

17TH OCTOBER 2023

10TH MEETING FOOD CONTACT MATERIAL NETWORK

CHEMICALS STRATEGY FOR SUSTAINABILITY (CSS)

ONE SUBSTANCE ONE ASSESSMENT (1S1A)

AN UPDATE



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OUTLINE



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INTRODUCTION: CSS and 1S1A



Chemical Strategy for Sustainability (CSS)

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

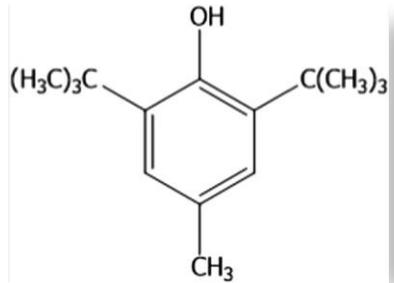
Innovating for safe and sustainable EU chemicals

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

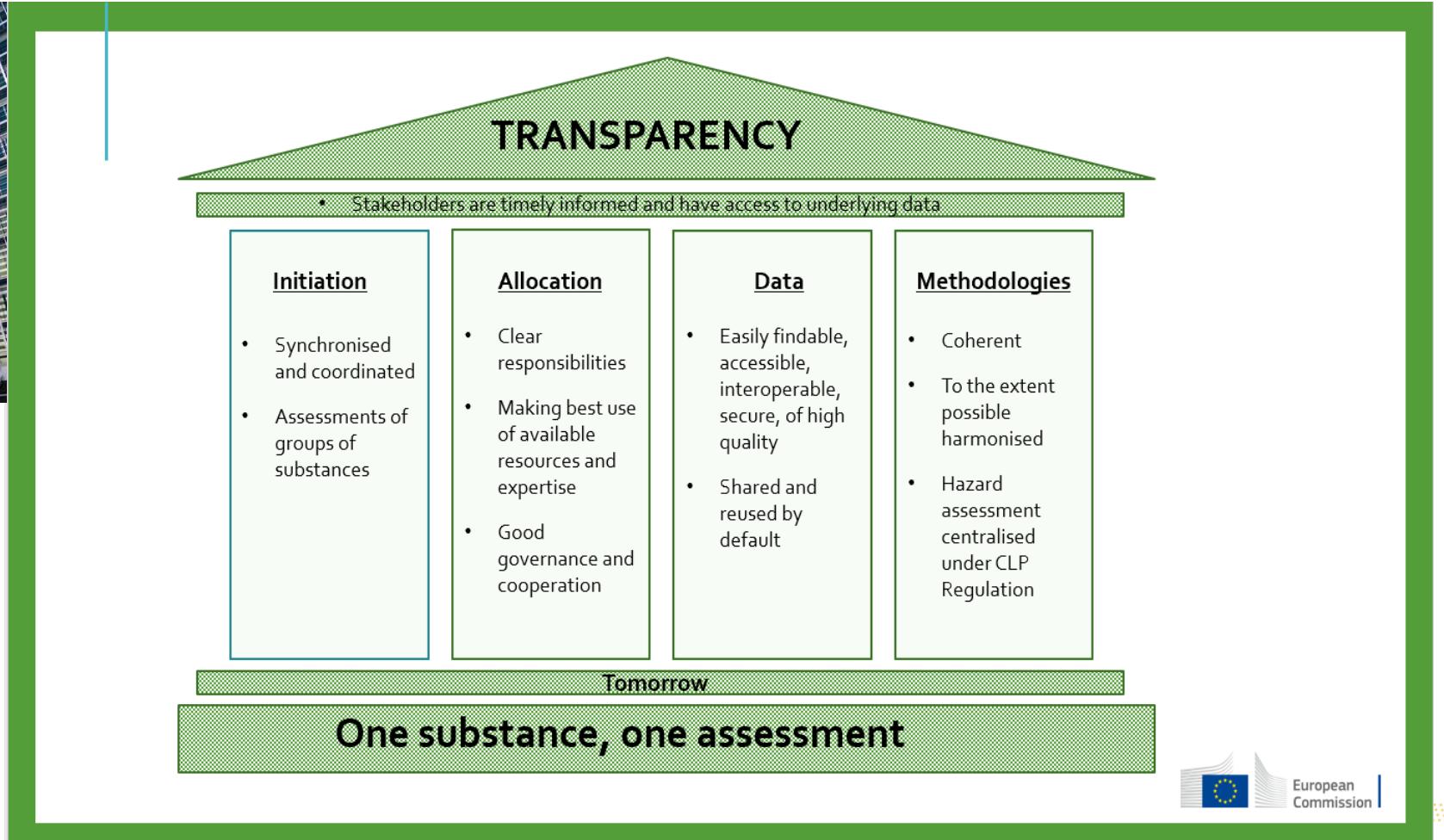
TOMORROW:

**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)



(Slide taken from EC Presentation to 80th Advisory Forum Meeting)



ONE SUBSTANCE ONE ASSESSMENT (1S1A) EFSA's Activities





Activities preparing 1S1A

Early identification of cross-cutting substances

- Piloting 1S1A; Analysis/Lessons learnt

Procurement Study to map DR and RAM

Contribution to the EU-Common Data Platform on Chemicals (EU-CDPC)

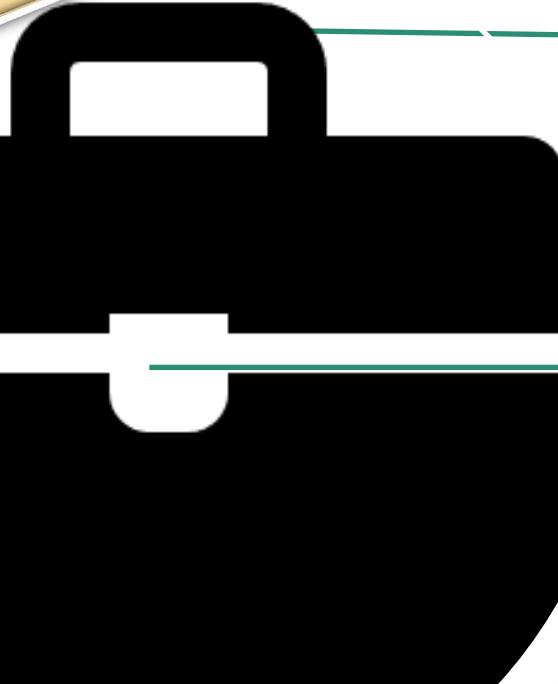
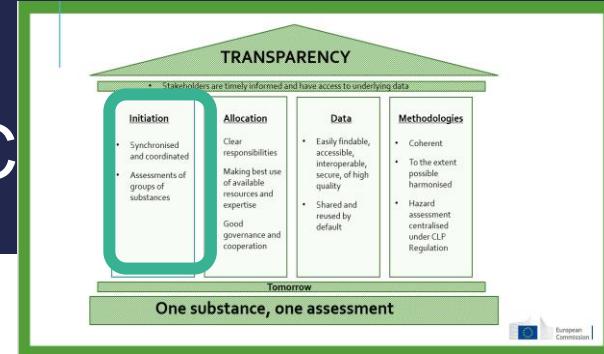
- OTHER: Focused 1S1A Inter-Agencies meetings
- Participation in various 1S1A preparatory activities led by EC: Repository of HBGV, Joint discussions with European Commission and Member States



IDENTIFICATION

Available databases and tools
Future: EU-CDPC

CROSS-CUTTING SUBSTANCES



WORK on SUBSTANCE IDENTIFIERS

10

Self-mandates

70

Generic
mandates

350

Applications for
Regulated products
mandates

Procedure to involve relevant
Agencies in place
(Mandate Dialogue phase)

IDENTIFICATION OF CROSS-CUTTING SUBSTANCES

- 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.
- EFSA has very recently started 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.
- 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>

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



Date of Entry	Date of Edit	Country	Organisation	Main Area	Title	Description
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	All	<input type="text"/>	<input type="text"/>
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".



IDENTIFICATION OF CROSS-CUTTING SUBSTANCES. FRAE



- EFSA has officially launched the **new journal *Food Risk Assess Europe (FRAE)***, an open access repository of selected scientific articles from **national food safety agencies across the EU**.
- As an addition to our EFSA Journal on Wiley, FRAE aims to promote collaboration and provide a stronger evidence base for the **EU risk assessment community**.
- More info at:



<https://www.efsa.europa.eu/en/publications/food-risk-assess-europe>



efsjournal@efsa.europa.eu



DATA SHARING / DATA USE AND RE-USE

- Feed additives
- Food Contact Materials
- Food additives, food enzymes and food flavourings
- Plant protection products



EUROPEAN FOOD SAFETY AUTHORITY

- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Classification, labelling and packaging of substances and mixtures (CLP)
- Biocidal products



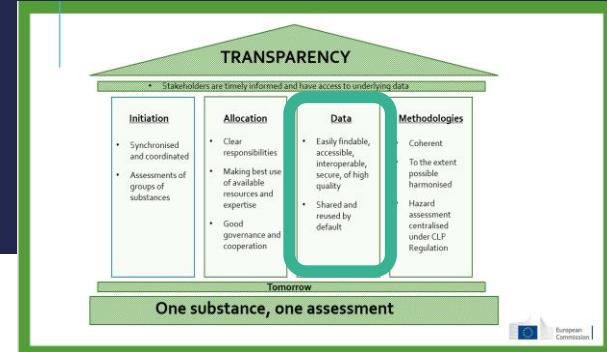
- Medicinal products for human use
- Medicinal products for veterinary use



- Safety of Toys
- Cosmetic products



- ❖ Common open data platform on chemicals
- ❖ Making data available in appropriate formats:
 - IUCLID for hazard and use data; IPCHEM for monitoring data



Legal

- Remove obstacles for reuse of data and better streamline flow of data



PILOTING 1S1A CONCEPT IN CONCRETE ASSESSMENTS

Collaboration with ECHA in the Implementation of Drinking Water Directive



Preliminary Work in the Drinking water Directive started in 2021 – EFSA contributed to the discussion of various topics: **Setting the tiers for toxicological data requirements, Information requirements on genotoxicity and reproductive toxicity, nanomaterials, Hazard and safety assessment and Substance identification and categorisation**



There are **3 pieces of legislation** already finalised:

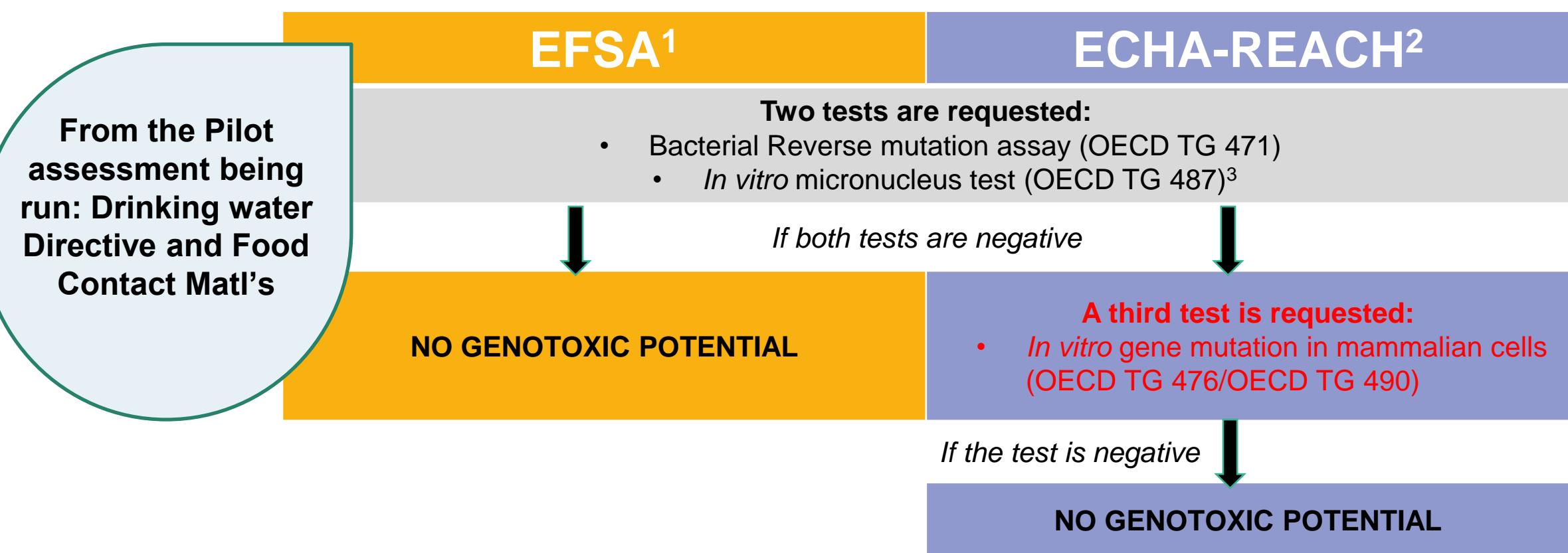
- **Implementing Act.** Collect the information Requirements.
- **European Positive List.**
- **Application process**



During the implementation phase, FCM colleagues will be **part of the DW-RAC Working group**



EXAMPLE OF DIVERGENCY ON DATA REQUIREMENTS



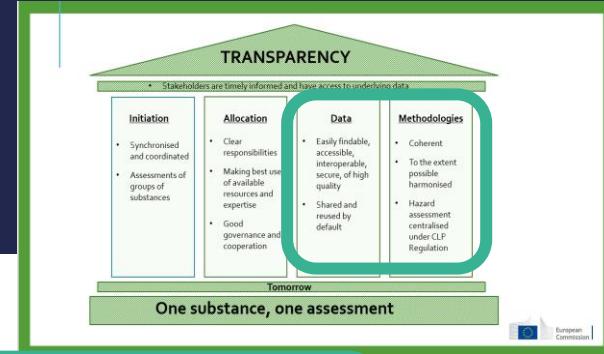
(1) Requirements from [Scientific Opinion of the EFSA's Scientific Committee of 2011](#) and [Clarifications of some aspects in 2017](#)

(2) Requirements from REACH Regulation, [Annex VII](#) (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE) and [Annex VIII](#) (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE)

(3) Until September 2022, the choice of '*In vitro* cytogenicity study in mammalian cells' or '*In vitro* micronucleus study' was possible for the second genotoxicity test. From September'22 only the '*In vitro* micronucleus study' is required as second test, and no choice is possible. Thus, the Decision of the ECHA's Member State Committee in its June 22's meeting approximates the approaches of the two Agencies.



ALIGNMENT DR AND RAM



PILOT findings

- Food Contact Material and Drinking Water (EFSA Sci. Ctee Guidance vs REACH)
- Data requirements for genotoxicity screening do not fully match

PROBLEM

- There might be other areas with misalignments in DR and RAM
- Work via Outsourcing. **Procurement Subject:** “Mapping of DR and RAM linked to the regulatory frameworks and remits of the relevant EU Agencies (ECHA, EFSA and EMA) and EC Scientific Committees (SCCS and SCHEER)”

RESULTS

- Expected by November 2023
- To be critically revised in the context of 1S1A

Work on GUIDANCES
Joint GUIDANCES



EU-COMMON DATA PLATFORM ON CHEMICALS



Hosting data on
CHEMICALS



Academic
Studies

Studies
Notification

Control vocabularies,
dictionaries, formats

Repository
of health
limit values

'Analytical' Tools
(QSAR Toolbox,
data analytics,
Query functions,
exposure models)

Status on Regulatory
Processes
Extended (P)ACT
Extended EUCLEF

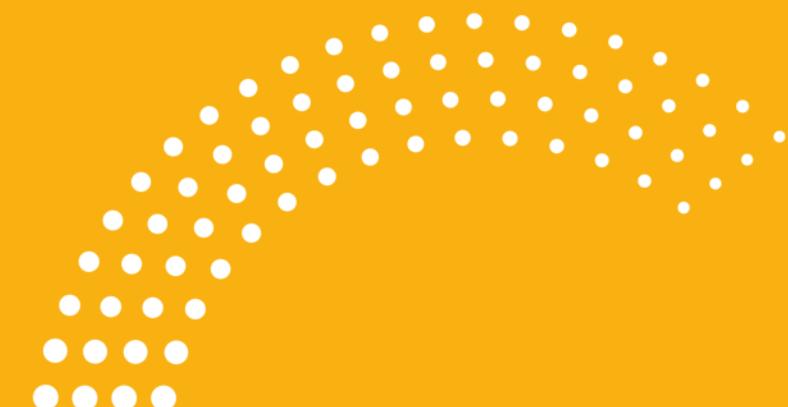
Outcomes of the
assessments

Central database(s) with regulatory
submissions



Occurrence data





ONE SUBSTANCE ONE ASSESSMENT (1S1A) Legal Proposals



'REVISION - CLASSIFICATION LABELLING AND PACKAGING REGULATION'

Revision CLP Regulation. Adopted 19/12/2022.

- 1) Delegated Act - Change of Annex I. Introducing NEW hazard classes
- 2) Proposal for a revision of the 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, [...]'*

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 classifications⁷⁶;



‘RE-ATTRIBUTION OF TASKS’

Reallocation of tasks derived from the 1S1A implementation and from EC Scientific Committees

Tasks to EFSA, to contribute in:

- Operation and governance of the EU-CDPC
- Adopting formats and preparing controlled vocabularies
- Early Warning and Action System on Chemicals



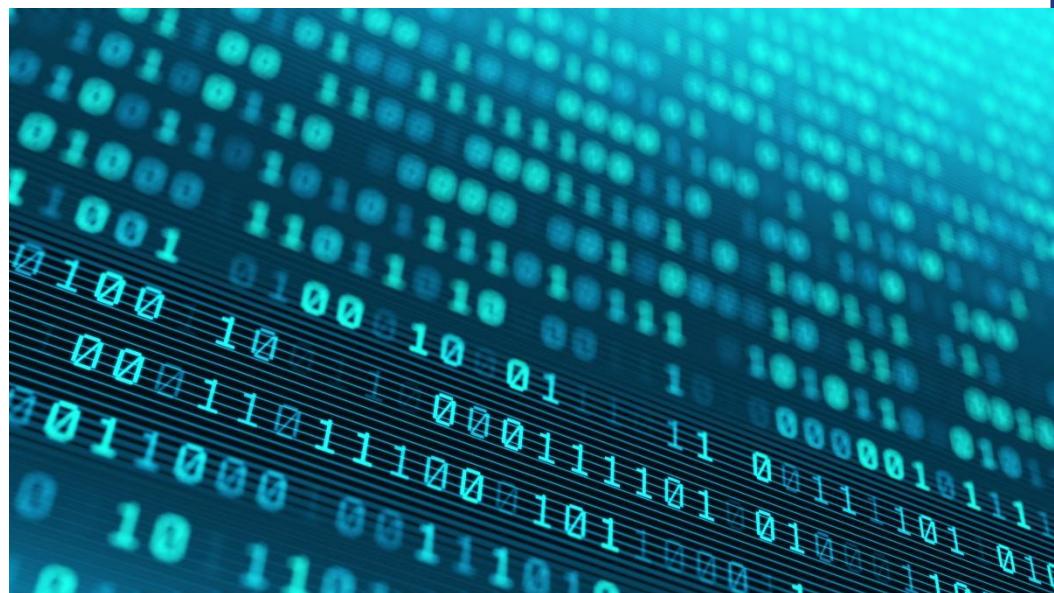
COOPERATION
MS and Agencies



Preventing/Avoiding
DIVERGING OPINIONS



‘CHEMICAL DATA’



- 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
- CSS Indicators





SUMMARY/Take-home messages



SUMMARY



Legislative Proposals to be adopted

CHANGES in the way of working

**Identification of Cross-cutting substances
Substance Identifiers**

**Data Sharing/Data re-use
STANDARD Data formats
INCREASED interaction with sister Agencies/MS**

**Towards Alignment Data Requirements and RA Methodologies:
Joint Working groups / Joint Guidance**





Q&A



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