

99<sup>TH</sup> ADVISORY FORUM  
PAPHOS, 04-05 MARCH 2026

# 1S1A SUPPORTING LEGISLATION

## IMPLICATIONS FOR EFSA AND MEMBER STATES



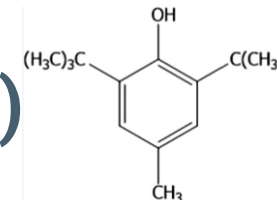
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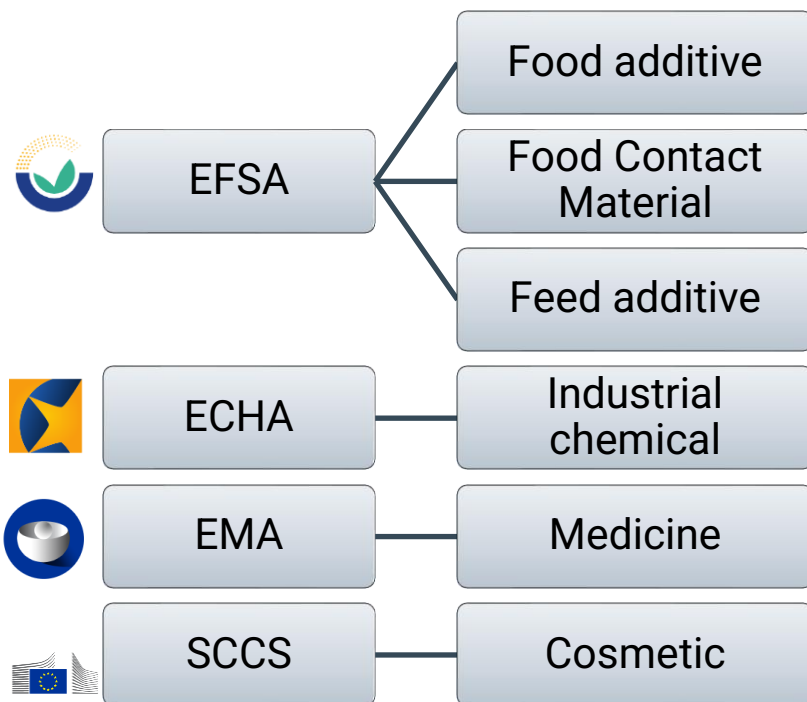
Food Ingredients and Packaging Unit

# ONE SUBSTANCE ONE ASSESSMENT (1S1A OR OSOA) – WHY?

## Example: Butylated Hydroxy Toluene (BHT)



**TODAY: Multiple assessments for the same substance**



**FUTURE: One Substance – One Assessment**

### Benefits:

- ✓ Synchronized assessments
- ✓ Shared dataset
- ✓ Efficient use of resources
- ✓ No duplication, fewer inconsistencies
- ✓ Simplified regulatory management



# OVERVIEW OF THE REGULATIONS SUPPORTING 1S1A

## Classification Labelling and Packaging (CLP) Regulation Revision (2023-2024)

New Provision: EFSA to be mandated to prepare CLH proposals

Introduction of new hazard classes for Human Health and Environment



## 1S1A Package (2026)

### DATA REGULATION

- Developing a unified data platform for chemicals that ensures data is findable, accessible, interoperable, and reusable
- Creating a comprehensive monitoring and forecasting framework for chemicals

### RE-ATTRIBUTION OF TASKS TO AGENCIES

- Reassigning scientific and technical responsibilities
- Enhancing collaboration among Union agencies in the chemical sector



# DATA REGULATION (I)

CLUSTER	TASK	ARTICLE
A	EU-Common Data Platform on Chemicals	3
	Implementation plan and Governance of the EU-CDPC	4
	Information platform for Chemical Monitoring (IPCHEM)	7
	Repository of Reference Values	8
	Information on Regulatory Processes. To be submitted to the EU-CDPC	10
	Environmental sustainability-related data	15
	Standard Formats – Application of IUCLID	17
	Controlled vocabularies	18
	Access rights and transparency	19
B	Database of Study Notifications	9
C	Human Biomonitoring Data	6
	Human Biomonitoring study	25
D	Uptake of peer-reviewed published research data	16
E	Use the chemicals data contained in the EU-CDPC	20
F	Framework of Indicators	21
G	Early warning and action system for emerging chemical risks	22
N/A	Data generation mechanism	24

- Annex I= 74 Regulations, from which 25 are EFSA's related Regulations
- Annex III= 34 Regulations from which 12 are EFSA's related Regulations



# DATA REGULATION (II): IMPACT ON EFSA

Cluster	PROVISION	UNIT
A	<b>EU-COMMON DATA PLATFORM ON CHEMICALS (EU-CDPC)</b> <ul style="list-style-type: none"> <li>▪ Minimum Viable Product: (1) Study Notifications, (2) OpenFood Tox, (3) Chemical Monitoring Data, (4) Food Chain Applications*, (5) Applications under PPPR (6) OpenEFSA</li> <li>▪ Rest of Chemicals Data</li> </ul>	[iDATA]
B	<b>DATABASE OF STUDY NOTIFICATIONS</b>	[FDP]
C	<b>HUMAN BIOMONITORING STUDY/DATA</b>	[MESE]
D	<b>UPTAKE OF PEER-REVIEWED PUBLISHED RESEARCH DATA</b>	[MESE]
E	<b>USE OF CHEMICALS DATA CONTAINED IN THE EU-CDPC</b>	[FDP]
F	<b>FRAMEWORK OF INDICATORS</b>	[iDATA]
G	<b>EARLY WARNING AND ACTION SYSTEM FOR EMERGING CHEMICAL RISKS</b>	[KNOW]

(\*) Food chain application dossiers containing chemicals data submitted through the E-submission Food Chain Platform by applicants under the following areas and available in structured formats:

- Regulation (EC) No 1831/2003-Feed additives
- Regulation (EC) No 1935/2004-Food Contact Materials
- Regulation (EC) No 1924/2006-Nutrition and Health claims
- Regulation (EU) 2015/2283-Novel foods



# DATA REGULATION (III): IMPACT ON MEMBER STATES



- Data to be included in the EU-CDPC:
  - ✓ Data generated through EU, national or international programs, or research on chemicals - Provided voluntarily by MSs or other parties, incl. third countries and held/accepted by EFSA
- Information on Regulatory Processes
- Environmental sustainability-related data
- Framework of Indicators
- Data produced through the data generation mechanism
- Human Biomonitoring study



# RE-ATTRIBUTION OF TASKS TO AGENCIES

## Cooperation with Member States and the Agencies for the

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



## Avoid/Minimise Diverging Opinions

- Measures to monitor any potential source of divergence
- If divergency appears, share all relevant scientific and technical information to identify the issues(s)
- The involved bodies should cooperate to resolve the disagreement. If they cannot a joint report shall be prepared
- In case of diverging opinions, opt for the advice that best protects the most vulnerable groups



# EFSA'S IMPLEMENTATION ACTIVITIES



Identification of **cross-cutting substances**



**Exchange of data**



Development of **EU Library of Food Safety Guidance Documents**  
in close collaboration with Advisory Forum and Focal Points



The new **EFSA's Guidance architecture model** involving Member States from inception



# LOOKING FORWARD

- Member States to contribute on mandatory and voluntary provisions resulting from the 1S1A Regulations.
- *Mapping* 1S1A actors in Member States, to better coordinate 1S1A issues, i.e. representatives working in the various chemical areas (food, feed, industrial chemicals, cosmetics, etc).
- Food and Feed representatives from Member States to engage in the 1S1A Expert Group coordinated by DG-ENV.



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