

MONITORING PROGRAMME FOR PHARMACEUTICALS, ILLEGAL SUBSTANCES, CONTAMINANTS AND MICROBIOLOGY IN AQUATIC PRODUCTS IMPORTED TO NORWAY FROM THIRD COUNTRIES

Annual report for 2023

RAPPORT FRA HAVFORSKNINGEN NR. 2024-30

Title (English and Norwegian):

Monitoring programme for pharmaceuticals, illegal substances, contaminants and microbiology in aquatic products imported to Norway from third countries

Overvåkingsprogram for legemidler, ulovlige stoffer, miljøgifter og mikrobiologi i akvatiske produkter importert til Norge fra tredjeland

Subtitle (English and Norwegian):

Annual report for 2023 Årlig rapport for 2023

Report series:

Year - No.:

Date:

Rapport fra havforskningen 2024-30 ISSN:1893-4536

10.09.2024

Author(s):

Julia Storesund, Martin Wiech, Bjørn Tore Lunestad and Rita Hannisdal (IMR)

Research group leader(s): Monica Sanden (Fremmed- og smittestoff (FRES)) og Amund Måge (Sjømat og ernæring) Approved by: Research Director(s): Gro-Ingunn Hemre Program leader(s): Livar Frøyland

Distribution: Open

Project No.: 15220, 15949

On request by:

The Norwegian Food Safety Authority (Mattilsynet)

Program: Trygg og sunn sjømat

Research group(s):

Fremmed- og smittestoff (FRES) Sjømat og ernæring

Number of pages: 12

Summary (English):

This report summarises results from the ongoing monitoring programme for veterinary border control on aquatic products imported to Norway from countries outside the EU and the European Economic Area in 2023.

Samples were collected by personnel at the Norwegian Border Inspection Posts (BIP). The Institute of Marine Research (IMR) carried out the analytical work on behalf of the Norwegian Food Safety Authority (NFSA). We want to thank NFSA for good cooperation during the conduct of this monitoring programme. A risk assessment for different groups of imported products formed the basis for the selection of analytical activities, where current trend of hazards, as reported in The Rapid Alert System for Food and Feed (RASFF) notification system and the compositional nature of the products and origin formed an up-to-date basis for the risk assessment.

A total of 114 seafood samples, were examined by a selection of analytical methods and assays for microorganisms and undesirable chemical substances.

Selected microbiological analyses were performed on 95 of the samples. Undesirable trace elements were measured in 12 samples, and persistent organic pollutants were measured in 21 samples. Analyses of residues of authorised veterinary and unauthorised and prohibited substances was performed in two samples. Histamine was examined in a selection of seven relevant samples.

Summary (Norwegian):

Denne rapporten oppsummerer resultater fra det pågående overvåkingsprogrammet for veterinær grensekontroll av akvatiske produkter importert til Norge fra land utenfor EU og EØS i 2023. Prøvene ble samlet inn av personell ved de norske grensekontrollstasjonene (BIP), og Havforskningsinstituttet utførte analysearbeidet på oppdrag fra Mattilsynet. Vi takker Mattilsynet for godt samarbeid under gjennomføringen av dette overvåkingsprogrammet.

En risikovurdering for ulike grupper av importerte produkter dannet grunnlaget for valg av analyseaktiviteter, der nåværende trend av farer, som rapportert i meldingssystemet Rapid Alert System for Food and Feed (RASFF), samt produktenes sammensetning og opprinnelse dannet et oppdatert grunnlag for risikovurderingen.

Totalt 114 sjømatprøver ble undersøkt med et utvalg analysemetoder for mikroorganismer og uønskede kjemiske stoffer. Utvalgte mikrobiologiske analyser ble utført på 95 av prøvene. Uønskede sporstoffer ble målt i 12 prøver og persistente organske miljøgifter (POPs) ble målt i 21 prøver. To prøver ble undersøkt lovlige veterinære legemidler og uautoriserte og ulovlige stoffer. Histamin ble undersøkt i sju relevante prøver.

Content

| 1 | Introduction | 5 |
|-----|---|----|
| 1.1 | Microbial parameters | 5 |
| 1.2 | Unauthorised and prohibited substances | 5 |
| 1.3 | Authorised veterinary drugs | 5 |
| 1.4 | Histamine | 6 |
| 1.5 | Undesirable trace elements | 6 |
| 1.6 | Persistent organic pollutants - POPs (dioxin, PCB, PBDE, PFAS) | 6 |
| 2 | Material and Methods | 7 |
| 3 | Results and Discussion | 8 |
| 3.1 | Microbial parameters | 8 |
| 3.2 | Unauthorised and prohibited substances | 9 |
| 3.3 | Authorised veterinary drugs | 9 |
| 3.4 | Histamine | 9 |
| 3.5 | Undesirable trace elements | 9 |
| 3.6 | Persistent organic pollutants – POPs' (dioxin, PCB, PBDE, PFAS) | 9 |
| 4 | Conclusion | 10 |
| 5 | References | 11 |

1 - Introduction

As a member of the European Economic Area (EEA), Norway is obliged to monitor the conformity of food and feed products imported to the EEA area. Included in this activity is analytical examinations of seafood with respect to microorganisms or the presence of undesirable substances. The Norwegian Food Safety Authority (NFSA) is the competent authority regarding veterinary border control in Norway. On behalf of NFSA, the Institute of Marine Research (IMR) carried out the analytical examination of the samples of aquatic products in this monitoring programme and elaborated this report.

1.1 - Microbial parameters

A selection of microbiological parameters were used to evaluate the safety and quality of seafood products and whether proper hygienic measures were applied during production or transport. To examine for possible faecal contamination, analyses for commonly applied indicator organisms were conducted, including assays for coliforms, thermotolerant coliform bacteria, bacteria in the Enterobacteriaceae family, Escherichia coli and enterococci. In addition, examination for coagulase positive staphylococci and sulphite reducing clostridia were conducted on a selection of samples, either heat treated or under vacuum. Furthermore, a selection of samples were examined for specific pathogens relevant for food safety, including norovirus, hepatitis A virus, Vibrio spp., bacteria in the genus Salmonella and Listeria monocytogenes. Vibrios are naturally occurring in marine and estuarine environments, with some species being potential human pathogens. There are currently no regulations on vibrios in food, however their presence in seafood is monitored as they are expected to become an increasing problem with increasing seawater temperatures. Salmonella are faecal bacteria commonly found in the gastrointestinal tract of warm-blooded animals, and may contaminate a range of food and feed items. Salmonella is one of the leading causes of food borne infections in the world and can cause serious disease in humans depending on serotype involved and the susceptibility of the infected person. L. monocytogenes (Lm) can be found among animals and humans, as well as in the environment. Lm can establish in food processing facilities due to their biofilm-forming abilities and natural resistance to commonly used decontaminants, from which they can contaminate food processed in those facilities. Lm can cause serious infections, particularly in young children, the elderly and people with a compromised immune system. It is an increasing food-safety issue that is mainly relevant for lightly preserved foods with an extended shelf-life and that are not intended for heattreatment prior to consumption, as exemplified by cold-smoked non frozen fish products. The EU microbiological criteria for Salmonella and Lm^1 , implemented by Norway has through the EEA agreement, formed a basis for the evaluation.

1.2 - Unauthorised and prohibited substances

Farmed seafood products were analysed for several unauthorised and prohibited veterinary medicinal products. Chloramphenicol is an antibiotic agent that exhibit activity against a broad spectrum of microorganisms. Due to a rare but serious dose-independent adverse effect (aplastic anaemia), this agent is not authorized in the treatment of food-producing animals, including fish. Nitrofurans were previously widely used in veterinary medicine as an antimicrobial agent. They were banned by the European Union (EU) in 1995 due to concerns about the carcinogenicity of possible residues in the edible tissue². Samples were also analysed for the dyes; malachite green, crystal violet and brilliant green; metronidazole and s teroids .

1.3 - Authorised veterinary drugs

Farmed seafood samples were analysed for residues of veterinary drugs that are authorised for use in food

producing animals, and checked for compliance according to the Maximum Residue Limits (MRLs) as listed in EU 2010/37³. The samples were analysed for residues of antibiotic agents, drugs used against intestinal parasites and anti sea lice agents.

1.4 - Histamine

The survey also included the biogenic amine histamine, following Commission Regulation (EU) No $1019/2013^4$ of 23 October 2013 amending Annex I to Regulation (EC) No $2073/2005^1$ as regards histamine in fishery products .

1.5 - Undesirable trace elements

Undesirable trace elements relevant for seafood safety occur naturally in the environment, with large geographical variations. The analysed levels reflect the geological presence, as well as anthropogenic sources. These compounds may accumulate in food chains and thus find their way into seafood. Farmed seafood can be affected via contaminated feed. The elements cadmium (Cd), mercury (Hg), and lead (Pb) were measured and the compliance of the values with the EU maximum levels (as listed in EC 1881/2006 and EU 2023/915)^{5,6} was evaluated. Arsenic (As), was also included, although there is currently no maximum level in seafood.

1.6 - Persistent organic pollutants - POPs (dioxin, PCB, PBDE, PFAS)

Persistent organic pollutants (POPs) form a diverse group of substances with a range of chemical and toxicological characteristics. POPs are persistent in the environment and accumulate in food chains. Some classes of POPs are considered a human health dietary risk. The compliance of selected samples with established maximum levels for food stuffs^{5,6} was evaluated for these contaminants: sum of dioxins (polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)), sum of dioxins and dioxins like PCBs (dl-PCBs), and the EU selected "non-dioxin like-PCBs". In addition, flame-retardant compounds in the polybrominated diphenyl ethers family (PBDEs) were measured. However, maximum levels in food have not yet been established for the BDEs. The EU recommends a monitoring of the BDE compounds in food⁷. Seafood is considered a potential contributor to BDE-99 exposure, which is the BDE compound considered most relevant to food-safety⁸. In 2023, maximum levels were established for per- and polyfluoroalkyl substances (PFAS). The levels were set for perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluoronanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS), individually and for their sum⁶. For the sum, lower bound concentration is calculated on the assumption that all the values below the limit of quantification are zero⁶.

2 - Material and Methods

Sampling was carried out by NFSA at the Norwegian Border Inspection Posts (BIPs) while analytical examinations and the writing of this report was carried out by IMR. The sampling targeted hazards associated with different imported products, and took into account import volumes, compositional nature of the products, results from previous monitoring, geographical origin of samples, and information available in the RASFF (Rapid Alert System for Food and Feed).

Fresh samples were shipped without delay to IMR whereas frozen samples were stored frozen in the BIPs until shipment in the frozen state to IMR for analysis. Upon arrival, samples were registered at the IMR sample reception unit, each sample was photographed, and relevant information registered in a Laboratory Information Management System (LIMS). Microbiological assays were done prior to all other sample handling procedures to prevent contamination. The samples were subsequently prepared for analyses and split in sub-samples (aliquots) for the different assays and analytical methods.

In general, the edible part was selected for analyses according to a manual specified for each type of sample. For undesirable chemical species where a legal maximum level is established, the tissue specified in the regulation was selected. The analytical methods and procedures used were quality assured and accredited according to the ISO 17025:2005 standard⁹, unless otherwise specified.

The evaluations of the analytical data in the report were based on the EU maximum levels and recommendations^{1,3,4,5,6}. The maximum levels provide a legal framework for trade. For undesirables with no established maximum level, interpretation of the analytical values was based on scientific expert opinions when available.

3 - Results and Discussion

A total of 114 samples from the NFSA at Norwegian BIPs, were examined by a selection of methods for microorganisms, and undesirable chemical species as shown in Table 1.

Table 1: Analyses performed on samples from different seafood groups. The "other" category includes all processed food items such as roe, crabsticks, fishcakes, battered, steamed, boiled, dried and salted, and marinated and canned food items.

| Samples and assays included in the Norwegian veterinary border control of seafood 2023 | | | | | | | | | | |
|--|------|-------------|-------------|----------|------------|----------------|-------|-----------------|--|--|
| | Fish | Crustaceans | Cephalopods | Bivalves | Feed/Flour | Marine Oils | Other | Total number | | |
| Microbiology | 42 | 23 | 7 | 4 | | 4 | 15 | 95 | | |
| Unauthorised and prohibited substances | 1 | 1 | | | | | | 2 | | |
| Authorised veterinary drugs | 1 | 1 | | | | | | 2 | | |
| Chemical spoilage indicators | 7 | | | | | | | 7 | | |
| Undesirable trace elements | 6 | 3 | 1 | | | 2 | | 12 | | |
| Dioxin, PCB, PBDE | 5 | | | | | 4 | 3 | 12 | | |
| PFAS | 6 | 3 | 1 | | | 2 | | 12 | | |

3.1 - Microbial parameters

Ninety-five samples were analysed for the presence of potential human pathogenic bacteria and spoilage bacteria. All samples were compliant with the regulations.

Of the 95 samples, 72 were examined for the presence of coliform bacteria. Six samples had levels above or at the detection limit (10 colony forming units, cfu/g), where the highest value found was 30 cfu/g. Further, 95 samples were analysed for the presence of thermotolerant coliform bacteria, but none had levels above the method detection limit (10 cfu/g). One sample was examined for the presence of *Escherichia coli*, and the numbers were below detection limit.

For enterococci, eight of 62 samples examined contained values at or above the detection limit of 100 cfu/g. The highest values detected were 700 cfu/g in breaded shrimp from Malaysia, 400 and 1100 cfu/g in two samples of frozen whiteleg shrimp from Viet Nam, and 200 cfu/g in a sample of frozen Japanese squid imported from Viet Nam.

All 95 sample were analysed for the presence of *Salmonella* and found negative. *Listeria monocytogenes* was detected qualitatively in one of the 49 samples analysed, and the subsequent quantitative analysis found the number to be below the detection limit of 10 cfu/g. The sample consisted of breaded cod imported from Great Britain, and as this product was not intended to be consumed without further heat treatment, the product was compliant with EU regulations.

Eleven samples were analysed for the presence of coagulase positive staphylococci. None of these samples had levels above the detection limit (100 cfu/g). Twelve samples were analysed for the presence of sulphite reducing clostridia. One sample consisting of fish oil from Morocco had 100 cfu/g, and one sample of processed squid from Viet Nam had 200 cfu/g. The detection limit of the method is 100 cfu/g.

Twenty samples were analysed for the presence of potentially human pathogenic *Vibrio* spp., and four samples of fresh eastern oysters imported from Canada were positive for the presence of *V. alginolyticus*. *Vibrio-* strains isolated from these samples were identified using MALDI-TOF MS.

Two samples were examined for the presence of Norovirus type I and II, as well as Hepatitis A by RT-PCR in accordance with ISO 15216-1:2017 (Horizontal method for determination of hepatitis A virus and norovirus in food using real-time RT-PCR -Part 1: Method for quantification). None of the samples were positive.

Fillets of fish from five samples were analysed for the presence of anisakid nematodes using the UV-press method (ISO 23036-1:2021)¹⁰. No parasites were observed in any of the samples examined.

3.2 - Unauthorised and prohibited substances

Analyses of nitrofurans and dyes were performed in one sample of whiteleg shrimp (*Penaeus vannamei Boone*) and one sample of longfin yellowtail (*seriola rivoliana*). The sample of longfin yellowtail was also analysed for metronidazole, chloramphenicol and steroids. No residue of unauthorised or prohibited substances were detected in the samples.

3.3 - Authorised veterinary drugs

Residues of authorised antibiotic agents were analysed in one sample of whiteleg shrimp (*Penaeus vannamei Boone*) and one sample of longfin yellowtail (*seriola rivoliana*). The sample of longfin yellowtail was also analysed for drugs used against intestinal parasites and anti sea lice agents. No residue of antibiotic agents or drugs used against intestinal parasites were detected in the samples. The anti sea lice agent, cypermethrin, was detected in the samples of longfin yellowtail, however the level was below the maximum residue limit (MRL). Cypermethrin is also used as a pesticide, and can therefore be transferred to farmed fish via the feed¹¹.

3.4 - Histamine

Histamine is a biogenic amine produced by bacterial degradation of the amino acid histidine, if scombroid fish species are exposed to improper storage or transport conditions. A total of seven relevant samples were selected for analysis, and all measured values were below the maximum permitted levels.

3.5 - Undesirable trace elements

A total of 12 samples were analysed for undesirable trace elements. No exceedances of the maximum levels for undesirable trace elements were found.

3.6 - Persistent organic pollutants - POPs' (dioxin, PCB, PBDE, PFAS)

Analyses of dioxin, dl-PCB, PCB6 and PBDE were performed in 12 samples, none of the results were above the established maximum levels. Analyses of PFAS were performed in 12 samples, also for this group of compounds, none of the results were above the established maximum levels.

4 - Conclusion

A total of 114 samples collected by the official staff at the Norwegian Border Inspection Posts of the Norwegian Food Safety Authority were examined for selected chemical and microbiological undesirables in 2023 .

Selected microbiological analyses were performed on 95 samples. One sample contained *L. monocytogenes*, but as the sample was not from a ready-to-eat product, it was considered compliant according to current regulations. Four samples harboured potentially human pathogenic *Vibrio* spp. However, there are currently no regulations or limits regarding the presence of these bacteria in food items and they were deemed compliant.

None of the other samples examined were identified with undesirable or unacceptable microorganisms.

Undesirable trace elements were measures in 12 samples of aquatic products. Further, 12 samples were measured for dioxin, dl-PCB, PCB6, PBDE, and PFAS were measured in 12 samples. None of the samples had levels exceeding the respective maximum levels.

Substances prohibited for use in animals intended for food were analysed in two samples, none of the substances analysed for were detected. Analyses of authorised veterinary drugs were performed in two samples, no residues were found.

The chemical spoilage indicator histamine was examined in seven relevant samples, and all values were below the maximum permitted level.

5 - References

(1) The European Commission. COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on Microbiological Criteria for Foodstuffs ; 2005. https://doi.org/10.1109/MACE.2010.5536537.

(2) Scientific Opinion on Nitrofurans and Their Metabolites in Food ; Wiley-Blackwell Publishing Ltd, 2015; Vol. 13. https://doi.org/10.2903/J.EFSA.2015.4140.

(3) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

(4) The European Commission. COMMISSION REGULATION (EU) No 1019/2013 of 23 October 2013 Amending Annex I to Regulation (EC) No 2073/2005 as Regards Histamine in Fishery Products; 2013.

(5) European Parliament and the Council of the European Union. Commission Regulation (EC) No 1881/2006 of 19 December 2006 Setting Maximum Levels for Certain Contaminants in Foodstuffs. Official Journal of the European Union 2006, Versão Con (364), 5–24.

(6) COMMISSION REGULATION (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

(7) COMMISSION RECOMMENDATION of 3 March 2014 on the Monitoring of Traces of Brominated Flame Retardants in Food (Text with EEA Relevance). https://doi.org/10.2903/j.efsa.2010.1789.

(8) EFSA Panel on Contaminants in the Food Chain (CONTAM). Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food ; Wiley-Blackwell Publishing Ltd, 2011; Vol. 9. https://doi.org/10.2903/J.EFSA.2011.2156.

(9) ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories . https://www.iso.org/standard/39883.html (accessed 2023-05-16).

(10) ISO 23036-1:2021 - Microbiology of the food chain — Methods for the detection of Anisakidae L3 larvae in fish and fishery products — Part 1: UV-press method . https://www.iso.org/standard/74372.html (accessed 2024-05-01).

(11) Bernhard, Annette, Atabak Mahjour Azad, and Rita Hannisdal. "Monitoring program for pharmaceuticals, illegal substances, and contaminants in farmed fish-Annual report for 2022." Rapport fra havforskningen (2023).



HAVFORSKNINGSINSTITUTTET

Postboks 1870 Nordnes 5817 Bergen Tlf: 55 23 85 00 E-post: post@hi.no www.hi.no