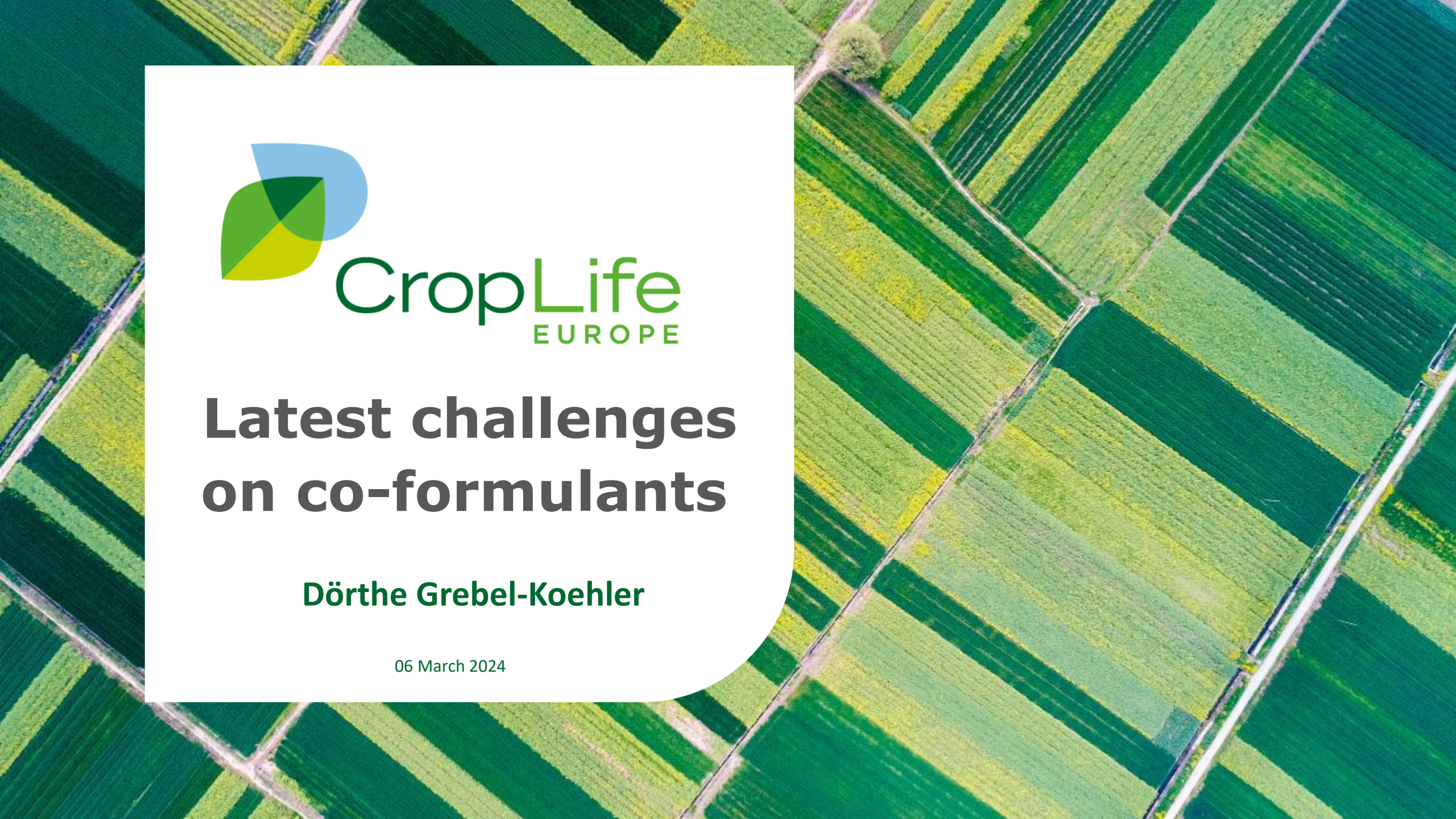

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Latest challenges on co-formulants

Dörthe Grebel-Koehler

06 March 2024

Co-formulants

and
Member State activities in evaluation

and the
GD on changes of the chemical composition of authorised PPP - SANCO 12638-2011 rev.3

in **CSS**

One Substance - One Assessment

CLP new hazard classes

Member State activities observed

Annex III to 1107/2009 - unacceptable co-formulants

- Compounds listed may not be used as a co-formulant
  - Could be present as impurities in co-formulants at maximum 0.1%

2022

- Requests for ‘full compositions’
  - Suppliers provided detailed information to requesting authorities
  - Fully reliant on suppliers - no means of control

2023

- Requests for co-formulant data
  - Varying types and details

2024

- Requests for information on certain impurities
  - Varying details

- Commission technical workshops on risk assessments for co-formulants

- Data maintained in country specific databases on co-formulants
- Competent authorities’ decision making not aligned within the zone or in EU27

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Pragmatic approach needed

Evaluation of co-formulants in (representative) formulations

- Translation of EFSA Technical Report and the 'Technical Workshop on Risk Assessments of PPP's into evaluation practice ongoing, solutions however pending
- **Repetitive collection of information**
  - EU evaluations in different legal frameworks
  - Non-EU evaluations
  - Classification
  - REACH registered endpoints
- Time intensive in collection and evaluation
- **Better management necessary, e.g.**
  - when already assessed
  - non-hazardous compounds
  - Focus on not yet assessed co-formulants

Complete composition of Product

N°	Trade name	Chemical name	Function	CAS number	EC / List number	REACH registration number	Content in g/L in the formulation*	Content in% w/w in the formulation
1	ACTIVE							
2	ACTIVE							
3	Co-formulant 1							
4	Co-formulant 2							
5	Co-formulant 3							
6	Co-formulant 4							
7	Co-formulant 5							
8	Co-formulant 6							
9	Co-formulant 7							
10	Co-formulant 8							
		TOTAL SUM						

1. NAME			
IDENTITY			Source/Reference
Chemical name (trade name if available)			
CAS number			
EC / List number			
Function			
Content in g/L			
Content in % w/w			

REGULATED SUBSTANCE - EU STATUS	
REACH Regulation	
Regulation (EU) No 872/2012	
Pesticide	
Cosmetic	

REGULATED SUBSTANCE – NON EU STATUS	
US EPA	
Canada	

TOXICOLOGICAL PROPERTIES			
CLP Regulation	Supplier SDS:		
	ECHA - Harmo	Degradation	Soil
			Water
	ECHA – Self classifications:		

ENVIRONMENTAL FATE AND BEHAVIOUR		
Degradation	Soil	
	Water	

ECOTOXICOLOGICAL PROPERTIES	
CLP Regulation	Supplier SDS
	ECHA - Harmonized Classification
	ECHA – Self classifications

- **Future proof technical solution needed**

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Set the right priorities and safeguard resources

Guidance Document on changes of the chemical composition of authorised PPP - SANCO 12638-2011 rev.3

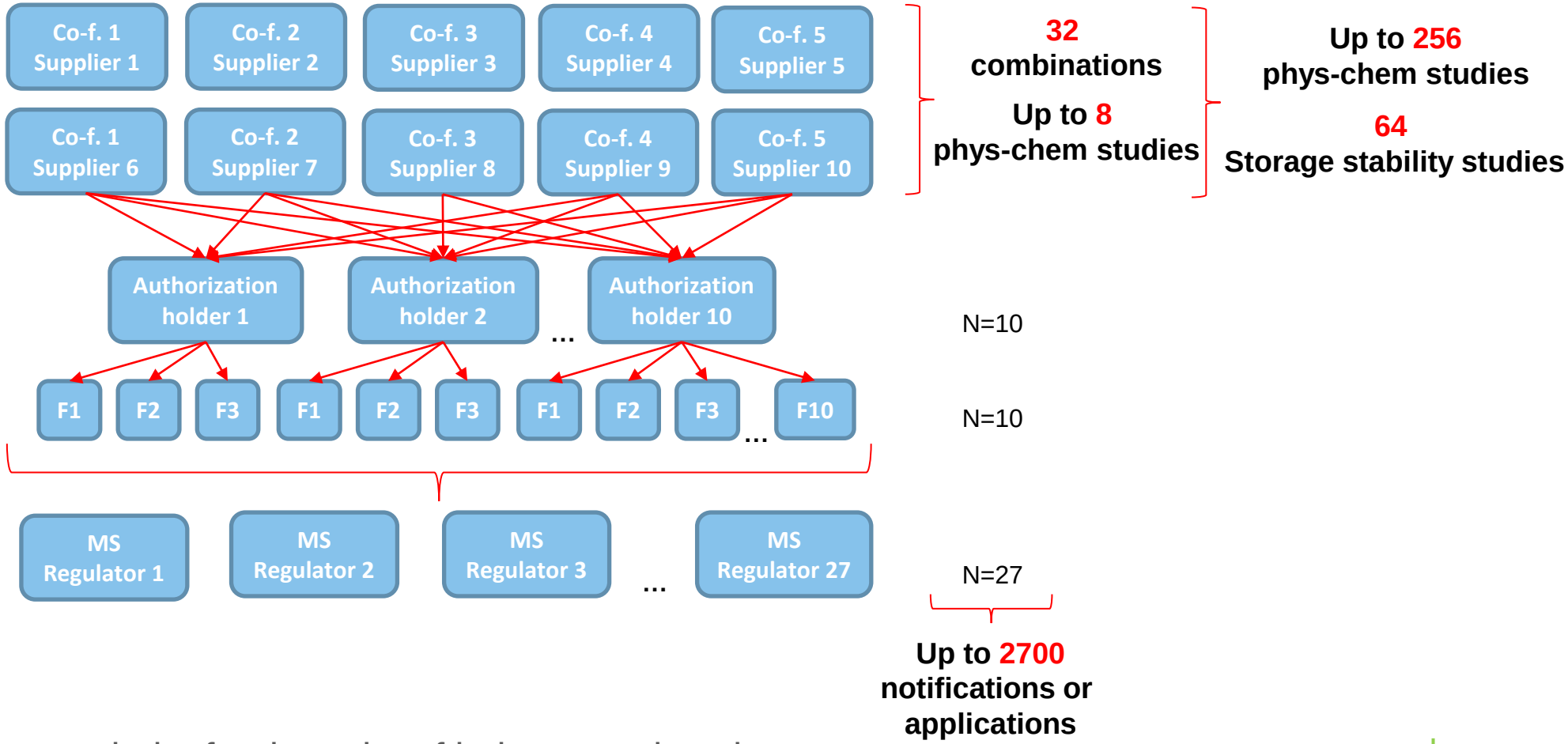
- Relating the equivalency of co-formulants in a newly harmonized approach

Old	New	Action	Authority response time
non-significant	Type 1: Administrative changes	Notification	3 months
	Type 2: Alternative co-formulants (including alternative sources)	Application	6 months
significant	Type 3: Change of composition		

- Dealing with perceived and not real changes in formulations
- Not in line with REACH principle of sameness
- Not focusing on hazardous components only
- Lacking predictability: Authority feedback needed for all and amendments to the change type possible - likely timeline impact
- **Many questions raised during commenting and ask for involvement and stakeholder exchange**

Multitude of studies can bind valuable resources

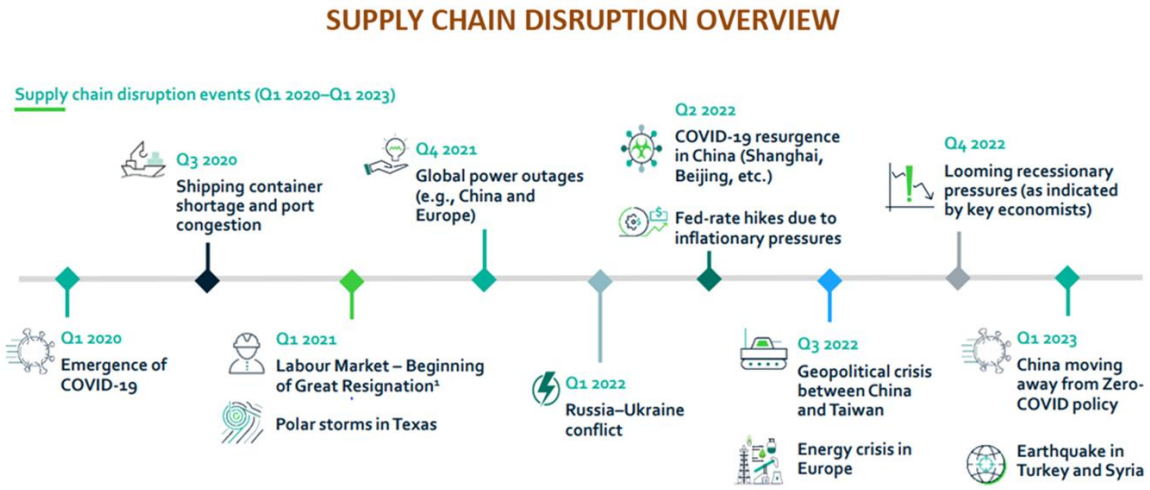
- Call for all combinations of alternative co-formulants to be tested – resource demanding



- Improvement needed – for the sake of industry and evaluators

Pressure on supply chain resilience and impact on food security

- Needs:
  - Rapid responses and predictability with alternate sources
- Challenges:
  - Dynamic situation through REACH registrations: data → assessments → classifications → impact in PPP's
  - Dynamic supply chains: site shutdowns due to accidents, weather, upstream supply issues, blocked sea lanes, logistics issues, and geopolitics
  - Divergence in opinions across Member States
- Consequences:
  - Inability of effective management
  - Fragmentation of the common market – but:
    - formulations are not manufactured for individual Member States
  - Drive to single sourcing and fragile supply chains
  - Vulnerability of food security

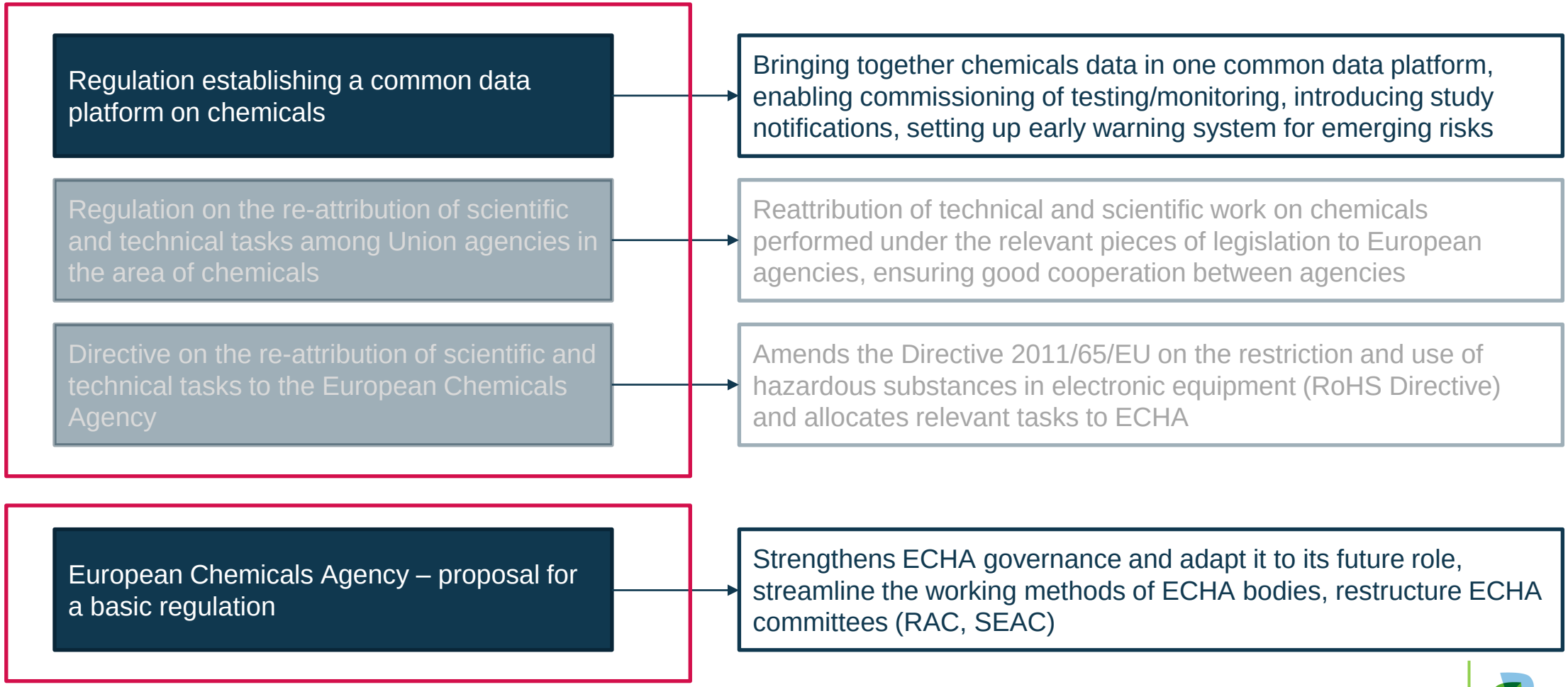


Source: The Smart Cube

One Substance – One Assessment (OSOA)

Legislative package

- To improve the efficiency, effectiveness, coherence and transparency of issuing safety assessments



One Substance – One Assessment (OSOA)

Regulation establishing a common data platform on chemicals – a possibility for co-formulants

- Bringing together chemicals data in one common data platform → all available data on co-formulants in one database
  - All data from chemical legislations in scope
  - Incorporate existing informational platforms
  - Repository with HH and ENV reference values
  - Full access for authorities, incl. confidential information
- Enabling commissioning of testing/monitoring → Data needed for assessment could be generated
  - When further information is considered necessary
  - Not to fulfill applicant's data requirements
  - Could be standard studies, monitoring and out-of-the-box testing
- Introducing study notifications → Overview on new studies for co-formulants
  - Notification of studies needed for compliance with EU regulatory requirements
  - PPP specific notifications stay with EFSA
  - Common approach for notifiable information
- Setting up early warning system for emerging risks → Early indicator for Annex III candidates

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Additional challenge from the new CLP hazard classes

ED HH and ENV, PBT/vPvB, PMT/vPvM

- Co-formulants are substances or mixtures and need to be self-classified within the transitional timelines – deviations in classification possible

Source: ECHA

- Communicated classifications changes for co-formulants will lead to
  - amendments in product composition
  - late revisions of product classifications
  - Increased dossier updates
- Label changes may occur on short notice and possibly multiple times within a shorter timeframe
  - amendment of the REACH Regulation will add to that

Take aways

- Current activities are repetitive and not future oriented.
- Sustainable work practices are essential - ensure manageable workload across all parties.
- Significant opportunity to collectively pursue enhanced regulatory measures.

For more information

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