How the Swedish Food Agency work with additives and enzymes in food.

Lecture given at the Bertebo Conference 2016-08-30
by

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Synopsis

- Short introduction to NFA and the Principles of Risk Analysis
- General Swedish policies
- Special Swedish interests, some examples
  - Nitrite, Artificial sweeteners, Azo dyes, Emulsifiers
- Communicating risks, national experience
- Risk ranking
  - The Swedish Risk Thermometer

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- National Food Agency
  - Staff: 550
    - 330 at HQ in Uppsala
    - 220 at local officies, slaughter-houses and boarder controls
  - Budget – 500 MSEK

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NFA work for

- **Safe food** and drinking water
- **Fair practices** in the food trade
- **Healthy eating** habits

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NFA
- instructions and guiding principles

- NFA shall
  - develop and perform laboratory analysis
  - conduct investigations on food composition and dietary habits
  - make risk and benefit assessments
  - develop legislation in the food area
  - perform food control
  - issue dietary advice to consumers
  - communicate with food industry and consumers on food related issues
- The work shall be guided by the **principles of risk analysis**

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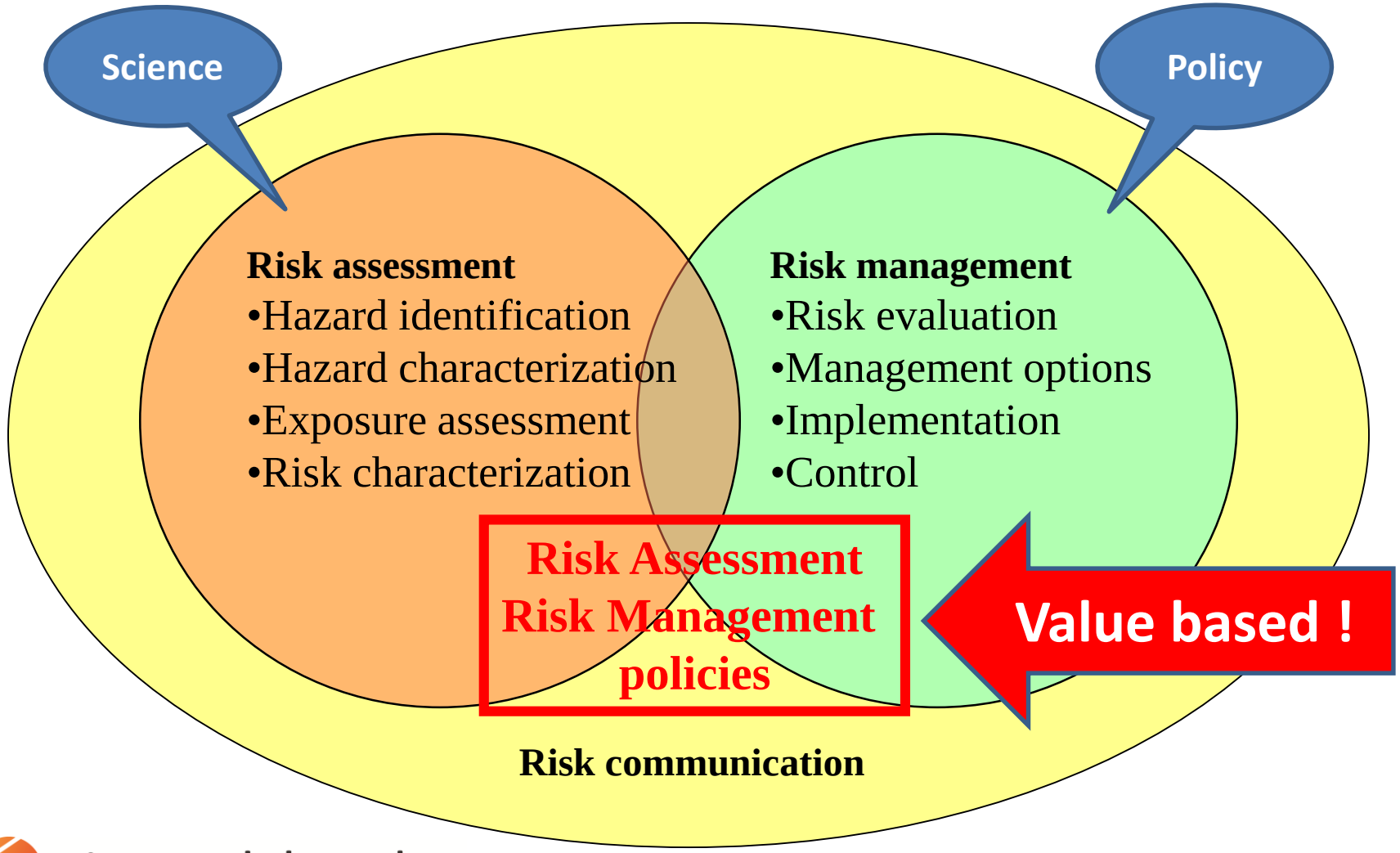
Risk analysis as a concept



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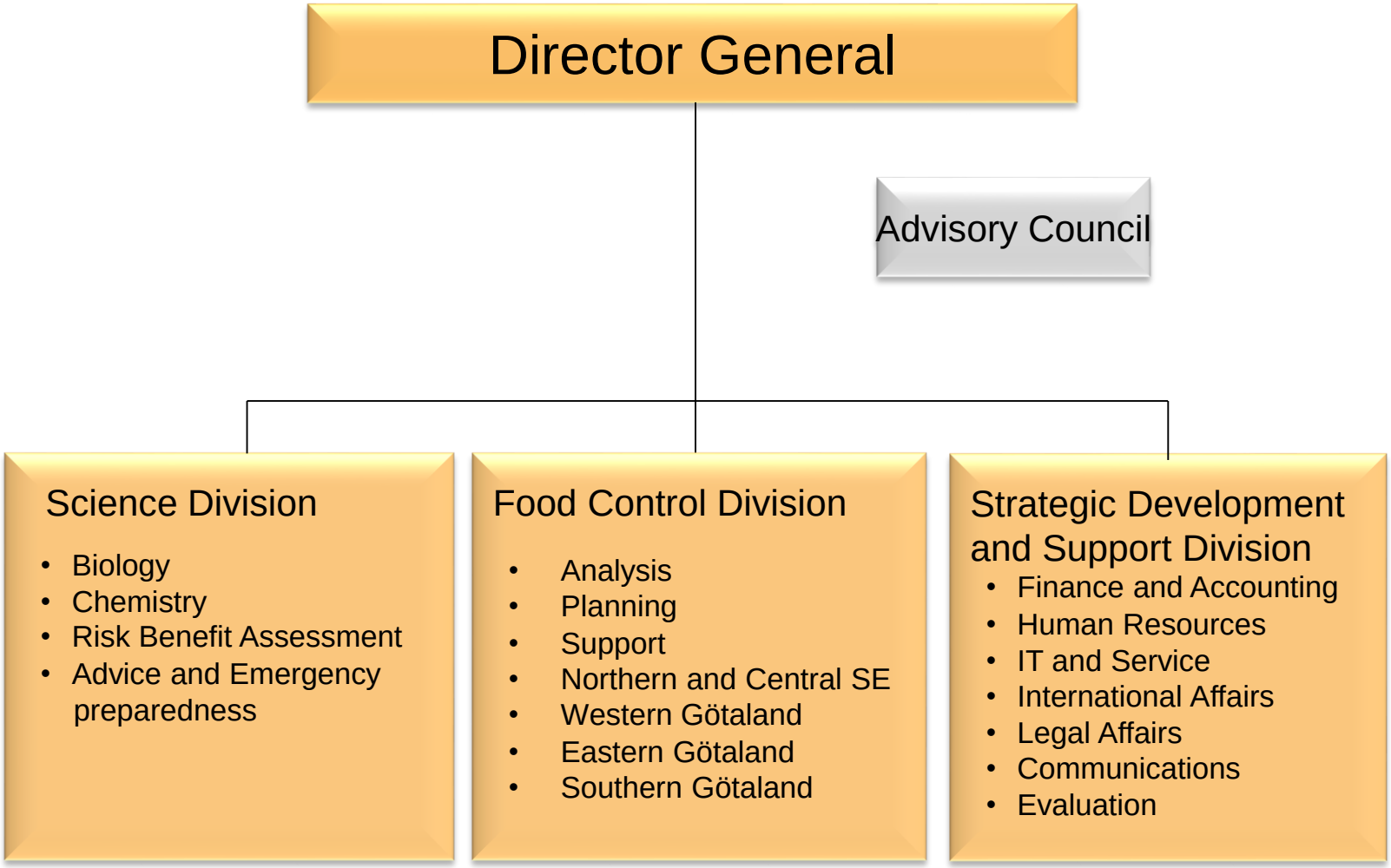
The National Food Agency



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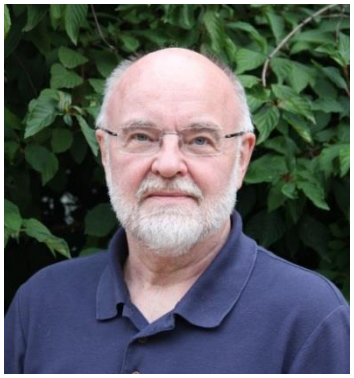
General Swedish policies

– resource allocation to scientific work with food additives



Additives were top priority in the 1970s. Registry of Additives set up. Phased out in the late 1980s. Due to financial constraints at NFA in 2002, the national work with risk assessments of additives was cut down. Focus was put on support to EFSA.

Kettil Svensson, Senior Toxicologist. CEF-panel 2008-2014

Nils-Gunnar Ilbäck, Professor, SCF before 1997 - 2003, WGs under CEF/ANS-panel 2005 and onwards.

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General Swedish policies - EFSA

- Hazard characterisation
  - No major divergent opinions
    - Allura red – conflicting opinions between EFSA panels – experimental studies were performed to help EFSA to clarify the issue
  - SE would like to see further development of the assessment procedures for
    - cumulative exposure
    - environmental risks (compare with feed additives!)
- Exposure assessment
  - EFSA assessment based on a Pan European food consumption pattern
  - Sponsors estimation of exposure
  - SE always look at sensitive groups from a national perspective
    - E.g. children, diabetics, known abnormal consumption patterns

General Swedish policies
- EU Commission, EU Council

- All additives in the EU must be authorised and listed with conditions of use in the EU's **positive list** based on:
  - a safety assessment made by EFSA
  - the technological need
  - ensuring that use of the additive will not mislead consumers
- "Demonstrate advantages for the consumers" –
  - earlier of importance in Sweden but today a secondary criteria

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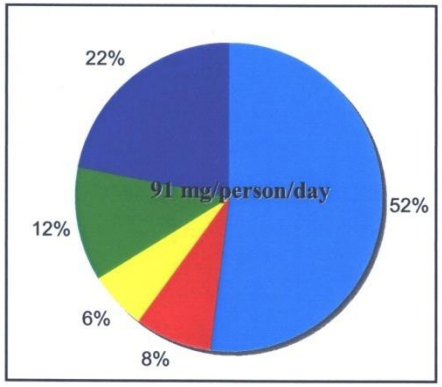
Swedish interest in nitrite

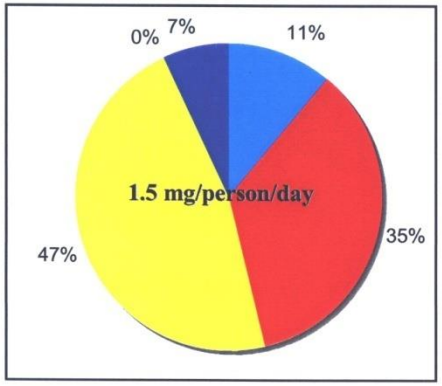
- Nitrite in meat products
  - Inhibit growth of *C. botulinum*
- Problems in risk assessment
  - Nitrite + amines = nitroso amines carcinogenic to animals
  - Formation of known animal carcinogens in man?
  - < 1 case/year – 100 cancer cases in Sweden?
- Substantial work on the formation and occurrence of N-nitroso compounds in foods started in the 1980s
- Nitrate – microbial reduction to nitrite
  - Nitrate a bigger problem than nitrite?
  - 5-20% of ingested nitrate converted to nitrite

Vegetables and fruit Animal-based products Other foods Beer Water Conversion of nitrate



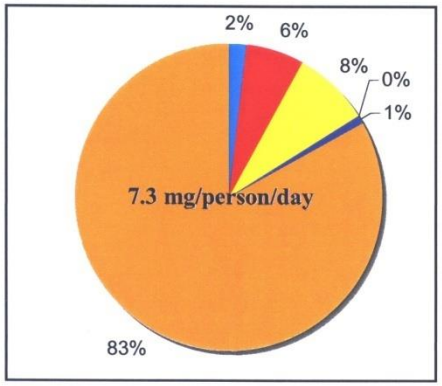
a) Dietary nitrate intake in the UK

Dietary nitrate intake in UK



c) Dietary nitrite intake in the UK

Dietary nitrite intake in UK



e) Total nitrite exposure(including endogenous conversion from nitrate) in the UK

Total nitrite exposure including endogenous conversion from nitrate in UK

- Vegetables and fruit
- Animal based products
- Other foods
- Beer
- Water
- Conversion of nitrate

Swedish interest in artificial sweeteners

- Cyclamate
  - Pharmacokinetic differences (formation of cyclohexyamine) between rats and man
    - Necessary to lower ADI (50% reduction)
  - Intake of cyclamate in diabetic children via table top sweeteners
- Aspartame
  - Phenylalanine source – real but limited problem
  - Formation of Methanol – irrelevant
  - Carcinogenicity – not relevant
    - Value of used models
  - CNS-effects – relevant in rare cases?
  - Efsa WG of National Experts
  - Support to the UK study on volunteers – not possible to substantiate alleged negative health effects

Swedish interest in Azo dyes

- Before 1995 – prohibited as additives in SE
  - Estimated 3,000 – 4,000 sensitive consumers with skin reactions.
- No exemption at EU entry 1995
  - No allergenitcity
  - Swedes not more sensitive than others
  - Initiated a media debate
- A study 2006
  - Presence in foods as stated in the product labelling
    - In cooperation with Swedish Asthma and Allergy Association, Regional Food Control
  - A questionnaire on the use to Swedish food producers
  - An in house project on the analysis of sweets and drinks on the market

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Azo dyes – 2006 study

- Azo dyes were declared in candies, drinks, desserts, flavour paste, noodles, chips and caviar.
  - The majority of products containing azo dyes were imported
    - A similar study 1999 only recorded only 1 product containing azo dyes
    - An increase in azo dye containing imported foods on the market since 1999
- Swedish food producers have a general policy of restriction
  - 7/58 producers of confectionary, drinks, ice cream and fish products use azo dyes
- Analysis of food samples
  - 11% of sweets contained azo dyes
    - A similar study 2001 showed that 15% of the studied sweets contained azo dyes
    - No increase in azo dye containing sweets on the Swedish market since 2001
  - No azo dyes were found in soft drinks

Swedish interest in emulsifiers

- Absorption of toxicants in Caco2-cells and mice
  - Aspenström 2012 – PhD thesis. Effects of fatty acids.
    - Docosahexae acid, DEHA increase uptake of Al and Cd in Caco2 cells
    - Oleic acid increase uptake of Al in Caco2 cells and mitoxantrone in mice
  - Hypothesis
    - Surface active compounds, including food additive emulsifiers can impair intestinal epithelium and contribute to increased absorption of molecules that are allergenic and/or autoimunnogenic.
    - Addressed by the EMRISK-WG of EFSA and submitted to the ANS panel for consideration

Some general Swedish trends

- Increased interest for “Clean label”
  - Less additives
  - Remove “unnecessary” ones
  - Replace with “natural components”
    - Citrus juice instead of Citric acid (E330), Nitrate rich extracts instead of nitrite
    - Minor ingredients or additives? Safety of the new alternatives.
- Increased interest for fighting “Food waste”
  - Addition of citric acid to prolong shelf life in stores and at home of e.g. potatoes. Different views on the appropriateness of this.
- A sensitive area in media terms
  - Consumers demand products with less additives
  - Most producers tries to accommodate this
  - Authorities focus on possible new problems

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Media and alarms!

- **BSE, Mad Cow Disease**
- **Dioxins in fish**
- **Acrylamide and cancer**
- **GMO**
- **Trans fatty acids and CVD**
- **Aspartame and cancer**
- **Azo dyes and hyperactivity**
- **Ehec in vegetables**
- **BPA in cans**
- **Norovirus in frozen raspberries**

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Hazard

Risk

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Communicating Risk Ranking

- Vital to rank risks in communication with consumers
  - Distorted media debate causing unnecessary fears
    - Need for a simple, transparent adaptive system
    - Facilitate understanding of the scientific process
  - Increase public trust in authorities
- Ensure proportionality of risk management response from a health perspective

The Risk Thermometer
(NFA 2015)

Four parts

- A way of expressing the toxicity of a chemical taking human exposure and severity of the toxic effect into account.
  - A severity-adjusted margin of exposure approach - SAMOE
    - a generalization of the current framework for chemical risk assessment
    - $BMDL_{10}$, AFs, severity factors (five options), exposure assessment
    - includes effects both with and without thresholds
- A model for uncertainty analysis
  - semi quantitative analysis of SAMOE components
- A risk classification approach
  - categorizes SARP values in terms of five health concern levels
- A graphical illustration of the results- tailored for different users

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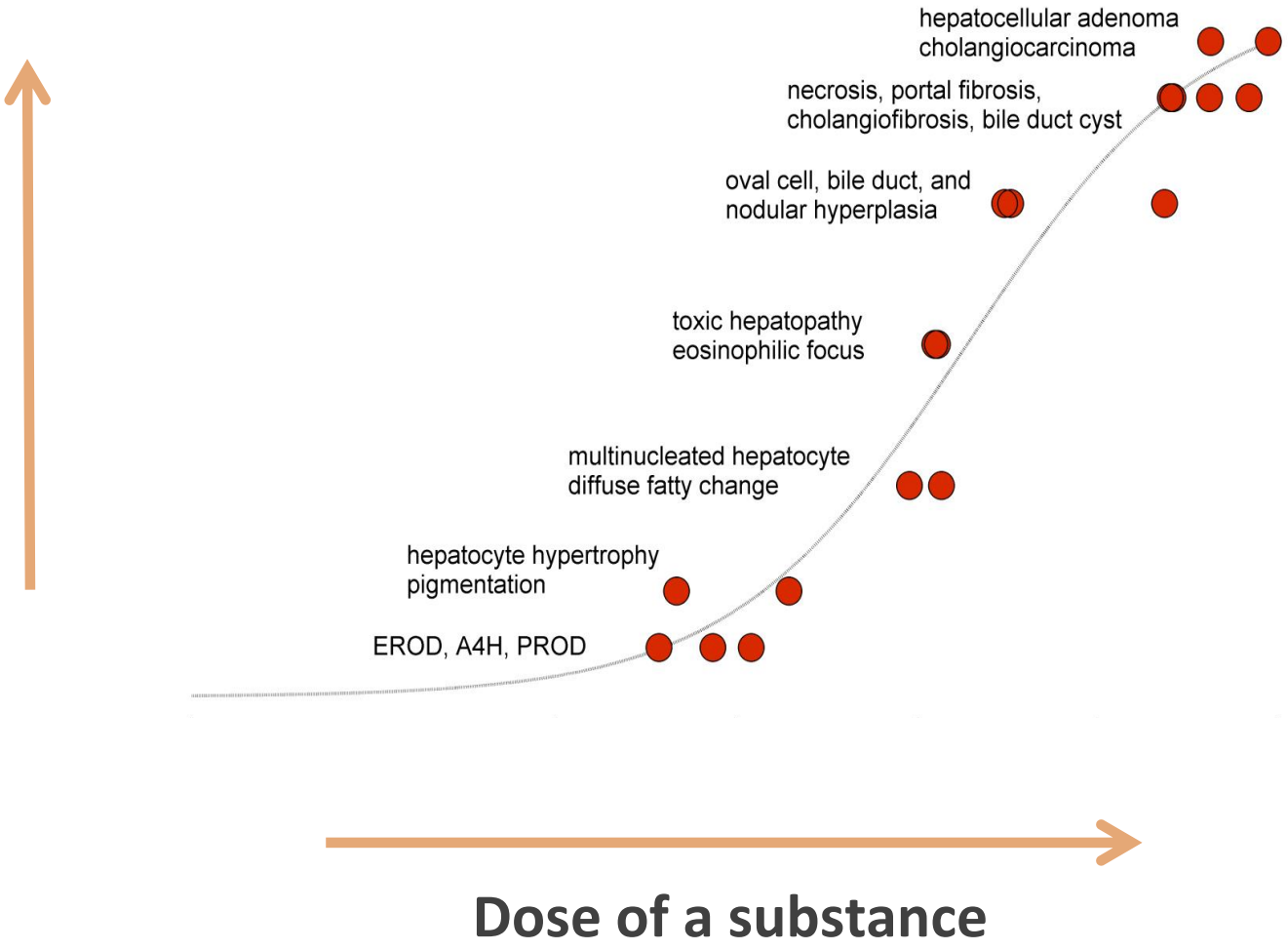
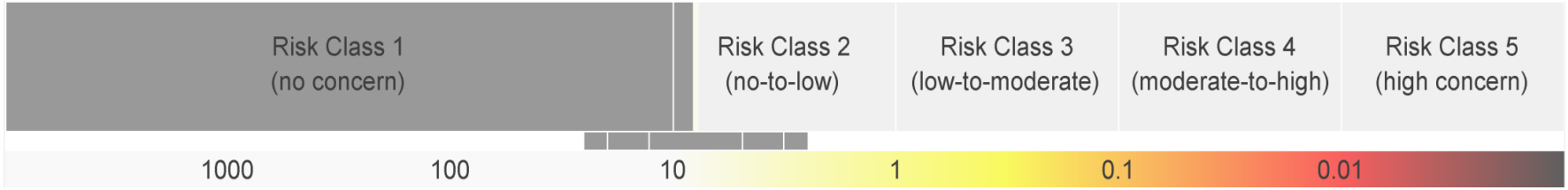

Severity
hepatocellular adenoma
cholangiocarcinoma
necrosis, portal fibrosis,
cholangiofibrosis, bile duct cyst
oval cell, bile duct, and
nodular hyperplasia
toxic hepatopathy
eosinophilic focus
multinucleated hepatocyte
diffuse fatty change
hepatocyte hypertrophy
pigmentation
EROD, A4H, PROD
Dose of a substance

Risk ranking – some examples

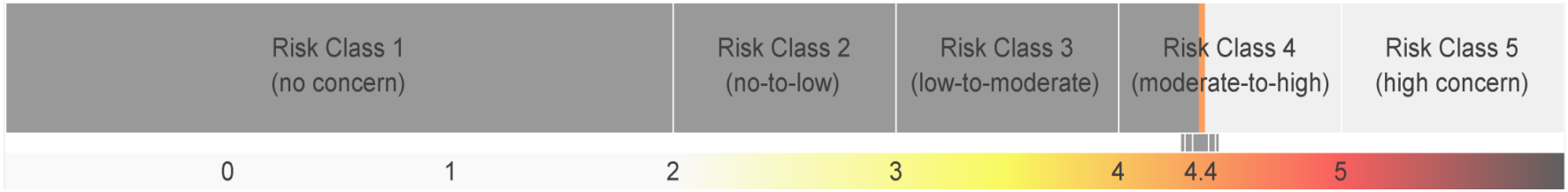
17 Organophosphates

children - average consumer



Lead from foods

adults - average consumer



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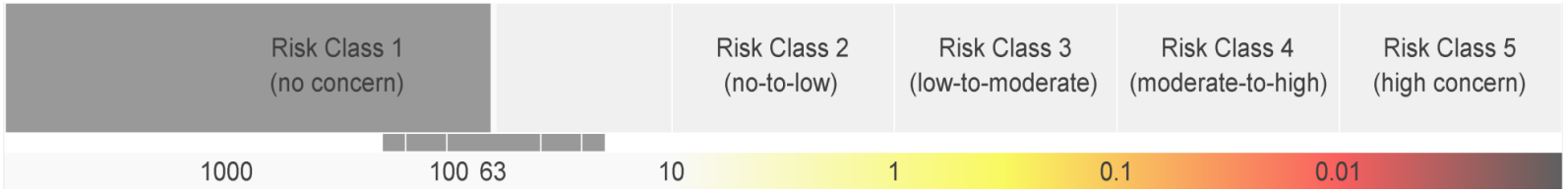
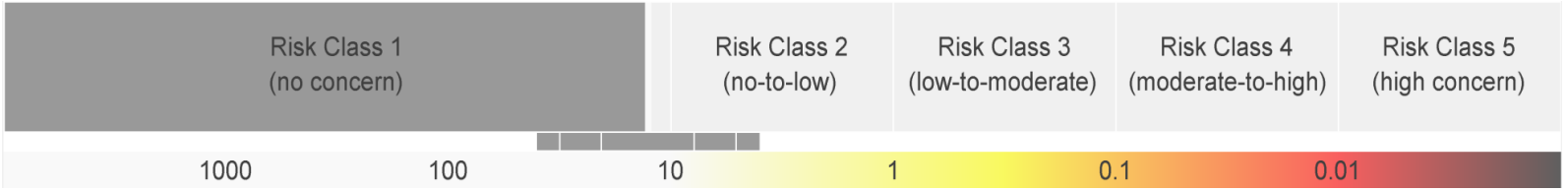
Neotame

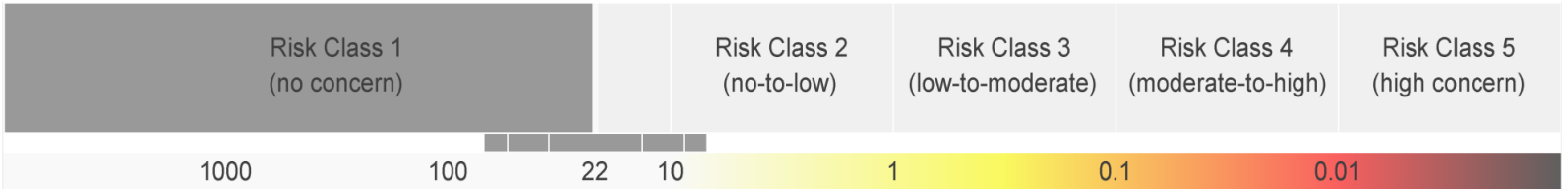
Adults, mean exposure (0.1 mg/kg/day)



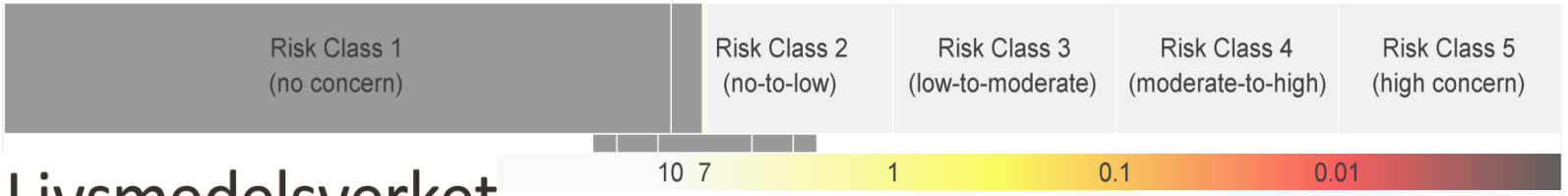
Adult, 90e percentile (0.5 mg/kg/day)



Children, median exposure (0.029 mg/kg/day)



Children, "heavy consumers" (0.09 mg/kg/day)



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Possible future developments?
Cocktail effect of additives

- Regulation of pesticides – introduction of CAGs (Cumulative assessment groups)
- If that will be introduced for food additives
  - A need for better precision in exposure assessment
  - Better alignment between food categories in the regulation of additives and Foodex2
  - More detailed information on the occurrence of additives
    - Azo dyes and hyperactivity in children, a cocktail of 6 different chemicals
    - Cumulative effects of emulsifiers
  - Not many MS have a reasonable good system for keeping track of additives occurrence data

Summing up

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Thank you for your attention!

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