

# REACH information and risk assessment of chemicals in Food Contact Materials

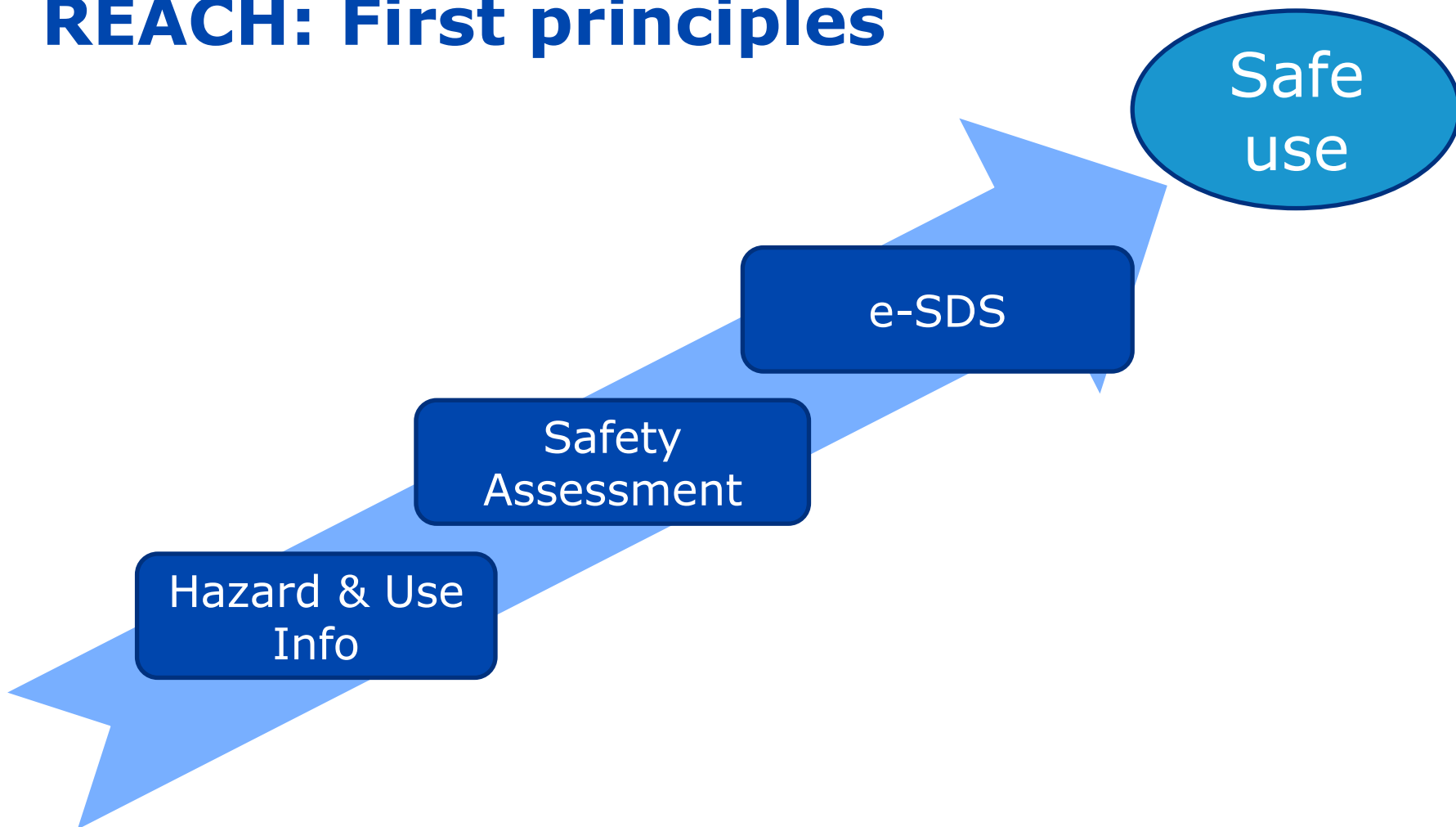
## CHEM Trust workshop

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Brussels

Andreas Ahrens  
Prioritisation Directorate  
Exposure and Supply Chain Unit  
European Chemicals Agency

- Reminder on REACH principles and processes
- What has REACH delivered so far
- Potential contribution of REACH to safety FCM
  - General
  - Example: Registration information (plastic additives overview)
  - Example: Restriction process (Phthalates)
- Limitations in contributing to safety of FCM
- Concluding remarks

# REACH: First principles



# Basic pillars of chemicals legislation

**Safe use  
of chemicals**

**Knowledge**

**Communication  
in the supply  
chain**

**Regulatory  
action**

# REACH & CLP: main processes & actors



## Registration

- Substances manufactured and imported into EEA are registered with ECHA
- Information for safe use is communicated in the supply chain



**Member States**

## Evaluation

- Testing proposal examinations
- Compliance checks of registration dossiers
- Substance evaluations



## Regulatory risk management

- Authorisation
- Restriction
- Harmonised classification and labelling

**Chemicals Safety  
Assessment  
and  
Supply chain  
communication**



# Chemical safety assessment needs information on substance properties and conditions of use

## Manufacturer



**Knows the properties of the substance**

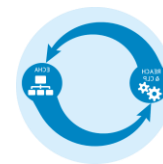
## Downstream user



**Knows how the substance is used**

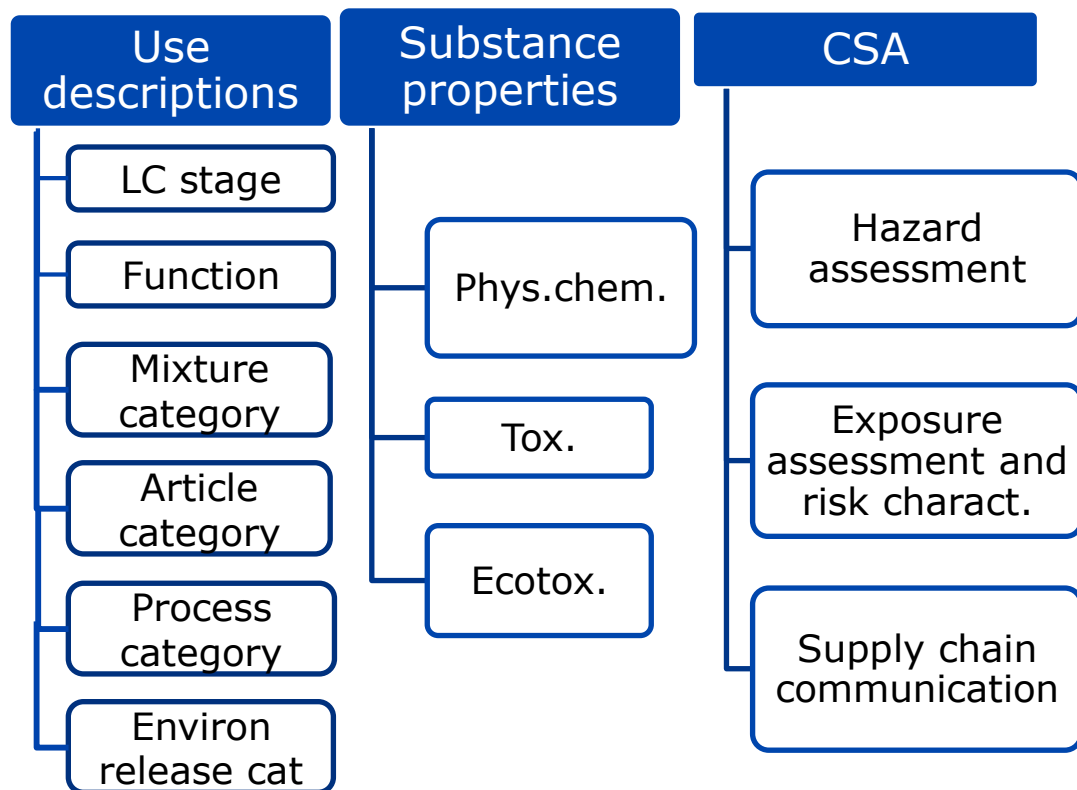
- Foreseen products and processes
- Concentrations and amounts
- Operational conditions
- Risk management measures

- Exchange of information (via supply chain or other means)
- Allocation of assessment responsibilities
- Capacity to carry out the assessment



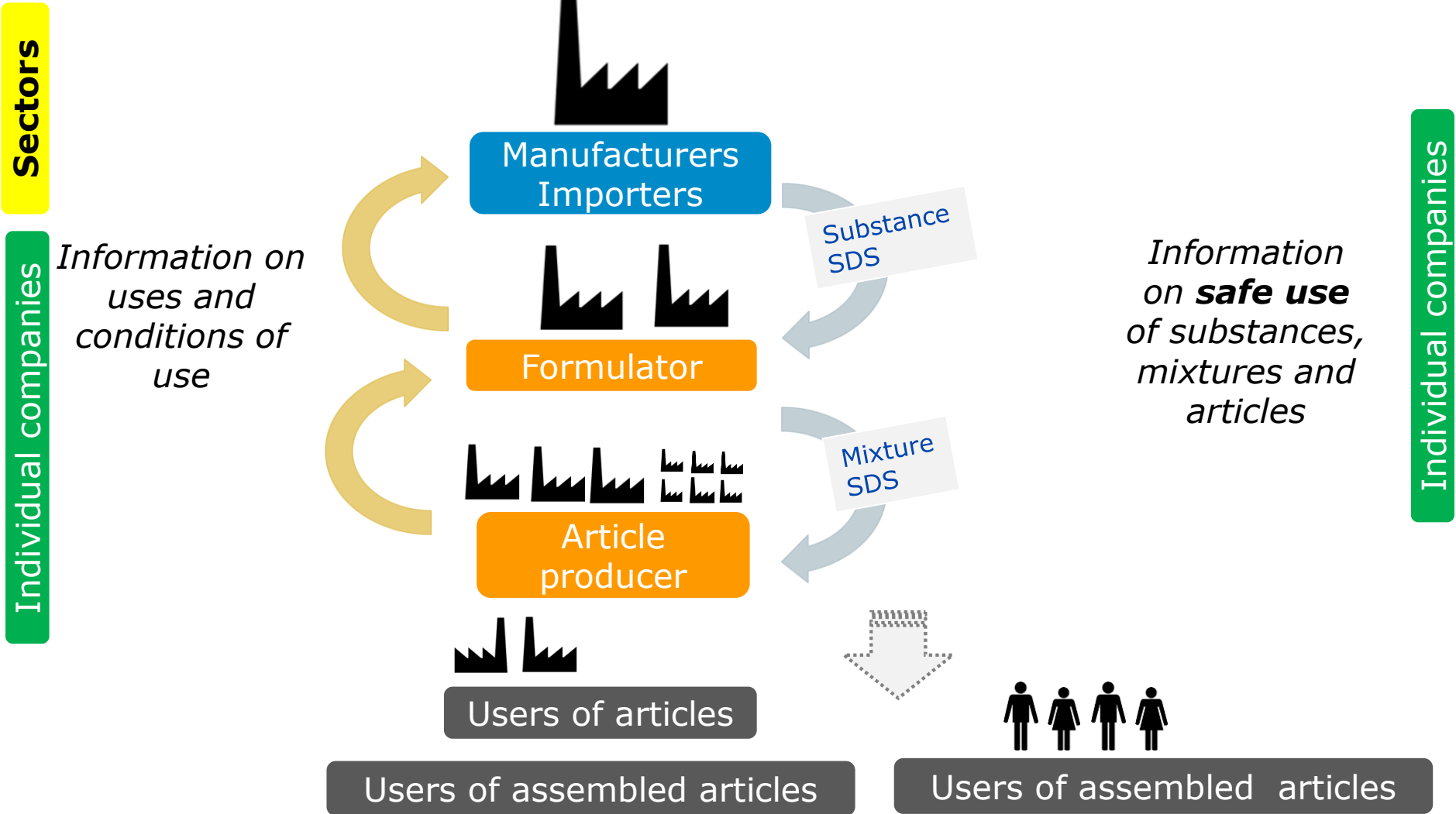
# REACH information requirements and Chemicals Safety Assessment (CSA)

- Requirements depend on tonnage
- Chemical safety assessment covers a substance's whole life cycle
- CSA aims to demonstrate how substance can be used safely (including as a component in materials and articles)

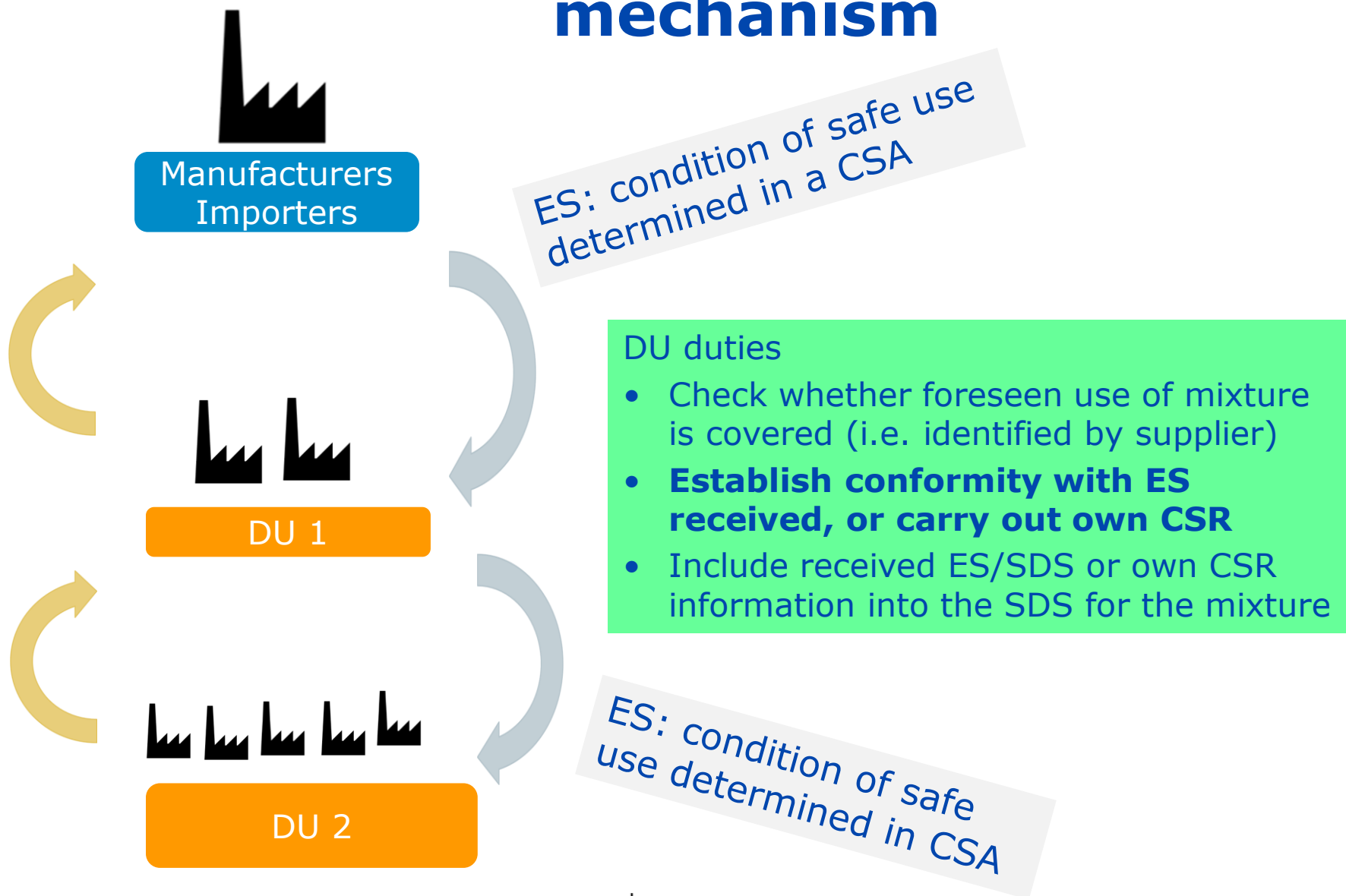




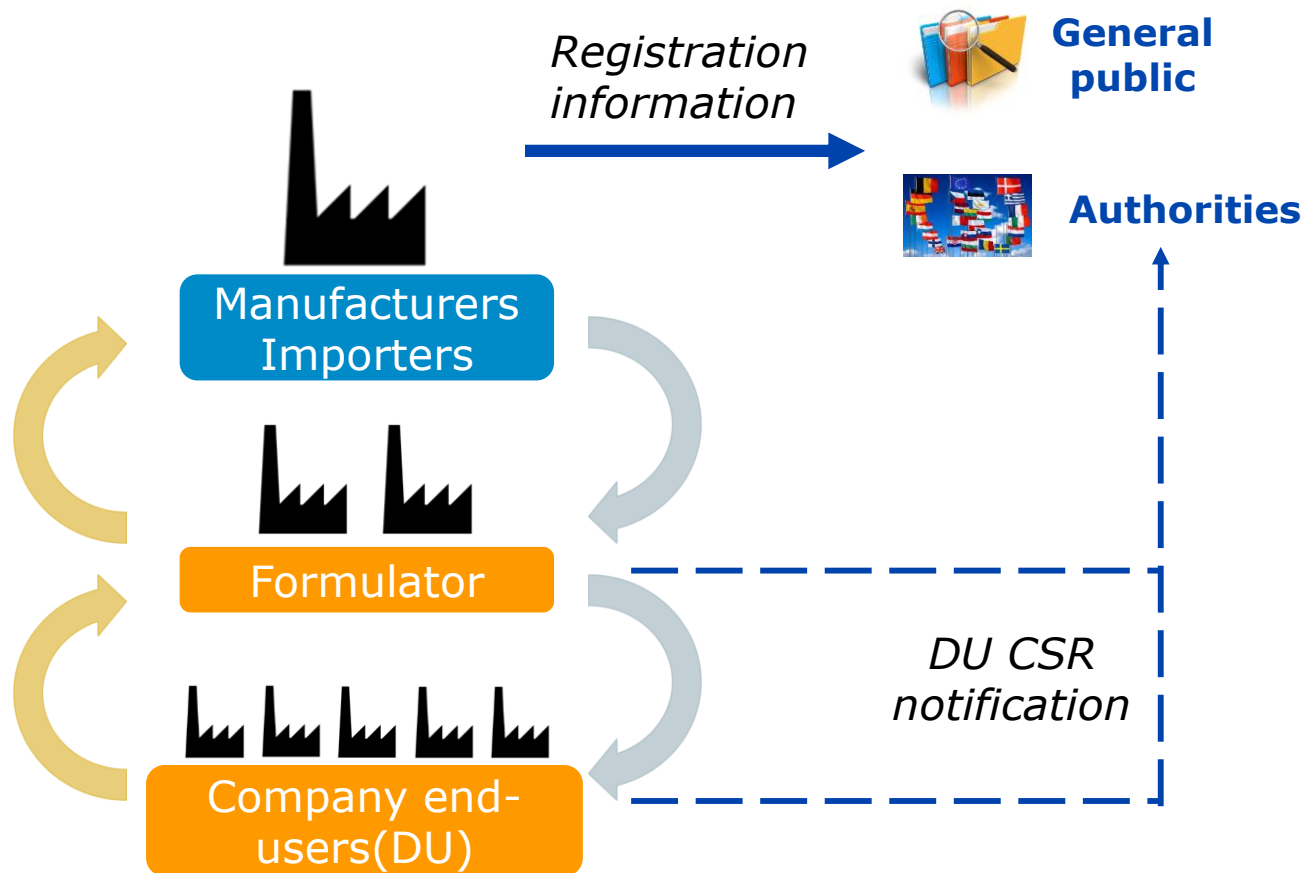
# B2B Supply chain communication



# REACH DU response mechanism



# Authorities get informed



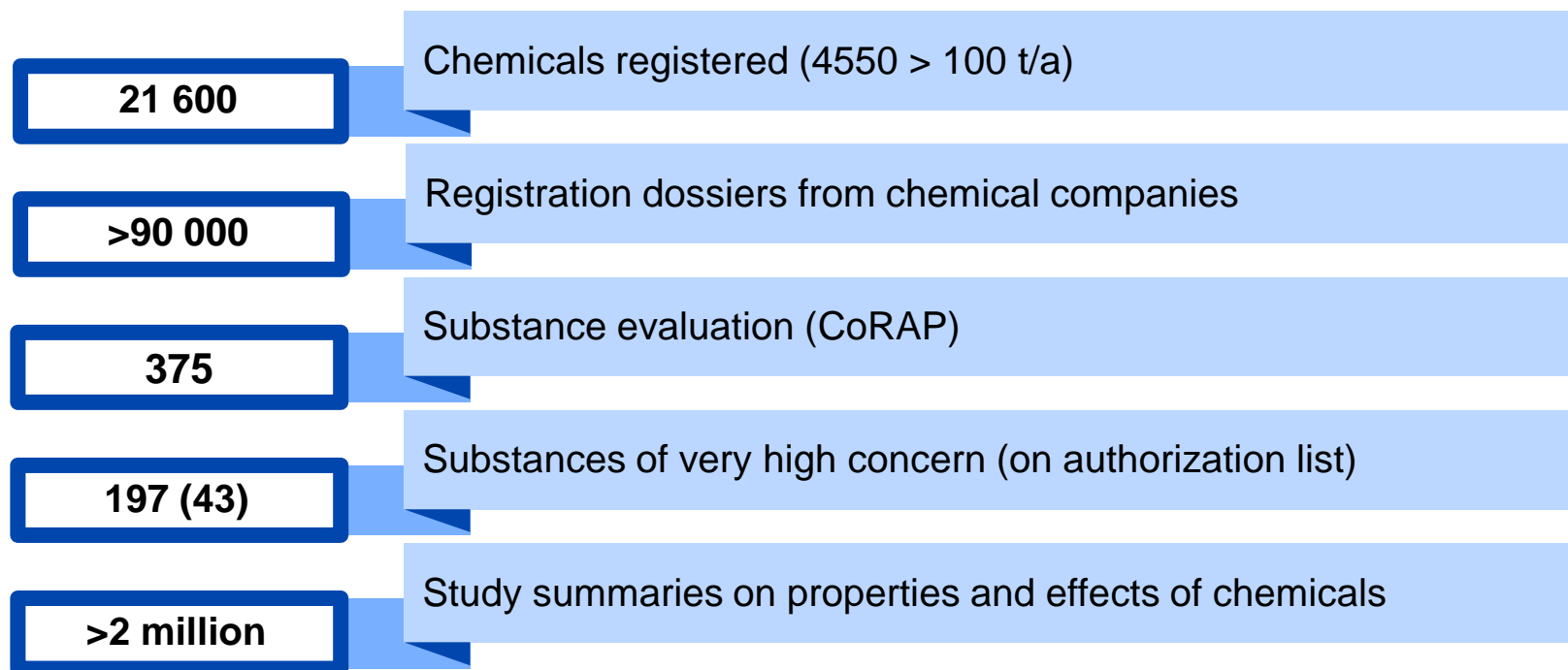
**What has REACH delivered  
so far**



Phase-in  
period  
successfully  
over!

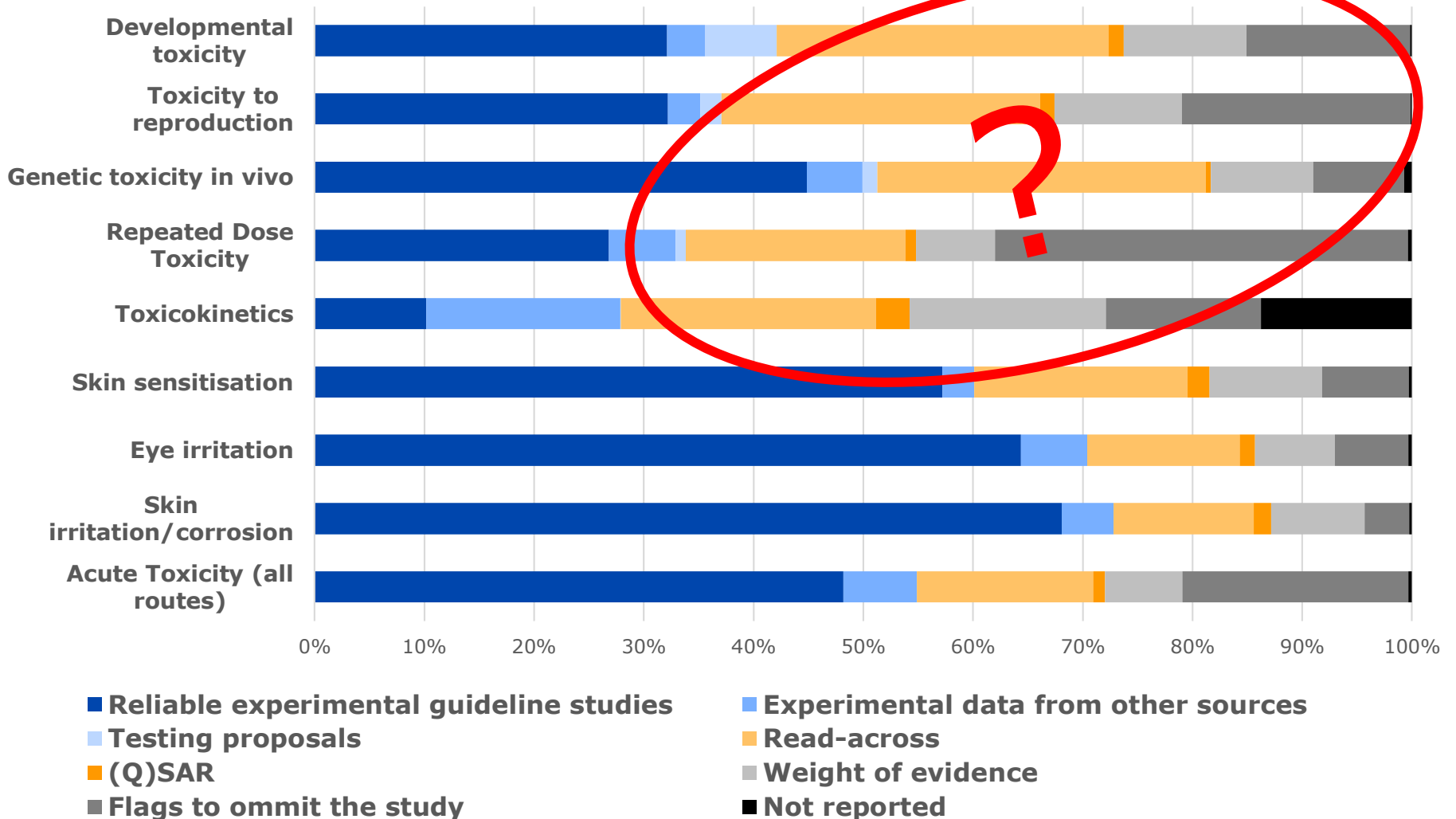


## Some figures



# Options used to meet the information requirements

~75% of registrations contain read-across



# **REACH contribution to FMC safety**



Plastics substance type	EU 1907/2006 REACH	EU 10/2011 plastic FCMs	EU 282/2008 Recycled plastic FCMs	EU 1272/2008 CLP
Monomers	✓	✓	✓	✓
Polymers	✗	✓	✓	✓
Catalysts	✓	✓	✓	✓
Polymerisation agents	✓	✗	✗	✓
Polymer stabilisers	✗*	✓	✓	✓
Solvents	✓	✗	✗	✓
Other additives	✓	✓	✓	✓
Colourants, pigments	✓	✗	✗	✓
NIAS	✗*	✓	✓	✗

## REACH registration scope:

- all substances manufactured or imported > 1t/a
- all uses (unless exempted from certain provisions)



# What can REACH/CLP contribute to FCM safety?

- FCM producers can make a rational choice among raw materials
  - All substances placed on the market > 1 t/a are registered with a defined identity, composition
  - Knowledge on substance properties based on common information requirements (> 10 t/a)
  - Harmonised method to complement classification of substances with toxicological benchmark (DNEL, PNEC)
- All substance data publicly accessible via ECHA website;
- Mechanisms to allocate safety assessment responsibility in the FCM supply chain
- Harmonised framework for exposure assessment and risk characterisation (implemented into the CHESAR tool)
- Mechanisms and tools for communication in supply chain about
  - conditions of safe handling and exposure control for workers
  - environmental emission prevention and control
  - measures to ensure inherently safe design of products

# What can REACH/CLP contribute to FCM safety?

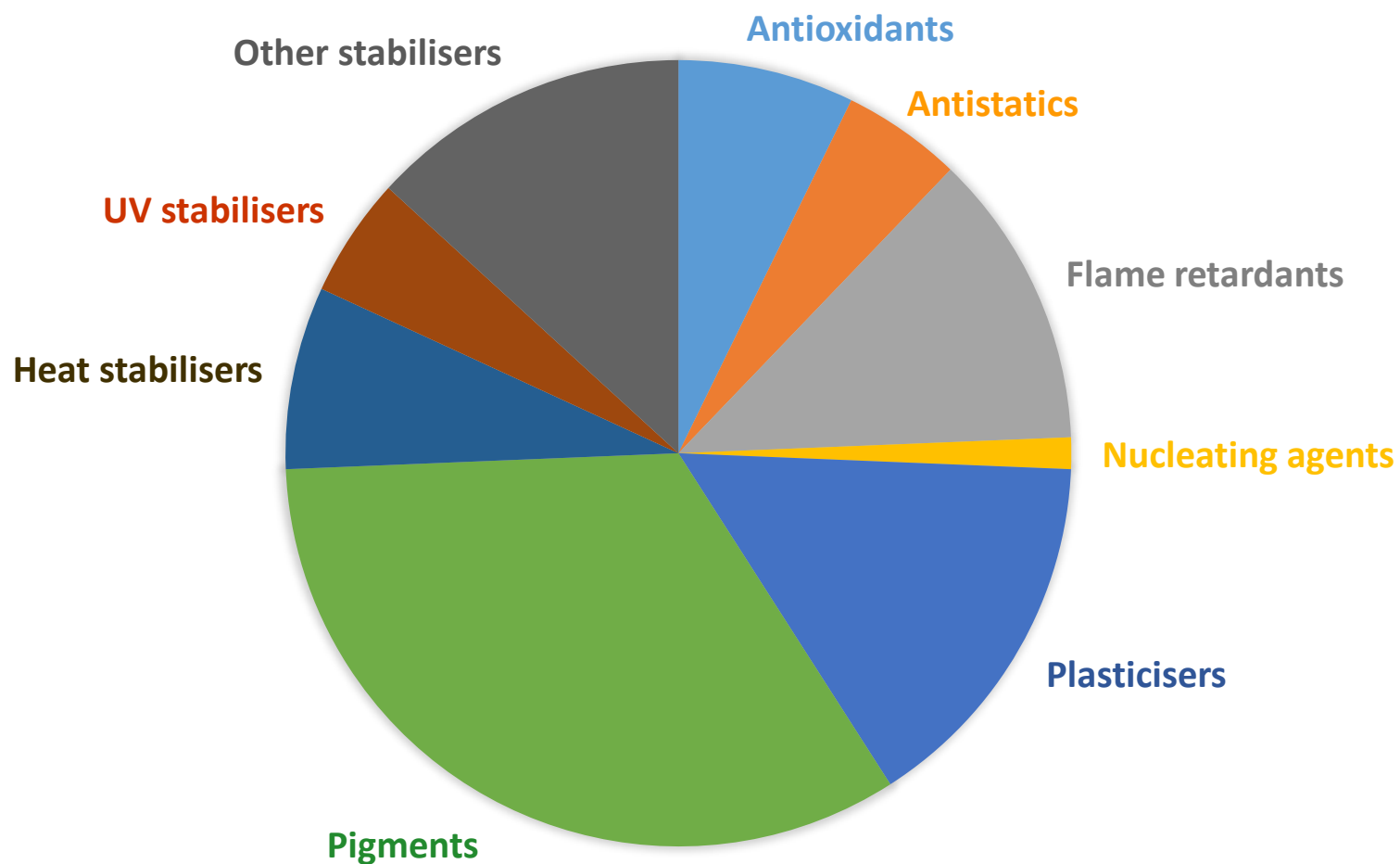
- Information for authorities on substances on the market
  - substance data and use pattern => regulatory priority setting
  - dynamic information source with updating duties
- Regulatory procedures to
  - identify substances of very high concern, including EDs;
    - communication/notification requirement if in article
    - authorisation
  - identify substances with significant data gaps to be closed
  - set up harmonised CnL (for priority substances)
  - restrict the use of substances
- Information on regulatory and pre-regulatory work: PACT  
<https://echa.europa.eu/pact>

# Example: Plastic additives initiative

- Kick-off Nov 2016
- REACH registration data-base as starting point
- Contribution from >20 sector groups, including compounders and converters
- Expert input to release ranking approach development (industry, academia & authorities)
- Project coordination: Cefic, ECHA, EuPC & PlasticsEurope
- Web-publication February 2019
- Extended information package available to MS in March 2019



# Proportion of additive functions



- Relative limited overlap between FCM positive list and confirmed high volume plastic additives.

	No of substances
High volume functional additives (registered > 100 t/a)	418
Listed substances in FCM in this	79
FCM additives and polymerisation aids listed in Annex 1	600 ?

## Key messages



- 418 high volume substances identified to be used as plastic additives in the EU.
- Around 15% false positives and false negatives in registration data base
- 60% not under regulatory scrutiny so far
  - Relative release potential plus hazard indication used for priority setting in regulatory screening
- Project enabled vertical communication in supply chain; information available:
  - Function for 90% of substances
  - Concentration and polymer-matrix about 60%
  - Article type and transformation product < 40%
- Mass-flow data to material types and article types still mostly lacking.

# Example: Phthalate restriction proposal

- Based on bio-monitoring data, body burden of general population exceeds cumulative RCR of 1

## Contributions

	Source Food	Source Article contact	Risk
DEHP	75%	25%	contributes
DIBP + DPB	25%	75%	lead
BBP	25	75%	minor

- REACH risk assessment across all sources, independent of the regulatory regime;

- REACH does not contribute to knowledge on polymers
- Remaining gaps in knowledge generation for higher Tier human health endpoints
- Use of substances in FCM is exempted from
  - REACH Chemicals Safety Assessment regarding human health
  - Authorisation if concern is on human health side
- No agreed methodology yet to assess release and exposure from article matrices during
  - Service life
  - Dismantling and recovery



- Harmonisation of approaches, methods and requirements across legislation desirable
- Dynamic update of information needed, with increasing knowledge on hazards
- Burden of proof on industry rather than authorities
- Holistic approach across regulatory regimes to exposure assessment and targeting of exposure sources

Andreas.ahrens@echa.europa.eu

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