Introduction and Background

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

Introduction

1. The Food Standards Agency (FSA) is considering the current advice and monitoring programme for marine biotoxins and whether there is a need to update or change existing legislative standards. The main purpose of this work is to identify any emerging marine biotoxins in UK waters, including increased occurrence due to rising temperatures as a result of climate change. The views of the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) were sought on whether the identified emerging marine biotoxins could pose a risk to human health.

2. A scoping paper and a summary paper were presented to the COT in 2023 and 2024 respectively (TOX/2023/59; TOX/2024/25). These provided an overview of emerging marine biotoxins with summaries of any available toxicological information, occurrence data with an emphasis on UK waters, estimated adult exposures to the marine biotoxins and any additional relevant

information. The Committee decided that it was not possible to conclude on the risks of the emerging biotoxins due to a lack of information, most notably toxicologic studies, without which deriving health-based guidance values (HBGVs) was not feasible. Instead a numerical risk ranking was proposed by the Committee and discussed in March 2025 (TOX/2025/15) to assist in prioritisation of the biotoxins. Risk rankings for each group of biotoxin were generated by assigning a numerical score to each biotoxin for the following categories: toxicity, occurrence, human case reports, and monitoring.

3. The following statement provides the risk ranking and advice of the COT on whether the identified emerging marine biotoxins would pose a risk to health.

4. Please note, pinnatoxin (PnTX) (TOX/2023/37) and pectenotoxin (PTX) (TOX/2023/58) have been discussed separately and have not been included in this statement.

Background

5. Marine biotoxins are natural toxic metabolites produced by marine phytoplankton and can bioconcentrate in shellfish, and along the food chain. If concentrations of these toxins in shellfish are sufficiently high, then consumption of these shellfish can result in human illness.

6. Marine biotoxins have previously been categorised based on clinical signs but are increasingly being categorised by chemical structure. The structural toxin groups that are generally considered to be of relevance to shellfish harvested in European waters are:

- Domoic acid group (DA),
- Saxitoxin group (STX),
- Okadaic acid group (OA),
- Pectenotoxin group (PTX),
- Azaspiracid group (AZA),
- Yessotoxin group (YTX),
- Cyclic imine group (CI).

7. Marine biotoxins can also be categorised according to their water solubility which determines the extraction protocol required for analysis. The DA and STX groups are hydrophilic, while the OA, PTX, AZA, YTX and CI groups are lipophilic. The DA group is associated with amnesic shellfish poisoning (ASP), the

STX group with paralytic shellfish poisoning (PSP) and the OA group with diarrhetic shellfish poisoning (DSP).

8. In the United Kingdom (UK) and European Union (EU), there are currently three major biotoxin groups that are regulated in shellfish, and which are subject to statutory testing to protect human health. The biotoxins specified within the Assimilated EU Regulation (EC) No. 853/2004 (E&W, and Scotland) and EU Regulation (EC) No. 853/2004 (NI) are PSP toxins (STX and relevant analogues), the lipophilic toxin group (OA, AZA, PTX and YTX) and ASP toxin (DA).

9. In the UK the Agri-Food and Biosciences Institute (AFBI) is the Great Britain (GB) National Reference Laboratory (NRL) for marine biotoxins. The Centre for Environment, Fisheries and Aquaculture Science (Cefas) are designated as the official laboratory (OL) for marine biotoxins in England, Wales and Scotland. Northern Ireland's NRL for marine biotoxins is Wageningen Food Safety Research (WFSR) and the designated OL AFBI who undertake analysis and reporting of shellfish official controls (OCs). A shift from biologically based assays (such as the mouse bioassay (MBA)) for marine biotoxin testing to validated chemical methods has been implemented in the UK and EU due to their increased specificity and ethical concerns over animal use, although biological methods may still be used in limited or exceptional cases.