** | | |
| | EQSD Inventories of emissions (not selected as key studies) | | |
| | Micropollutants in wastewater and sewage sludge (pended check on possible overlapping with Undeman, 2022) | | |
| | Riverine: EEA Pesticides indicator (to the extent not overlapping with WATERBASE) | | |
| | KEMI exposure indicator (not selected as key study) | | |
| | **Identified, but not retrieved** | | |
| | Further inputs information from reports, scientific articles | | |

| PRESENCE (marine levels) 2015-2024 | INPUTS (inputs to Baltic Sea) 2015-2024 - main sources - | ANALOGOUS CONCERNS 2015-2024 | MODES OF ACTION |
|---|---|---|---|
| | Atmospheric deposition: any further info in EBAS database | | |
| | Market volumes: national registers | | |
| | Market volumes: EU-based information held by JRC for sectors other than REACH | | |
| | Outputs of the JRC modelling exercise (WFD 2nd prioritization cycle) | | |
| **TOXICITY/EFFECTS THRESHOLDS** | | | |
| **Used at Step 1** | | **Used at Step 1** | |
| Proposed EQS in draft amendment of EU EQSD (as of 01.2023) | | Biological effects: BAC and EAC under HELCOM indicators | |
| HELCOM HAZ indicators thresholds | | Biological effects: For further biological effects, calculated BAC and EAC specific for the Baltic Sea region | |
| EQS in EQSD | | Munitions/explosives: Fauser et al., 2023 | |
| Posthuma et al., 2019 (SSD-based) (selected pharma) | | | |
| Lowest MSFD national (2018) | | | |
| Lowest WFD national for River Basin Specific Pollutants (2nd RBMP) (coastal, riverine) | | | |
| NORMAN Lowest PNECs | | | |
| **Used only at later Step** | | | |
| Further thresholds from JRC works leading up to the candidates to the EU Priority / Watch Lists | | | |
| EU CLP Regulation: harmonized classification | | | |
| **Identified, but not retrieved** | | | |
| Lowest MSFD national (2024) | | | |
| Lowest WFD national (3rd RBMP) (coastal, riverine) | | | |
| Thresholds from EU REACH Registration dossiers, Dossier/substance evaluation processes, EU CLH support documents, EU BPR assessment reports for biocidal active substances | | | |
| Further scientific databases | | | |
| Further scientific articles | | | |