



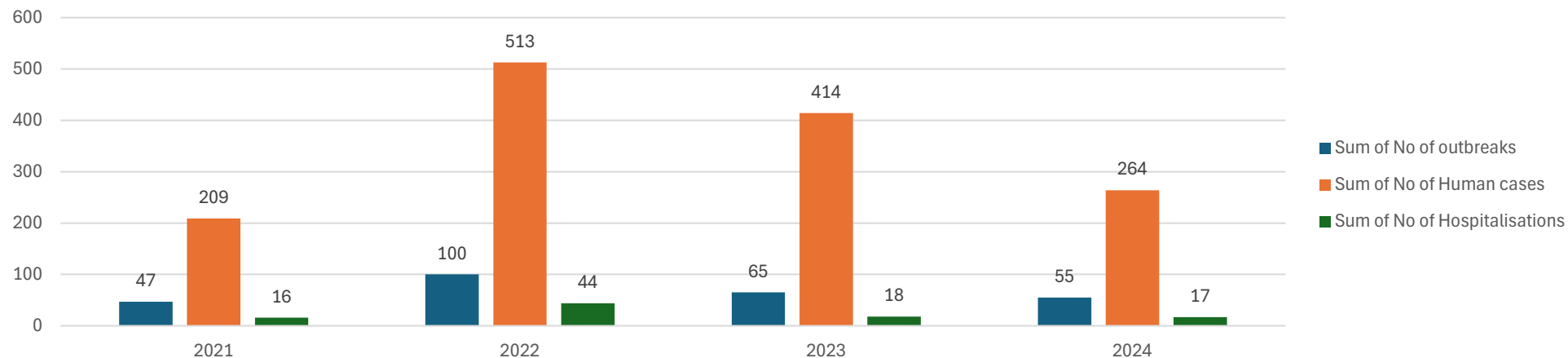
Histamine overview report

DG(SANTE) F1 - Food

NAS network meeting – 2 June 2026

Why Histamine?

- common toxicity - fish ingestion
- increased number of cases



Why Histamine?

- SANTE F audits:
 - control challenges & non-compliances
- Hygiene and temperature control key
- Fraudulent practices



Objective



- Up-to-date view of implementation of official controls (including testing)
- Challenges
- Good practices



Process

1. Questionnaires to CAs
2. MS replies to the questionnaires
3. Overview report

Outcomes

- Overview report will be published soon at:
- <https://ec.europa.eu/food/audits-analysis/overview>



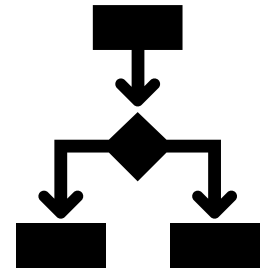
Main conclusions



- Official control systems include risk-based official controls over histamine at relevant parts of the production chain.
- These controls are supported by laboratory testing of official samples in designated and accredited laboratories

Competent authorities procedures-training

- In general procedures in place and inspectors trained.
- Several MSs
 - Gaps with procedures not covering key aspects.
 - Room for improvement in staff training.



Good practices

- IE, ES and PT include all relevant elements both in their procedures and in the training for their staff. 90 to 100% staff formally trained covering all required aspects of histamine.

Official controls over Food Business Operators

- Controls verify that operators have adequate HACCP procedures and checks for fish susceptible to histamine formation.
- Challenges for operators to comply due to:
 - a lack of understanding or training
 - and difficulties in implementing sampling plan and laboratory methods required.



HACCP



Sample units and pooling

- Sample units
 - Most MSs require 9 sample units
 - Some apply flexibility and fewer samples taken
 - Reliability of analytical results?
- Pooling
 - 7 MSs allow pooling under different conditions
 - Accuracy of results
 - No harmonisation



Validation of laboratory testing methods

- Regulation 2073/2005: Lack of clarity for use and validation of alternative methods (against ISO 19343) and use of other analytical methods.
 - ISO 16140-2 microbiology testing.
 - Different criteria when authorising alternative/other analytical methods
 - CAs accept other analytical methods validated in accordance with internationally accepted protocols. No harmonised criteria.
 - Over/underestimation? Limits applied?

Good practices

- 10 Member States require that operators use accredited laboratories for the analysis of histamine. This provides for a higher level of reliability of the test results.



Official sampling and testing



- Sampling
 - All MSs sample and test for histamine within official controls.
 - All MSs but one take 9 subsamples.
 - Three MSs allow pooling of samples with adjusted acceptability limits.
- Laboratory testing
 - No EURL.
 - Formally designated labs
 - In general accredited and with satisfactory PTs.
- Laboratory methods
 - 8 MSs reference method
 - Validation of alternative methods done on the basis of international accepted protocols

Example of good practice

- In 12 Member States, a national reference laboratory for histamine has been formally designated.

Matters for consideration for Member States

1. **To ensure that all staff conducting official controls in the fishery products food chain are trained to properly assess histamine related matters.** This would allow for more consistent official controls to detect unsuitable practices and the harmonisation of the criteria for both official controls and sampling.
2. **To develop/improve procedures related to the official controls regarding histamine.** This would allow for better harmonisation of official controls.
3. **To support small business operators to train their staff.** Shortcomings of the knowledge and understanding of the rules related to histamine sampling and testing have been identified as one of the main challenges encountered during official controls.



Matters for consideration for the Commission services

1. **To develop or adopt a suitable standard for the validation of alternative methods against the reference method**, as the one mentioned in Article 5 or Regulation (EC) 2073/2005 is meant for microbiological methods and it is not suitable for histamine. This would allow for the use of alternative methods which may enhance competitiveness and robustness of the testing network of laboratories used by the operators.
2. **To clarify under which circumstances (if any) pooling can be done and which limits should be used.**
3. **To clarify to Member States whether the number of unit samples for histamine may be reduced**, and in such a case, what should be the applicable acceptance criteria.
4. **To provide clear guidelines and criteria to the competent authorities for the acceptance of other analytical methods** validated in accordance with internationally accepted protocols.



New areas of work of F1 related to fishery products

- Audit Series on specific processed fishery products 2027-28: focus on industrially produced fishery products that use mechanically separated fish meat (typically traded in blocks) and fish paste (industrial surimi) as their raw material.
 - 4-5 Member States
 - 3-4 Third countries
- Fact-Finding Series on fish oil 2026-27: focus on human grade fish oil:
 - 3 Member States
 - 3 Third Countries





Thank you



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