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USP/FCC Open Forum

Elemental Impurities in Food Ingredients: Pathways to Reducing Levels

October 24—25, 2022
9:00 AM—2:00 PM EDT | Virtual

GLOBAL PERSPECTIVE ON ELEMENTAL IMPURITIES IN FOOD INGREDIENTS – PART 2: CHEMICAL CONTAMINANTS IN FOOD, EUROPEAN PERSPECTIVE

Baden-Württemberg

24.10.2022

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Agenda

- EU green deal – EU perspektive
- Food
- Food additives
- Drinking water
- Mineral water
- Conclusion

European Union

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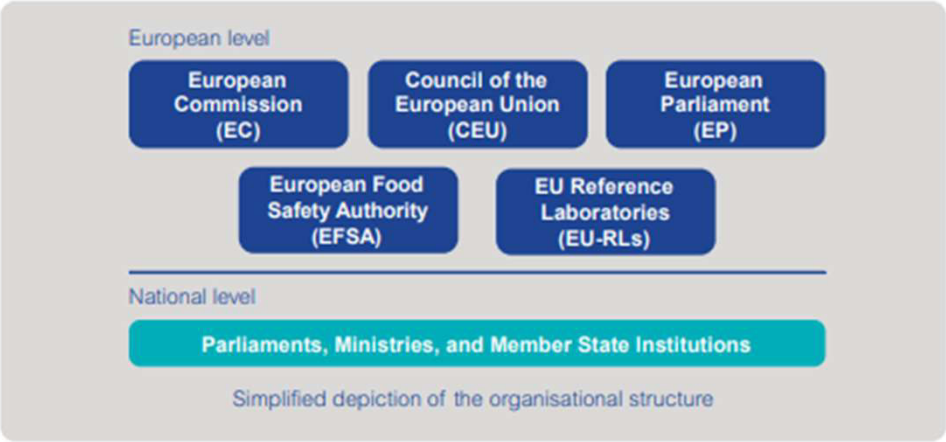
Chemisches und Veterinär-untersuchungsamt Karlsruhe



EC
European Commission

- European law making
- Risk management
- Food safety policy

Location: Brussels, Belgium
http://ec.europa.eu

CEU
Council of the European Union

- European law making
- Food safety policy
- Risk management

Location: Brussels, Belgium
http://www.consilium.europa.eu

EP
European Parliament

- Food safety policy
- European law making
- Risk management

Location: Strasbourg, France
http://www.europarl.europa.eu

EFSA
European Food Safety Authority

- Risk assessment
- Risk communication

Location: Parma, Italy
http://www.efsa.europa.eu

Source: BfR EU Almanach on food safety (2021)

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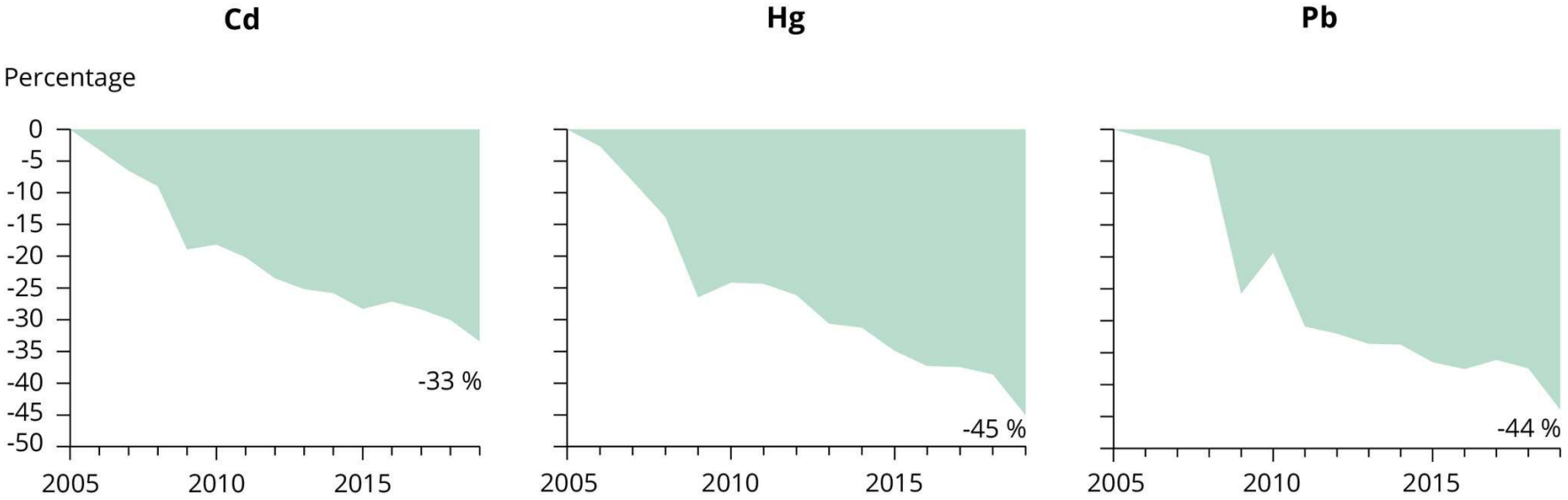
EU perspective

- Reduction of emissions of Cd, Hg and Pb in Europe over the past decades



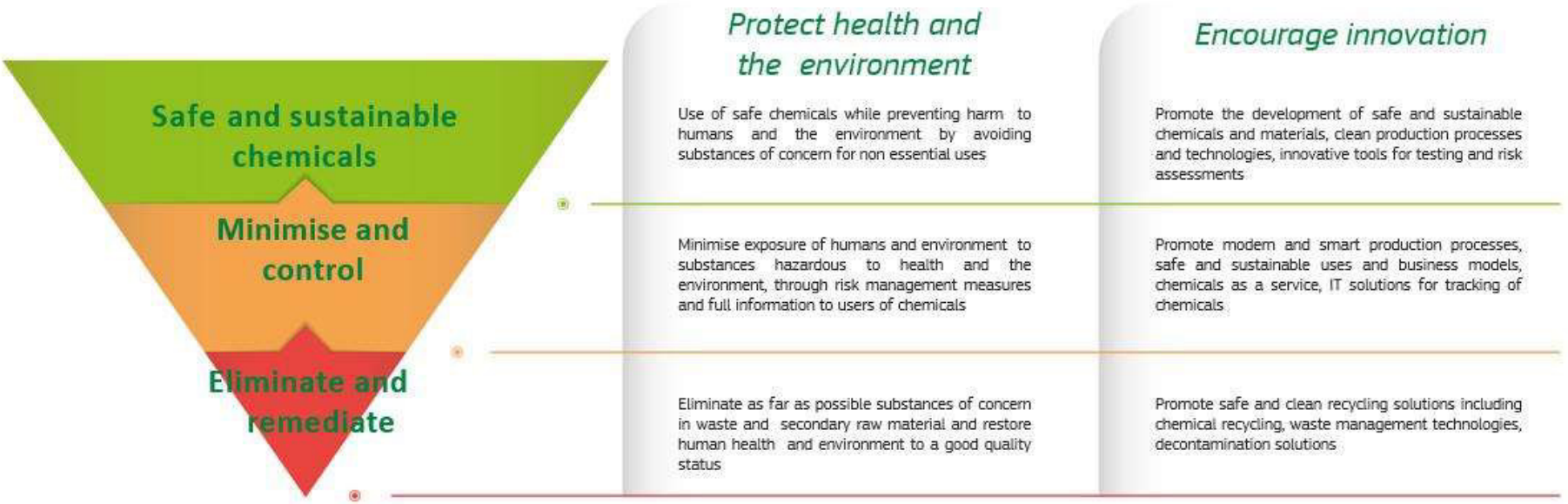
ECA: The figure shows changes in cadmium (Cd), mercury (Hg) and lead (Pb) emissions between 2005 and 2019, based on data reported by EU Member States under the United Nations Economic Commission for Europe (UNECE) Convention on Long-range Transboundary Air Pollution (Published 28 Sep 2021)

EU perspective

- EU Green deal: transformation towards a zero-pollution, competitive, climate-neutral economy by 2050
- zero pollution ambition: goal to protect better human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment'

COM (2020) 667: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions

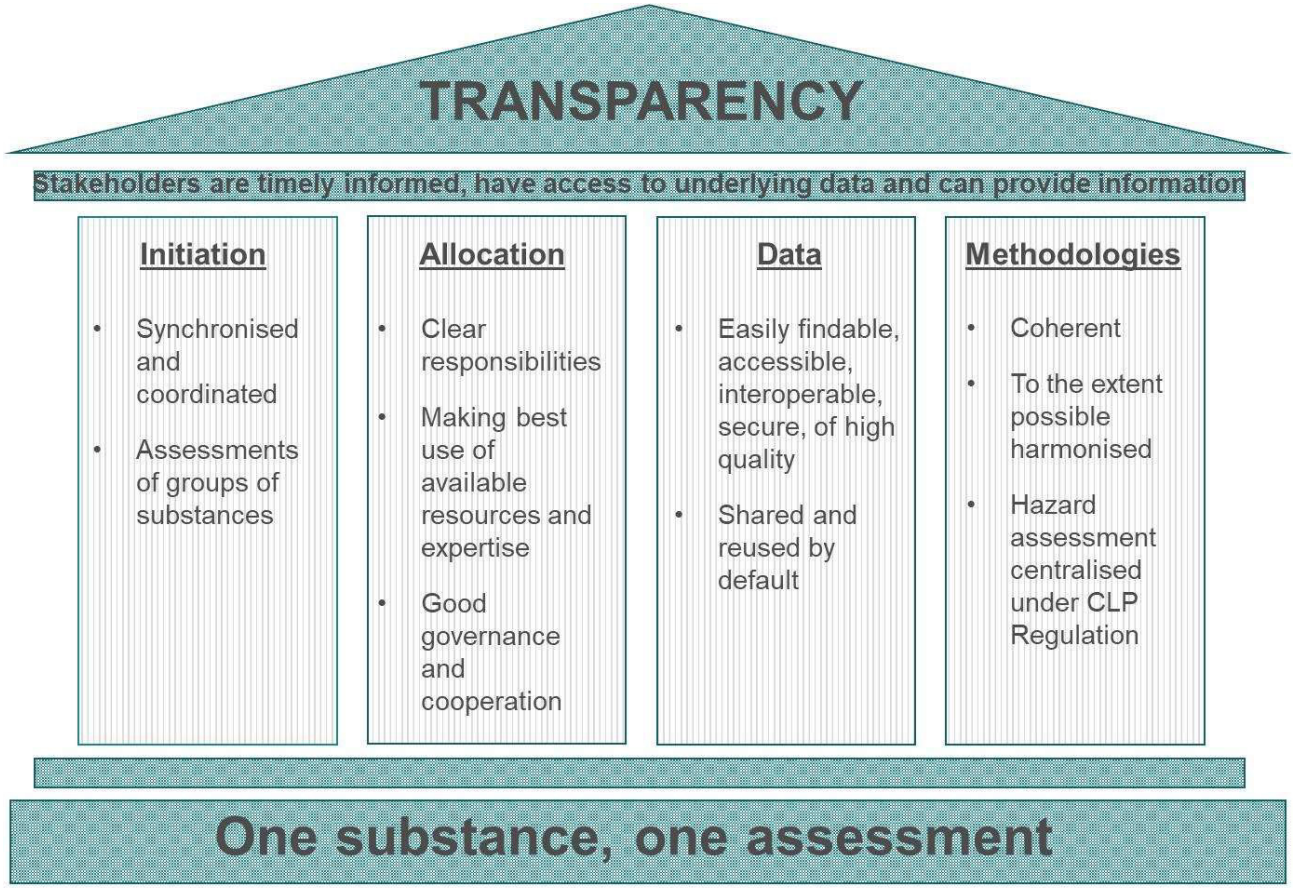
Zero-pollution



- plan to restrict certain substances in products for certain users while allowing limited exemptions under conditions clearly defined in law.

taken from: COM (2020) 667: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions

Change of governace



taken from: COM (2020) 667: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions

Current plans

- Restrictions Roadmap under the Chemicals Strategy for Sustainability published as Commission Staff Working Document SWD (2022) 128 published on 25.4.2022
- Until the proposed changes have been assessed and introduced in regulations the strategy aims to 'prioritise carcinogenic, mutagenic and reprotoxic substances (CMRs), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, immunotoxicants, neurotoxicants, substances toxic to specific organs and respiratory sensitisers substances for (group) restrictions' for all uses.

Current plans

- the Commission has prepared a roadmap to prioritize these substances for (group) restrictions under REACH
- resulted in the Rolling List of (groups of) substance(s) for restriction:
- contains: many organic compounds such as PFAS, PAH, but also inorganic compounds/elements such as Lead (Pb), Lead chromate, Nickel
- Rolling List will be regularly reviewed

Current state of play - food

- source of elemental impurities in food is still environmental pollution
- tolerable weekly intake is still toxicological principle for heavy metals (risk based approach)
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
- regulates maximum levels for Mykotoxins, Nitrates, Dioxins and PCBs, 3-MCPD but also for Lead (Pb), Cadmium (Cd) and Mercury (Hg)

Current state of play - food

- Official Food Control Laboratories of the member states are enforcing regulation under Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
- collecting data via monitoring and surveillance programs

Current state of play - food

Section 3: Metals

	Foodstuffs (1)	Maximum levels (mg/kg wet weight)
3.1	**Lead**	
3.1.1	Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	0,020
3.1.2	Infant formulae and follow-on formulae (4) (8)	0,020
3.2	**Cadmium**	
3.2.1	Meat (excluding offal) of bovine animals, sheep, pig and poultry (6)	0,050
3.2.14	Vegetables and fruit, excluding leaf vegetables, fresh herbs, fungi, stem vegetables, pine nuts, root vegetables and potatoes (27)	0,050
3.2.15	Leaf vegetables, fresh herbs, cultivated fungi and celeriac (27)	0,20

Current state of play - food

3.4	**Tin (inorganic)**	
3.4.1	Canned foods other than beverages	200
3.4.2	Canned beverages, including fruit juices and vegetable juices	100

	Foodstuffs (1)	Maximum levels (mg/kg wet weight)
3.4.3	Canned baby foods and processed cereal-based foods for infants and young children, excluding dried and powdered products (3) (29)	50

3.3	**Mercury**	
3.3.1	Fishery products (26) and muscle meat of fish (24) (25), excluding species listed in 3.3.2. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	0,50

Current state of play - food

- Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
- methods of analysis and performance criteria of methods

Current state of play – food additives

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
- Community lists of approved food additives as set out in Annexes II and III
- conditions of use of food additives in foods, including in food additives and in food enzymes
- European Food Safety Authority (EFSA) provides opinion (risk assessment) and European Commission/European Parliament is acting as the regulator

Current state of play – food additives

- Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council
- regulation only provides limits, no analytical methods
- setting of specifications and limits is not fully harmonized

Food additives

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E 122 AZORUBINE, CARMOISINE

Synonyms	CI Food Red 3
Definition	Azorubine consists essentially of disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Azorubine is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	14720
Einecs	222-657-4
Chemical name	Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate
Chemical formula	$C_{20}H_{12}N_2Na_2O_7S_2$
Molecular weight	502,44
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt $E^{1\%}_{1cm}$ 510 at ca. 516 nm in aqueous solution

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Food additives

Description	Red to maroon powder or granules
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 516 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 1 %
Organic compounds other than colouring matters:	
4-aminonaphthalene-1-sulfonic acid	Total not more than 0,5 %
4-hydroxynaphthalene-1-sulfonic acid	
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

Regulatory Lab Perspective

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- Current limits are basically working and are analytical feasible (distance between LOQ and limit is acceptable)
- Rate of non conforming products concerning heavy metals in EU is low (data reported via EU Rapid Alert System for Food and Feed)
- Non conforming products are mostly herbal remedies (imported into EU), healing earth (Heilerde), capsules (supplements), and herbs sold as Traditional Chinese Medicine (fraud)

Regulatory Lab Perspective

- Liver and kidneys from cattle
- Fish (long living predatory fishes)
- Challenging elements are: lead, arsenic, cadmium and mercury

Current situation – drinking water

- Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption

Parameter	Parametric value	Unit
Arsenic	10	µg/l
Cadmium	5.0	µg/l
Lead	5	µg/l
Mercury	1.0	µg/l

Current situation – mineral water

- Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters – limits from drinking water are used

Parameter	Parametric value	Unit
Arsenic	10	µg/l
Cadmium	5.0	µg/l
Lead	5	µg/l
Mercury	1.0	µg/l

Conclusion

- EU green deal and zero pollution ambition will have influence on legislation and limits of elemental impurities in food (and food additives)
- Roadmap is published
- Current limits are not fully harmonized due to different responsibilities in EU
- Lead seems to be on top of the priority list for inorganic compounds
- Question remains about analytical capabilities for much lower limits

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THANK YOU FOR YOUR ATTENTION – QUESTIONS?

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