

Risk-Ranking of Chemicals at the Swedish Food Agency

Salomon Sand

Department of Risk-Benefit Assessment

Swedish Food Agency (SFA)

sals@slv.se

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Risk-ranking of chemicals

- Activity at the Swedish Food Agency since 2014
- Risk ranking of chemical and microbiological hazards in food (GP/EFSA/AFSCO/2017/01)
 - EFSA Grant 2017 - 2022
 - Swedish Food Agency and Finnish Food Authority
- Presentation will overview methods, and further applications since the EFSA-funded project

Risk Ranking of Chemical and Microbiological Hazards in Foods - Research Project and International Workshop

Salomon Sand¹, Jukka Ranta², Roland Lindqvist¹

¹Swedish Food Agency, ²Finnish Food Authority

Abstract

The purpose of this project was to improve the ability to perform risk ranking of current chemical and microbiological hazards in foods. The work was performed in three work packages (WPs) comprising an overview of chemical and microbiological risk assessment (WP1), development of methods for risk ranking (WP2), and the organisation of an international workshop (WP3). The developmental work consisted of 1) a method for chemical hazards that was also adapted for newer toxicological effect data, and 2) an exposure model applicable to both types of hazards in its design. Conclusions at the workshop included that risk ranking fundamentally would provide added support to risk management and risk communication. Both probability and severity of a health effect was regarded to be relevant to incorporate in the metric used for risk ranking. Measures of health burden were regarded as useful by many participants but there was no consensus on the most preferable metric. The value of other metrics, including less data intensive ones, was also noted. While risk ranking should be based on risk assessment principles, management aspects would ultimately need to be considered on top of this. Participants were positive to a joint framework for both chemical and microbiological hazards, but several challenges were identified. In the face of a general lack of desired data it was regarded to be important to make efficient use of the available information, and it may be advantageous if methods are compatible with different sets of evidence. It is recommended that the common metric for risk ranking is further resolved in terms of what aspects it should account for, the usefulness of particular or different metrics, as well as the concept of a tiered approach. Development of an overarching guidance for risk ranking addressing the many types of rankings possible is proposed.

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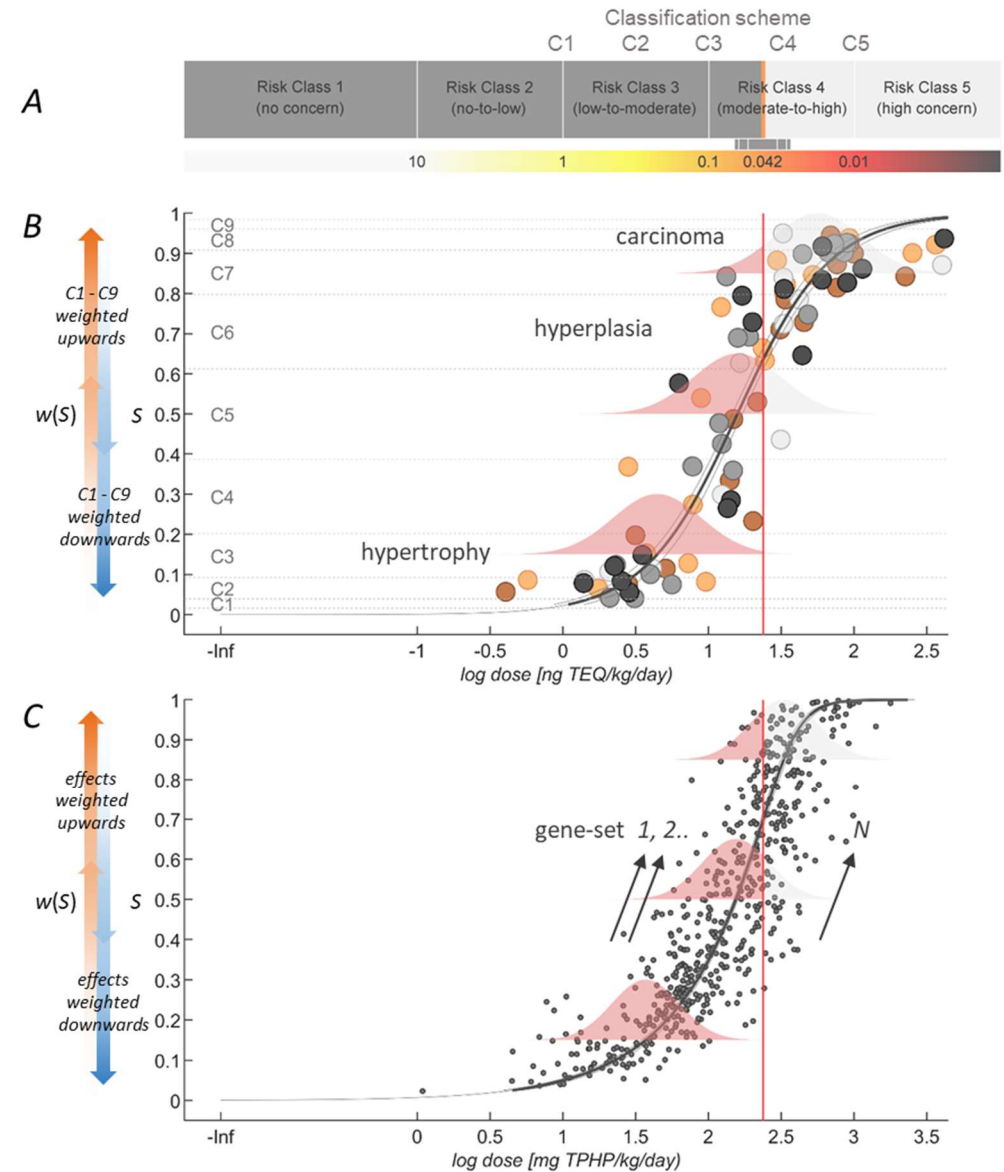
Key words: (risk ranking, chemical, microbial, dose-response, severity, health burden, DALY)

Correspondence: scientific.cooperation@efsa.europa.eu

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Overview of methods

- Set of approaches developed at that differ in complexity and data requirements
- Improve the ability to compare chemical exposures to support prioritizations
- Uses the traditional framework as a starting point, and adds a severity consideration
- Set of methods are now (together with other approaches) proposed as part of EFSA's new guidance on risk benefit assessment of foods



Overview of methods

A: The Risk Thermometer (SFA 2015)

Pragmatic approach that standardizes the HBGV

Metric: severity-adjusted margin of exposure

B: Multiple effects (Sand et al. 2018)

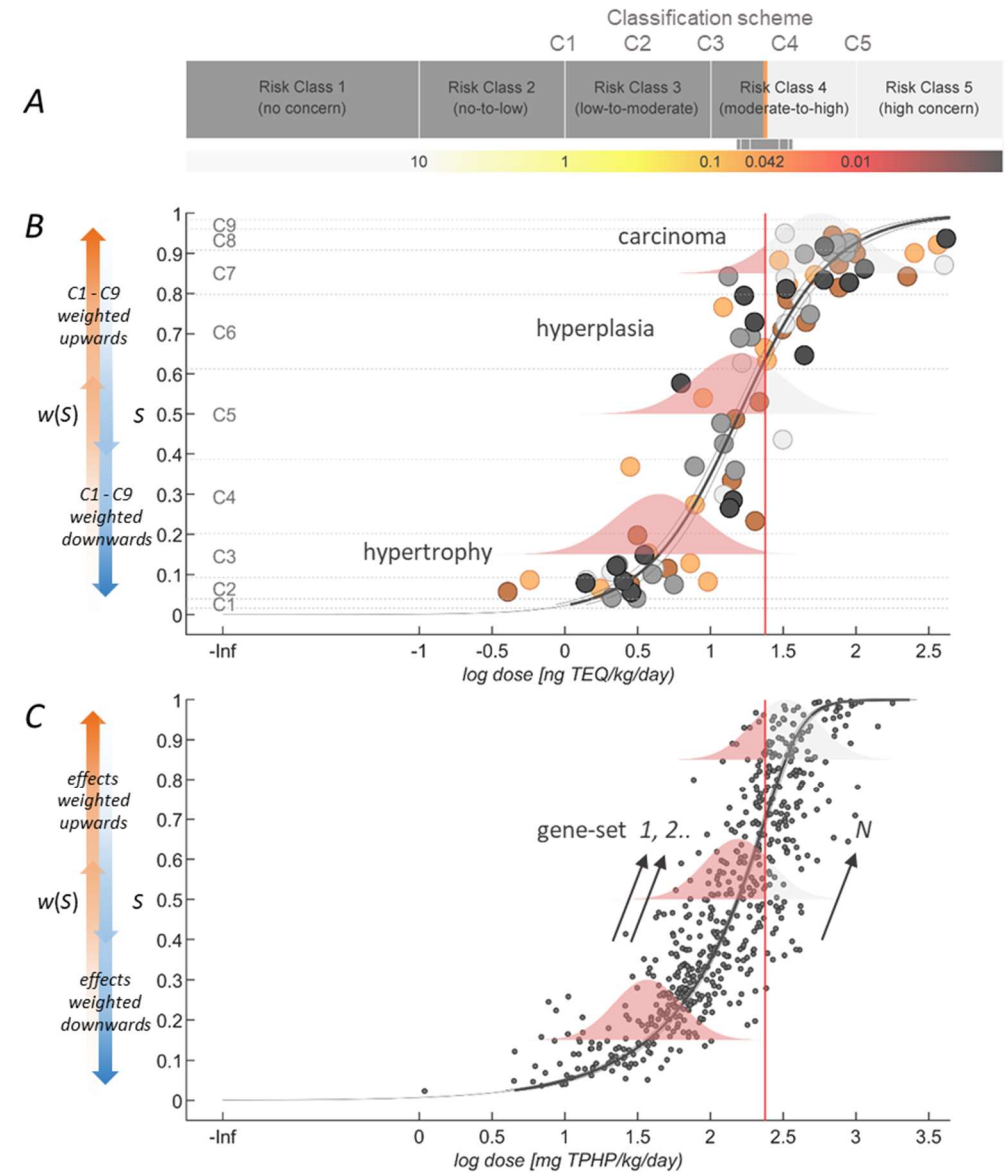
Integrates toxicity data beyond the critical effect

Metric: integrated probability of effect, or integrated probability of exceeding benchmark doses

C: Multiple effects (Sand 2022)

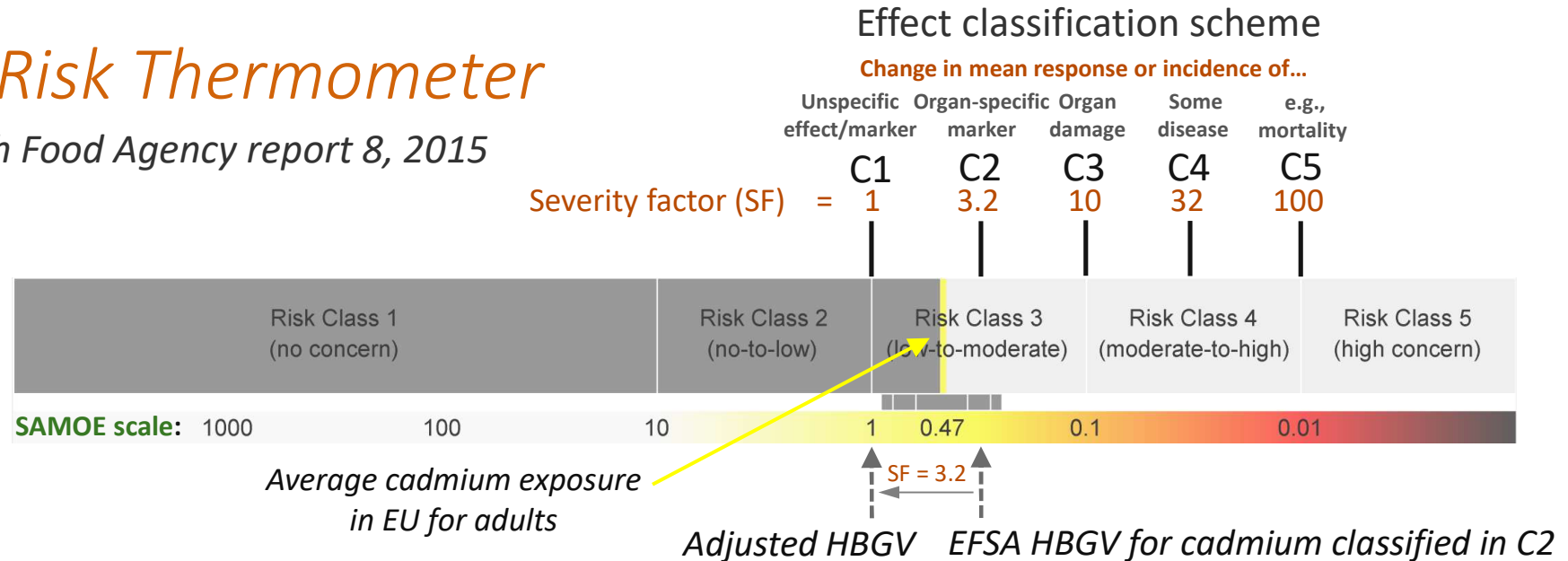
Adapt. towards future of chemical risk assessment

Metric: integrated probability of effect, or integrated probability of exceeding gene-level benchmark doses



SFA Risk Thermometer

Swedish Food Agency report 8, 2015



- Severity-adjustment of HBGV to reflect a “mild” effect
- Severity-adjusted margin of exposure: **SAMOE** = adjusted HBGV / exposure
- C1 to C5 represents a broader take on the “dose makes the poison”
- Associated severity factors (SFs) cleared by risk management
- Risk classification scale, Risk Class 1 to 5, also based on risk management
- Importance of SF may be modulated by factor, $f \times [1 \ 3.2 \ 10 \ 32 \ 100]$

SFA Risk Thermometer

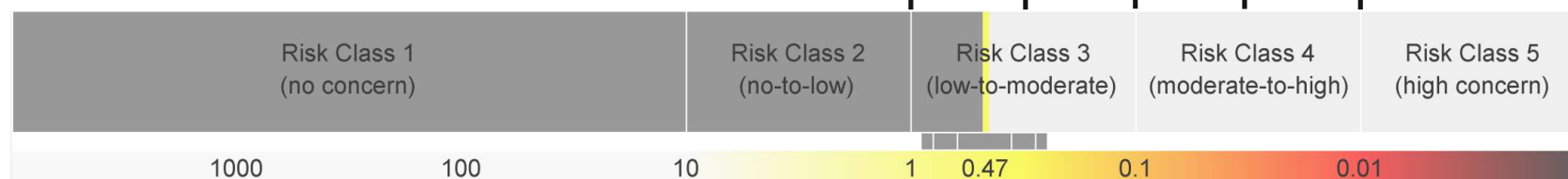
Swedish Food Agency report 8, 2015

Effect classification scheme

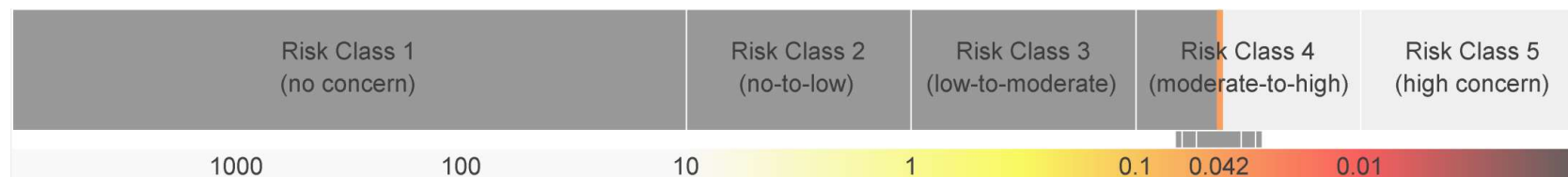
Change in mean response or incidence of...

Unspecific effect/marker Organ-specific marker Organ damage Some disease e.g., mortality

Severity factor (SF) = C1 = 1 C2 = 3.2 C3 = 10 C4 = 32 C5 = 100



EFSA TDI for cadmium
(kidney marker - C2)



EFSA RP for lead
(kidney disease - C4)

Applications since EFSA-funded project

- Risk Thermometer part of scoring approach for determination of food control program for contaminant, and has also been used to support prioritizations within the residue control at SFA
 - Prioritization of food - chemical combinations
- Drinking water project
 - Collaboration with Swedish Agricultural University
 - Project financed by Swedish Water
 - Risk Thermometer as a tool to help water suppliers to assess/prioritize the need for chemical barriers
 - Report not officially published yet
- Use of Risk Thermometer within recent SFA Market Basket study

Future perspectives

Pragmatic Risk Thermometer

- “Probability profile”/”integrated response” instead of “margin of exposure”
- Develop/improve interpretation of “Risk Classes”
- Further work on the usability for water suppliers

Further developed model/s for joint consideration of multiple effects

- Can integrated response support quantitative health impact assessment, e.g., estimation of DALY? And can it generalize to food components besides chemical hazards?
- Extended sensitivity analyses related to weights and correlated uncertainty
 - How important are the selected weights?
 - Is joint consideration of multiple effects beneficial from an uncertainty viewpoint?
- Further testing application of the model to genomic dose-response information

Conclusion

- Our practical experience indicate that a more comparative risk assessment provides a better link to risk management/decision making
- Concept would benefit from development of internationally agreed effect classification scheme/s for harmonized severity/effect ranking

Thank you



Livsmedelsverket

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