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2024/907

# **COMMISSION RECOMMENDATION (EU) 2024/907**

#### of 22 March 2024

## on the monitoring of nickel in food

THE EUROPEAN COMMISSION.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

### Whereas:

- (1) Nickel is a widespread component of Earth's crust and is ubiquitous in the biosphere. Its presence in food can arise from both natural and anthropogenic sources.
- In 2015, the European Food Safety Authority ('the Authority') adopted its scientific opinion on the risks to public (2) health related to the presence of nickel in food and drinking water (1). The opinion identified reproductive and developmental toxicity as the critical effect for the risk characterization of chronic oral exposure to nickel. Eczematous flare-up reactions and worsening of allergic reactions were identified as the critical effect for acute oral exposure to nickel of nickel-sensitized humans.
- Data related to occurrence of nickel in food and drinking water were available in 15 Union Member States. However, (3) as 80 % of the total collected data were collected in one Member State, the Authority concluded that a more geographically diverse data set would be needed to verify the occurrence of nickel in food throughout the Union.
- In order to collect more occurrence data for nickel in food, by means of Commission Recommendation (EU) 2016/1111 (2) Member States were recommended to perform monitoring on the presence of nickel in food in 2016, 2017 and 2018.
- (5) Taking into account these new occurrence data and new scientific information, on 24 September 2020 the Authority adopted an update of the risk assessment of nickel in food and drinking water. (3)
- The Authority concluded that nickel may cause both chronic and acute effects. On the basis of the critical chronic (6) effect of pregnancy loss, a tolerable daily intake (TDI) of  $13~\mu g/kg$  bw was established and the Authority concluded that this TDI was exceeded in toddlers, children between 36 months and 10 years old and also, in some cases, in infants. Even though pregnancy loss is not a relevant effect for the young age groups, the TDI is also protective for other effects which are relevant for the younger age groups, such as neurotoxic effects. The Authority therefore concluded that this exceedance of the TDI may raise health concerns in these young age groups. The Authority confirmed that the critical acute effect are eczematous flare-up reactions in the skin elicited in nickel sensitised humans, which concerns about 15 % of the population. The Authority concluded that the lowest observed adverse effect level for this effect is 4,3 µg nickel/kg bw and that a margin of exposure (MOE) of 30 or higher is needed to protect against this effect. This MOE of 30 is not achieved for the mean and 95th percentile exposure, which raises a health concern for nickel sensitised individuals.
- Taking into account the available occurrence data, maximum levels have been established for nickel in various foods (7) in Commission Regulation (EU) 2023/915 (4).

<sup>(1)</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water. EFSA Journal 2015;13(2):4002, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j. efsa.2015.4002.

Commission Recommendation (EU) 2016/1111 of 6 July 2016 on the monitoring of nickel in food (OJ L 183, 8.7.2016, p. 70, ELI: http://data.europa.eu/eli/reco/2016/1111/oj).

EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on an update of the risk assessment of nickel in food  $and\ drinking\ water.\ EFSA\ Journal\ 2020; 18(11): 6268,\ https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6268.$ 

Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: http://data.europa.eu/eli/reg/2023/915/oj).

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(8) However, for some foods, which are relevant contributors to the exposure to nickel, insufficient occurrence data were available to allow to determine the appropriate maximum levels. Therefore, further occurrence data should be collected for those foods. In particular, in order to establish the contribution of different species of fish and other seafood to the nickel content of baby food, fish and other seafood used for the manufacture of such food should be monitored.

(9) In order to ensure that the samples are representative for the sampled lot and that the analytical results are reliable and comparable, Commission Regulation (EC) No 333/2007 (3) should be followed,

### HEREBY RECOMMENDS:

- 1. Member States, in collaboration with food business operators, should monitor during the years 2025, 2026 and 2027 the presence of nickel in food.
- The monitoring should include food supplements, chocolate, chocolate spreads, nut spreads, cocoa beans, cereal
  based products (in particular, breakfast cereals, cereal flakes and oat milling products), ready-to-eat soups, coffee,
  tea, vegetables, seaweeds, oilseeds, soy based products, such as tofu and soy based drinks, pulses, nuts, fish and
  other seafood.
- 3. Member States should, where needed, gather knowledge on mitigation measures for the reduction of nickel levels in food. Member States should also ensure that known mitigation methods are effectively communicated and promoted to farmers and food business operators and that these mitigation measures are progressively implemented by farmers and food business operators.
- 4. The sampling procedures and the analyses should be performed in accordance with the requirements for sampling and analysis laid down in Regulation (EC) No 333/2007.
- 5. Member States and food business operators should provide the monitoring data to the Authority on a regular basis, together with the information and in the electronic reporting format as set out by the Authority, for compilation into one database. For samples of chocolate, the cocoa solids content of the sample should be specified. For samples of tea, the type or species of tea, including its Latin name, should be specified. For seaweed, the species, including its Latin name, should be reported and whether the data concern fresh or dry seaweed.

Done at Brussels, 22 March 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission

<sup>(5)</sup> Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down methods of sampling and analysis for the control of levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29, ELI: http://data.europa.eu/eli/reg/2007/333/oj).