



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
 - ➔ Comments and new data on the occurrence of inorganic arsenic in specific fish and seafood species.
 - ➔ MLs for iAs in fish and seafood were removed from the proposal.
 - ➔ Member States agreed to deal with the MLs for fish and seafood in a separate proposal.

Arsenic: Regulation (EU) 2023/465 on new or lowered MLs for arsenic in food (MLs in mg/kg)

3.5	Arsenic (inorganic arsenic for 3.5.1 to 3.5.4 and total arsenic for 3.5.5) ⁽⁵⁰⁾	
3.5.1	Cereals and cereal based products ⁽⁵¹⁾	
3.5.1.1	Non-parboiled milled rice (polished or white rice)	0,15
3.5.1.2	Parboiled and husked rice	0,25
3.5.1.3	Rice flour	0,25
3.5.1.4	Rice waffles, rice wafers, rice crackers, rice cakes, rice flakes and popped breakfast rice	0,30
3.5.1.5	Rice destined for the production of food for infants and young children ⁽³⁾	0,10
3.5.1.6	Non-alcoholic rice-based drinks	0,030

Arsenic: Regulation (EU) 2023/465 on new or lowered MLs for arsenic in food (MLs in mg/kg)

3.5.2	Infant formulae⁽³⁾ ⁽²⁹⁾, follow-on formulae⁽³⁾ ⁽²⁹⁾, foods for special medical purposes intended for infants and young children⁽³⁾ ⁽²⁹⁾ and young child formulae ⁽²⁹⁾ ⁽⁵⁷⁾.	
3.5.2.1	-marketed as powder	0,020
3.5.2.2	-marketed as liquid	0,010
3.5.3	Baby foods⁽³⁾,⁽²⁹⁾	0,020
3.5.4	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars ⁽¹⁴⁾	0,020
3.5.5	Salt	0,50

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 ⁽²⁴⁾ ⁽²⁵⁾ , excluding species listed under point 3.5.2.2	0,020
3.5.2.2	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : 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 ⁽²⁶⁾ : 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 ⁽²⁶⁾	
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

- Separate proposal on MLs for inorganic arsenic in fish and other seafood.
 - New data from Member States, stakeholders and third countries → for several specific species there are indications that the initially proposed MLs needs to be increased.
 - 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 and, where possible, the data should also be submitted to EFSA.
 - Q2-Q3 2023 continuation of the discussions with MS in the Working Group on Industrial and Environmental Contaminants in Food and targeted stakeholder consultation.
 - Targeted adoption Q2-Q3 2024.

Questions?

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