European Commission

Health and Food Safety

OVERVIEW REPORT

EU Member State Survey on Histamine controls in fish 2025

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and Food Audits and Analysis

DG(SANTE) PR-2024-0002

OVERVIEW REPORT

ON

THE OFFICIAL CONTROL SYSTEMS REGARDING HISTAMINE IN FISH

EXECUTIVE SUMMARY

The report describes the outcome of a project looking at Member States' approach to histamine in fishery products carried out in 2025 and 2026.

Histamine toxicity (or scombroid poisoning) is a form of food poisoning associated with the consumption of spoiled fish. There are regular reports of consumers being affected by histamine toxicity each year, some requiring hospitalisation. Appropriate hygiene and maintenance of the cold chain during handling, storage, transport and distribution are key to reduce the risk associated with histamine.

In general, 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. However, this report identifies gaps in the official control procedures and significant weaknesses in staff training in some Member States.

Official controls reveal the challenges for operators to comply with the rules on histamine, due to lack of understanding or training and difficulties in implementing the sampling plan and the testing methods used. In some cases, the competent authorities accept that operators modify the sampling plan established by the European Union (EU) rules, which calls into question the consistent implementation of the requirements through the EU.

The EU rules on testing histamine provides operators with the use of alternative histamine testing methods which are to be validated against the reference one, or other analytical methods that shall be validated in accordance with internationally accepted standards. However: i) the rules do not provide for an adequate standard to carry out the validation of alternative methods against the reference one, and ii) there are not harmonised criteria in the Member States for accepting the validation of other analytical methods.

All Member States sample and test for histamine as part as their official controls and laboratories are formally designated and are accredited in most cases. The EU reference method (EN ISO 19343) is used by around half of the Member States and others use a wide range of other analytical methods validated in accordance with international protocols.

In the absence of an EU Reference Laboratory for histamine, there is not a body in the EU leading in harmonisation of methods and practices. Several Member States have designated National Reference Laboratories to cover this gap in their territory.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
EU	European Union
EURL	European Union Reference Laboratory
FBO	Food Business Operators
HACCP	Hazard Analysis and Critical Control Points
OCR	Official Controls Regulation - Regulation (EU) 2017/625
RASFF	Rapid Alert System for Food and Feed

1 INTRODUCTION

Histamine is a biogenic amine that poses significant food safety concerns, particularly in fishery products derived from species rich in the amino acid histidine. Notably, species such as tuna, mackerel, and sardines contain high levels of free histidine in their muscle tissues. Post-mortem, this histidine can be converted into histamine through the action of specific bacteria which possess the enzyme histidine decarboxylase (including *Morganella spp.*, *Klebsiella spp.*, *Enterobacter spp.*, and *Proteus spp.).*

After fish are caught and die, bacterial invasion can occur rapidly, facilitated by the breakdown of tissue integrity, allowing bacteria to move from external surfaces and through bodily fluids into the muscle layers. The circulatory pathways and tissue decomposition (spoilage) further enable bacterial spread. These bacteria thrive, particularly in suboptimal storage conditions such as warmer temperatures, accelerating the conversion of histidine into histamine.

Improper handling and delayed cooling of fish post-capture can exacerbate histamine production, leading to potential health risks such as scombroid food poisoning, characterized by symptoms like flushing, headaches, and gastrointestinal distress. Therefore, maintaining the integrity of the cold chain and practicing good hygiene during the handling and processing stages are critical prevention strategies to ensure the safety and quality of fishery products.

Food business operators (FBOs) are responsible for properly handling and/or processing fishery products and to maintain the cold chain through all the stages from catch/harvest to retail. Competent authorities shall implement appropriate, and risk based official controls in order to verify operators' compliance with the European Union (EU) rules, including sampling and laboratory testing.

2 OBJECTIVES, SCOPE AND METHODOLOGY

In 2025, the EU Commission's Directorate for Health and Food Audits and Analysis submitted a questionnaire on the official controls related to histamine in fishery products to the competent authorities of the 27 EU Member States. This report outlines the analysis of the responses to this questionnaire.

The main objective of the questionnaire was to obtain a comprehensive up-to-date EU wide view of the implementation of official controls (including associated laboratory testing) over histamine in fishery products, challenges/areas where more clarity or guidance is required, instances of "good practice" and measures aiming to address the existing challenges as well as a more accurate picture of the level of compliance

The scope of the project is linked to the current EU food law, in particular with the matters covered by Regulations (EC) No 852/2004, No 853/2004 and Regulation (EU) No 2017/625.

The project focused on:

- Fishery products derived from tuna and other species associated with a significant or high content of histidine.
- Official controls on the fishery products mentioned above and the associated FBO along the production chain.
- Laboratories used for testing samples for histamine and the methods of analysis.

3 BACKGROUND

Legislative framework

The EU has a comprehensive regulatory framework regarding fishery products and the related official controls.

All FBO, regardless of their size or type, must comply with basic hygiene requirements. Since 2006, the EU has applied a harmonised food hygiene policy known as the "Hygiene Package", which sets a single framework of rules for all food and food businesses across Member States. Rules on hygiene of foodstuffs were adopted in April 2004 by Regulations (EC) No 852/2004 and 853/2004 of the European Parliament and of the Council.

In addition, Commission Regulation (EC) No 2073/2005 lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by FBO when implementing the general and specific hygiene measures. This Regulation lays down the maximum levels of histamine permitted in fishery products from fish species associated with a high amount of histidine, particularly belonging to the families: *Scombridae* (e.g. mackerel, tuna and bonito), *Clupeidae* (e.g. herrings and sprats), *Engraulidae* (e.g. anchovy), *Coryfenidae* (e.g. mahi-mahi, dolphinfish or dorado), *Pomatomidae* (e.g. bluefish) and *Scombresosidae* (e.g. the Atlantic saury).

The role of the competent authorities with regards to performing official controls and other official activities, is laid down by Regulation (EU) 2017/625 of the European Parliament and of the Council (hereafter, the Official Control Regulation - OCR). Among others, the OCR requires that inspections target FBOs that pose a higher risk.

Practical arrangements for the performance of official controls on products of animal origin intended for human consumption are laid down in Commission Implementing Regulation (EU) 2019/627: Title VI lays down specific requirements and uniform minimum frequency of official controls with respect to fishery products, and Article 70 sets out that official controls shall include random testing for histamine to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

Official oversight

FBO shall ensure that foodstuffs comply with the relevant microbiological criteria laid down in Regulation (EC) 2073/2005, and therefore, the applicable histamine limits. To this end, the FBOs at each stage of food production, processing and distribution, including retail, shall take measures to ensure that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use. The competent authority shall verify compliance with these rules in accordance with the OCR and relevant implementing acts which introduce measures to ensure laws are implemented in the same way throughout the EU countries.

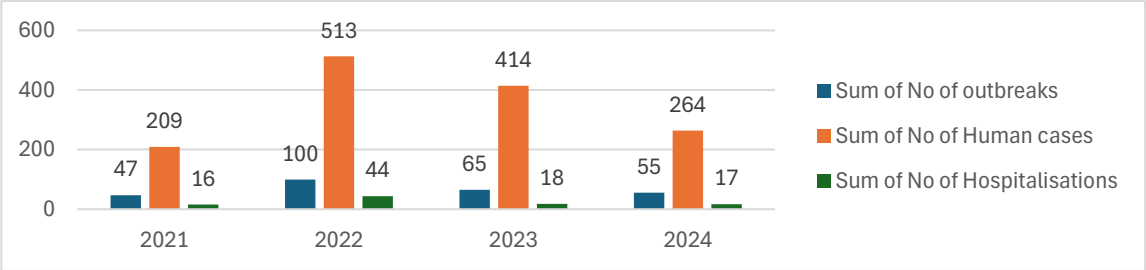
Statistical information shows that the total EU catch in 2024 was an estimated 3.2 million tonnes live weight (Source: EUROSTAT) of which, at least 1.5 million tonnes (around 46%) are species associated with a high content of histidine, and therefore, with a higher risk of producing histamine if appropriate handling and processing practices are not observed.

4 FINDINGS AND CONCLUSIONS

Foodborne outbreaks caused by histamine, RASFF Notifications and National alerts

Every year, the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) present the results of zoonoses monitoring and surveillance activities carried out in the 27 Member States. The chart below shows the data gathered for the period 2021 to 2024 regarding the number of foodborne outbreaks caused by histamine, the number of human cases and the number of hospitalisations. Overall, there is a decreasing trend in outbreaks since the peak of 2022 and the number of outbreaks with hospitalisations remaining in the same level. No deaths were reported due to histamine over this period.

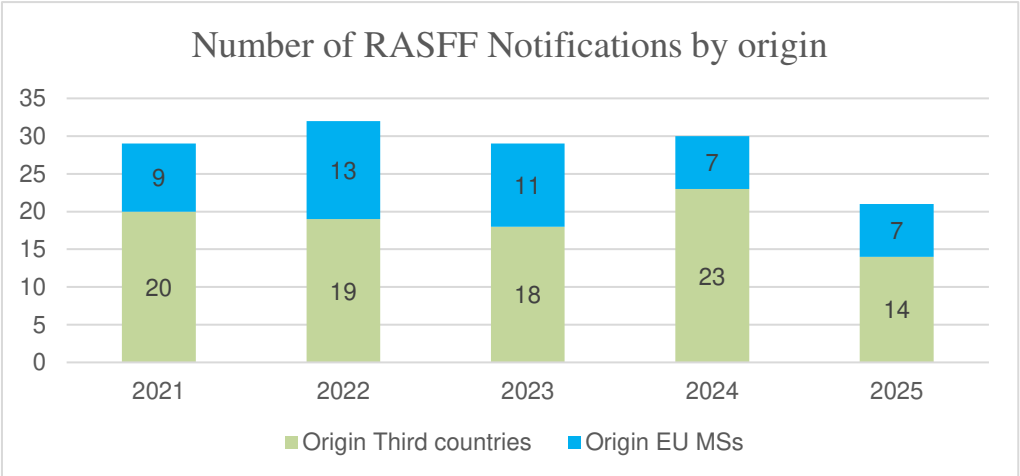
Chart 1. Number of outbreaks/human cases/hospitalisations linked to histamine for the period 2021 to 2024.



As part of the food safety tools, the EU established a Rapid Alert System for Food and Feed (RASFF) to ensure the exchange of information between member countries to support a swift reaction by the food safety authorities in case of risks to public health resulting from food or feed so that they can take immediate action to avert the risk.

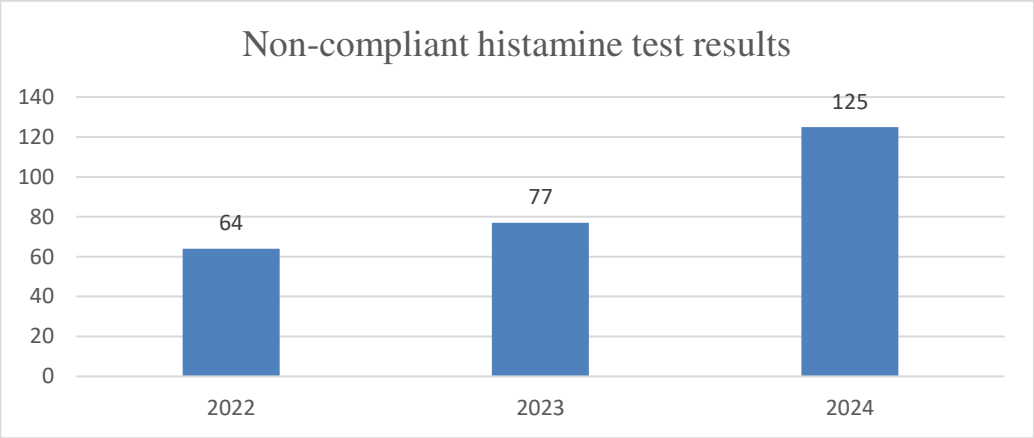
Chart No2, shows the number of RASFF notifications issued in the period 2021 to 2025. This shows that there are regular notifications (with both Member State and third country origin), albeit there has been a significant decrease in 2025. However, the available data are insufficient to confirm a trend.

Chart 2. Number of RASFF notifications associated to histamine for the period 2021 to 2025 by origin of the product.



In addition to RASFF notifications, Member States can issue national alerts that are not communicated to the RASFF portal in cases where the fishery products have remained in the country. Member States were asked to provide information on the number of samples that were non-compliant regarding histamine content which did not trigger a RASFF notification. The following chart shows the figures for the period 2022 to 2024 which indicates a significant increase in the number of national alerts over recent years.

Chart 3. Number of non-compliant histamine test results not triggering RASFF notifications



For these non-compliant histamine results not linked to RASFF notifications, three Member States identified practices that may have led to histamine formation:

- Related to temperatures and cold chain:
  - Poor preservation of the product, including unsuitable temperatures during storage and distribution.
  - A break or "rupture" of the cold chain, which promotes the growth of histamine-producing bacteria affecting the stability of the fish during distribution and marketing.
  - Storage and handling at an unsuitable temperature, which accelerate the conversion of histidine to histamine.
  - Inadequate freezing and refreezing processes which may degrade the quality of the fish and promote the accumulation of histamine. Inadequate defrosting in for example frozen anchovy.
  - In the case of frozen tuna fillet, inadequate freezing and refreezing processes were detected.
- Related to fraudulent practices:
  - In a case of yellowfin tuna (*Thunnus albacares*), ascorbic acid was detected, at levels exceeding the maximum dose established for its use in the treatment of fish (an illegal treatment). This treatment affects colour changes and may mislead consumers with regard to freshness.
  - Presence of nitrites and nitromyoglobin, indicative of an illegal treatment to simulate freshness and prolong the shelf life of the product. Neither nitrates nor nitrites are authorised for use in fishery products, whether processed (except herring and pickled sprat) or unprocessed. These results seem to indicate

fraudulent practices with the aim of changing the appearance (and apparent freshness of the fish) and extending the time the product can remain on the market, which could lead to the formation of histamine, with consequent implications for food safety.

- Too long use after opening the cans.
- Unhygienic processing steps during drying or salting.

Conclusions

Histamine is a regular, long-standing cause of food poisoning in consumers.

Appropriate hygiene and strict temperature control during handling, storage, transport and distribution are key to reducing the risk associated with histamine.

Some competent authorities have identified temperature control issues and certain fraudulent practices that may lead to placing of unsafe product in the market.

Competent authorities and training

In 23 Member States, official controls related to histamine are harmonised throughout the country. In the case of the other 4 Member States, the existence of multiple different competent authorities has led to the implementation of different procedures. In these countries, official controls on fishery products are carried out either by multiple autonomous local authorities, or by different competent authorities depending on the stage of the chain. 22 Member States indicate that they have procedures in place specifically related to the official controls of histamine.

The official control procedures of these 22 Member States may include a number of elements relevant for histamine. The extent to which these elements are also included as part of the training of staff conducting official controls, is shown in the following table:

Elements of the official control procedures	**No of MSs including this element in their official control procedures**	**No of MSs including this element in the training of staff**
Aspects related to fish species of concern regarding histamine	20	22
Guidance on how to check that FBOs' HACCP procedures adequately cover the specific hazard of histamine in species of concern regarding the possibility of high histidine content	17	17
Sampling methodology	21	20
Testing methods	19	15
Targeting of sampling	20	18
Information on aspects that may lead to/support histamine formation in species of concern	17	17

In general, Member States indicate that their sampling targets species with high content of histidine and that sampling is conducted in line with Regulation (EC) No 2073/2005.

Member States were also asked to provide what percentage of the official control staff performing fishery controls has received training containing aspects related to histamine. Responses showed that:

- In five Member States no training has been provided on aspects related to histamine.
- Ten Member States indicated that the percentage of trained staff ranged between 80% to 100%.
- In three Member States, the percentage of staff trained on aspects of histamine was below 20%.
- Nine Member states could not provide statistical information.

Good practices

- Countries like Ireland, Spain and Portugal have included all relevant elements for histamine controls both in their procedures and in the training for their staff, and between 90 to 100% of their staff conducting inspections on fishery products have been formally trained covering all required aspects of histamine.

Conclusions

In general, competent authorities have procedures in place including histamine aspects and staff conducting inspections have been trained. However, there is room for improvement as there are several Member States with gaps in their official control procedures or weaknesses in staff training (to the extent that their ability to detect shortcomings could hinder the effectiveness of controls).

Official controls of FBOs

All 27 Member States have in place official controls to verify if FBOs handle/process correctly fish with high content of histidine. In particular, official controls routinely check that operators' Hazard Analysis and Critical Control Point (HACCP) procedures identify histamine as a hazard and that suitable own checks are carried out by the operators.

The competent authorities of 8 Member States highlighted the challenges they encounter in their controls over histamine regarding operators' HACCP based procedures:

- Five Member States highlight the lack of adequate knowledge by FBOs of the legislation and in particular, Regulation (EC) 852/2004 and Regulation (EC) 2073/2005 (which identifies species of concern). This was particularly evident in small establishments (post primary production) where operators were not fully aware of the importance of the implementation of good hygiene practices as a means of controlling histamine. Specifically, the following was noted:
  - Deficiency in the training of the personnel of companies responsible for quality control.
  - Insufficient awareness of operators of the need to control histamine and correctly apply procedures.

- FBOs are not fully aware that histamine is not eliminated in further steps of the production process, once it is formed due to poor hygiene practices in previous steps.

- Poor operator compliance with temperature control requirements.

- Difficulties in the implementation of sampling plans and method validation:
  - Problems in the implementation of the sampling plans laid down in Regulation (EC) No 2073/2005, especially in small enterprises.
  - The need to validate the sampling methods of operators to ensure their effectiveness.
  - Difficulty in assessing the soundness of sampling plans when pooling samples.
  - Costs of laboratory analysis in the context of own checks, are (according to the operators) too high.

- Insufficient controls over and deficiencies in the reception of raw material:
  - Lack of adequate controls on the reception of intermediate products (salted products, vacuum packed fish fillets) from other establishments or imported from other countries.
  - The operator relies on the guarantees provided by its supplier without carrying out its own verification.

- Problems in the control and conservation of products:
  - Inadequate maintenance of storage temperatures during marketing.
  - Non-compliances in the validation of defrosting processes.
  - Difficulties in keeping samples of each batch in the sample library by operators.

- Difficulties in histamine controls in the wholesale market:
  - Lack of controls by operators on fresh tuna.
  - Analytical results are usually obtained after the date of consumption of the product, making it difficult to make decisions.
  - Rapid marketing on wholesale markets (sale of the product within hours), which prevents systematic checks before distribution.

- Fraudulent processing techniques used during the processing of products that are difficult to detect, and legal loopholes in current rules that make it difficult to stop these practices. For example, product may be labelled to indicate that arginine has been used as an aroma, when in reality it is a precursor of nitric oxide, which helps keep the red colour of tuna stable and gives the appearance of freshness.

- Certificates/analysis reports submitted from third countries that are not verifiable because the examination method is not known, or the histamine levels are reported in units that do not provide comparability to the requirements of Regulation (EC) No 2073/2005.

Official controls include the verification of the reliability of the operators' sampling and testing for histamine in 24 Member States. 10 Member States described the aspects

checked for this verification and referred to compliance with Regulation (EC) 2073-2005 regarding for example the number of subsamples, the method of analysis, and that test results are compliant with the limits.

Conclusions

Official controls in all Member States verify that operators have adequate HACCP procedures and checks when handling or processing fish susceptible to histamine formation. Official controls reveal the challenges for operators to comply with the rules and that this is due to a lack of understanding or training and difficulties in implementing the prescribed sampling plan and laboratory methods required by EU rules for testing histamine.

Regarding the operators' sampling and testing, competent authorities were requested to provide their approaches to three specific questions: number of sample units; whether the authorities allow that operators to pool the samples before testing, and which testing methods are accepted - including the considerations regarding validation of alternative methods.

Number of sample units:

In their controls to operators, 24 Member States require that samples consist of 9 sub-samples as this is a requirement set out in Annex I to Regulation (EC) 2073/2005. In 4 Member States, the number of subsamples may be reduced where there is a) a history of good operator compliance, b) batches of small quantities, c) small fish or b) large fish, where one sample is sent to the laboratory which is subsequently divided into 9 subsamples. One Member state accepts 3 or 9 subsamples, and 2 Member states did not provide information on sample units.

Conclusions

Most of the Member States require operators to take 9 subsamples for histamine testing in line with the requirements of Regulation (EC) 2073/2005. However, some Member States apply flexibility approaches and allow for fewer subsamples to be taken which hinders the statistical grounds that support the establishment of such sampling plan with 9 units. This compromises the reliability of the analytical test result.

Pooled samples

Pooling samples in microbiological food analysis is a technique that combines multiple individual samples into one larger sample for testing. In the case of testing for histamine, the competent authority was required to describe whether they accept that FBOs combine the nine subsamples into one sample. Most Member States (20) do not accept pooling samples, while 7 replied that it is acceptable.

When pooling is accepted, some Member States have established stricter criteria for the acceptable upper limit of histamine in the analysis result:

- If the analysis result is above 7 mg/kg for the pooled sub-samples, all sub-samples must subsequently be analysed individually.

- Legislated upper limit (200 mg/Kg) divided by numbers of samples pooled. If the limit is exceeded all units must be analysed separately.

- Allowed only if the quantification limit of the method is sufficient to detect below the overall limit divided by the number of subsamples which is set as the new limit for the pooled sample. If this level is exceeded during the overall analysis (ex >20 ppm), an analysis of the 9 units as pert the sampling plan of the Regulation is requested.

- If the pooled sample value exceeds 15 mg/kg, a confirmatory analysis is carried out on individual samples. In these cases, the sample size in the confirmatory analysis is usually n=1.

- Two Member States indicate that the lower limit (100 mg/kg) set in Regulation (EC) 2073/2005 applies. One considers the upper limit (200 mg/Kg).

Conclusions

Most of Member States do not allow operators to pool sub-samples. However, there are Member States accepting pooling of samples. This approach can lead to inaccurate results, further exacerbated by the fact that there are no harmonised criteria for the limits set or the interpretation of the results.

Method and validation of alternative methods

Regulation (EC) 2073/2005 lays down the specific rules for testing in Article 5. The analytical method for histamine is the reference method ISO 19343.

The use of alternative methods is acceptable provided they are validated against the reference method in accordance with EN ISO 16140-2. The Regulation also allows for the use of proprietary methods provided they comply with certain rules. FBOs may use other analytical methods than those validated where such methods "have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority".

Member States did not provide information on whether modification of acceptance limits is considered when methods, other than the reference one, are used for testing histamine.

In their response to the questionnaire:

- 17 Member States require operators to use the reference method as per Regulation (EC) 2073/2005.

- 2 other Member States indicate that ISO 19343 is to be used, and alternative methods are accepted but without describing what steps are required to validate these methods in order to be accepted by the competent authorities.

- Another 8 Member States provided incomplete information (referring to "HPLC", but not the ISO method) or required "accredited methods" without indicating which one. One Member State did not provide any information.

More specifically, with regard to the validation procedures presented by operators and accepted by the authorities for alternative methods:

- Five Member States do not accept alternative methods.

One Member State indicated that the validation of an alternative method in accordance with EN ISO 16140-2 is not accepted because this ISO Standard applies to microbiology testing, whereas histamine requires chemical testing and does not fall under this category.

- 22 Member State accept alternative standards, of which:
  - One Member State referred to Guidance document of the EU Commission SANTE/11813/2017([1]) to be used as the validation procedure for histamine. Another Member State highlights that histamine is a chemical criterion and ISO 16140-2 does not apply and calls for an agreement within the EU to clarify this matter.
  - One Member State indicated that validation is accepted if it is according to Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling.
  - Two Member States require that operators demonstrate that other analytical methods have been validated by recognised bodies.
  - Seven Member States accept internal or in-house validations of the method. In some cases, Member States clarify the acceptance criteria:
    - Authorities require that the internally validated method should be included in the accreditation scope of the laboratory.
    - Regular comparison with HPLC obtaining equivalent results and participation at least once a year in an external proficiency test.
    - Good separation of the histamine peak is demonstrated by the laboratory

Uncertainty regarding validation of laboratory methods

Regulation (EC) 2073/2005 lays down the microbiological criteria for certain microorganisms (acceptability being based on the absence, presence or number of micro-organisms) and where relevant, includes their toxins and metabolites. Histamine is obtained by the decarboxylation of amino-acid histidine produced by the action of microorganisms and is a metabolite for which food safety criteria have been established.

This Regulation lays down the conditions for using (and validating) alternative analytical methods to the reference methods cited in the Regulation (Chapters 1 and 2). However, as the Regulation focuses on microbiology, the validation methods cited are intended for microbiological and not chemical testing.

The Regulation also foresees that FBOs may use other analytical methods than those validated or certified, where such methods have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority.

The use of other analytical methods validated in accordance with internationally accepted protocols, but which have not been validated against the reference method may call into question the use of the limits laid down in Regulation (EC) 2073/2005, as it is known that different methods may overestimate or underestimate the concentration of

[1] SANTE/11813/2017 Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed.

histamine in the sample.

Competent authorities have different criteria when authorising alternative or other analytical methods. The responsibility of the competent authorities to authorise the use of other analytical methods increase the burden on them and challenges the official control system regarding the capacity to take informed and consistent decisions through the Member State and the EU.

In 17 Member States, the authorities require that operators use accredited laboratories for the analyses of histamine. The other 10 Member States do not require accreditation on the basis that it is not mandatory under the EU rules.

Member States were questioned about the acceptancy of reducing or replacing FBOs' testing on the basis that either their suppliers or authorities have tested the product of the FBO.

No Member State accepts a reduction of the operator's planned testing on the basis that official samples were tested by the competent authorities, and 25 out of the 27 Member States do not accept replacing neither. Two Member States would accept that the operators do not test the batch of products that have been sampled for official controls by the authorities.

Several Member States (14) are more inclined to accept the reduction of operator's samples when suppliers have tested the product. When suppliers have tested the product, total replacement of the testing is accepted by 9 Member States.

Good practices

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

Conclusions

There is a lack of clarity with regard to the use and validation of alternative methods (against the EU reference method EN ISO 19343) and use of other analytical methods for histamine due to the fact that:

a) The ISO validation standard (ISO 16140-2) cited in Regulation (EC) 2073/2005 applies to microbiology testing and not histamine (a chemical) and due to this reason 5 Member States do not accept that FBOs use alternative methods.

b) There is a wide range of criteria that Member States apply when assessing the acceptance of the validation protocols for alternative methods against the reference method.

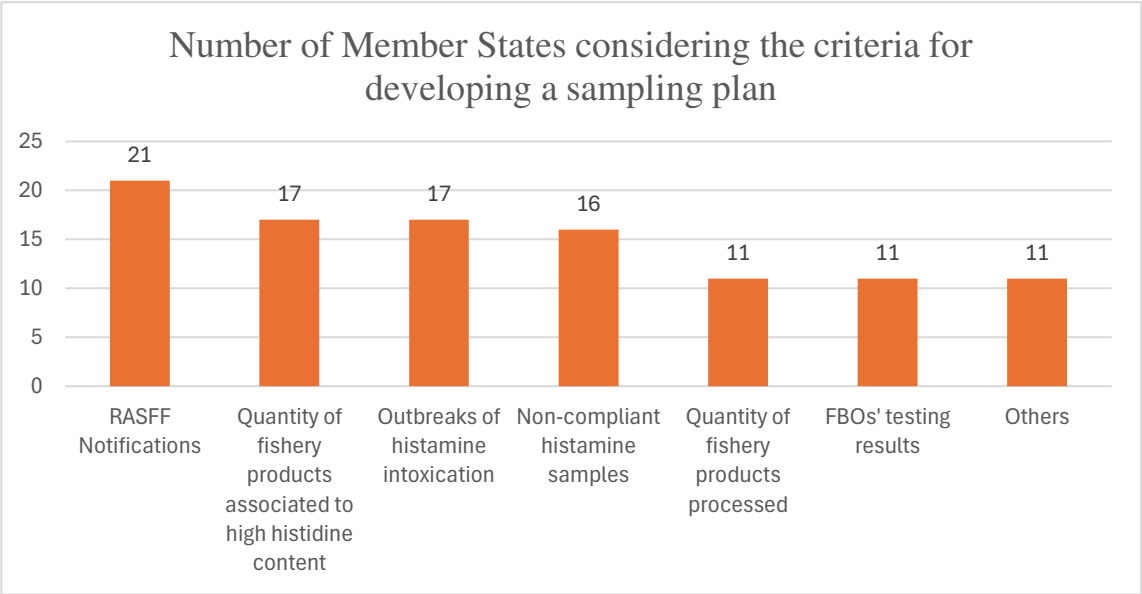
c) It is a prerogative of competent authorities to accept other analytical methods validated in accordance with internationally accepted protocols. However, there is not a harmonised criteria among these countries on the criteria for the acceptance of such validation schemes.

Official samples

All the 27 Member States take samples of fishery products for testing histamine as part of their official control systems.

For developing their sampling plan, the competent authorities have indicated the main criteria taken into account are as shown in the following chart:

Chart 4. Competent authorities' criteria for developing sampling plan



Member States were asked to identify the approach taken for official samples for testing histamine. The chart below shows the main types of sampling chosen by Member States:

Chart 5. Type of sampling of official controls

Regarding the nine-subsamples laid down in Regulation (EC) 2073/2005, the following table describe the approach taken by Member States.

Type of sampling			
	Less than 9 subsamples	9 sub-samples from nine individual fishes from a representative batch handled in the same conditions	9 sub-samples from the same fish (large individuals)
Number of Member States carrying out this type of sampling	1 Member State	25 Member States	6 Member States

The Member State taking less than 9 sub-samples described the compliance limit applied:

- Upper compliance limit (M) ([2]) divided by number of pooled samples. If the limit is exceeded for the pooled samples, each individual sample must be analysed separately. For 3-8 sample units. If one sample is between m and M further investigations should be performed. If two samples are between m and M the lot is not acceptable. If any sample is above M the lot is not acceptable.

In 24 Member States pooling of samples before testing is not allowed. In the other three Member States, pooling is acceptable "to streamline the process and minimise environmental impact, saving both technician time and reducing chemical usage".

- In one case, the applicable limits have been set to the quantification level which is significantly lower than the maximum levels permitted by Commission Regulation (EC) 2073/2005. If a pooled sample exceeds this limit of quantification (7 mg/kg), the individual subsamples must be analysed. In the view of the Member State, this approach incorporates a substantial safety margin. For instance, if one sample with a content of 63 mg/kg is pooled with eight samples devoid of histamine, the measured histamine content would result in a reanalysis of the individual samples (63 mg/kg divided by 9 equals 7 mg/kg). In comparison one sample can legally contain up to 200 mg/kg, which translates to a content of 22.2 mg/kg in a pooled sample.

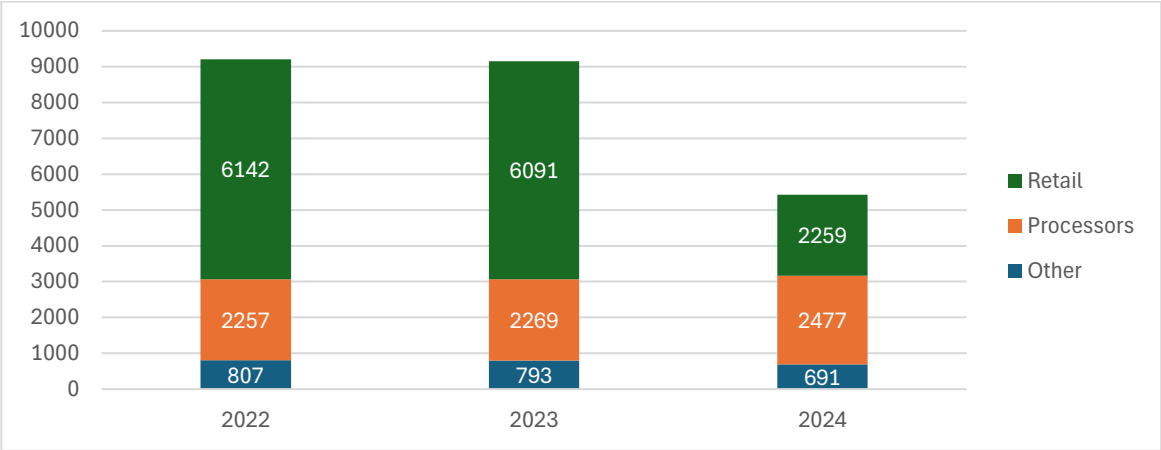
- In another Member State, the limit applied to the pooled sample is 22mg/Kg, and in case this limit is exceeded, all the individual samples are to be analysed separately.

All the 27 Member States declare that they do not use screening as part of their controls.

[2] Regulation (EC) 2073/2005 defines the sampling plan for histamine as 9 units comprising the sample, of which, 2 samples could give values between the lower limit "m" (100mg/Kg) and the upper limit "M" (200mg/Kg). Sample is not satisfactory when a unit exceeds the upper limit.

The number of official samples tested in the EU in the period from 2022 to 2024 is detailed in the following chart including the type of operator where the samples were obtained.

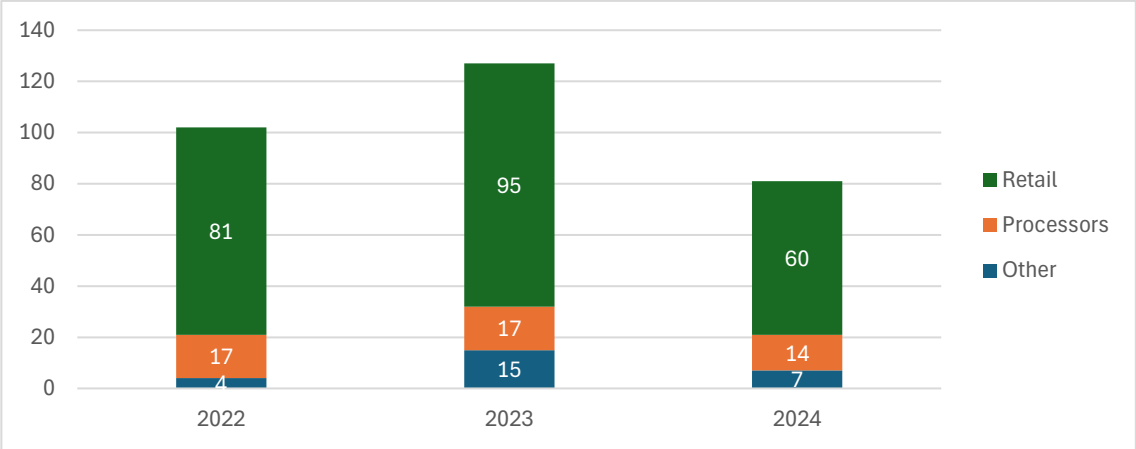
Chart 6. Number of official samples tested in the EU from 2022 to 2024



The significant drop in the number of samples in 2024 is mainly explained by the fact that one Member State that used to take a significant number of samples in previous years, did not take any sample at retail level in 2024.

The number of non-compliant samples are shown in Chart No 7:

Chart 7. Number of non-compliant samples from 2022 to 2024



Member States have defined the type of operator "other" to include border inspection posts "BCP", auction halls, wholesales stores and transport companies.

The following table shows that the percentage of non-compliant test for histamine has increased from 2022 to 2024. Due to the nature of the questionnaire, it is not possible to assess the root cause of this increase, which is more significant in the case of retail samples (from 1.32% in 2022 to 2.66% in 2024).

Year	No of samples	Non-compliant samples	% Non-compliance
2022	9206	102	1.11%
2023	9153	127	1.39%
2024	5427	81	1.49%

Conclusions

All Member States sample and test for histamine as part as their official controls, and with one exception, all takes the 9 subsamples as established in the sampling plan rules of the EU. However, three Member States allows for the pooling of the 9 subsamples into one and have adjusted the acceptability limits to this practice.

Laboratories and Testing Methods

National reference laboratory

The OCR lays down the rules for the Commission to designate European Union reference laboratories (EURL), and all the obligations, tasks and the responsibilities of such EURL. Examples of such responsibilities are the contribution to the improvement and harmonisation of methods of analyses, providing details and guidance on the methods of laboratory testing, and also by organising regular interlaboratory comparative testing or proficiency test.

Currently there is not a designated EURL for histamine, as the Commission has not considered there is a recognised need. In the absence of a EURL for histamine, Article 100(1) of the OCR allows for Member States to designate a national reference laboratory.

Example of good practice

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

Official laboratories

All Member States except one indicated that their competent authorities have formally designated laboratories testing official samples for histamine in line with requirements of Article 37 of the OCR.

The laboratories used for testing official samples are accredited in all 27 Member States. However, in two Member States, the method used for testing histamine is not included in the accreditation scope of the laboratory which does not comply with requirement of Article 37(4)(e) of the OCR.

Except in one Member State, all laboratories testing official samples for histamine participated in relevant proficiency test or interlaboratory comparisons in the period 2021-2024. The results of these proficiency tests were satisfactory except for one of the laboratories.

Conclusions

There are formally designated laboratories for testing official samples for histamine, and these laboratories are, in general, accredited and participating in inter-laboratories proficiency tests with satisfactory results in most MS.

Methods for testing official samples for histamine

In 8 Member States, the method used for histamine is EN ISO 19343, which is the reference method set out in Annex I to Regulation (EC) 2073/2005.

Alternative methods are declared to be used in 11 Member States and in 8 Member States they stated that both the reference method and alternative methods can be used. In most of the cases where an alternative method is used, Member States indicate that these have been validated.

The applied compliance limits for histamine when using alternative methods remains the same as those provided in Regulation (EC) 2073/2005 for the reference method.

No Member State confirmed that validation of the histamine testing method had been carried out in line with ISO 16140-2 (which is the standard set out in Article 5(5) of Regulation (EC) 2073/2005 for validation of a microbiological analytical test). According to their replies, the validations of the alternative methods were done on the basis of internationally recognised protocols and is continuously evaluated in the context of the participation of laboratories in relevant inter-laboratory proficiency testing.

Last paragraph of Article 5 of Regulation (EC) 2073/2005 provides for the possibility to validate other analytical methods in accordance with international accepted protocols. In the case of FBOs, the use of other analytical methods must be authorised by the competent authority. Therefore, this type of validation is acceptable for official laboratories.

When alternative methods are validated, the trueness and the precision of the methods are assessed during the validation procedure.

Some Member States justified the use of alternative methods or other analytical methods:

- The alternative method used differs from the reference method mainly in terms of the stages of derivatisation and detection. On the basis of the available data comparing the two methods, this method produces better results than the reference method.

- The alternative method was developed and used instead of ISO 19343 as the ISO method was found it to be more labour intensive and unwieldy, more problematic and no better than their analytical method.

- The alternative method used was developed before ISO 19343 had been issued.

Conclusions:

A significant number of Member States do not use the reference method indicated in Annex I to Regulation (EC) 2073/2005 for histamine testing. Alternative methods have been developed and used, which are trusted by the competent authorities.

Official laboratories have validated their alternative methods in accordance with internationally accepted protocols.

5 MATTERS FOR CONSIDERATION BY 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.

6 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**.**

ANNEX I - LEGAL REFERENCES

Legal acts quoted in this report refer, where applicable, to the last amended version.

Legal Reference	Official Journal	Title
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
Reg. (EU) 2017/625 *Official Controls Regulation*	OJ L 95, 7.4.2017, p. 1	Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
Regulation (EU) 2019/627	OJ L 131, 17.5.2019, p. 51–100	Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls.
Regulation (EC) No 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004, p. 1	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Regulation (EC) No 853/2004	OJ L 139, 30.4.2004, p. 55	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

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