

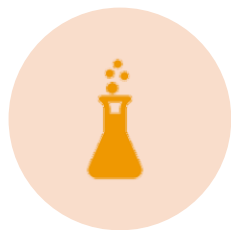
22 November 2022

8th Meeting Food Contact Material Network

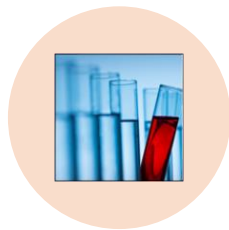
Chemicals Strategy for Sustainability (CSS) One Substance One assessment (1S1A)

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Trusted science for safe food



1. CHEMICALS
STRATEGY FOR
SUSTAINABILITY



2. ONE SUBSTANCE,
ONE ASSESSMENT



3. GETTING
PREPARED FOR
THE CSS-1S1A



4. OVERALL
SUMMARY



5. QUESTIONS

1. Chemicals Strategy for Sustainability

Strategy lead by DG ENV and DG GROW

CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS)

ONE of the 8 strategies of the EU Green Deal

- ❖ 1. Innovating for safe and sustainable EU chemicals
- ❖ 2. Stronger EU legal framework to address pressing environmental and health concerns
- ❖ 3. Simplifying and consolidating the legal framework
- ❖ 4. A comprehensive knowledge base on chemicals
- ❖ 5. Provide a model inspiring chemicals management globally



1. Boosting Innovation:

Promote the transition to safe and sustainable chemicals, materials and products

- Develop EU safe and **sustainable-by-design criteria** and a EU-wide support **network**
- **Provide funding** for the green and digital transition of the production/use of chemicals (Horizon Europe, recovery instruments, cohesion funds, Life)

2. Strengthening Legislation:

- **All chemicals** on the market to be used safely and sustainably.
- Substitute and minimise as far as possible **substances of concern: *Endocrine disruptors, PFAS, Mixtures, Environmental Impact***
- Avoid the **most harmful chemicals** in consumer products esp. for vulnerable groups

New hazard classes

Concept of 'essential uses'

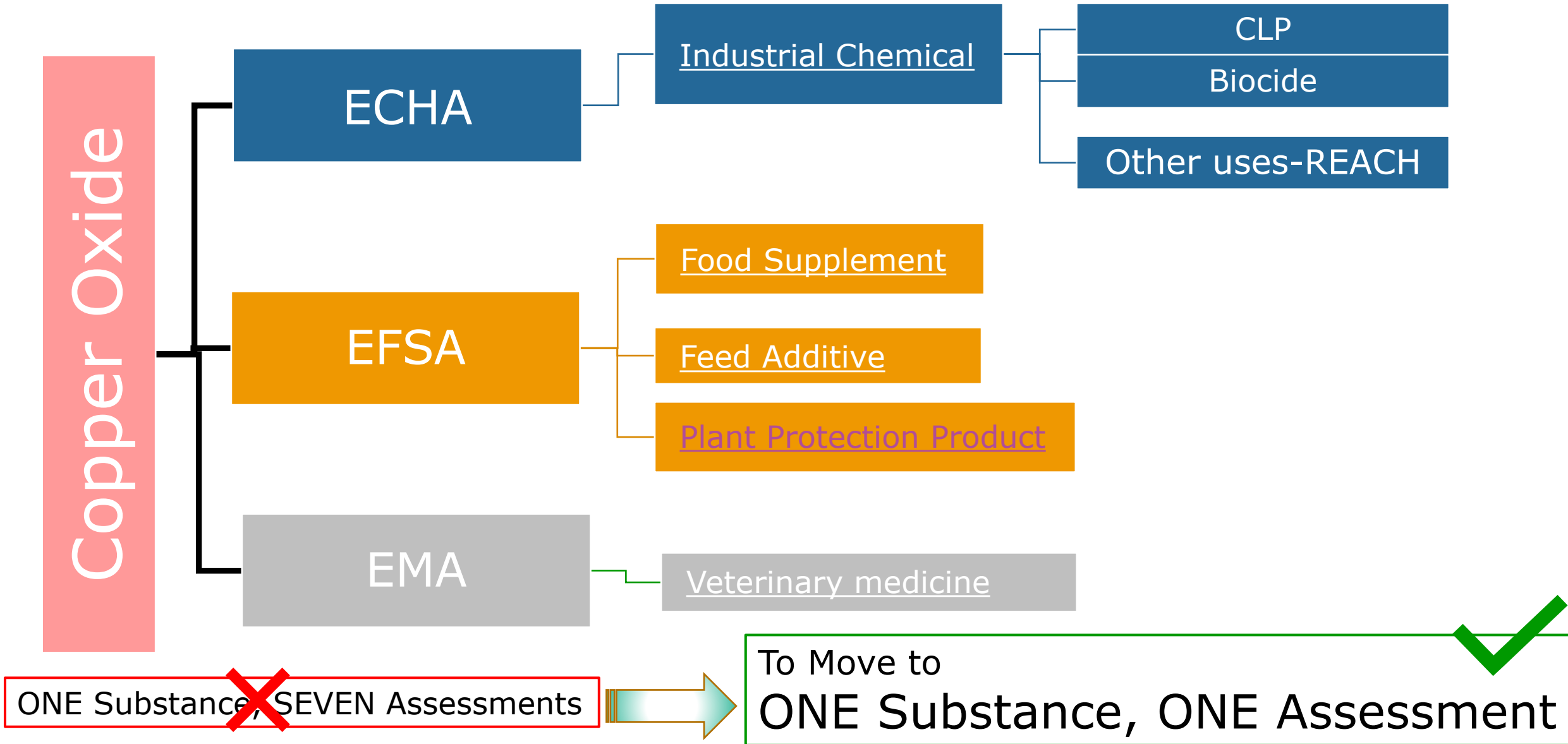
4. A comprehensive knowledge base:

- Establish a **EU research & innovation agenda** for chemicals
- Improve **knowledge on chemical properties and uses**

5. Setting the example globally:

- Promote the use of the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** and propose new hazard classes
- Sound management of chemicals in **international cooperation**
- Chemicals **banned in the EU** not for export

2. One Substance, One Assessment (I)



2. One Substance, One Assessment (II)

**Simplifying and consolidating the legal framework: 'One Substance One Assessment':
27 actions, towards the 'One Substance One Assessment', 1S1A**

➤ **COORDINATE** the hazard and risk assessment across chemicals: use of a single Public Authorities Coordination Tool*, an expert group and a Commission coordination mechanism

➤ Revision of the CLP Regulation

➤ Revision of the REACH Regulation

➤ Removal of legislative obstacles for re-use of data, streamlining the data flow across legislation



2. One Substance, One Assessment (III)

Simplifying and consolidating the legal framework: 'One Substance One Assessment' – Cont.

- Re-allocation of EU technical and scientific work on chemicals to Agencies
- Review of the definition of nanomaterial
- Establishment of an EU repository of human and environmental health-based limit values
- Establishment of an open platform on chemical safety data and tools for accessing relevant academic data
- Proposal to extend the principles of the Transparency Regulation to Regulatory frameworks beyond Food/Feed



2. One Substance, One Assessment (IV)

Simplifying and consolidating the legal framework: 'One Substance One Assessment' – Cont.

- Data should be easily findable, interoperable, secure, shared and reused by default.

- Data to be made available in appropriate formats and tools – i.e. [IUCLID](#) and [IPCHEM](#)



- Risk assessment methodologies: more coherent and, to the extent possible, harmonised.
- Hazard assessment centralised under the CLP Regulation.

3. Getting prepared for CSS-1S1A

Setting a series of activities, in coordination with the sister agencies and with the EC

- Participation in the EC Working Groups to implement the CSS
- Establishment of collaboration fora with ECHA, EMA and with the JRC.
- Running Pilot assessments where to test the 1S1A, with reporting, including lessons learnt
- OUTSOURCING Preparatory Work --- Procurement to map the Data Requirements and Assessment methodologies across the Regulatory frameworks of ECHA, EFSA, EMA and the two EC Committees.
 - Appointment of a Coordination Person

Drinking Water (DW) and Food Contact Materials (FCM)-1

Regulatory Framework	DW	<ul style="list-style-type: none">• Drinking water Directive• REACH Regulation / CLP Regulation / BPR Regulation
	FCM	<ul style="list-style-type: none">• Food Contact Materials (FCM) Regulation (Regulation (EC) No 1935/2004)• FCM List• Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
Guidance	DW	<ul style="list-style-type: none">• Corresponding ECHA Guidance being drafted• 4MS Initiative (4MSI = DK, DE, FR, NL and UK) methodology and Member State positive lists and provisions
	FCM	<ul style="list-style-type: none">• Guidelines on submission of a dossier for safety evaluation of substances present in articles intended to come into contact with food• EFSA's cross-cutting guidance documents
Other	DW	<ul style="list-style-type: none">• WHO Guideline for Drinking Water Quality (GDWQ)

Drinking Water (DW) and Food Contact Materials (FCM)-2

- DG ENV contacted EFSA in September 2019. Meeting at EFSA with ECHA, EC DG ENV / DG SANTE and JRC in February 2020.
- EFSA is participating as observer in DW meetings
- Key issues being discussed between ECHA and EFSA

Data requirements

- Toxicological studies

Methodologies

- Migration tiers

Common data platform

- Technical Dossier format

- Ongoing discussion between ECHA and EFSA on IUCLID

Phthalates

Mandate on the “Re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials”.
The EC mandate indicated collaboration with ECHA.

Part 1. Preparatory work

Task 1. Identification and prioritisation of phthalates for risk assessment

Task 2. Development of protocols:

Protocol for exposure assessment



Protocol for hazard assessment

Task 3. Call for data on occurrence in food and FCM

Part 2. Risk Assessment

**EFSA's procedures/guidance
shall be followed ≠ ECHA**



1S1A

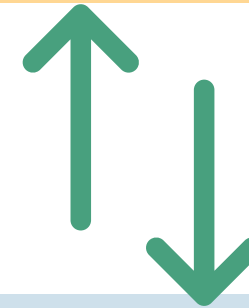


BISPHENOL A (BPA)



EFSA's *scientific opinion* on the re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs is endorsed by the CEP Panel (November, 2021)

EFSA is working on an Updated Assessment



ECHA's work on bisphenols groups

- BPA and BPA derivatives
- BPS and BPS derivatives
- BPF and BPF derivatives

[Overall strategy for bisphenols](#) (April, 2022)

SILVER

ECHA Biocidal Product. Regulation (EU) No 528/2012

EFSA Food Contact Material. Regulation (EC) No 1935/2004

[Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials \(FCM\) by EFSA and ECHA.](#) Joint EFSA – ECHA document February 2020

[Safety assessment of the substance silver nanoparticles for use in food contact materials.](#) August, 2021

DOCUMENT ON LESSONS Learned:

- **REGULATORY ENVIRONMENT**
- **DATA**
- **METHODOLOGIES**
- **PROCESSES**

The EFSA's RA considered the ADI set by ECHA



FUTURE CHALLENGES / SUSTAINABILITY

- Precise coordination from all Regulatory areas, and all involved actors
- Stronger Cooperation across Agencies, and with Member States
- DATA: Interoperable, re-usable
- METHODOLOGIES: more coherent, harmonised (where possible)

Promoting safe and sustainable-by-design chemicals

Protect consumers, vulnerable groups and workers from the most harmful chemicals

Extend the **generic approach** to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative.

Define **criteria for essential uses** to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society

Strengthen protection of workers

Protecting people and the environment from the combination effects of chemicals

