## Discussion

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

35. The risk ranking method was applied to six emerging marine biotoxins scoring each 1-5 points according to four different categories, i.e., monitoring, human case reports, toxicity and occurrence data where a maximum possible score of 20 points could be achieved indicating the highest possible risk. An overview of the rankings has been provided in Table 7.

Table 7. Summary table of risk rankings generated for each of the six groups of emerging marine biotoxins according to four categories (maximum score of 20).

Toxin	Score	e M	Т	Η	0
ттх	19	4	5	5	5
PITX	17	5	5	5	2

MC	15	4	3	5	3
BTX	13	4	4	3	2
SPX (CI)	13	4	5	1	3
GYM (CI)	11	4	4	1	2

M = Monitoring; T = Toxicity; H = Human case reports; O = Occurrence; CI = Cyclic imine.

36. The decision tree and weighing the available data provided a priority list for the six emerging marine biotoxin groups, ranking them according to their potential risk to human health in the UK.

37. TTX and PITX were ranked as high risk due to their neurotoxic endpoints observed in animal studies and their case reports of human fatalities from intoxication. Both scored high due to a lack of monitoring, however compared to TTX, PITX has not yet been detected in UK waters or shellfish thus scoring lower overall.

38. MCs rank third despite toxicological data reporting moderate adverse health effects including gastroenteritis and hepatoxicity, compared to more severe neurotoxic endpoints of the other marine biotoxins. MCs rank higher due to reports of human deaths after intoxication, i.e., compared to BTX for which only intoxications were reported and the CIs SPX and GYM which have no known human case reports. The detection of MCs in Lough Neagh Northern Ireland also attributes to the risk of MC over BTX and GYM which have both only been reported in northern EU.

39. Two toxins SPX and BTX achieved an identical score of 13 with the differences being due to their H, O and T scores. The COT agreed that in the instance of a tied score human data would be prioritised followed by toxicology/experimental animal data, and lastly occurrence data. Applying the Committees weighing of the evidence, BTX ranks higher than SPX, due to reported intoxications of BTX compared to no available human information for SPX.

40. GYM achieved the lowest score due to an absence of any published reports of intoxication in humans. In addition, GYM also achieved a low occurrence score as it has only been reported in France.

### Uncertainties

41. The key challenge in risk ranking these emerging marine biotoxins is the lack of toxicological/human data and occurrence data in UK waters. Most of the toxins are not routinely monitored, in the UK or other EU countries and therefore it is unclear whether these biotoxins could already be in UK waters. This adds considerable uncertainty when considering the prioritisation of which toxins pose the greatest risk to the UK population.

42. The potential underreporting of intoxications, especially in individuals suffering from mild to moderate adverse health effects, such as nausea and vomiting, could lead to a considerate underestimation of the risk, resulting in a lower risk ranking. Given the severity of the effects, underreporting may potentially be less significant for neurotoxic endpoints, but this may especially be a problem for gastrointestinal symptoms. There is also considerable uncertainty whether reported adverse health effects were caused by one specific biotoxin, or a combination of biotoxins or other potential complications. In a lot of cases, data on the specific marine biotoxin was lacking. Reports of mild or moderate health effects were likely not monitored long term so symptoms could have worsened, or other issues could have arisen later, that were not directly thought to be associated with the biotoxin.

43. Toxicity data is limited for all emerging marine biotoxins discussed in this statement. LD50s from a limited number of animal studies were used to help distinguish risk profiles; however, the small number of studies limited the reliability of the risk estimation and added further to the overall uncertainty of the rankings.

44. Insufficient toxicological data also means HBGVs could not be derived and a reliable estimate of exposure to emerging marine biotoxins could not be conducted.

45. The approach proposed here to risk rank the emerging marine biotoxins cannot account for the possibility of exposure to multiple toxins.

46. For cyanotoxins there is a substantial lack of data for all except MCs, hence they have not been included in this risk ranking. Sufficient data were not available to apply a read across method. Hence, it is unclear whether or how they

may contribute to the reported adverse effects of MC.