Public health risks of histamine and other biogenic amines from fish and fishery products

THE PROBLEM
Scombrotoxin fish poisoning (SFP), often called “histamine poisoning”, is caused by ingestion of certain species of marine fish with high levels of histamine and possibly other biogenic amines. In some parts of the world, SFP is a major cause of food-borne illness. The fish species involved contain high levels of free histidine in their tissue and include tuna and other pelagic species like mackerel, sardines, and anchovy. When these species are subjected to temperature abuse\(^1\) during and/or after harvest, bacterial decarboxylation of histidine leads to histamine formation. Other biogenic amines produced as a result of bacterial growth in fish may potentiate histamine’s effect.

Risk management challenges
Codex Alimentarius through its standards and guidelines aims to provide countries with tools to manage food safety issues such as histamine in fish. Together with guidance on good practices, different histamine limits have been established by Codex as indicators of decomposition and as indicators of hygiene and handling. However, many of these limits were established in a pre-risk assessment era and their scientific basis is unclear. As food safety management moves towards more risk- and evidence-based approaches, there is a need to review existing limits to ensure that they are scientifically based and take into account all the available evidence. At the request of Codex, FAO and WHO have elaborated scientific advice on the public health risks associated with histamine from fish and fishery products through an expert consultation process.

RISK ASSESSMENT
In the FAO/WHO risk assessment\(^2\), the hazard identification process considered all biogenic amines and concluded that there is compelling evidence that histamine is the most significant causative agent of SFP and that histamine can be used as an indicator of SFP. Using the available data for hazard characterization, it was also concluded that 50 mg histamine is the no-observed-adverse-effect level (NOAEL) and based on a serving size of 250g, it was calculated that the maximum concentration of histamine in a serving that would not cause adverse effect is 200 mg/kg. Based on data made available by industry, the meeting noted that when food business operators apply good production practices.

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1. Generally higher than 25 °C for more than 6 hours or for longer at lower temperature
hygienic practices (GHP) and the hazard analysis critical control point (HACCP) system, levels of histamine in fish products less than 15 mg/kg were achievable.

It is recognized that further research is needed in particular to clarify the critical role played by histamine and other biogenic amines in the pathogenesis of SFP.

**RISK MANAGEMENT**

**Prevention and control**

- Histamine formation and SFP can be easily controlled. The risk from SFP is best mitigated by applying basic GHPs and, where feasible, a HACCP system. FAO provides a number of resources as well as technical assistance to support the implementation of GHPs and HACCP systems.

- Appropriate sampling plans and testing for histamine should be used to validate the HACCP systems, verify the effectiveness of control measures, and detect failures in the system.

- Sensory evaluation remains a highly useful tool for quality control programmes, but acceptable sensory quality cannot be taken as final assurance of low histamine, nor can low histamine be taken as final assurance that fish is not decomposed.

**Histamine sampling plans**

The purpose of testing is not to control the problem of SFP, but rather to verify that all the necessary control measures have been implemented effectively in the system and remove implicated products from the market. In order to provide more explicit guidance on sampling approaches the FAO/WHO expert meeting analysed a range of sampling plans implemented under different scenarios of histamine levels. Examples of attributes sampling plans appropriate to different levels of tolerance for samples above 200 mg/kg, and for different assumptions about the standard deviation of histamine concentration within lots are provided in the expert meeting report. However, this cannot cover all scenarios and following one of the recommendations of the expert meeting, FAO and WHO have developed a user-friendly tool to support decision-making related to the establishment or use of sampling plans for detection of histamine at the national and /or operational level. The tool provides support in two main areas related to sampling for histamine:

- **Designing a Sampling Plan**
  - This tool function attempts to find sampling plans which meet user-defined objectives, by searching for combinations of the number of samples (n) and a concentration threshold (m).

- **Analyzing the performance of a Sampling Plan**
  - This tool function estimates the probability of accepting lots of product tested according to a user-defined sampling plan.

The FAO/WHO histamine sampling plan tool - [www.fstools.org](http://www.fstools.org) - is a free resource available to national authorities and operators to support the development of an appropriate sampling plan.

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