ACRYRED The COST Action CA21149 ACRYRED

Concentration Targets: An Acryred View

Neil Buck, on behalf of AcryRed Working Group on Concentration Limits

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- Prevailing authoritative approach to limit setting
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- Take home messages

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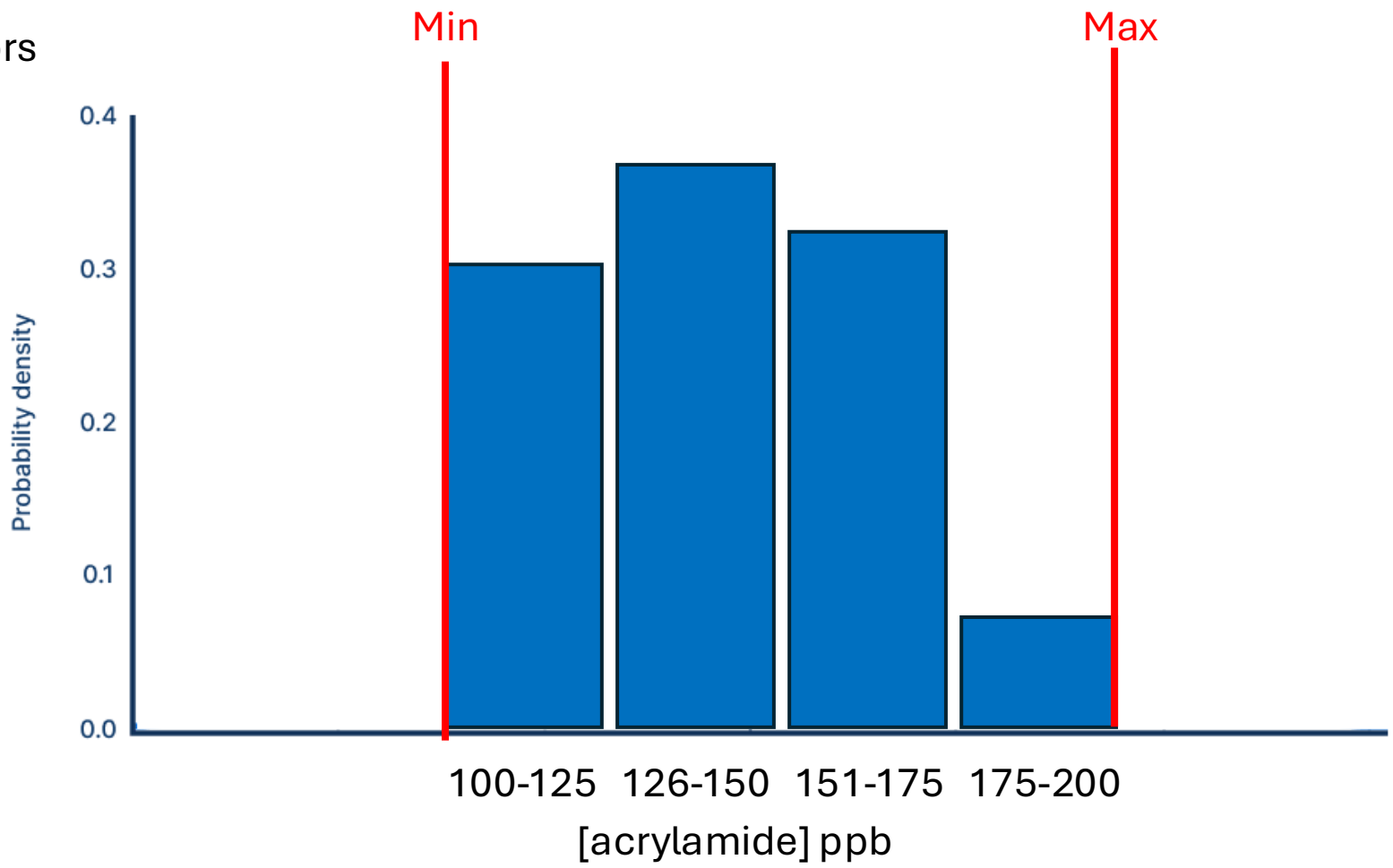
Concentration limits are needed to understand if mitigation is needed and its success

Concentrations from the perspective of food operators



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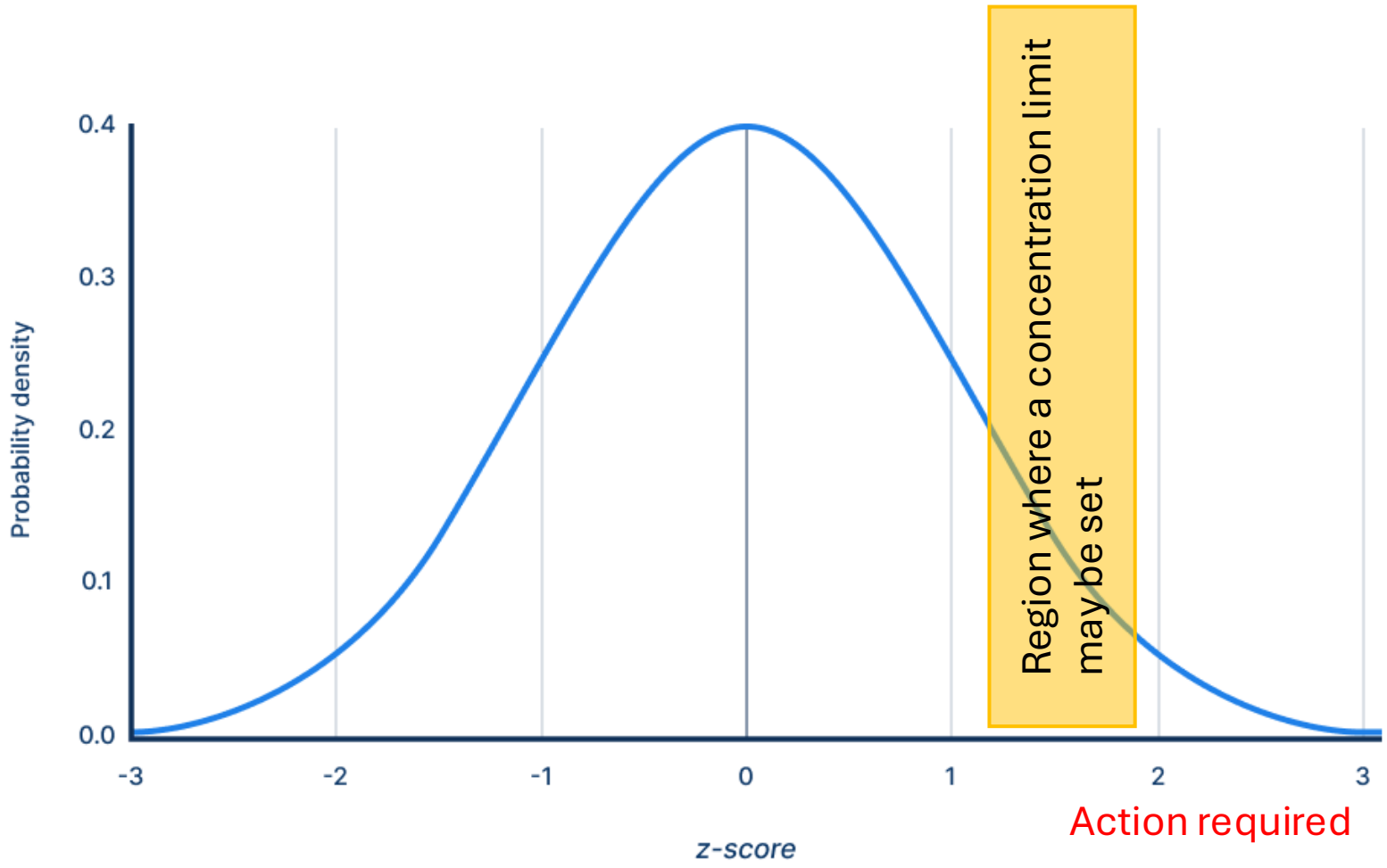
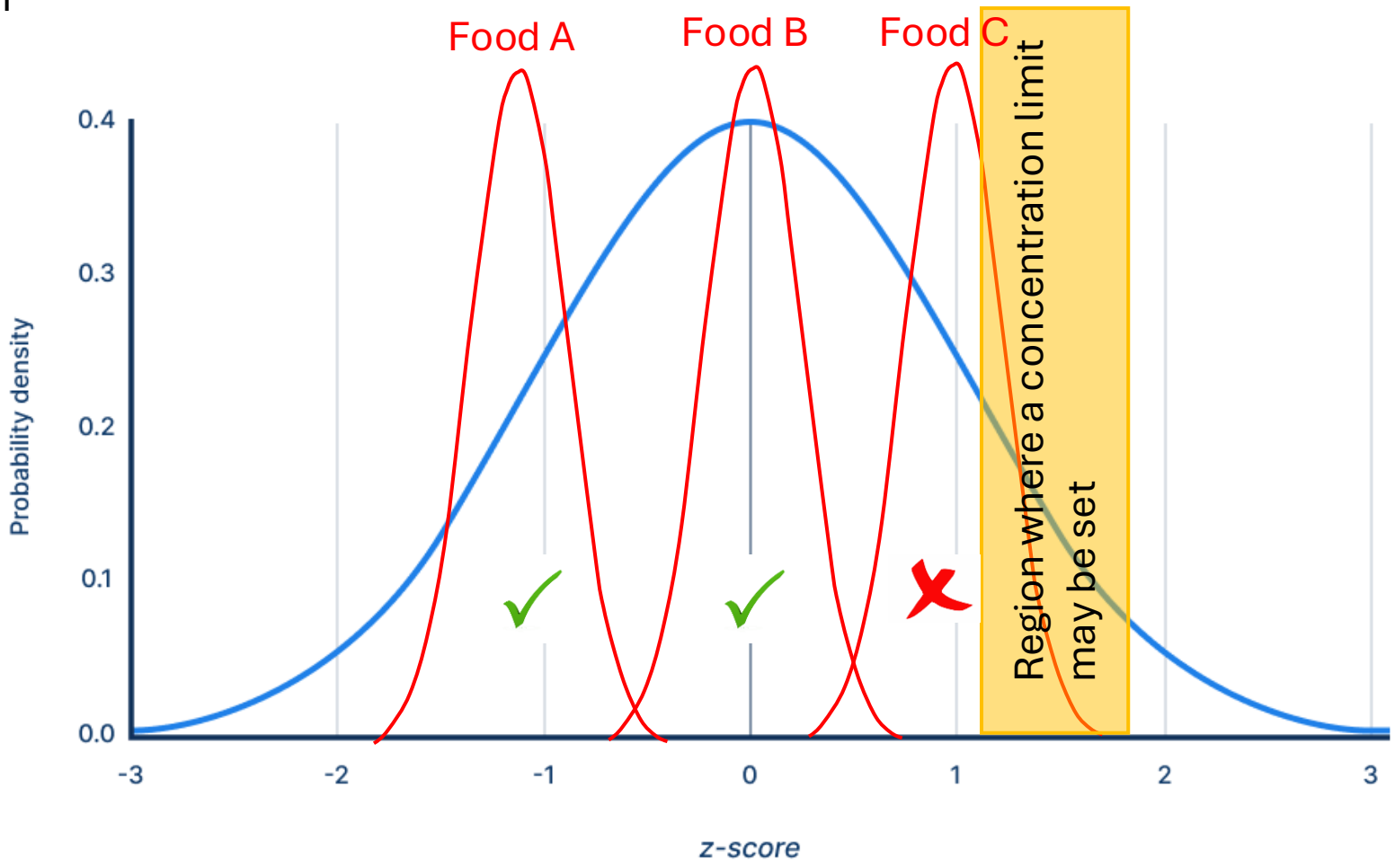
Concentration limits are needed to understand if mitigation is needed and its success

Concentrations from the perspective of authorities



The reality of setting concentration limits for broad food categories

Reality of regulatory approach



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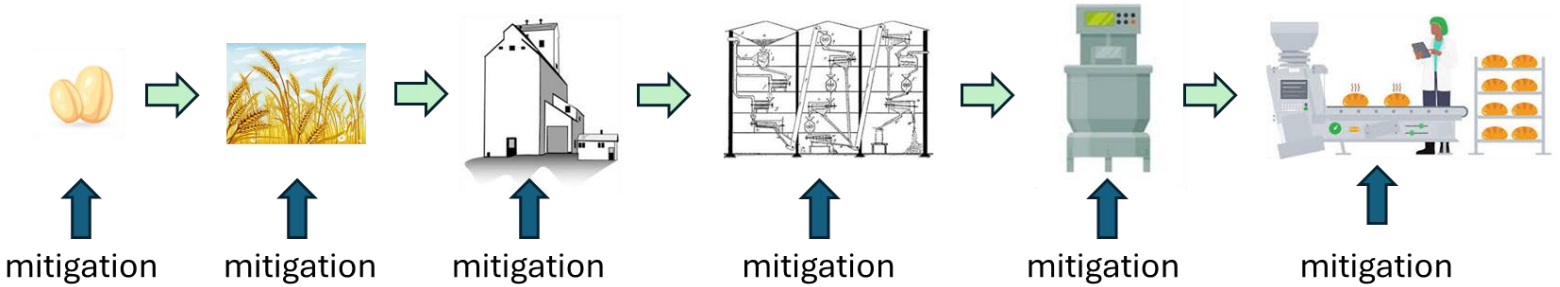
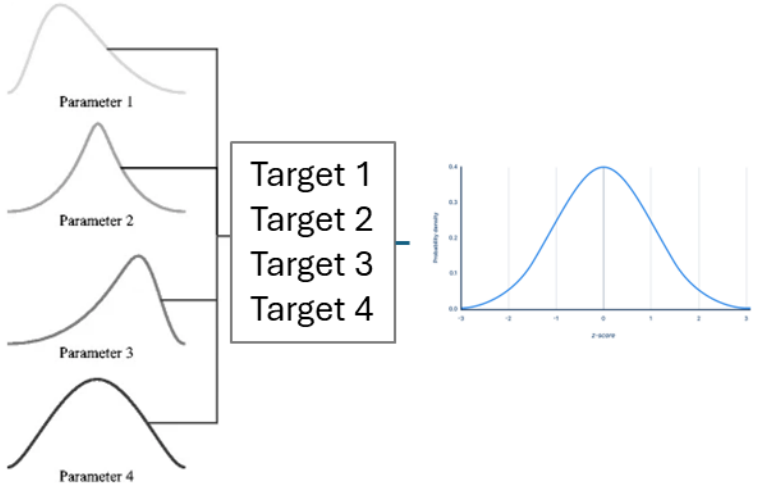
Concentration limits can never be fully representative



Variables to consider

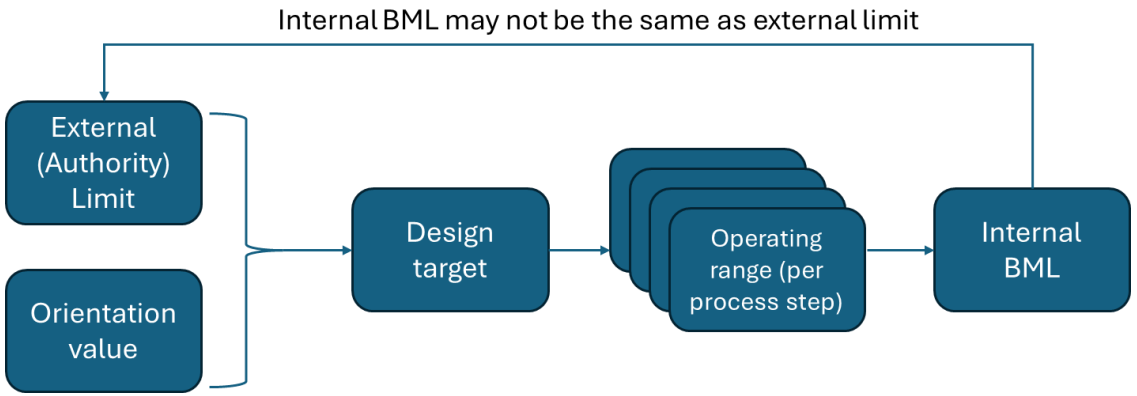
Effect of Compounded Variability

Diversity of Foodstuffs within a product category



Concentration limits need to be translated by food operators

New product development:

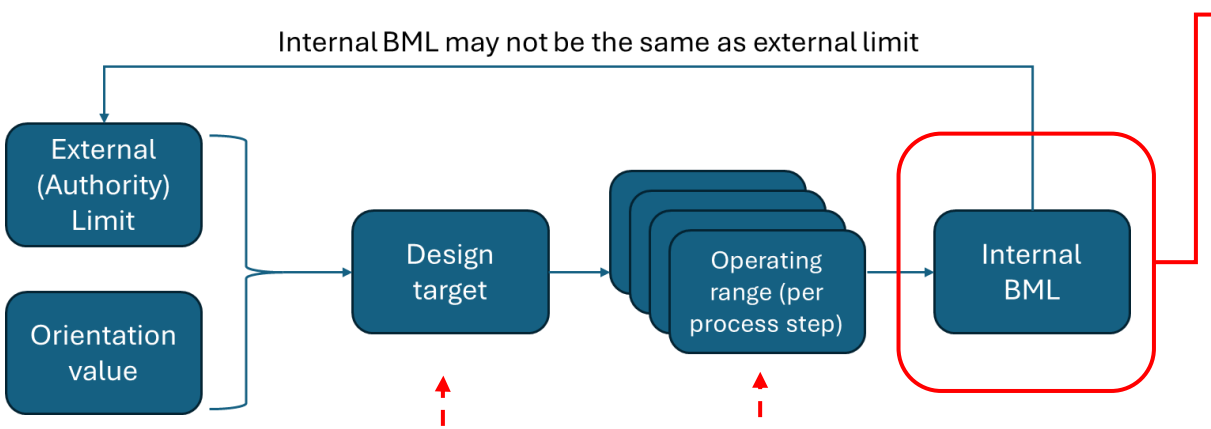


External Limit should be converted into Internal Limit(s)

Existing products:

Concentration limits need to be translated by food operators

New product development:



Existing products:

Distance from internal BML	Actions
Close to limit (< x ppb)	Process mitigation: Trial method a
Medium distance from limit (x to <y ppb)	Process mitigation Trial methods a+ b
Far from limit (>y ppb)	Product mitigation

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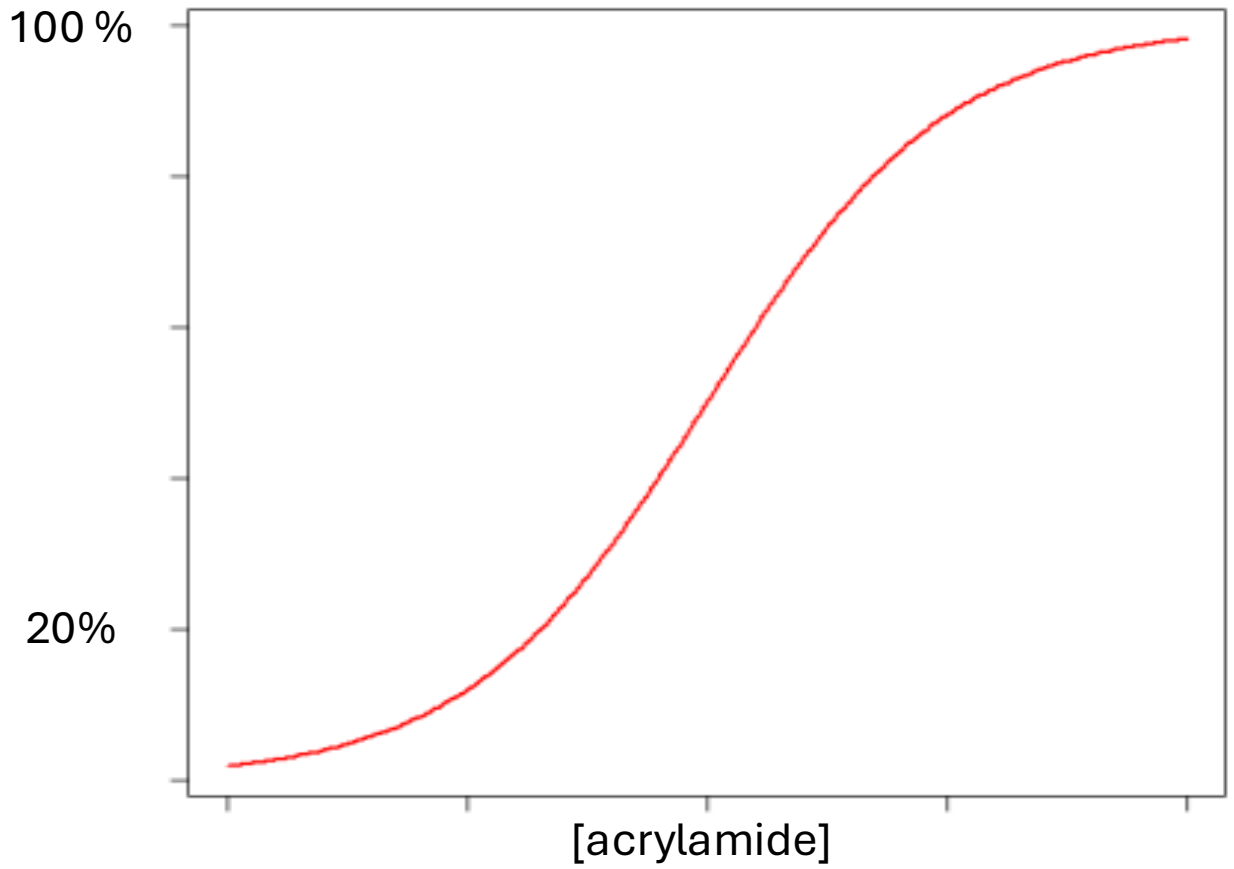
Mitigation has consequences

Cumulative distribution of products within a food category



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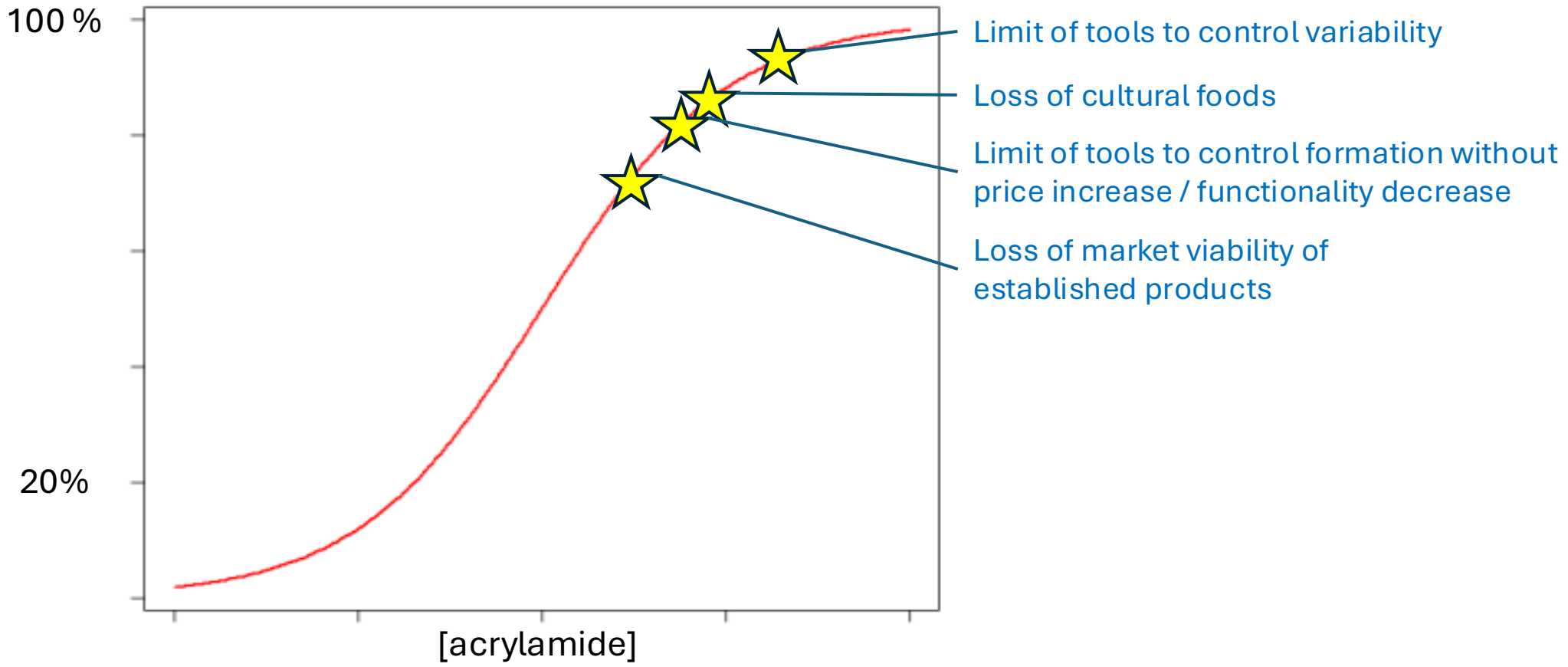
Mitigation has consequences

Cumulative distribution of products within a food category



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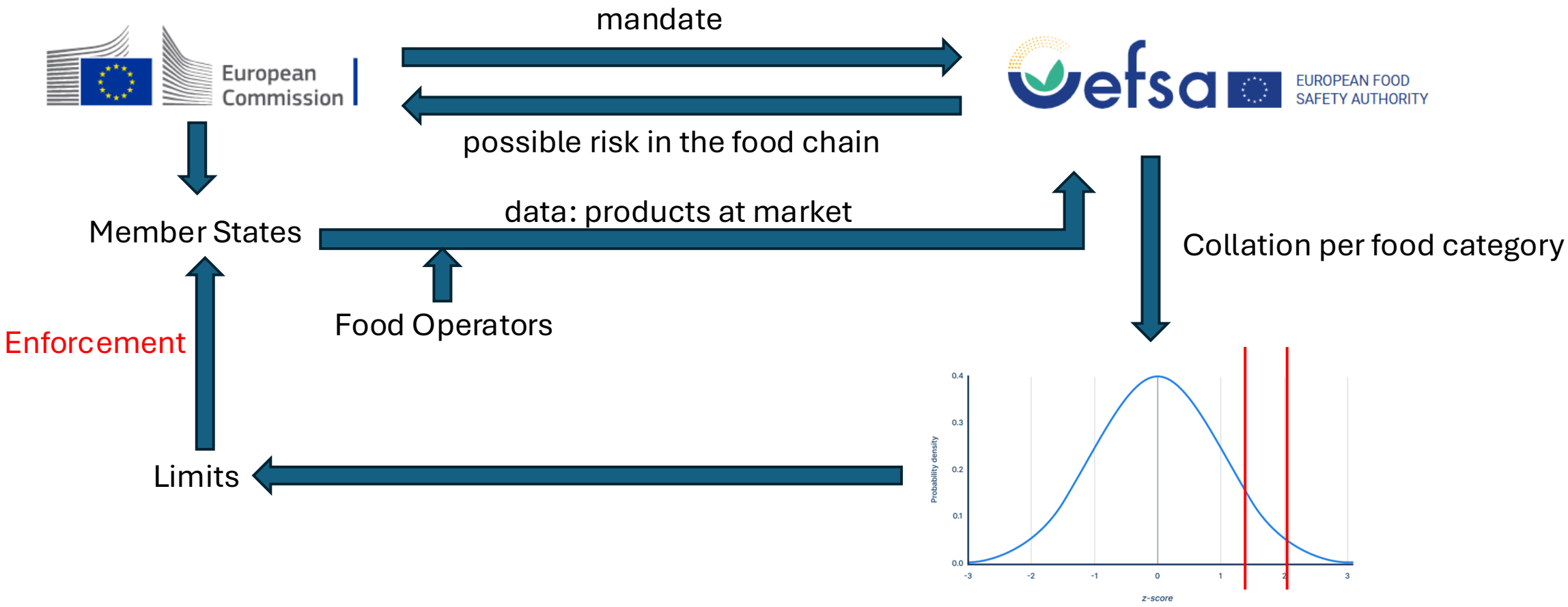
Practical Aspects

Summary

- Limits work best for specific products. The wider the food category the more problematic the limit.
  - Penalisation of specific foods
  - Representiveness of the data
- Limits at finished product level, need to represent multiple variables in the upstream. Compounded variability.
- Food operators have to translate limits into operational measures.
- Acrylamide cannot be ‘continuously reduced’ unless society is willing to accept changes to foods that are available
  - Home cooked foods continuously increase their proportion of overall acrylamide exposure

EU authoritative approach to limit setting

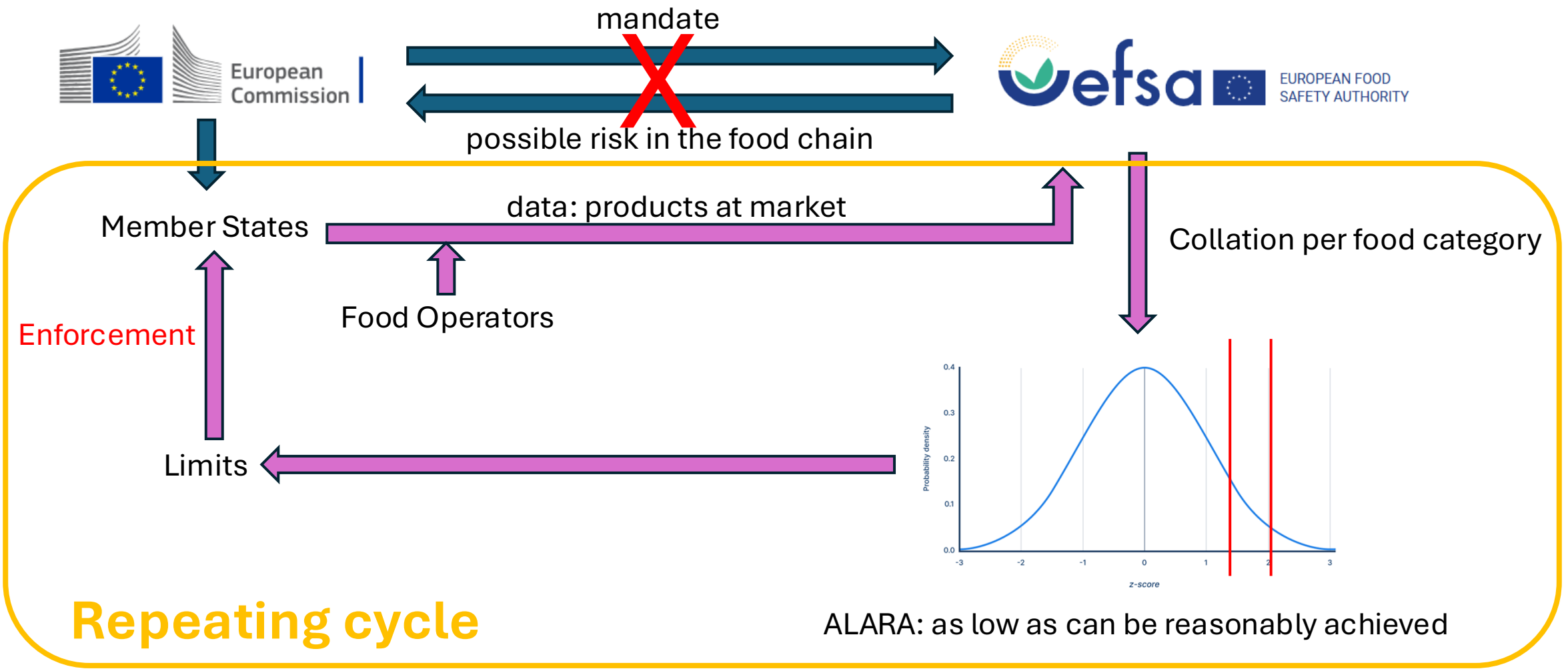
Initial derivation of limits



ALARA: as low as can be reasonably achieved

EU authoritative approach to limit setting

Once limits are established



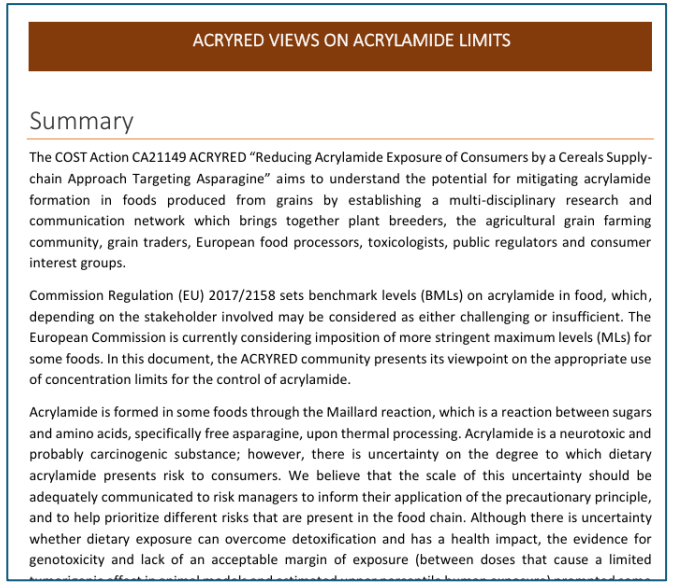
A few words about ALARA – as low as can be reasonably achieved

- ALARA requires a continuous reduction in concentrations.
- In the case of genotoxic carcinogens, the prevailing risk management approach is that there is no safety threshold.
- Despite the risk management approach, risk assessors widely accept that safety thresholds are the reality for such compounds (physiological detoxification mechanism exist).
- In fact, EFSA does already apply a *de facto* safety threshold to determine whether (or not) there is an unacceptable risk in the food chain (which then stimulates EC to take action, or not).
- However, such established approaches are difficult to translate into 'safe' exposures per type of food (only used to calculate risk as either acceptable or not, at the level of the overall diet).
- Whilst:
  - the regulatory construct demands that 'contaminants' be continuously reduced,
  - and risk managers consider that genotoxic carcinogens are not acceptable at any exposure,
  - and risk assessment methods have not developed to better quantitate risk from genotoxic carcinogens …
- It remains the case, that when a safety concern is identified due to exposure from all foods, the regulatory approach is to reduce concentrations in every food under the ALARA approach:
  - Irrespective of the contribution of that food to overall exposure
  - *Ad infinitum*, irrespective of whether a reevaluation of risk using the '*de facto* safety threshold' would indicate acceptable risk

AcryRed View

ACRYRED VIEW ON ACRYLAMIDE LIMITS

- We reviewed how limits can be set
- Identified the approach we believe is appropriate as a part of acrylamide mitigation



ACRYRED VIEWS ON ACRYLAMIDE LIMITS

Summary

The COST Action CA21149 ACRYRED "Reducing Acrylamide Exposure of Consumers by a Cereals Supply-chain Approach Targeting Asparagine" aims to understand the potential for mitigating acrylamide formation in foods produced from grains by establishing a multi-disciplinary research and communication network which brings together plant breeders, the agricultural grain farming community, grain traders, European food processors, toxicologists, public regulators and consumer interest groups.

Commission Regulation (EU) 2017/2158 sets benchmark levels (BMLs) on acrylamide in food, which, depending on the stakeholder involved may be considered as either challenging or insufficient. The European Commission is currently considering imposition of more stringent maximum levels (MLs) for some foods. In this document, the ACRYRED community presents its viewpoint on the appropriate use of concentration limits for the control of acrylamide.

Acrylamide is formed in some foods through the Maillard reaction, which is a reaction between sugars and amino acids, specifically free asparagine, upon thermal processing. Acrylamide is a neurotoxic and probably carcinogenic substance; however, there is uncertainty on the degree to which dietary acrylamide presents risk to consumers. We believe that the scale of this uncertainty should be adequately communicated to risk managers to inform their application of the precautionary principle, and to help prioritize different risks that are present in the food chain. Although there is uncertainty whether dietary exposure can overcome detoxification and has a health impact, the evidence for genotoxicity and lack of an acceptable margin of exposure (between doses that cause a limited

The basis upon which the limit is set

- Safety-based
- As low as reasonably achievable (ALARA)
- ALARA + Safety-based

The consequence of exceeding the set limit

- Aspirational targets (Indicative level / Benchmark level, BML)
- Market acceptability (Maximum level, ML)

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The basis upon which limits are set

Limit	Risk Management Objective	Type of Limit	How the limit is derived	Key points
Safety-based	Prevent harm	Static limit	Derived from safety data	Difficult to apply prospectively (what change in exposure per food is possible and needed to achieve safety goal)
ALARA	Minimize exposure	Limit is continuously reviewed	Derived from current market practice	Simple to apply, but effect on risk mitigation is not known
ALARA + Safety-based	Minimize exposure to prevent harm	Limit is continuously reviewed to both prioritize mitigation efforts and check progress towards a health protection goal	Derived from both safety data and current market practice	Combines the above so that the limits are simple to apply but are subsequently adapted based on risk mitigation

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The consequence of exceeding the limit

	Aspirational Targets (eg Benchmark levels)	Market Acceptability Limits (eg Maximum levels)
Advantages	➢ Important for products that were established at market before legal requirements ➢ Enable flexibility to account for acrylamide variability within individual products ➢ May be proportionate to the understanding of risk	➢ Easy to enforce (enforcement agents simply test product at market) ➢ Strong driver for compliance across the wider industry
Disadvantages	➢ Significant effort required by enforcement bodies ➢ Resulting lack of enforcement does not incentivise compliance across the wider industry ➢ Uncertainty on how much acrylamide in a product is considered too much	➢ Do not provide flexibility to account for unpredictable acrylamide variability ➢ Causes a focusing of compliance effort on the topic, as opposed to other food safety topics ➢ Cause significant market disruption, despite unclear consumer benefit ➢ The time it takes for analysis can cause supply chain disruption, esp short shelf-life products

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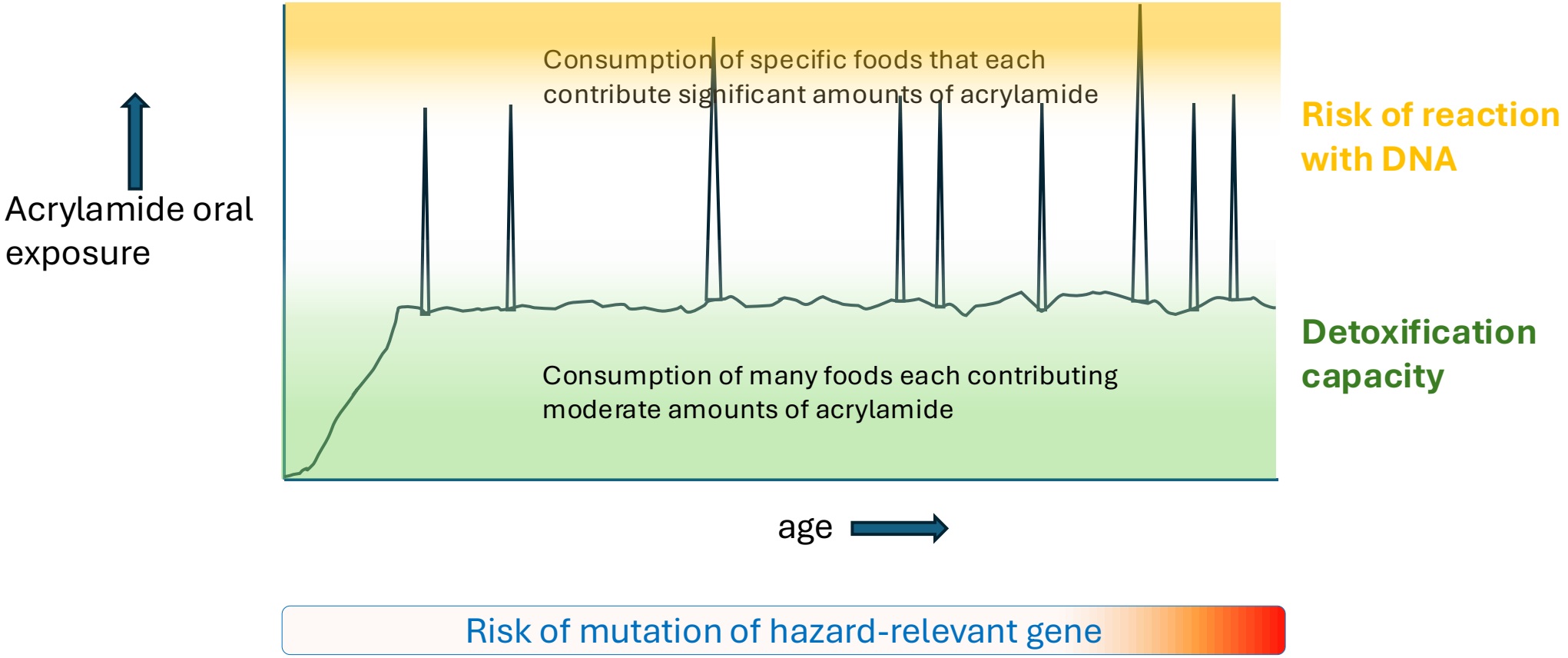
Our View

Foundational Principles

- Uncertainty on the degree to which dietary acrylamide presents risk to consumers should be adequately communicated to risk managers to inform their approach.
- There should be a benefit-risk approach especially for foods that are important sources of nutrition e.g. wholegrain cereals, or those with limited mitigation options e.g. organic. Such products should not be penalized via acrylamide limits.
- Well-functioning regulatory systems establish a tangible link between consumer risk and the control measure applied:
  - the differential contribution of foods to exposure should be clarified to optimize requirements,
  - objectives: reduce background exposure and focus on foods with higher concentrations and may be eaten at a frequency and quantity that tangibly increases exposure compared to background.
- The basis for limit setting should be 'ALARA + Safety':
  - pragmatic initial setting of limits followed by targeted prioritization of foods,
  - effectiveness in achieving exposure and therefore risk reduction should be reviewed periodically.
- Given that dietary acrylamide is currently considered an unacceptable risk. Risk management should be linked to how exposure drives the risk:
  - stable chronic exposure from systematic presence in many foods, suitable for BMLs,
  - intermittent significant spikes of exposure from specific foods, suitable for MLs.

ACRYRED Mutation risk associated with dietary gentoxic substances

Illustrative example of the association between exposure and risk



Our View

BMLs & MLs

- There is a complementary role for BMLs and MLs as a part of exposure mitigation:
  - BMLs are appropriate to mitigate 'background' dietary exposure, they provide flexibility to manage variability, have been shown to be effective, so should remain the principal method by which background exposure to acrylamide via multiple sources in the diet is managed.
  - MLs should be used only to enable focused attention when there is exposure beyond the background.
  - The application of MLs is also logical for products specifically intended for consumers who are likely to be most sensitive to the adverse effects (i.e. infants and young children).
- In the case of a food that does not meet the assigned BML:
  - If it contributes significantly to overall exposure, a ML should be considered,
  - If it does not contribute significantly to overall exposure, create a sub-category in the BML system.
- Where there are food categories within which there is a large variety of products with different acrylamide formation potential, separate subcategories should be established. This would reduce the penalization of specific foods and allow more precise monitoring of concentrations.

Our View

Enforcement & the role of Industry

- BMLs have not been subject to enforcement to date:
  - Greater understanding is needed of how enforcement authorities have monitored and controlled against BMLs to prepare for the application of MLs.
  - it is not clear the degree to which many food operators are prepared for more stringent measures,
  - There is likely limited experience of extrapolating regulatory limits to 'operational limits'. The consequences of acrylamide variability within a product resulting in transgression of a limit are more serious if the limit is linked to market action.
- MLs should be justified related to consumer exposure and not on ease of enforcement (compared to BMLs).
- Greater transparency is needed from food operators on how products meet limits such that information is readily available for enforcement bodies:
  - a template needed to capture data and mitigation efforts undertaken.
- A closer cooperation is needed between authority agencies and Food Operators, e.g. data sharing on detailed food consumption databases and monitoring concentrations in different foodstuffs.

Consumers & home cooking

- It is important that consumers are adequately informed on risk and risk management they may take.
  - Consumers on a whole are not properly aware of risk and mitigation, especially with aspects related to foods that are consumed daily.

Conclusions

- BMLs linked to mitigation were an innovative solution:
  - Flexibility to factor high variability within products, and difficulty in assigning food categories
  - Appropriate given uncertainty of adverse effects
  - Shown to be effective in helping lowerer concentrations within foods

- MLs, should not happen without consideration of:
  - How MLs can be linked to risk reduction
  - The preparedness of wider food operators, and potential for market disruption

- Innovation is needed in how regulation is designed:
  - Transparency of the benefit to consumer safety
  - Solutions that maximize overall societal benefit