

22-24 OCTOBER 2024

11<sup>TH</sup> MEETING FOOD CONTACT MATERIAL NETWORK



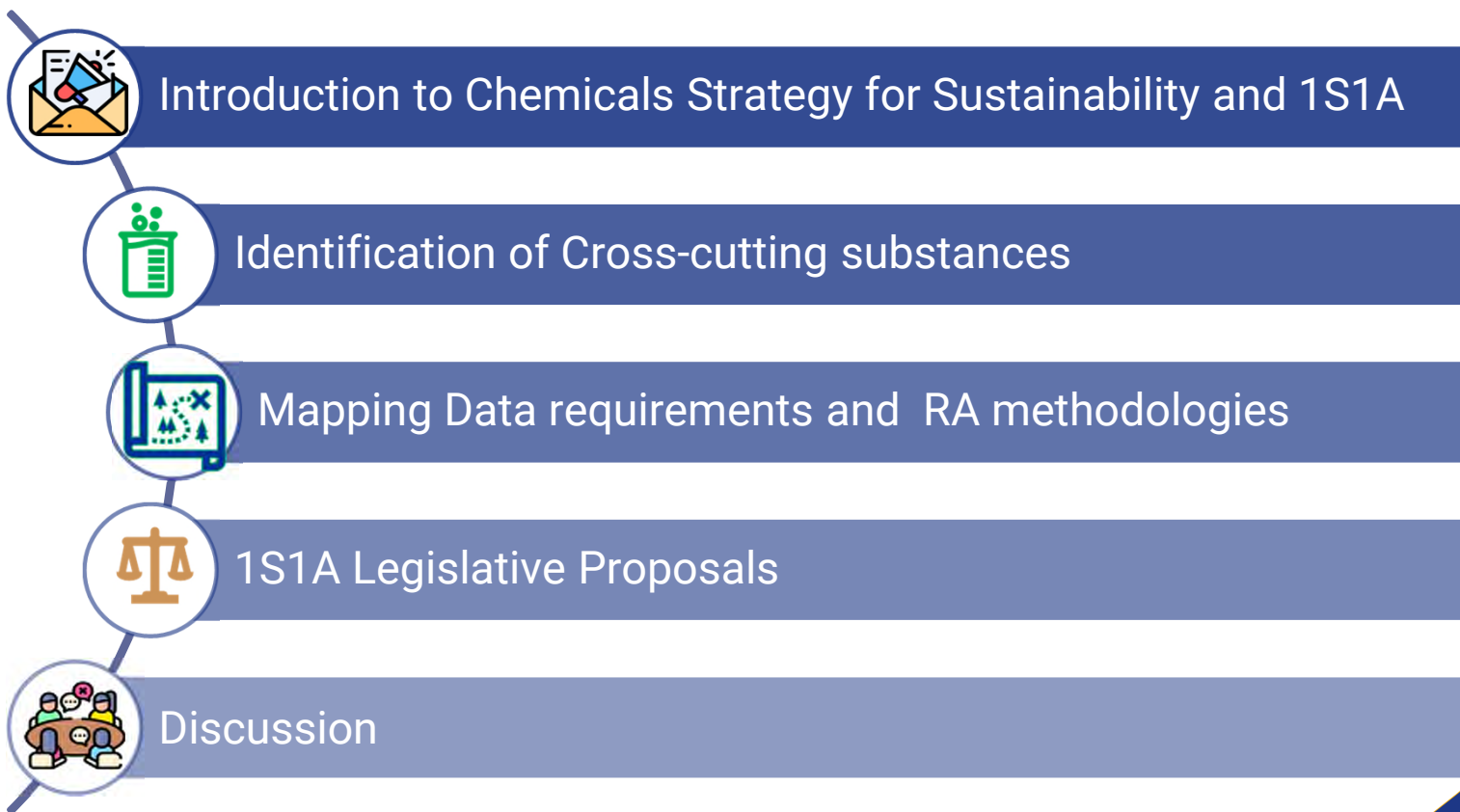
# **CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS) ONE SUBSTANCE ONE ASSESSMENT (1S1A)**

## **AN UPDATE**

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## AGENDA





# INTRODUCTION: CSS and 1S1A



# Chemical Strategy for Sustainability (CSS)

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## EU Green Deal

## 'Toxic-Free Environment'

## October 2020

Stronger EU legal framework to address pressing environmental and health concerns

**Simplifying and consolidating the legal framework.-**  
**One Substance One Assessment**

Innovating for safe and sustainable EU chemicals

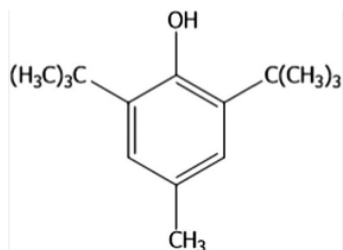
Establishing a comprehensive knowledge base on chemicals

Providing a model to inspire chemicals management globally





# ONE SUBSTANCE ONE ASSESSMENT (I)



**Butylated hydroxy toluene (BHT)**

IUPAC name: 2,6-di-tert-butyl-p-cresol

CAS number: 128-37-0

**TODAY:**

**One Substance, SIX Assessments  
(one per use)**

Food Contact  
Material

Feed additive

Industrial  
chemical

Food  
Additive

Medicine-  
excipient

Cosmetic

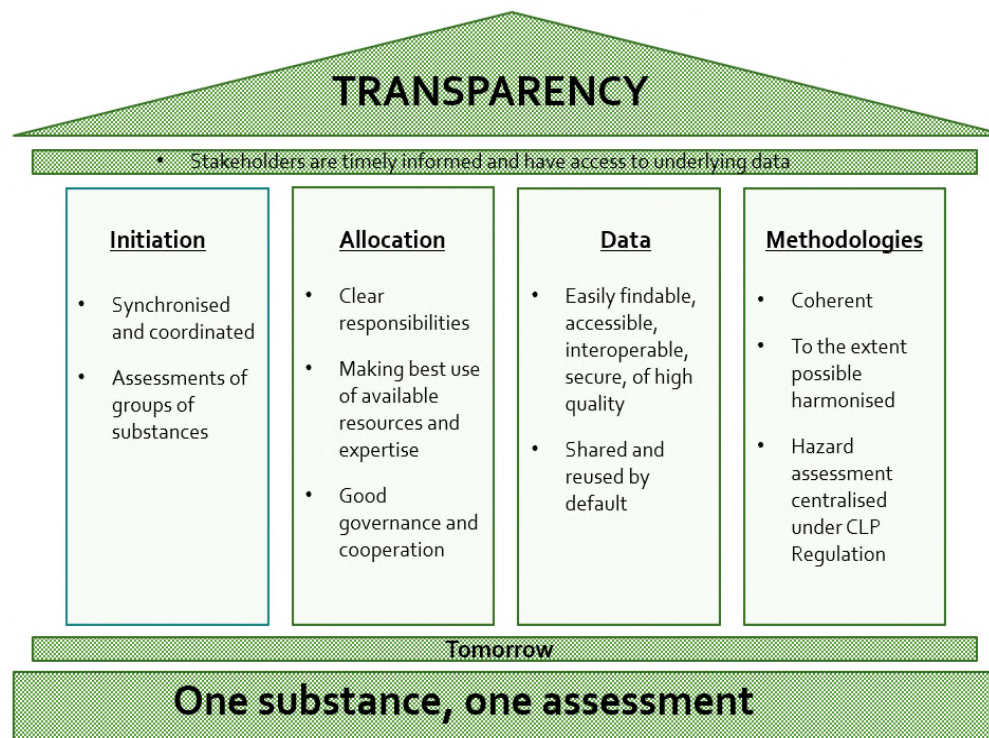
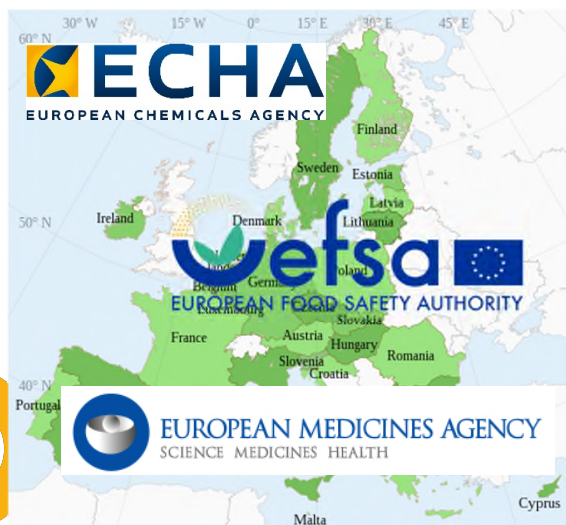
**TOMORROW:**

**One Substance, ONE Assessment  
with all uses**

- *Synchronised*
- *Same dataset*
- *Best use of resources*
- *No duplication, no risk of divergencies*
- *Facilitate the regulatory management*



# ONE SUBSTANCE ONE ASSESSMENT (II)





# ONE SUBSTANCE ONE ASSESSMENT (1S1A)

## EFSA's Activities





# Activities towards 1S1A

Early identification of cross-cutting substances

Harmonisation of Data Requirements and Risk Assessment Methodologies

# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES (I)

- The objective is to identify cross-cutting substances among all actors in EU performing risk assessment of chemicals. These are: EFSA, ECHA, EMA, the EC Sci Committees (SCCS and SCHEER) and the Member States.
- From October'23 to February'24 EFSA run a pilot to check cross-cutting substances (with the MSs and the sister Agencies and the two EC Sci Ctees) early in the Risk assessment process.

## RESULTS

- Total of 30 applications received during the piloting period were checked.
- Cross-cutting hits were found for 16 cases: (7) with ECHA, (6) with EMA, (2) with MSs and (1) with the SCCS.
- The time required to search for one substance ranged from 15 to 90 minutes.
- About 20 databases to be consulted among Agencies/Institutions.

## CONCLUSIONS

- ❑ The search is very complex, due to the several datasets to be checked
- ❑ If the search is limited to one point in time and carried out only by one Institution, there is the risk of being incomplete
- ❑ Substance identification might be an issue

# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES (I)

## Cross-cutting substances signaled to EFSA

BENZALDEHYDE – Being evaluated under REACH (Ongoing: Dossier evaluation, Substance evaluation).

BUTYLATED HYDROXYANISOLE (BHA) – Substance evaluation under Community Rolling action plan (CoRAP). Potential Endocrine disruptor.

TALC (E 553b) – Harmonised classification adopted as Carc. 1B.

MELAMINE – Harmonised classification adopted as Carc. 2 and STOT RE 2.





# IDENTIFICATION OF CROSS-CUTTING SUBSTANCES (III)

- Member States perform risk assessments of substances that might be found in food/feed: their on-going and past assessments are collected in a database which was developed by EFSA in 2016:


**MS RA Plans:** <https://r4eu.efsa.europa.eu/app/database>



MS RA Plans

Date of Entry	Date of Edit	Country	Organisation	Main Area	Title	Description
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="All"/>	<input type="text" value="All"/>	<input type="text" value="All"/>	<input type="text" value="All"/>
2023-02-17	2023-02-17	Lithuania	KTU	Biological Hazards Chemical Hazards	Research on innovative methods for the product production and safety assurance	The aim of the work was to investigate the possibilities of wet extrusions and high-pressure technology applications on the parameters and shelf-life durability.
2023-02-17	2023-02-17	Lithuania	KTU	Nutrition	Investigation of the influence of minerals and probiotic micro-organisms on the properties of a plant-derived butter-type product and development of an innovative technology for a butter analogue enriched with minerals and probiotics	Development of technology for a plant-derived butter-type product enriched with minerals and probiotic microorganisms. T food".

- We also invite you and your relevant colleagues to familiarize with the MS RA Plans database. And also with the **OpenEFSA**



QUESTIONS PUBLIC CONSULTATIONS EXPERTS

Questions

21849 results found [Export \(21849\) questions to CSV](#)



Microsoft Excel  
ma Separated Val



**1S1A:**

## **STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES: *BACKGROUND***

### **Piloting 1S1A:    Drinking Water Directive Food Contact Materials**



Data requirements for genotoxicity do not fully match

Identify other misaligned areas

**Contract: RPA Europe & FoBiG**



**Study Report:** <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2023.EN-8540>



## 1S1A:

# STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES: *RESULTS*

### DATA: some high-level findings

- Migration rate for food contact materials defines data requirements for toxicity
- Data for environmental fate/ecotoxicity conditioned to phase 1 trigger values (different in feed, vet. and human medicines)
- No data requirements for environmental fate and ecotoxicity for food chemicals
- Data requirements exist for substance identity, physico-chemical properties and toxicity in all areas
- Quality standards to perform the studies (GLP, other)



## 1S1A:

# STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES: *RESULTS*

### METHODS: some high-level findings



#### Principal Risk Assessment Methods

- ✓ Category 1: Risk factor = exposure / reference value
- ✓ Category 2: Risk factor = reference value / exposure

#### Names of reference values – human health

- REACH (**DNEL**)
- Biocides (**AEL, ADI**) Pesticides (**AOEL, ADI**)
- Food (**ADI**) Feed (**ADI**) Vet. medicines (**ADI**)



## HARMONISATION NEEDS



- Terminology
- Approaches to define data requirements
- Specific data requirements for each endpoint
- Testing provisions to meet a data requirement
- Risk Assessment definitions
- Provisions in the hazard assessment
- Exposure assessment – Models and tools

1S1A:

## STUDY OF MAPPING DATA REQUIREMENTS AND RISK ASSESSMENT METHODOLOGIES: *PROPOSED NEXT STEP*

### Relevant Stakeholders

- EFSA, ECHA, EMA, EC
- To analyse/validate the findings
- Areas where alignment would be prioritised



### Organisation of a workshop – Nov' 24



- Agreement on areas to start alignments
- Discussion on continuity of the activity



### Proposal of the establishment of the EU Library of Food/Feed Guidance Documents







# ONE SUBSTANCE ONE ASSESSMENT (1S1A)

## Legal Proposals



# 'CLP REVISION'

Revision CLP Regulation. Adopted by EC on 19/12/2022.

- 1) Delegated Act - Change of Annex I. Introducing NEW hazard classes. New rules in force as of **20 April 2023**: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707>
- 2) Proposal to amend the text of CLP Regulation – Change of body text:
  - NEW: Right for the Commission to develop CLH proposals
  - NEW: **Empowerment for Agencies** *'The Commission may ask ECHA or EFSA to prepare a proposal for harmonised classification and labelling of substances and, [...].'*
  - Approved by the European Parliament and Council in June 2024

## METHODOLOGIES AND DATA

The Commission will:

- ensure that the CLP Regulation is the **central piece for hazard classification** and allows the Commission to initiate harmonised classifications<sup>76</sup>;



## 'RE-ATTRIBUTION OF TASKS'

Proposal for a Regulation on the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.

Adopted by EC on 7/12/2023

Reallocation of tasks derived from the

1S1A implementation and from  
EC Scientific Committees

Tasks to EFSA, to contribute in:

- Provision of relevant scientific Opinions
- Exchange of data and information
- Development of scientific methodologies for the assessment of chemicals



COOPERATION  
MS and Agencies

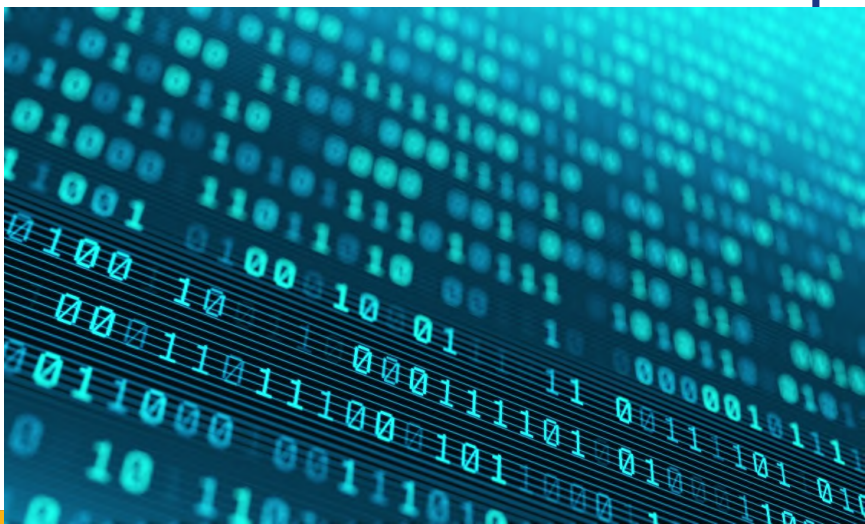


Preventing/Avoiding  
DIVERGING OPINIONS



## 'CHEMICAL DATA'

Proposal for a Regulation establishing a common data platform on chemicals.  
Adopted by EC on 7/12/2023



- **EU-Common Data Platform on Chemicals**
- **Data inter-operability, data use and re-use, removal of legislative barriers**  
*Crucial element in the success of 1S1A*
- **Framework of CSS Indicators**
- **Early Warning and Action System on Chemicals**





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## Q&A



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