Management Board

29 June 2022

Highlights from 108th SC Plenary (27-28 April 2022)

Simon More

Chair of the EFSA Scientific Committee

Trusted science for safe food

European Food Safety Authority

Opinion on risk assessment of COPPER

- Review of the existing health-based guidance values for copper and exposure from all sources.

- EFSA contact: Maria Bastaki

Native copper
Jonathan Zander (Digon3) derivative work
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Background & Commission mandate

- ADI of 10 mg/day
  - EFSA Conclusions on Pesticides Peer Review (2018, 2008)
  - WHO, supported by animal data
- UL of 5 mg/day
  - Scientific Committee on Food (2003)

- To provide a scientific opinion on an ADI for copper that can be used by the Commission as a reference value in managing copper-containing regulated products
- To perform a new estimation of copper intake, taking into account all sources of exposure

Conclusions

- The SC established an ADI of 0.07 mg/kg bw (equivalent to 5 mg/day in adults), based on prevention of hepatic retention, which is considered conservative and sufficiently protective for all age groups.

- The main contributing food categories to the dietary exposure to total copper across the different age groups and all surveys were grains and grain-based products, where copper PPP have no authorised use.

- The contribution of copper from its use as a PPP to overall dietary exposure is negligible.

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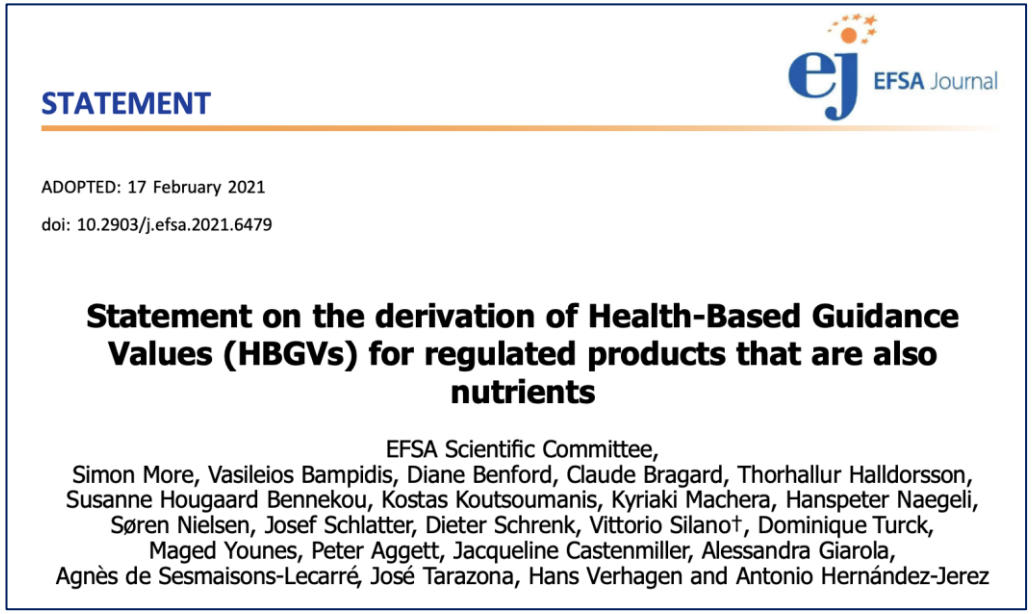
- The contribution of copper from non-oral sources to total exposure is also negligible.

Key challenges

Adversity

- *'Hepatic retention is indicative of potential future (and possibly sudden) onset of copper toxicity under conditions of continuous intake and can be considered an early predictor of adversity in chronic toxicity assessment'*

The HGBV Statement (2021)



STATEMENT

EFSA Journal

ADOPTED: 17 February 2021

doi: 10.2903/j.efsa.2021.6479

Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients

EFSA Scientific Committee,
Simon More, Vasileios Bampidis, Diane Benford, Claude Bragard, Thorhallur Halldorsson, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Kyriaki Machera, Hanspeter Naegeli, Søren Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano†, Dominique Turck, Maged Younes, Peter Aggett, Jacqueline Castenmiller, Alessandra Giarola, Agnès de Sesmaisons-Lecarré, José Tarazona, Hans Verhagen and Antonio Hernández-Jerez

Residues of active substances in food of animal origin

EFSA contact: Davide Arcella & Bruno Dujardin

Commission mandate

- EMA and EFSA to develop a common approach on exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides
  - Assess currently available assessment models, including international efforts towards integration
  - Recommend a common approach for exposure assessment compatible with current scientific knowledge for future use by EFSA and EMA in routine assessment of veterinary medicinal products, feed additives and pesticides

Recommendations

- Preferred method/reasonable alternative
  - Data
  - Methods

SC work programme

Ongoing/agreed areas
Biomarkers of effect *(point of departure for reasons other than adversity)*
ApisRAM *(honey bee colony health)*
Risk-benefit assessment *(guidance update)*
Margin of exposure *(guidance update)*
Default values *(guidance update)*
Expert knowledge elicitation *('living guidance')*

Areas for further consideration *(not addressed elsewhere)*

Areas for further consideration *(not addressed elsewhere)*
RA of microorganisms used in the agri-food chain *(including ERA, history of safe use)*
Assessment of allergenicity RA in food and feed derived for biotechnology products
Evaluation of natural materials and food components for use in food contact materials
Estimation of relative potency factors
Environmental aspects of RA for food additives and flavourings
Guidance to support assessment of *in vitro* mode of action studies

Feedback from the SC on the BPA draft opinion

A two-step mandate on BPA re-evaluation was received in 2016:

- to establish a methodology for defining the hazard assessment protocol, and
- To re-evaluate the risks to public health relating to the presence of BPA in foodstuffs.

The aim of the assessment is to evaluate whether the new scientific evidence still support the previous temporary Tolerable Daily Intake (t-TDI) established by EFSA (2015).

Based on the available dietary exposure estimates, the CEP Panel concluded that there is a health concern from dietary BPA exposure for all age groups.

A public consultation on the draft opinion was launched in Nov 2021 and closed in February 2022. The WG is currently screening the comments received and further exchange with other Stakeholders, EU Member States, and FDA and EMA representatives.

The SC discussed aspects of the risk assessment approach as they were applied during the production of the draft Opinion.