EFSA 7th ROUNDTABLE WITH INDUSTRY ASSOCIATIONS

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WG on Derivation of Health Based Guidance Values (HBGV) for regulated products that are also nutrients

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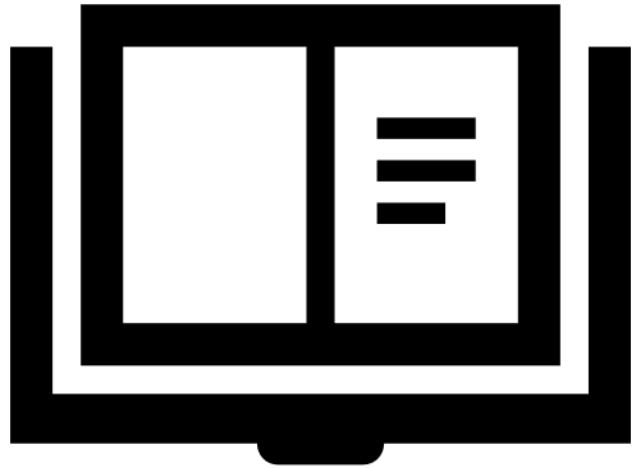
1. Context and Background

- The HBGV for nutrients are the Upper Levels (UL) established by the NDA Panel
- For food additives and pesticides, EFSA regularly establish HBGVs, e.g. Acceptable Daily Intakes (ADI)
- Some nutrients are also used as regulated products, requiring regulatory assessment (e.g. phosphates and chlorides as additives, copper in pesticides and feed additive)
- This can lead to a complex situation: two EFSA assessments requiring the establishment of HBGVs for the same substance under different regulatory frameworks

2. Terms of Reference

1. Define the general approach on how to estimate the risk to consumers regarding the exposure to **additives and other substances in regulated products which are also nutrients**.
2. To advise on the terms and definitions that should be used by EFSA.
3. Consider how to present to risk managers information relevant for their decision-making, covering the overall risk for consumers from all exposure sources, as well as the specific contribution from the exposure related to the regulated product.
4. Provide some recommendations for using and combining experimental animal studies and human nutrition information when setting HBGVs for regulated substances that are also nutrients.

3. Document´s overview



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        3.3.1 Hazard identification and characterisation of chemicals in food
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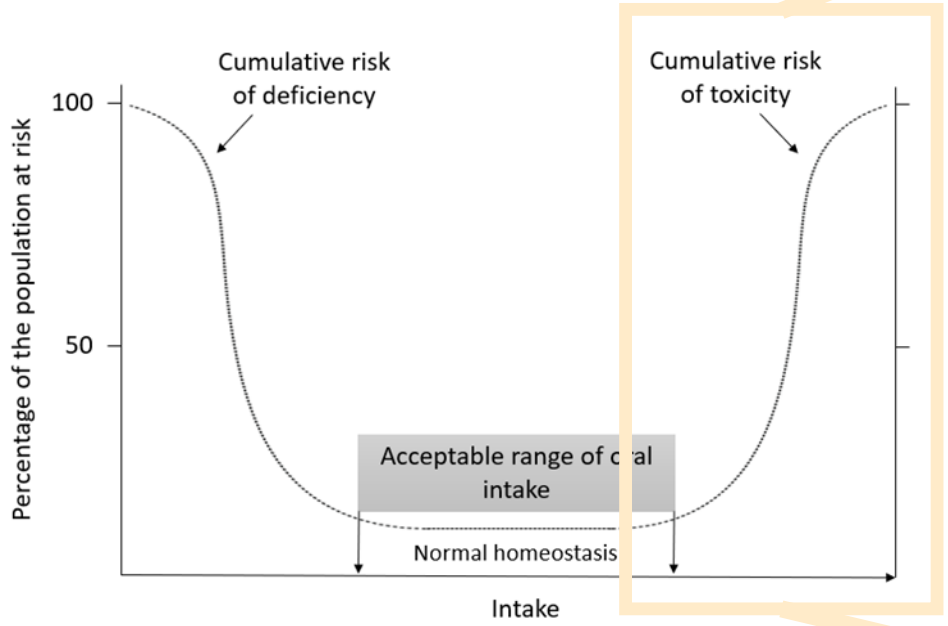
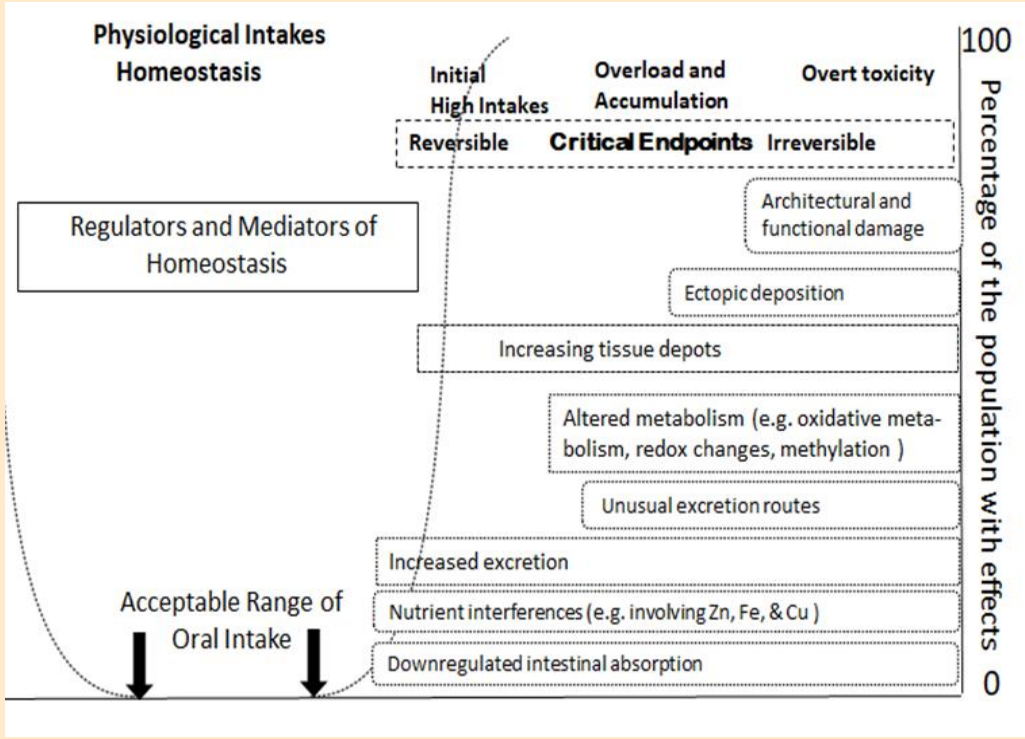
Appendix B. Illustrations of the endogenous kinetics and homeostatic mechanisms of essential trace elements

Annex A. Review of current EFSA approaches for establishing HBGVs for nutrients used as regulated products

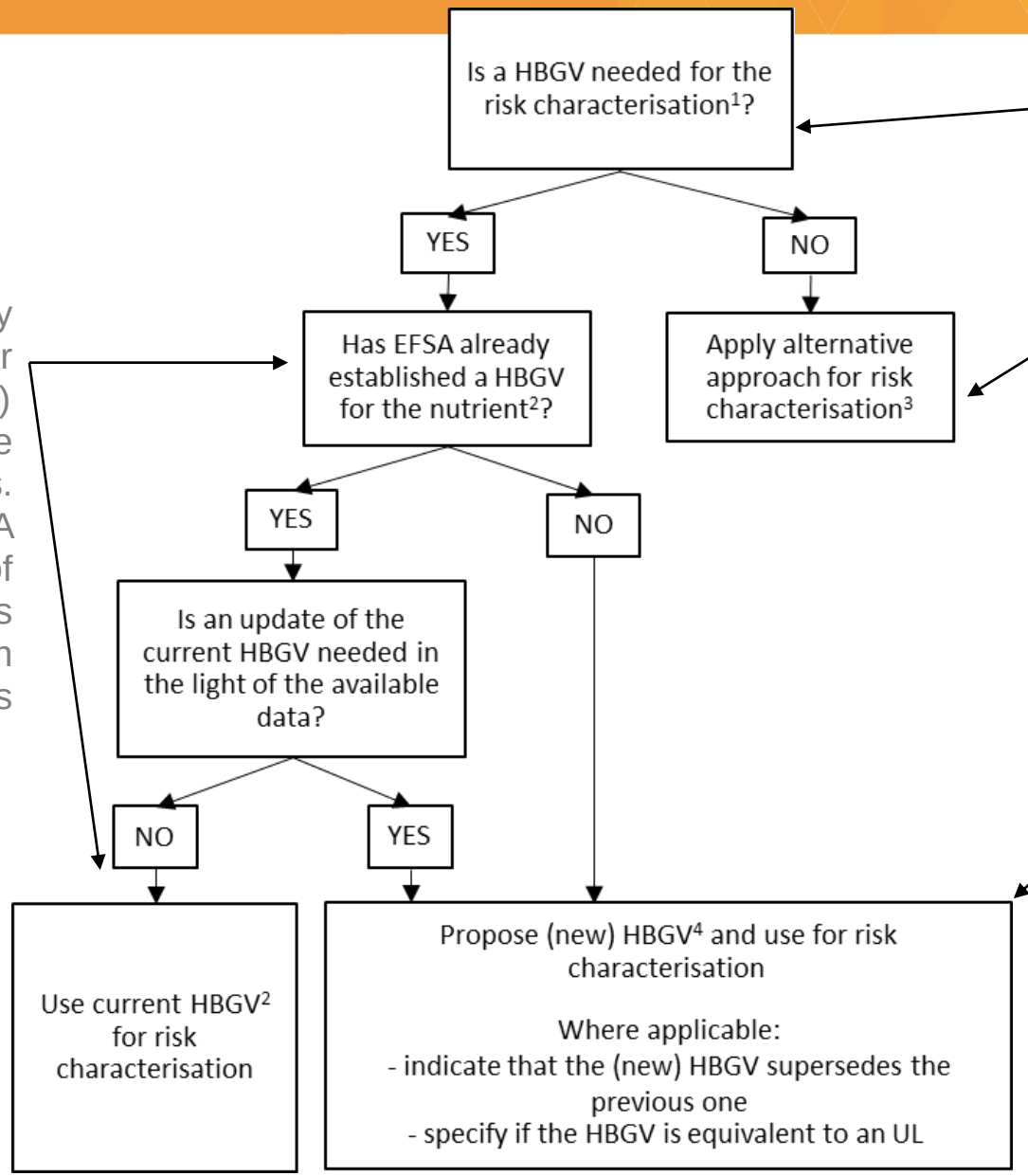
3. Key scientific elements





- Hazard assessment should consider that the regulated substance is a nutrient
- Exposure assessment should consider the contribution from the regulated use and the intake from other dietary sources
- Risks characterisation should be based on the total intake of the nutrient

3. Decision tree for risk characterisation



1. The need for establishing a HBGV should be established according to the sectoral legislation.

2. This includes ULs established by the SCF/NDA Panel or other HBGVs for nutrients (e.g. ADI) established by other Panels in the context of previous assessments. Indications from the SCF/NDA Panel on the highest level of intake where there was reasonable confidence in data on the absence of adverse effects may also be considered.

3. Examples of alternative approaches include, for example, the application of a margin of exposure (MoE); comparative approaches in which the regulated product under evaluation can be considered "as safe as" already authorised products; or estimations based on the relative contribution of the use as regulated product to total dietary intake.

4. When data are insufficient for establishing a HBGV, an indication on the highest level of intake where there is reasonable confidence in data on the absence of adverse effects may be provided.

4. Next steps

- Public consultation will end TODAY
- All comments will be addressed
- Adoption by the Scientific Committee expected by end of 2020
- Implementation in 2021

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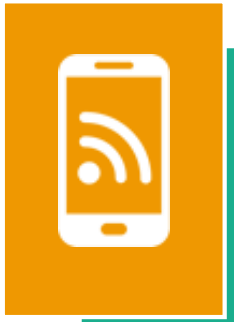

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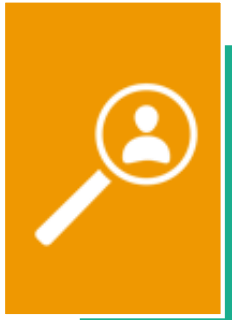

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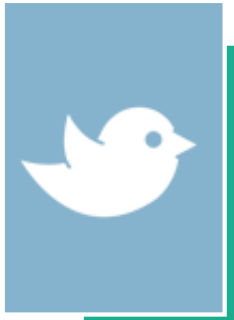

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