



## **Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment**

### **Statement of Advice on the Risk to Human Health from Consumption of Bivalve Molluscs (shellfish) Harvested from UK Waters Associated with Marine Biotoxins: Lay Summary**

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked by the Food Standards Agency (FSA) to evaluate whether emerging marine biotoxins found in shellfish harvested from United Kingdom (UK) waters may pose a risk to human health.

Marine biotoxins are naturally occurring toxic compounds produced by certain types of algae. These biotoxins can accumulate in shellfish such as mussels and oysters and may cause illness if consumed. The presence of some biotoxins in UK or European Union (EU) waters is already known and they are routinely monitored and regulated in the UK. Others are considered “emerging marine biotoxins” because they have not previously been prevalent in UK waters but may become so due to several factors, including environmental changes such as climate change and warming seas. These factors can alter the global distribution of marine biotoxin-producing algae, increasing the likelihood that emerging marine biotoxins will be detected in UK waters and shellfish.

Groups of emerging marine biotoxins with related chemical structures and potencies have been identified through literature searches and by evaluating assessments from other authorities such as the European Food Safety Authority (EFSA) and Centre for Environment, Fisheries and Aquaculture Science (Cefas). These biotoxins

are not yet regulated or included in official monitoring programmes, so there is very little data on their current prevalence, levels, or distribution. Toxicological studies are also limited. As a result, the COT could not undertake a full risk assessment. Instead, it developed a numerical risk ranking approach to determine which emerging marine biotoxins might be of higher potential concern.

This risk ranking approach is a prioritisation tool; it is not a measure of current risk to UK consumers and does not replace a formal risk assessment. The risk ranking will, however, support prioritisation of marine biotoxins and decision-making by policy colleagues.

The numerical risk ranking approach considered four different categories of evidence: (1) the extent to which each toxin is currently monitored; (2) the available toxicological data based on animal studies; (3) documented reports of human illness or death; and (4) whether the toxin has been found in UK or EU shellfish and waters, and if possible how frequent that occurrence is.

Using this approach six groups of emerging marine biotoxins were prioritised from highest to lowest risk: tetrodoxins (highest), palytoxins, microcystins, spirolides, brevetoxins and gymnodimines (lowest). Other toxins, including azaspiracids, pteriatoxins and domoic acid analogues, were also considered but were excluded from the risk ranking due to insufficient information. A “read across” (using data from similar toxins) approach was explored to generate temporary rankings for these toxins but the Committee found this method was too uncertain to provide robust scores.

The risk ranking approach in general is limited by a lack of data, including: (1) the absence of routine monitoring programmes, meaning that in most cases it was unclear whether these emerging biotoxins are already present in UK waters or shellfish; (2) the potential underreporting of human illness, especially in cases in which only mild or moderate symptoms such as diarrhoea are experienced and individuals may not seek medical attention or report their symptoms; (3) missing information on human case reports that could influence the observed effects, such as pre-existing health conditions, possible exposure to multiple biotoxins and how long symptoms of illness lasted; and (4) the limited amount of toxicological data available on these emerging marine biotoxins. These limitations preclude the

derivation of health-based guidance values (HBGVs). The lack of an HBGV further limits the conclusions that can be drawn on potential risks to public health because it is not possible to establish a level of exposure that would cause no adverse effects.

Despite the uncertainties in the database, the risk ranking approach applied in this assessment provides a useful prioritisation tool to support decision-making. As more data become available, the understanding of risks associated with these marine biotoxins will improve and a formal risk assessment may become possible.

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