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Identification of potential emerging chemical risks in the food chain associated with substances registered under REACH– REACH 2

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European Food Safety Authority

Emerging risks identification in EFSA

Emerging risks

Introduction

The successful identification of emerging risks is at the heart of protecting public health and the environment. By identifying emerging risks in the food chain early, EFSA supports risk managers in anticipating risks and taking effective and timely prevention measures to protect consumers. Identifying emerging risks also helps to improve EFSA's ability to meet future risk assessment challenges.

EFSA defines an emerging risk as: "A risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard."

Networks

Emerging risk identification is a complex process requiring broad expertise and close cooperation with Member States, stakeholders, and EU and international agencies. Dedicated networks provide the structures needed to exchange experience, methods and data and to assess emerging issues.

- Emerging Risks Exchange Network
- Discussion Group on Emerging Risks

Methodologies

In recent years, EFSA has taken a number of practical steps to assist with the identification of emerging risks, including:

- Developing a methodological framework.
- Implementing operational processes for emerging risk identification.
- Identifying and assessing selected sources of information.
- Developing and testing tools to collect and filter relevant information.

2019

- Applicability of a food chain analysis on aquaculture of Atlantic salmon to identify and monitor vulnerabilities and drivers of change for the identification of emerging risks
- Final Report: Applying a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH - REACH 2

2018

- Emerging risks identification on food and feed – EFSA
- Project DEMETER: Concept Note for an Emerging Risks Knowledge Exchange Platform (ERKEP) Framework

2017:

- Event report on the EFSA Session organised under the International Association for Food Protection (IAFP) 2017 European Symposium on food safety

2016:

Study background:REACH 1

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Development of a novel scoring system for identifying emerging chemical risks in the foo chain

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The European Food Safety Authority (EFSA) is responsible for risk assessment of all aspects of f including the establishment of procedures aimed at the identification of emerging risks to food s a scoring system was developed for identifying chemicals registered under the European REACH that could be of potential concern in the food chain using the following parameters: (i) environme based on maximum aggregated tonnages and environmental release categories; (ii) biodegrada environment; (iii) bioaccumulation and *in vivo* and *in vitro* toxicity. The screening approach wa 100 data-rich chemicals registered under the REACH Regulation at aggregated volumes of at tonnes per annum. The results show that substance-specific data generated under the REACH can be used to identify potential emerging risks in the food chain. After application of the procedure, priority chemicals can be identified as potentially emerging risk chemicals through the of exposure, environmental fate and toxicity. The default approach is to generate a single total scc substance using a predefined weighting scenario. However, it is also possible to use a pivot tabl

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EXTERNAL SCIENTIFIC REPORT

FoBiG Fraunhofer

APPROVED: 10 June 2016

Final report: Testing a procedure for the identification of emerging chemical risks in the food chain

External scientific report. OC/EFSA/SCER/2014/03

[1]Fraunhofer ITEM, [2]FoBiG

Annette Bitsch[1], Marie-Léonie Bohlen[2], Sylvia Escher[1], Oliver Licht[1], Jan Oltmanns[2], Klaus Schneider[2], Axel Wibbertmann[1]

Abstract

The objective of this study was to develop and test a procedure for the identification of chemicals registered under the REACH Regulation that are of potential health concern and are likely to occur in the food chain. For this purpose, 100 data-rich substances registered under REACH together with four

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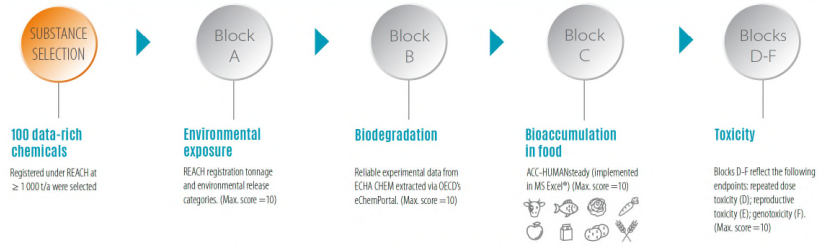
TESTING A PROCEDURE FOR THE IDENTIFICATION OF EMERGING CHEMICAL RISKS IN THE FOOD CHAIN

C. Merten, J. Oltmanns, M. –L. Bohlen, S. Escher, O. Licht, M. Macleod, V. Silano, N. Georgiadis, G. Kass

INTRODUCTION

The aim of this study was to develop and test a procedure that uses substance-specific data generated and made available in electronic form under REACH for the identification of chemical substances of potential concern in the food chain.

METHODOLOGY



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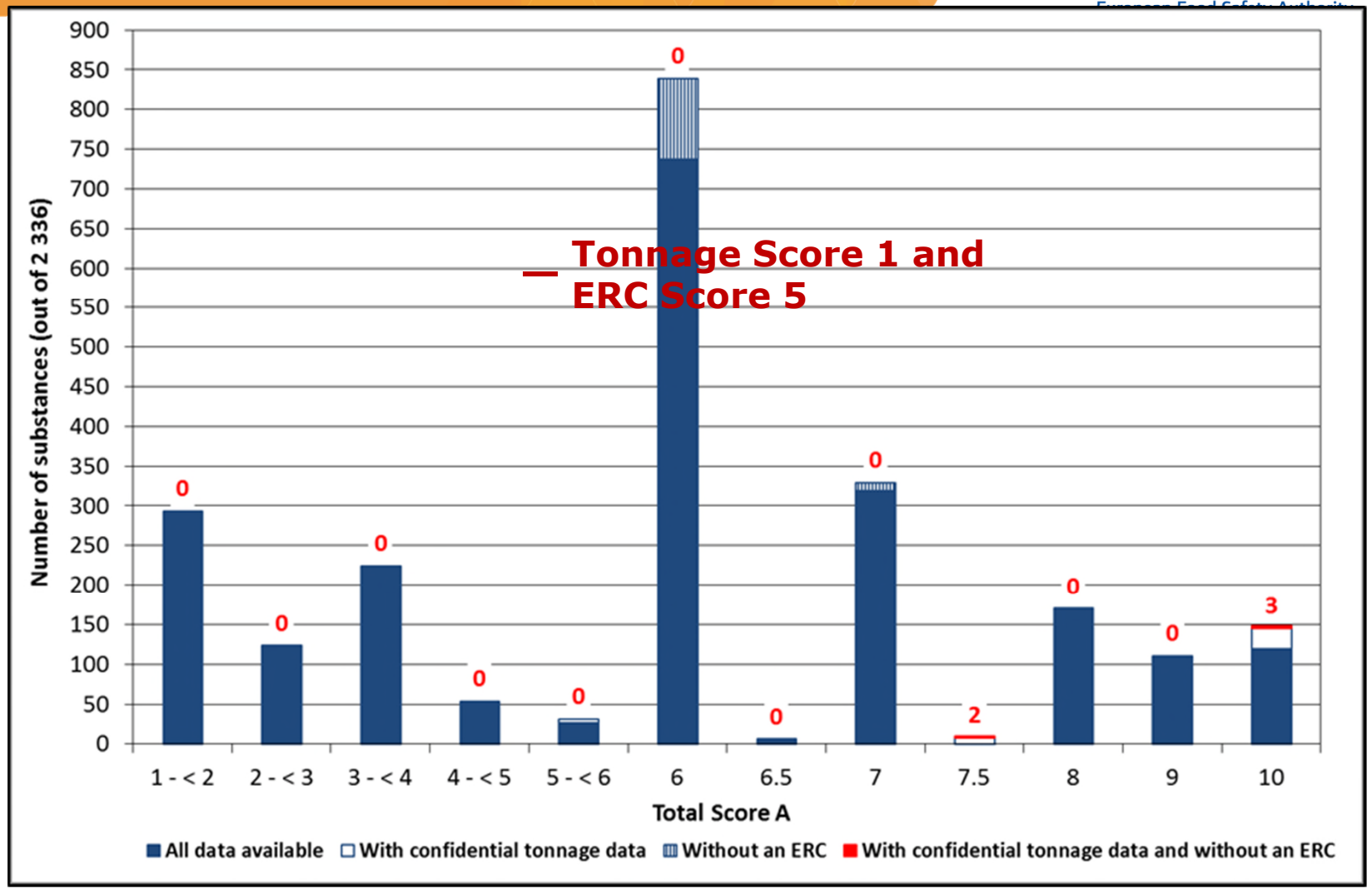
REACH 2: Project summary: Tasks

- Task 1 – Substance selection: 15 021 -> **2 336**
- Task 2 – Environmental release (Block A)
- Task 3 – Biodegradation (Block B)
- Task 4 – Bioaccumulation (Block C)
- Task 5 – Toxicity (Block D, based on classifications)
- Task 6 – Prioritisation & evaluation of prioritised substances
- Task 7– In-depth evaluation of 10 selected substances

Environmental releases (Block A)

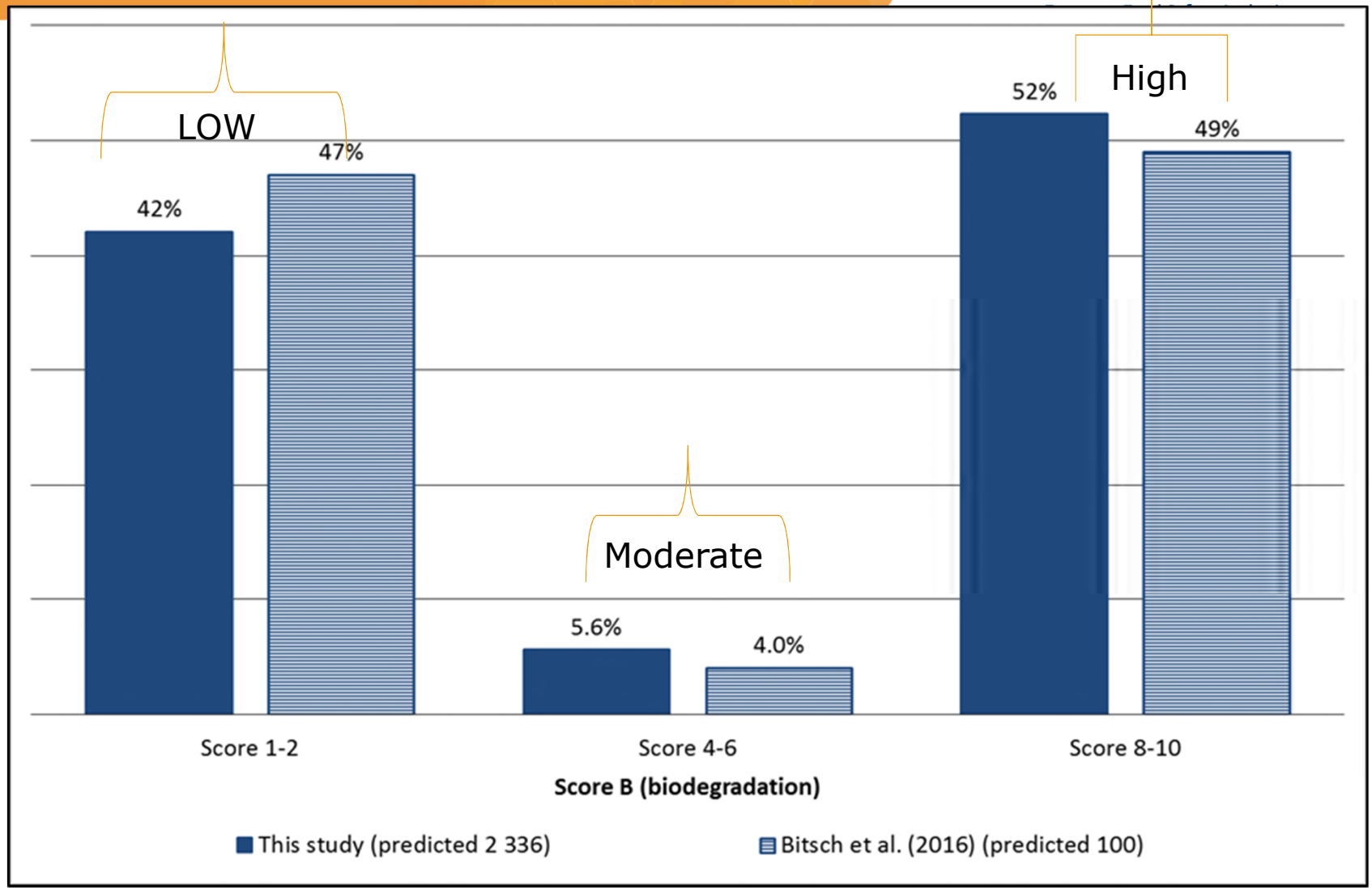
- ERC Score: based on release fractions in ECHA Guidance and use pattern (MAX: 5)
- Tonnage Score: Maximum of total tonnage band under REACH (MAX: 5)
- 60 possible scores



Biodegradation (Block B)

3 possible classes:

- ✓ Readily biodegradable: score 1 & 2
- ✓ Inherently biodegradable: score 4 & 6
- ✓ Not readily biodegradable: (score 8) & Not inherently biodegradable: (score 10)



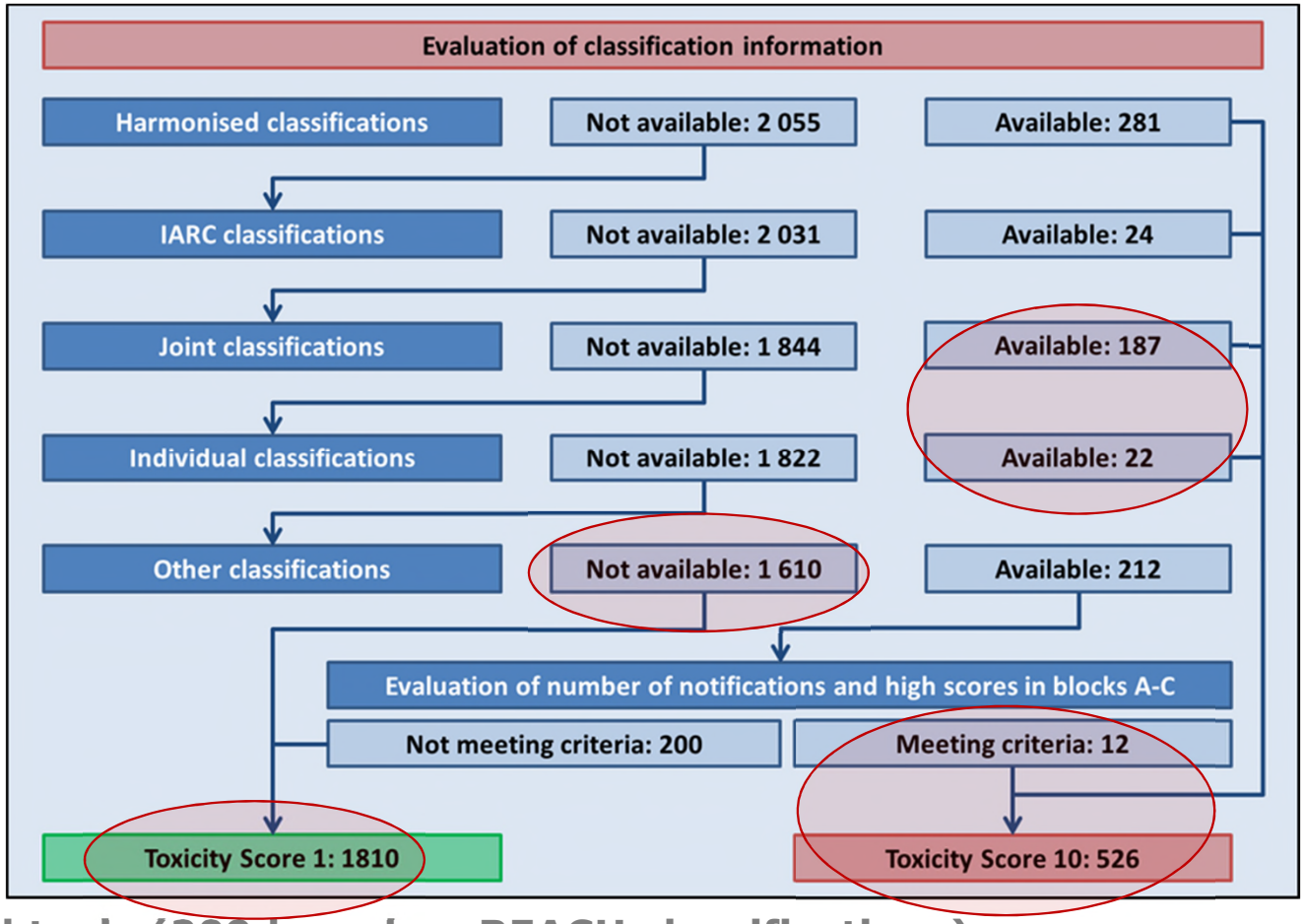
Bioaccumulation (Block C)

- Method from pilot study
- ACC-HUMANsteady batch version
- Assessment of 11 food (e.g. fish, milk, tuber, fruit) and 1 feed (grass) categories
- All input values predicted in QSAR Toolbox (and defaults)
- If substance predicted to strongly accumulate in at least one of the food categories ->score 10 assigned for block 10;

-> <u>40 % of data predicted to strongly bioaccumulate (score 10) in food</u>

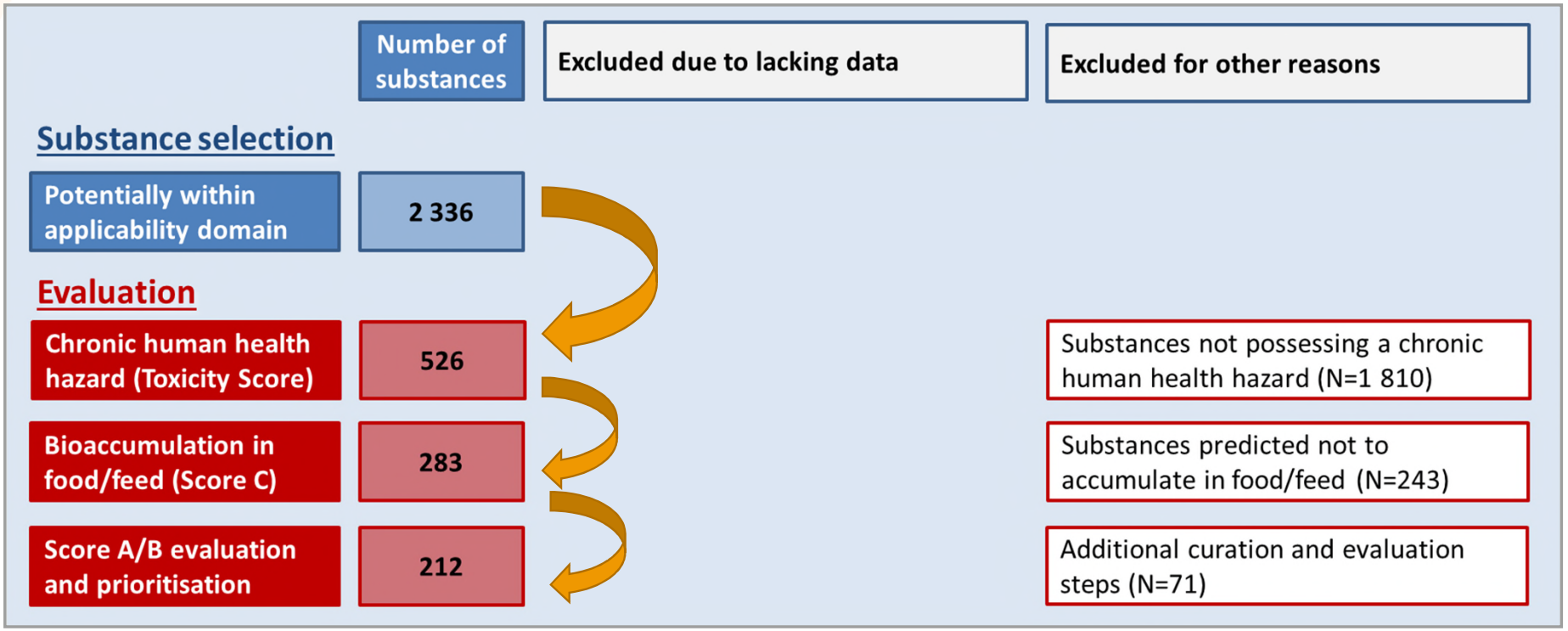
- Highlight: Comparison with screening criteria according to ECHA Guidance for PBT Assessment

Toxicity (Block D)



- **23 % considered toxic (209 based on REACH classifications)**
- **77 % not considered toxic (majority with toxicity score of 1 have no classifications)**

Prioritisation



212 priority substances

- 81 % with little or no potential for biodegradation
- 96 % with reliable toxicity data (remaining from 'other classifications')
- Most not yet assessed for their presence in food/feed

Overall summary and conclusions

- 212 priority substances (9.1 % of the 2 336 substances):
  - ✓ Some of the highest-ranking substances also prioritized by other and/or assessed in-depth (e.g. bisphenol A, HBCDD) -> valid prioritisation results
  - ✓ However, >52 % not yet assessed with respect to human exposure via the food chain -> identification of emerging chemicals;
  - ✓ 53 % assigned a toxicity score of 10 based on classifications in REACH registration dossiers study -> identified substances that would not have been recognized if only harmonized classifications were used (or IARC);
- In-depth evaluation of 10 substances
  - ✓ Environmental release, biodegradation and toxicity assessment confirmed -> valid prioritisation results
  - ✓ Robust data on occurrence in food/feed generally lacking -> next steps
- Overall findings
  - ✓ Link between chronic health hazard and possible exposure via the food chain (such a link previously not recognised for most substances)
  - ✓ Data are not sufficient to conclude on ‚emerging risk‘
  - ✓ 212 priority substances are ‘emerging chemical issues

Next research step

REACH 1:
2014 – 2016
Method development

REACH 2:
2017-2019
Method application

Follow up:
REACH 3
2020 -2022
Screening of prioritised substances

Communication & outreach for collaboration

- EFSA:
  - ✓Emerging risk exchange network (EREN)
  - ✓Scientific Committee
  - ✓CONTAM panel
  - ✓CEF panel
- Europe
  - ✓ECHA, EEA, DG ENVI, DG SANTE, JRC
- International
  - ✓CODEX JECFA, ILMERAC, WHO RA emerging risk network, NORMAN network

- In preparation of the next project phase:
  - ✓Do Member States have any occurrence data on these priority substances: food/feed and/or environment?
  - ✓Please let EFSA know on any plan to screen for any of the priority substances at Member State level.
  - ✓Any interests in a collaboration with EFSA on a follow up project?

Acknowledgements

- **EFSA project team :**
  - ✓Matthew MacLeod
  - ✓Hubert Noteborn
  - ✓Vittorio Silano
  - ✓Georges Kass
  - ✓Caroline Merten

For further reading:

Jan Oltmanns, Marie-Léonie Bohlen, Sylvia Escher, Markus Schwarz, Oliver Licht, 2019. Final report: Applying a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH – REACH 2. External Scientific Report. OC/EFSA/SCER/2016/01-CT1. EFSA supporting publication 2019:EN-1597 URL link: https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1597

Data generated in this project available at ZENODO: https://zenodo.org/record/2613616#.XQeMLv7gqHs