Risk ranking method

In this guide

This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

22. In the absence of data to establish HBGVs and conduct a risk assessment, a numerical risk ranking method was deemed appropriate to provide a consideration of risk that policymakers can use to inform decisions on whether legislative standards should be updated or changed.

23. A decision tree was proposed to clearly depict the main considerations and to set out the amount of data available for each biotoxin, given the sometimes-limited database (Figure 1). Combining the decision tree with numerical scores for each step of the decision tree clearly depicts the underlying considerations and the weighing of the data. The decision tree considered four main categories of information: monitoring, toxicological data, i.e., human case reports and/or animal tox data, and occurrence data. Each group of emerging biotoxin is numerically scored on a scale of 1-5 for all categories generating a maximum score of 20 where higher scores represent a greater risk to public health. The considerations and weighing of evidence for each group of biotoxin were provided in tabular form, accommodated by a clear narrative

explaining the underlying considerations and providing a transparent depiction of which data was driving the risk ranking.

24. An attempt at risk ranking AZA analogues, DA analogues and PtTX, groups which had insufficient data for any of the four categories, was attempted by using an analogue biotoxin (TOX/2025/15); however, the Committee concluded that using an analogue for non-hazard categories was unsuitable. The analogue approach was retained in the decision tree (Figure 1) as a potential future method for creating temporary risk rankings for other biotoxins with limited information.

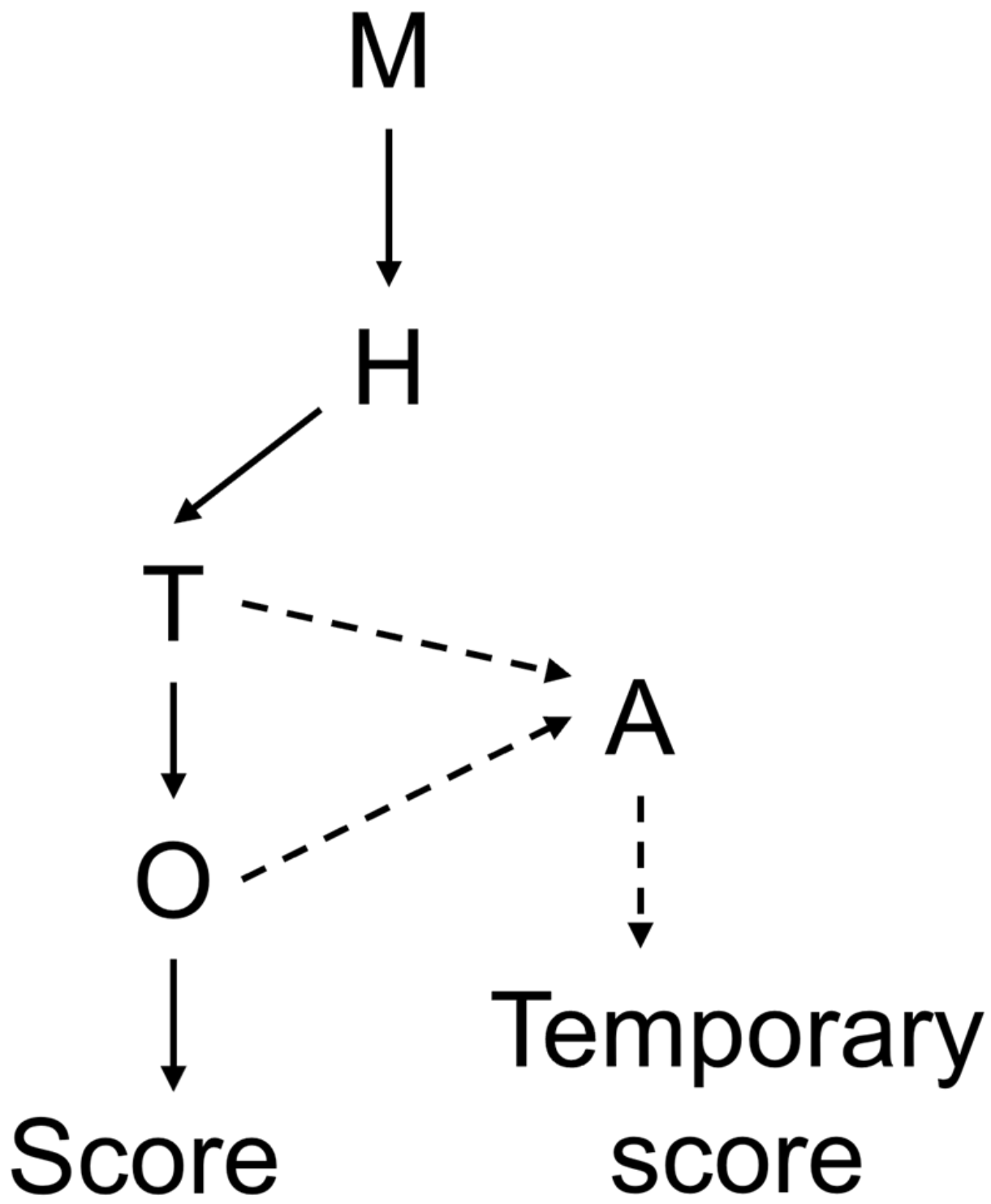

Figure 1 is shown in black text against a white background.

Figure SEQ Figure * ARABIC 1. Risk ranking decision tree. M = monitoring; T = toxicity; H = human case reports; O = occurrence; A = analogue. Dashed lines represent the potential path for analogues in the absence of data for T and/or O.

Monitoring

25. Monitoring considered whether the toxins were included in any recent or ongoing official marine biotoxin monitoring programmes either in the UK or EU. Toxins which were extensively monitored were considered the least risk and hence given the lowest score. Information on unofficial research monitoring programmes and monitoring in countries outside the EU may be available, resulting in higher scores. No monitoring was considered the highest risk as the prevalence of the toxin was unknown and therefore the risk was unknown. In these instances, the highest score would be applied.

Human case reports

26. Human case reports considered whether documented cases of human intoxications were available, their severity, and whether any fatalities have been reported. Higher scores were given to toxins for which both intoxications and fatalities have been reported and lower scores for toxins with reports of intoxications but no fatalities. The number of case reports was not considered as it was too variable between toxins, and the information, in general, was very limited. Toxins without information or reports of fatalities or intoxications have also been given a score; however, please note that no reports do not necessarily indicate that no intoxication (potentially even fatalities) have occurred. Underreporting has been noted as an uncertainty for marine biotoxins in general.

27. For this category there are only three scoring options as due to the limited information and uncertainties it was not considered possible to distinguish them further, but the scores have been designated 1, 3 and 5 to maintain an equal weighting of this category compared to the others.

Toxicity

28. Toxicity considered the known adverse effects of each toxin, identified from *in vivo* animal studies, usually mice or rat. Neurotoxic effects were ranked highest followed by gastrointestinal effects and lastly mild effects such as weakness and general unwellness. A numerical score from 1-5 has been applied, to the endpoints described above and to the consideration on the lethal dose (LD50). Whether a LD50 was considered ‘high’ or ‘low’ or rather ‘higher’ or ‘lower’, was, in this instance, determined qualitatively via the Committee’s

judgement rather than quantitatively (i.e., specific LD50 ranges) due to the limited data available. The LD50s were considered to assist in differentiating toxicity profiles between biotoxins; however, the LD50s are based on a limited toxicological database and there was a high uncertainty how much weight can be assigned to them.

Occurrence

29. Occurrence considers documented cases of detection of these toxins either through official routine inspections, one off incidents and/or research efforts. Detection in UK waters was ranked highest followed by Northern EU waters, as they are most like the temperature profile in UK waters. Detection in Mediterranean EU waters would rank lower as the water profile would be different to the UK's, however, this may change with climate change and increasing water temperatures. Detection outside the UK and EU has not been considered here and would only be considered useful, if no other data were available.

Scoring

30. Scoring was conducted as follows:

Monitoring (M):

- 1 point - extensively monitored in the UK.
- 2 points - extensive monitoring (EU/UK).
- 3 points - moderately monitored (in some countries but not across all/UK).
- 4 points - limited monitoring (in EU/UK).
- 5 points - no monitoring.

Human case reports (H):

- 5 points - documented cases of human intoxications with fatalities.
- 3 points - documented cases of human intoxications without fatalities.
- 1 point - no documented cases.

Toxicity (T):

- 5 points - causes severe neurotoxic effects with low LD50.
- 4 points - causes severe neurotoxic effects with relatively high LD50.
- 3 points - causes gastrointestinal effects with low to moderate LD50.
- 2 points - causes gastrointestinal effects with relatively high LD50.

- 1 point - causes mild other effects or high LD50 for other affects than the ones listed above.

Occurrence (O):

- 5 points - frequently detected in UK waters or no data available.
- 4 points - occasionally detected in UK waters.
- 3 points - rarely detected in UK waters.
- 2 points - detected in Northern EU waters.
- 1 point - detected only in Mediterranean EU waters.

Analogues

31. Initially an analogue approach was proposed for scoring novel AZAs and PtTXs, toxins with no to very limited information available. The approach suggested using a structurally similar analogue to fill the data gaps and generate a temporary score. However, the Committee concluded that without evidence to show that, for example, that the occurrence of one biotoxin directly relates to the occurrence of another, using analogues for all four scoring categories was associated with high uncertainty and would not result in a robust/appropriate score. The Committee suggested that in general, using suitable read-across methods could be applied in the future, especially to the hazard category, i.e., toxicity (human, animal).

32. As there was no to very limited data available for PtTX and novel AZAs in all categories the Committee considered it not appropriate to apply analogues here and did not include them in their final risk ranking.