Risk assessment of bioplastic based food packaging materials

NewPack WORKSHOP
New BioBased Film for Packaging
www.newpack-h2020.eu
Development of innovative bioplastics for the food sector

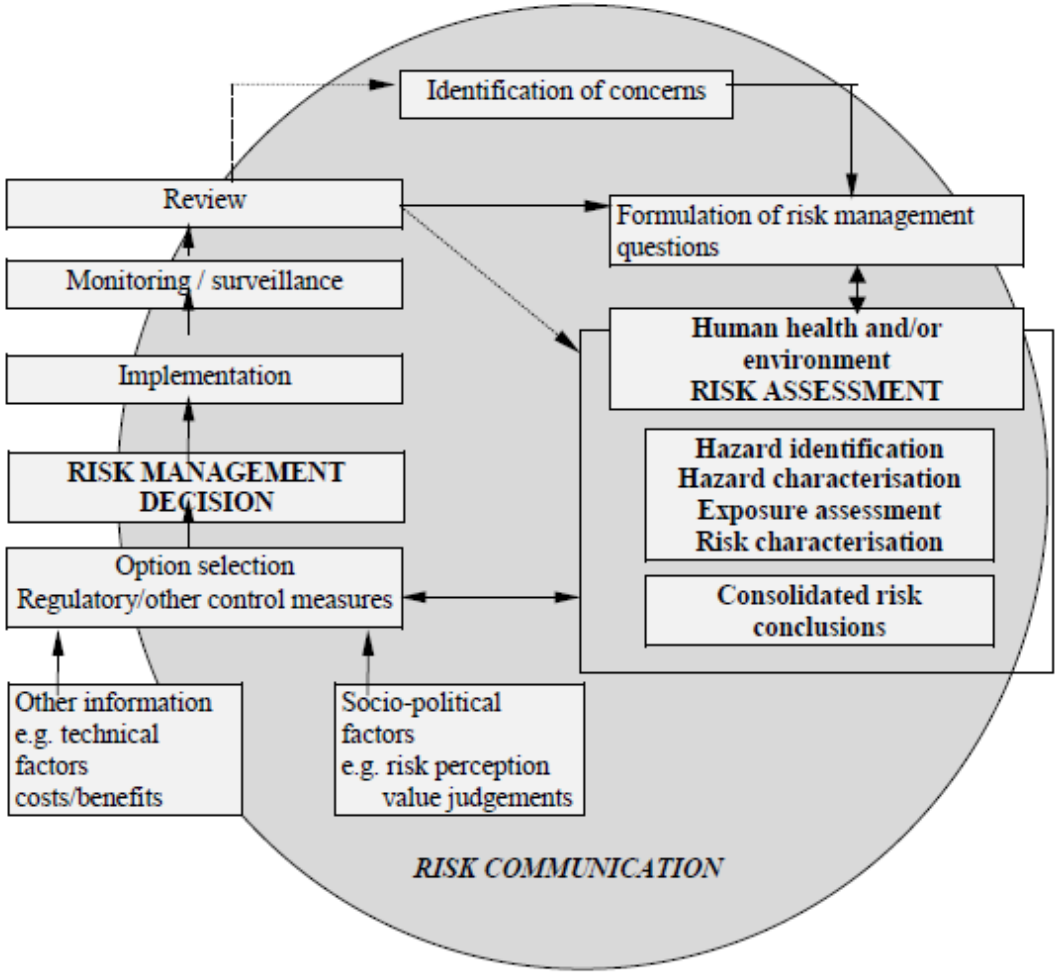
Francesca Mostardini- Piacenza, November 19th,2019

Risk assessment:

What is it?

How it works?

1.Risk assessment



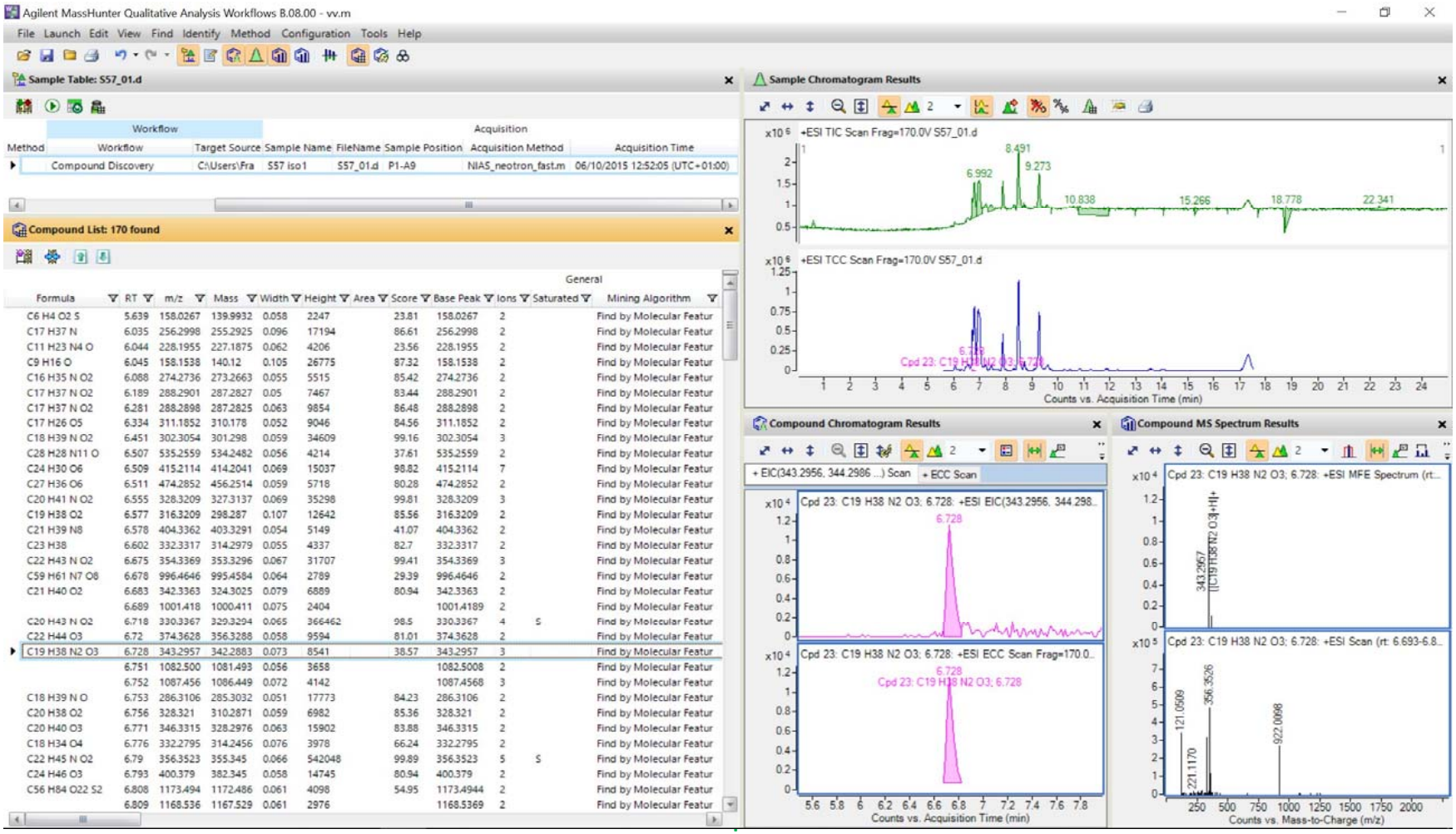
Concern:

IAS: Substances intentionally added in the formulation of materials in contact with food (monomers, additives, catalysts, etc.)

NIAS: Substances NOT intentionally added in the formulation of Products in contact with food (oxidation, degradation, reaction products, etc.)

NLS: Substances NOT listed in the lists of chemical compounds allowed for the production of the various Material in contact with food (see specific annexes in force for the various materials)

Monitoring & Identification



REGULATION IN FORCE: REQUIREMENTS

Art 19 –Reg. EU 10/2011: RISK ASSESSMENT

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

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Art 3 –Reg. CE 1935/2004: SAFETY CLAUSE

Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

Risk assessment: step

1. Identification of the hazard capable of determining adverse effects on public health

2. Hazard characterization: qualitative and / or quantitative assessment of adverse effects in relation to exposure to the administered dose

3. Exposure: qualitative and / or quantitative determination of contaminant ingestion with the diet and possibly with other sources:

- Frequency with which the contaminant occurs in the diet
- Consumption data

4. Risk characterization: qualitative and / or quantitative estimation including the uncertainty, probability and severity with which the adverse effect can occur in a given reference population

5. Risk management

WORK FLOW

Step	Activity
1. State of the art of substance in existing legislation or database or website research	Web-database search
2. Exposure assessment	Define Estimated Daily Intake level for the reference population **EDI worst case (mg/person/day) = 1 kg food/person/day * Migration (mg/kg food)**
3. Migration data	Migration into food for materials not specifically regulated such as biobased
4. Food consumption data	Efsa Comprehensive Database
5. Food Packing Data	Pack ratio S/V

Threshold of Toxicological Concern (TTC)

Structural class	Description	TTC exposure limit (μg/person/day)
Cramer class I (least toxic)	Substances with simple chemical structure and for which efficient modes of metabolism exist, suggesting a low order of oral toxicity.	**1800**
Cramer class II (intermediate)	Substances which possess structures that are less innocuous than class I substances, but do not contain structural features suggestive of toxicity like those substances in class III.	**540**
Cramer class III (most toxic)	Substances with chemical structures that permit no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional groups.	**90**
Organophosphates	Organophosphate structures which may have neurotoxic properties	**18**
Threshold of regulation	Substances for which there are no structural alerts for genotoxicity	**1.5**
Genotoxicity alerts	Substances for which there are structural alerts for genotoxicity but which are not aflatoxin-like, azoxy- or N-nitroso-compounds	**0.15**

Risk Characterization

EDI < TDI or Specific migration < self-derived SML = PRODUCT IS SAFE!

In case of **EDI >TDI = PRODUCT IS NOT SAFE!**

- ✓ STEP:
- ✓ Redefine risk characterization
- ✓ Produce / find more toxicological data
- ✓ Reduce the migration of the substance
- ✓ Evaluate the exposure again

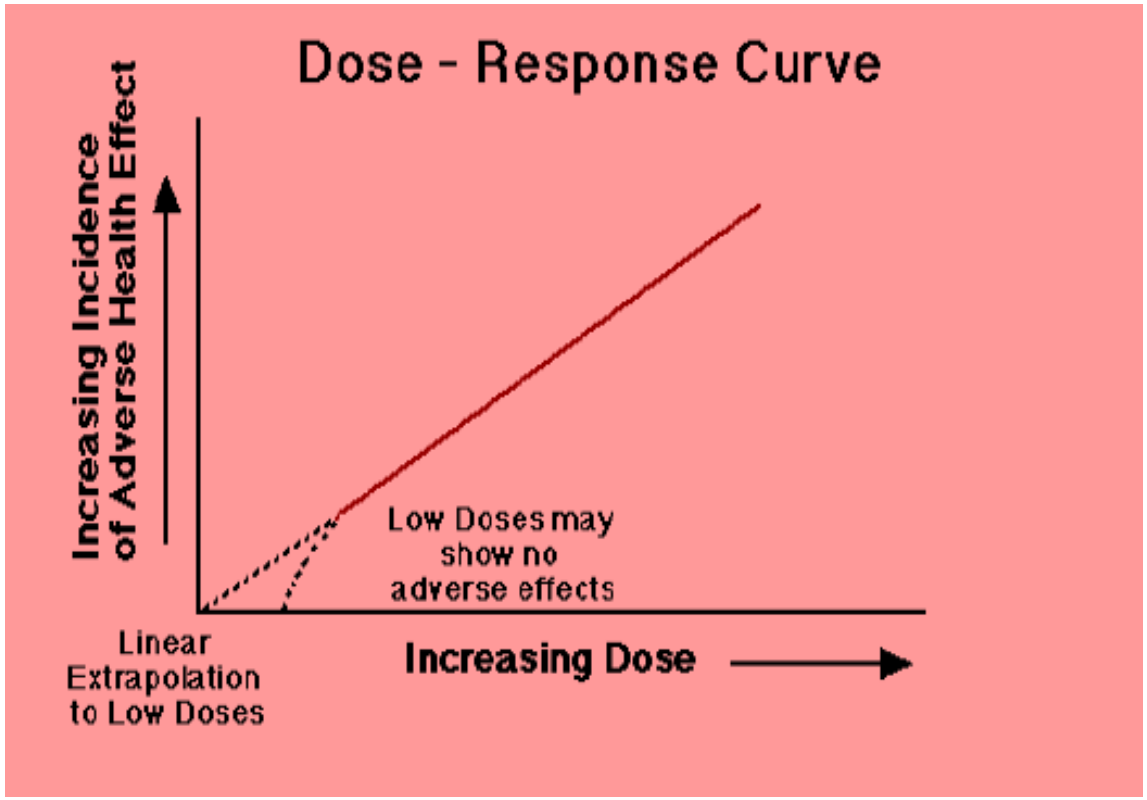
“Towards an exposure-based regulatory approach in Europe”

Note:

- We don’t eat 1kg of fatty food daily for all our life;
- Intake of single portions does not account for exposure to quantities as high as in one kg;
- **Exposure** shall be considered,

~~***Migration➔Hazard = Risk***~~

How specific restrictions are established?



S0….

NOAEL = No Observed Adverse Effect Level [mg/kg body weight]

ADI = Admitted Daily Intake = NOAEL / 100 [mg/kg body weight]

SML = Specific Migration Limit = ADI x 60 kg body weight / 1 kg food per day [mg/kg food]

Current assumption for the calculation of SML: 1 kg of fatty food eaten everyday, all packed in plastics containing the same migrant

How exposure can be calculated?

1. How much of a given food (or food family) is in contact with a certain packaging material (or a certain category of packaging materials);

2. How much of that food is eaten by consumers in the daily diet.

Easy to say…

- Needs to define:
  - Food families
  - Packaging materials categories
  - Tolerable level of migrating substances
  - What does dietary intake means (50%ile, 90%ile etc.)
- Needs to agree the above with regulatory authorities;
- Needs to be accepted by packaging chain's industries

FCM: Exposure assessment

To estimate dietary exposure to a substance migrating from a food packaging material, information is needed on:

- ✓ the types of foods packaged,
- ✓ the nature of the packaging material,
- ✓ migration data,
- ✓ packaging usage factors
- ✓ food consumption.

Several uncertainties……..

- ✓ Availability of toxicity data of a substance (hazard) and its dose (exposure).
- ✓ The extrapolations from animal data to possible human hazards
- ✓ Another tool for hazard identification may be epidemiological studies
- ✓ Exposure and ways to assess a more realistic dietary exposure are the key issues

Other issues

SML limits are usually based on a TDI or ADI accounting for a lifetime exposure of a substance present in a foodstuff

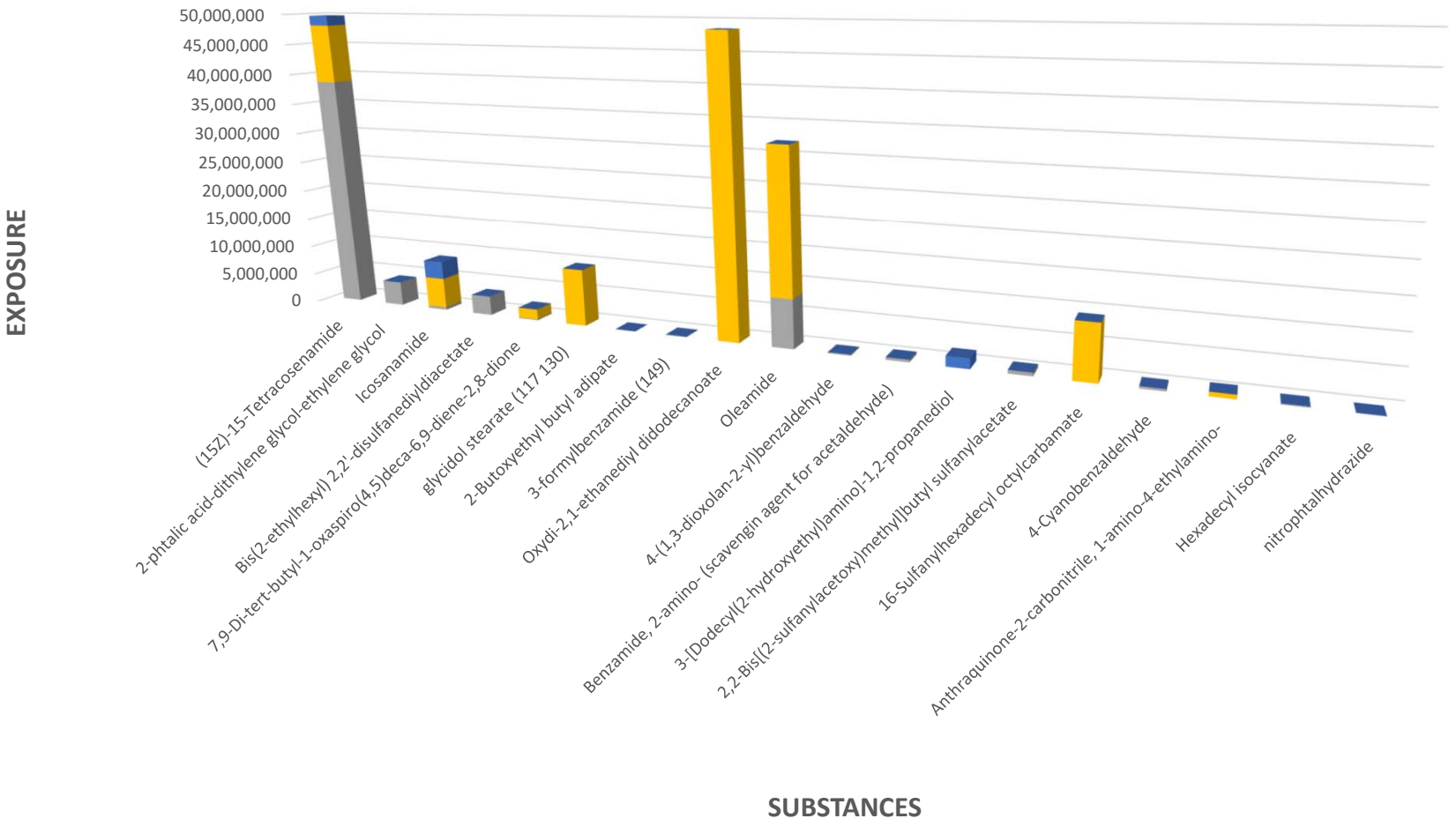
The daily ingested amount of a specific food item will vary considerably during an approximate lifetime of 70 years.

Food packaging will also vary, and the level of the substance will vary.

The consumer's total food consumption will vary, depending on sex, age and other factors.

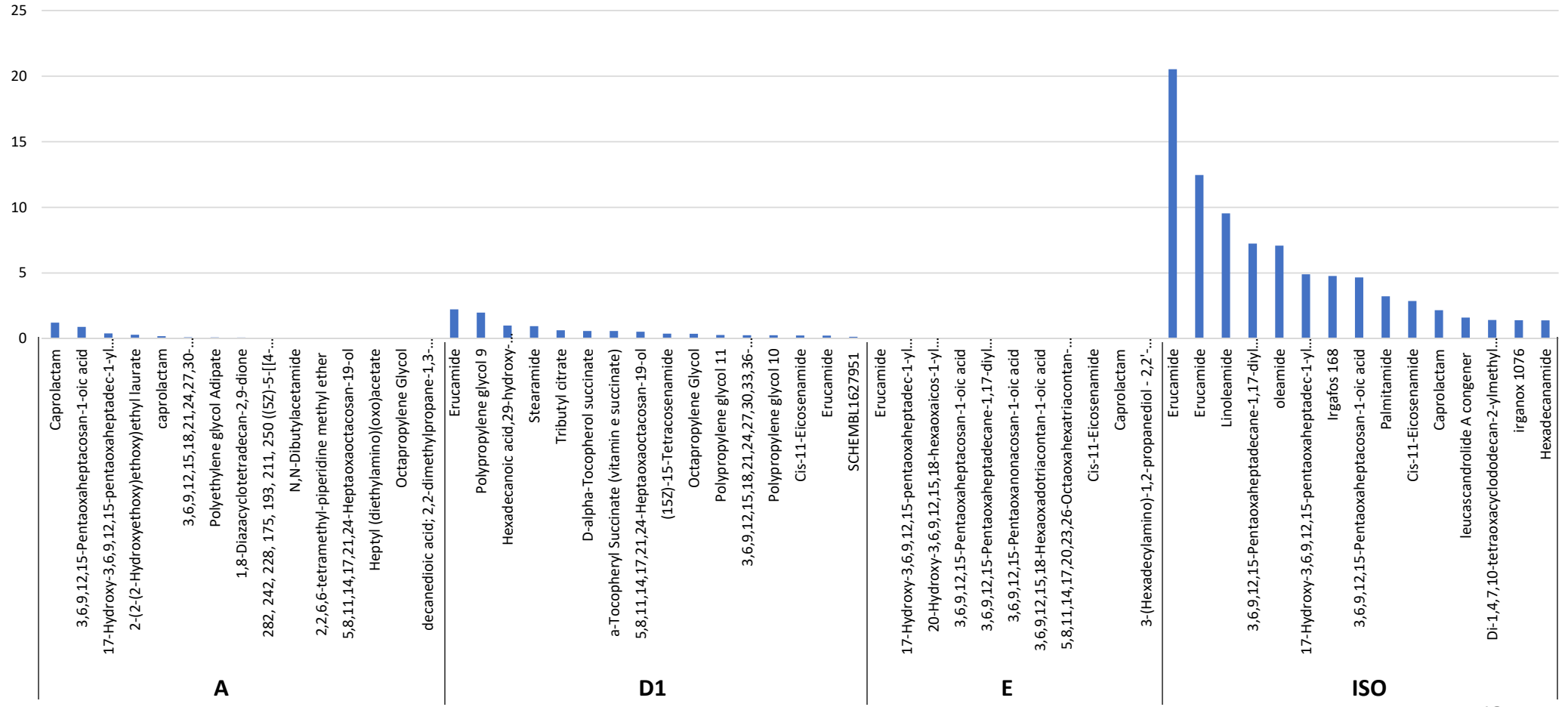
Legislative restrictions in foods presumably will never be expressed in exposure terms!!!

PRIORITY


EXPOSURE
50,000,000
45,000,000
40,000,000
35,000,000
30,000,000
25,000,000
20,000,000
15,000,000
10,000,000
5,000,000
0
(15Z)-15-Tetracosenamide
2-phtalic acid-dithylene glycol-ethylene glycol
Icosanamide
Bis(2-ethylhexyl) 2,2'-disulfanediyldiacetate
7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione
glycidol stearate (117 130)
2-Butoxyethyl butyl adipate
3-formylbenzamide (149)
Oxydi-2,1-ethanediyl didodecanoate
Oleamide
4-(1,3-dioxolan-2-yl)benzaldehyde
Benzamide, 2-amino- (scavengin agent for acetaldehyde)
3-[Dodecyl(2-hydroxyethyl)amino]-1,2-propanediol
2,2-Bis[(2-sulfanylacetoxy)methyl]butyl sulfanylacetate
16-Sulfanylhexadecyl octylcarbamate
4-Cyanobenzaldehyde
Anthraquinone-2-carbonitrile, 1-amino-4-ethylamino-
Hexadecyl isocyanate
nitrophtalhydrazide
SUBSTANCES

EXPOSURE - OUTPUT

Rate % of each substance to total ingestion



RISK MANAGEMENT

- Self-derived limits
- Potential restrictions on use for the downstream chain
- Substitution alternatives
- Introduction of CCP monitoring
- Decision Making and Risk Comunication

THANK YOU FOR YOUR ATTENTION

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