



**Directorate-General for Health and Food Safety**

# **Market Advisory Council Working Group 30 March 2023: inorganic arsenic in fish.**

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# Regulatory framework on contaminants in food

- Council Regulation (EEC) No 315/93
  - Food containing a contaminant in an amount, which is unacceptable from the public health viewpoint, shall not be placed on the market.
  - Contaminant levels shall be kept as low as can reasonably be achieved (ALARA) by following good practices at all the stages of the production.
  - In order to protect public health, the Commission may where necessary establish the maximum tolerances for specific contaminants.
- Commission Regulation (EU) 2023/915 (Former Regulation (EC) No 1881/2006)
  - Establishes **maximum levels** for certain contaminants in food
    - => MLs can be established, when evidence becomes available, which indicates a **risk to human health**
    - => MLs are established on the basis of occurrence data according to the **ALARA principle**

# Arsenic

- 2009 EFSA opinion:
  - Range of (BMDL01) values between 0,3 and 8  $\mu\text{g}/\text{kg}$  b.w. per day for cancers of the lung, skin and bladder, as well as skin lesions.
  - The estimated dietary exposures for average and high consumers lies within the range of the BMDL01 and therefore the possibility of a risk to some consumers cannot be excluded.
- Regulation (EU) 2015/1006
  - MLs for rice and rice-based products
- Recommendation (EU) 2015/1006
  - Recommended monitoring during 2016, 2017 and 2018 of arsenic in a wide range of foods, preferably by determining the content of inorganic arsenic and, if possible, the organic and total arsenic content.

# Arsenic

- 2021 EFSA exposure assessment
  - Main contributors to the exposure: rice and rice-based products, other grains and grain-based products not containing rice, food for infants and young children and fruit juices. In the adult population **fish and other seafood** were an apparent source of exposure.
- Discussions with Member States on Maximum Levels (MLs) for inorganic arsenic in **rice and rice-based products, foods for infants and young children, fruit juices, fish and other seafood.**
- Targeted stakeholder consultation 12/2021
- SPS notification 05/2022

# Arsenic

- MLs for inorganic arsenic (mg/kg wet weight), which were notified to WTO.

3.5.2.	Fish, crustaceans and bivalve molluscs	
3.5.2.1	Muscle meat of fish <sup>(24)</sup> <sup>(25)</sup> , excluding species listed under point 3.5.2.2	0,020
3.5.2.2	Muscle meat of the following fish <sup>(24)</sup> <sup>(25)</sup> :  anchovy ( <i>Engraulis species</i> )  eel ( <i>Anguilla species</i> )  halibut ( <i>Hipoglossus species</i> )  mackerel ( <i>Scomber species</i> )  plaice ( <i>Pleuronectes species</i> )  shad ( <i>Alosa species</i> ),  sprat ( <i>Sprattus sprattus</i> )  shark ( <i>all species</i> )	0,080

# Arsenic

- MLs for inorganic arsenic (mg/kg wet weight), which were notified to WTO.

3.5.2.3	Crustaceans <sup>(26)</sup> : the maximum level shall apply to the edible parts of crustaceans (muscle meat from the appendages, white muscle meat of the cephalothorax and white muscle meat of the abdomen, where relevant).	0,070
3.5.2.4	Bivalve molluscs <sup>(26)</sup>	
3.5.2.4.1	Bivalve molluscs other than those mentioned under 3.5.2.4.2	0.090
3.5.2.4.2	Clams ( <i>Myidae</i> , <i>Cardiidae</i> , <i>Veneridae</i> and <i>Arcidae</i> species) and horse mussel ( <i>Modiolus modiolus</i> )	0,35

# Arsenic

- New data from Member States, stakeholders and third countries
  - For several specific fish and seafood species there are indications that the initially proposed MLs needs to be increased.
- Regulation (EU) 2023/465 with new or revised MLs for rice and rice-based products, foods for infants and young children, fruit juices.
- Separate proposal on MLs for inorganic arsenic in fish and other seafood (SANTE PLAN/1241/2023)
  - By 31 December 2022 Member States, Third Countries and stakeholders were invited to send additional data on inorganic arsenic in specific fish and other seafood species to DG SANTE.
  - In 2023 and 2024: continuation of the discussions with MS in the Working Group on Industrial and Environmental Contaminants in Food and targeted stakeholder consultation.

# Arsenic

- MLs iAs for fish meat – under discussion

3.4.5	Muscle meat of the following fish		<p>The maximum level applies to the wet weight.</p> <p>Where fish are intended to be eaten whole, the maximum level applies to the whole fish.</p> <p>In case of dried, diluted, processed and/or compound food, articles 3(1) and (2) apply.</p>
3.4.5.1	Species other than those listed under 3.4.5.2	0,10	
3.4.5.2	Anglerfish, monkfish and giant stargazer ( <i>Lophius species</i> ; <i>Kathetostoma giganteum</i> ), flatfishes ( <i>Pleuronectiformes species</i> ), haddock ( <i>Melanogrammus aeglefinus</i> ), herring ( <i>Clupea species</i> ), ray ( <i>Rajidae species</i> ) and shark (all species).	0,50	



# Arsenic

- MLs iAs for fish crustaceans – under discussion

3.4.6	Crustaceans		<p>The maximum level applies to the wet weight.</p> <p>The maximum level applies to muscle meat from appendages and abdomen, which means that the cephalothorax of crustaceans is excluded. In case of crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) the maximum level applies to the muscle meat from appendages.</p> <p>In case of dried, diluted, processed and/or compound food, articles 3(1) and (2) apply.</p>
3.4.6.1	Crabs and crab-like crustaceans ( <i>Brachyura</i> and <i>Anomura</i> ), prawn and shrimps (all species).	0,10	
3.4.6.2	Crustaceans other than those listed under 3.4.6.1 and 3.4.6.3.	0,20	
3.4.6.3	Langoustine ( <i>Nephrops norvegicus</i> ) and rock lobster ( <i>Jasus species</i> )	1,5	

# Arsenic

- MLs iAs for molluscs – under discussion

3.4.7	Bivalve molluscs		<p>The maximum level applies to the wet weight.</p> <p>In case of <i>Pecten maximus</i>, the maximum level applies to the adductor muscle and gonad only.</p> <p>In case of dried, diluted, processed and/or compound food, Articles 3(1) and (2) apply.</p>
3.4.7.1	Scallops	0,10 mg/kg	
3.4.7.2	Bivalve molluscs other than those listed under 3.4.7.1	0,50 mg/kg	
3.4.8	Cephalopods	0,050 mg/kg	<p>The maximum level applies to the wet weight.</p> <p>The maximum level applies to the animal without viscera.</p> <p>In case of dried, diluted, processed and/or compound food, Articles 3(1) and (2) apply.</p>

# Arsenic

- Transitional measures under discussion
  - Foods lawfully placed on the market prior to the application date may remain on the market until their date of minimum durability or use-by date
- Next steps
  - Vote in scheduled in Q1/Q2 2025
  - Application Q2/Q3 2025

# Questions?

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