Discussion

In this guide

35. The risk ranking method was applied to six emerging marine biotoxins, allocating each a score of 1-5 points according to four different

categories, i.e., monitoring, human case reports, toxicity and occurrence data. 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	M	T	H	O
TTX	19	4	5	5	5
PITX	17	5	5	5	2
MC	15	4	3	5	3
SPX (CI)	14	4	5	1	4
BTX	13	4	4	3	2
GYM (CI)	11	4	4	1	2

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

36. This process 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 case reports of human fatalities from intoxication. Both scored high due to a lack of monitoring; however, PITX has not yet been detected in UK waters or shellfish and therefore scored lower than TTX overall.

38. Although the toxicological data for MCs reported moderate adverse health effects including gastroenteritis and hepatoxicity, they rank third, which puts their score ahead of other marine biotoxins with more severe neurotoxic

endpoints. The reason for MCs higher score were the reports of human fatalities after intoxication, while there were only reports of intoxications reported for BTX (no fatalities) and no reports for CIs, SPX and GYM. The detection of MCs in Lough Neagh Northern Ireland also contributes to the higher risk of MC compared with BTX and GYM, which have both only been reported in northern EU.

39. SPX ranks fourth above BTX despite there being no reported human cases of SPX exposure (compared to BTX with reported intoxications). Both are neurotoxic in animal studies; however, the LD50 measured in animal studies was several folds higher for BTX than SPX. In addition, while BTX has only been reported in France, SPX has recently been detected in shellfish across the UK, resulting in a slightly higher overall score for SPX.

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

41. While there are no tied scores, the COT agreed that in the instance of a tied score, human data should be prioritised, followed by toxicology/experimental animal data, and lastly occurrence data. This approach was considered most conservative for protecting consumers.

Uncertainties

42. The key challenge in risk ranking these emerging marine biotoxins was 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 toxins posing the greatest risk to the UK population.

43. Climate change and rising sea temperatures are a potential concern when it comes to the occurrence of marine biotoxins. However, due to the extremely limited available data, especially for the UK, the extent to which this has influenced current occurrence levels or will affect future biotoxin distribution remains unknown.

44. The potential under-reporting of intoxications, especially in individuals suffering from mild to moderate adverse health effects such as nausea and vomiting, could lead to underestimation of the risk associated with a particular biotoxin, resulting in a lower risk ranking. Given the severity of neurotoxic effects,

under-reporting is less likely for these endpoints, but under-reporting may be a particular 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 many cases, data on the specific marine biotoxin to which a subject had been exposed was lacking. Reports of mild or moderate health effects were likely not monitored in the long term so symptoms could have persisted, worsened, or other issues could have arisen later that were not directly thought to be associated with the biotoxin.

45. Toxicity data was 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. The animal studies also focused on acute effects meaning there was very limited information on potential chronic effects of biotoxins. The limited available animal and human evidence on both emerging and regulated biotoxins, does indicate that measures to protect against acute effects also protect against chronic effects. However, a level of uncertainty remains around the potential chronic health effects of marine biotoxin exposure.

46. Insufficient toxicological data also meant that HBGVs could not be derived and reliable estimates of exposure to emerging marine biotoxins could not be conducted.

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

48. For cyanotoxins there was a substantial lack of data for all except MCs; cyanotoxins were not included in this risk ranking. Sufficient data were not available to apply a read-across method. Hence, it is unclear whether or how cyanotoxins may contribute to the reported adverse effects of MC.