Meeting REACH Regulation

Registration 2018 and beyond

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- REACH basics
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  - Scope and exemptions
- Registration 2018 deadline
  - What we expect
  - Cooperation with other registrants
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- Deadline is over - what is next?
- SME
- Substances in articles
  - SVHC
  - Authorisation

REACH in nutshell

Objective of REACH

- REACH recital 1: *"[…] ensure a high level of protection of human health and the environment as well as the free movement of substances, in mixtures and in articles, while enhancing competitiveness and innovation. […]"*

- To ensure a safe(r) use of chemicals

- REACH addresses both environment and human health (workers and consumers)

Terminology (Art. 3 REACH)

- Under REACH:
  - **substance** as such(art. 3.1): manufactured or imported
  - **mixture** (previously "preparation"): "*mixture or solution of two or more substances*"
  - **article**: "*object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*"

- Usually, "products" cover "articles" and "mixtures", as well as combinations of those

Main principles of REACH

- Only EU-based legal entities have obligations under REACH… but to comply, they need input from their non-EU suppliers!

- "*Reversal of the burden of the proof*": **Industry's responsibility** to ensure proper risk management of chemicals, **incl. performing risk assessment**

- Main source of information for public authorities: Registration dossiers

Main principles of REACH

- Industry responsible for safe manufacture and use
  - Registration and dissemination for transparency;
  - Not an approval system.
- Deal with the 'burden of the past' with a systemic program for registration of old chemicals
  - Get adequate information on hazards while minimising the unnecessary use of experimental animals;
  - Risk management at company level by supply chain communication;
  - Risk management at European level by regulatory means.

- Risk = Hazard * Exposure

Registration and responsibility

- Responsibility for the management of the risks of substances lies with industry;
- Registration provisions requires industry to collect and generate data (where needed);
- Risks related to these substances should be assessed by industry
- Appropriate risk management measures should be developed by industry and communicated to users;
- To ensure that industry meet these obligations in a transparent manner, industry is required to submit a dossier containing all this information to the Agency;
- Most of the information in the dossier is published on ECHA's website (non-confidential part);
- Registered substances are allowed to circulate on the internal market.

Core elements of Registration

- Registration applies to
  - Substances manufactured or imported above 1 t/a
  - Substances on their own or in mixtures (and substances in articles under certain conditions)
- "One substance, one registration" principle requires joint registration of the same substance
- Registration contains
  - Hazard information
  - Assessment of the risks regarding each use, and
  - Risk management measures and operational conditions

Data Sharing and Joint Submission

- One substance, one registration – Implementing Regulation on the Joint Submission of Data and Data-sharing ((EU) 2016/9 of 5 January 2016)
- Sharing of data between companies
  - Prevents unnecessary testing
- Common information submitted jointly
  - Classification and labelling
  - Hazard information
- Company specific information submitted individually
  - Composition
  - Tonnage
  - Uses

Exemptions from registration

- Product and process oriented research and development (PPORD) when notified
- Substances covered by relevant EC legislation
- Article 2(7) exemptions
  - Substances included in Annex IV (minimum risks due to intrinsic properties)
  - Substances covered by Annex V (registration inappropriate or unnecessary)
  - Substances already registered and recovered in the EU
  - Substances already registered and exported from and re-imported into the EU

Regarded as registered

- Notified substances (Notification of New Substances - NONs, Directive 67/548/EEC)
  - Registration required when the next tonnage threshold is reached
- Plant Protection Product active substances and co-formulants
- Biocidal active substances

Polymers under REACH

- Polymers are exempted from registration (and evaluation) due to a low concern in relation to their high molecular weight
- BUT, manufacturers and importers of polymers must register the monomer substances and other substances used for the manufacture of polymers under certain conditions
  - E.g. not yet registered up the same supply chain

Registration 2018

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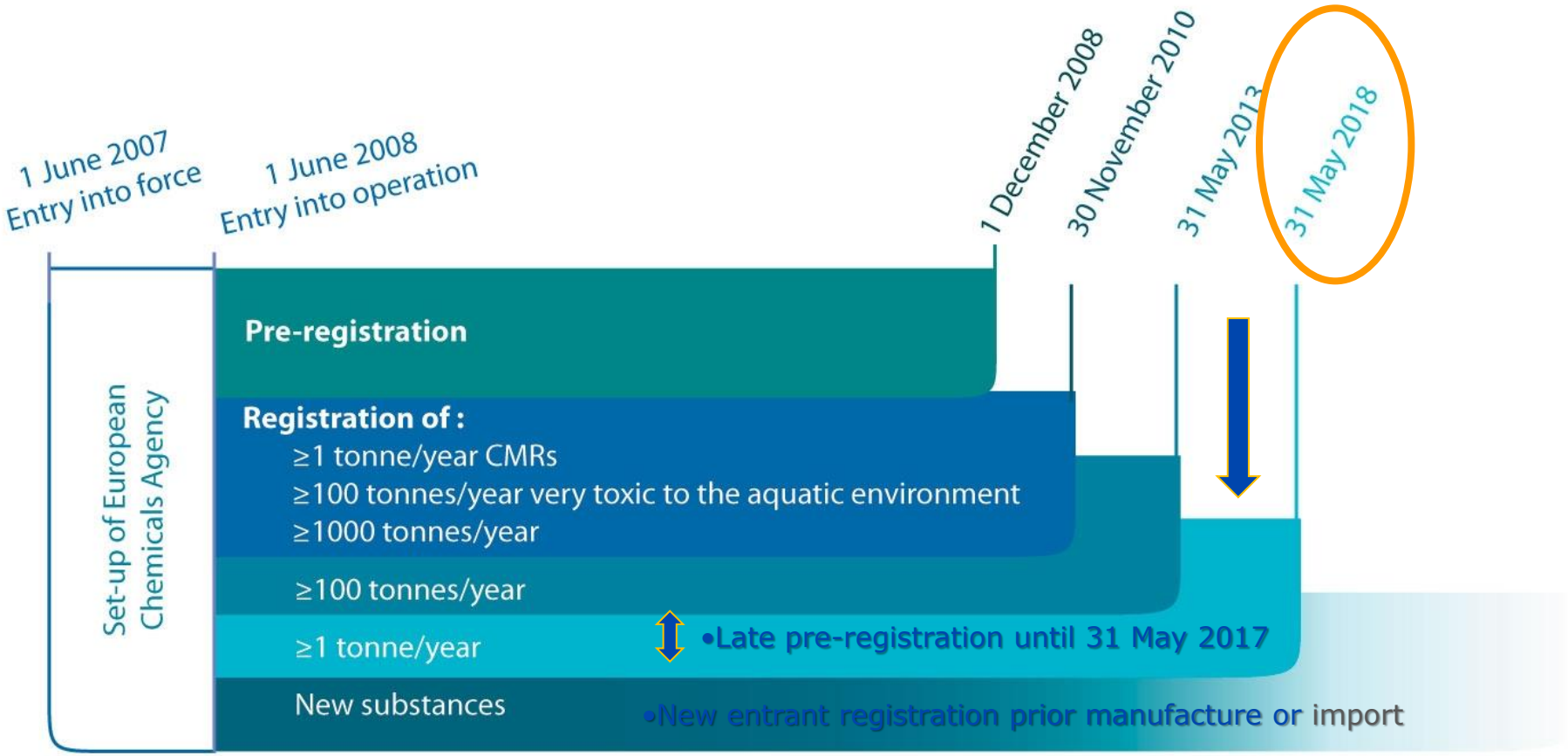
REACH Registration deadlines



Company types in 2013

Role in the supply chain	%
Manufacturer	40%
Manufacturer and importer	12%
Importer	25%
Only Representative of a non-EU manufacturer	23%

Non-EU companies can export to the European Union through two different routes under REACH: either via an importer who has registered the substance, or by appointing an Only Representative.

Registration: at the core of REACH

- Registration process is vital
- Dossiers show what industry knows about its portfolio and if it can demonstrate safe use
- Basis for all other processes:
  - Informed decisions by authorities
  - Safety instructions in the supply chain
  - Information available to the general public

2018 deadline: what we expect

	2010	2013	2018
Substances	~ 3 400	~ 3 000	up to 25 000
Dossiers	~ 20 000	~ 9 000	up to 60 000

- Many more registrations
- Less companies registering the same substance
- Higher % of SMEs
- Less information → need to generate new data

Status update: where we are

- Around **15 000** DL-2018 registrations received for **6 500** substances (i.e. for phase-in substances registered <100 tonnes/year)
- Substances registered for the first time for DL-2018: **4 200**
- Companies registering for the first time in 2017: **801**
- DL-2018 registrations from SMEs in 2017: **16%**
- Registrations from outside the EU: **43%** from importers and **28%** from only representatives

Figures as of 30 January 2018

Current observations

- Number of registrations slightly higher than estimated (+17%)
- Number of substances remains low
- Most registrations are for existing substances
- Majority of submissions come from outside Europe
- Percentage of SMEs lower than expected

Follow the progress

- Regular statistics on our website
- Interactive infographic (all registrations, per country and type)
- Find your lead registrant
- 'Information on chemicals' web pages

https://echa.europa.eu/regulations/reach/registration/registration-statistics

Cooperate with the existing registrants

Sameness established ✓

…but how to work with the existing registrants ?

What to consider?

- Negotiations with existing registrant?

- Finances:
  - Cost of data?
  - Consultant / expert support?
  - Dossier preparation?
  - Cost of administration?

- Challenges?
  - What to do in case of disagreements?
  - How to understand what you're asked to pay?

Forms of cooperation in a SIEF

- Consortia vs. SIEF agreement
  - Consortia: larger SIEFs, groups of substances/SIEFs
  - SIEF agreement: smaller SIEFs, one SIEF per substance
  - SIEF is mandatory under REACH; consortia optional
  - Consortia do not replace SIEFs

- SIEF agreement vs. data sharing agreement
  - Data sharing agreement mandatory (Implementing Regulation on joint submission of data and data sharing)

Implementing Regulation on Joint Submission of data and data sharing

- 26 January 2016 entry into force
- Clarifies provisions of REACH, namely "OSOR" enforcement
  - Companies have to cooperate
  - Better balance between potential and existing registrants
  - IT-implementation closes loopholes
  - "ECHA token"

Transparency

- Itemisation of data and administrative costs
  - Must be in relation to information requirements
  - Must be justified
  - Must be provided upon request without undue delay

- Cost-sharing model must include reimbursement mechanism

Item	Tonnage band	Cost of study	Administration cost	Justification
Study 1	1-10 t	1 000 €	100 €	Justification 1
Study 2	1-10 t	2 000 €	80 €	Justification 2
Study 3	10-100 t	3 000 €	130 €	Justification 3
Token	N/A	-	50 €	Justification Token
SIEF	10-100 t	-	500 €	Justification SIEF

Reimbursement scheme

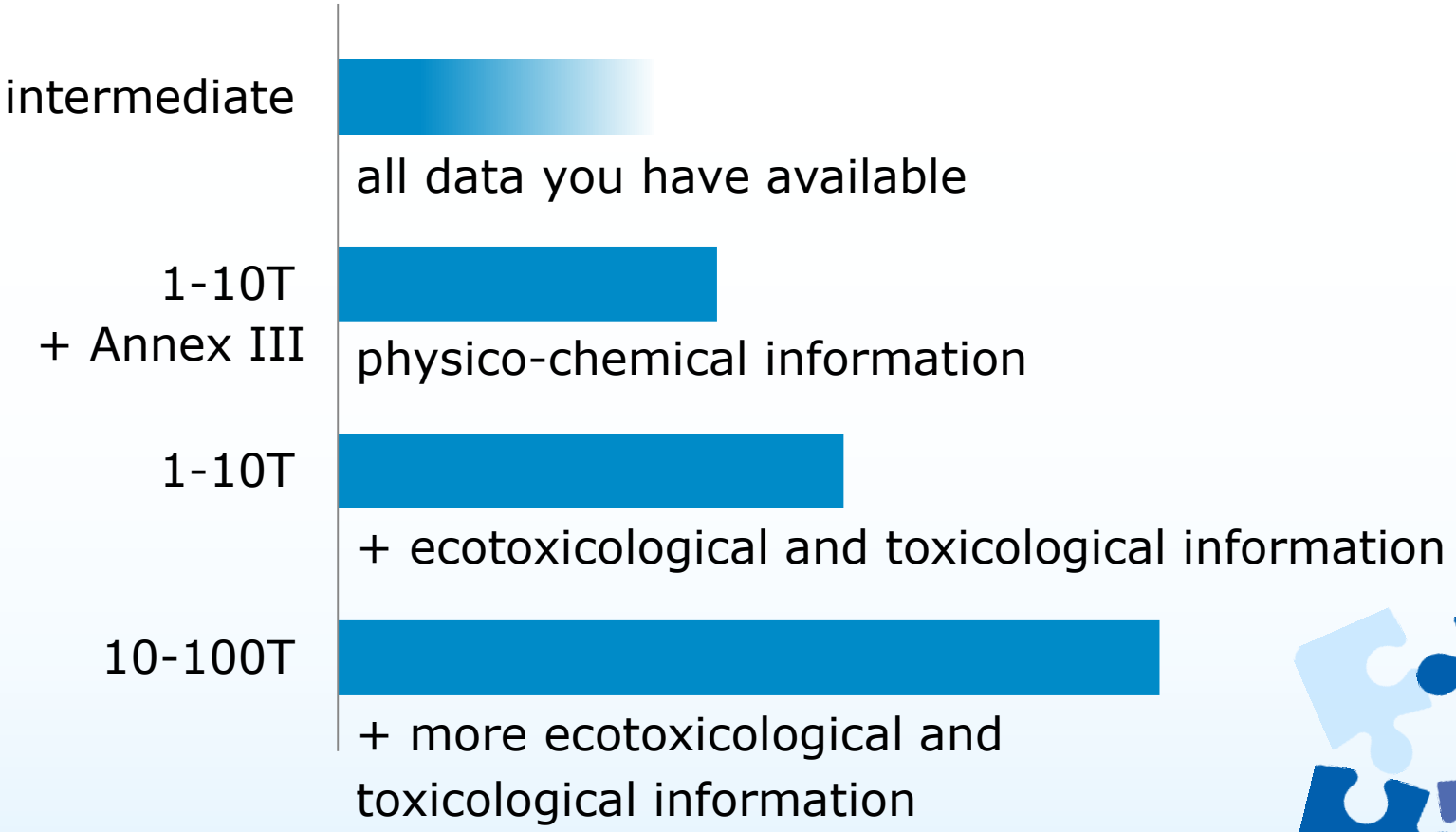
- Each time a new potential registrant buys access to the data, the overall costs for each co-registrant will reduce

- Having a reimbursement scheme is mandatory

Fairness and non-discrimination

- Equal rights for all co-registrants
- Unanimous agreement needed for waiving from itemisation and reimbursement
- Model ‘fair’ in 2010 might not be ‘fair’ to 2018 registrants

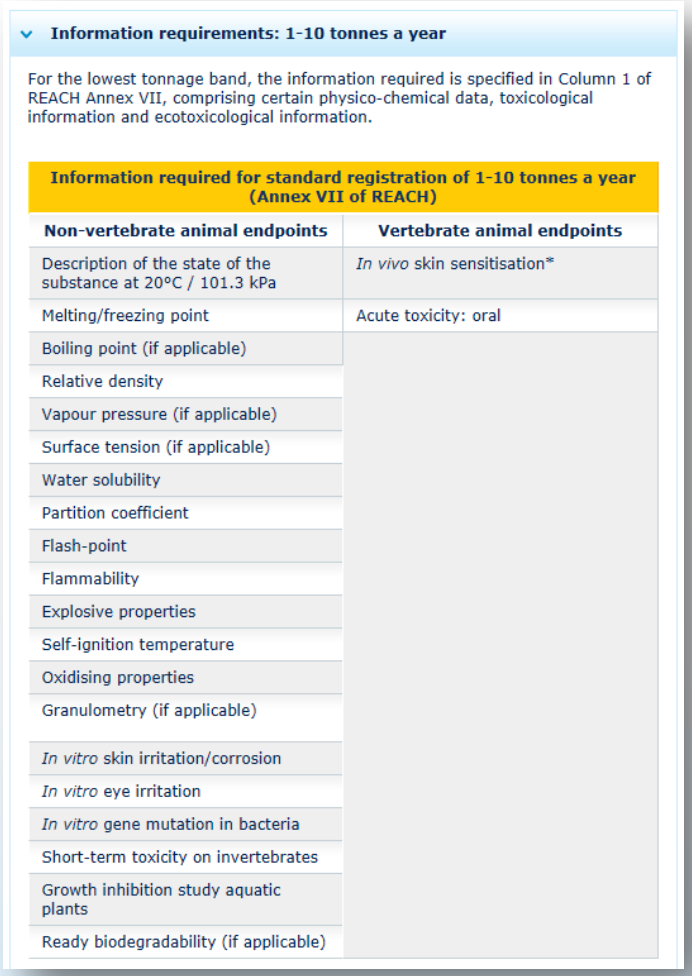
Know your needs



Know what REACH requires from your registration

- If you manufacture or import 1-10 tonnes of the substance per year, you need to provide information on up to 22 endpoints

echa.europa.eu/regulations/reach/registration/information-requirements



Information requirements: 1-10 tonnes a year

For the lowest tonnage band, the information required is specified in Column 1 of REACH Annex VII, comprising certain physico-chemical data, toxicological information and ecotoxicological information.

Information required for standard registration of 1-10 tonnes a year (Annex VII of REACH)	
Non-vertebrate animal endpoints	**Vertebrate animal endpoints**
Description of the state of the substance at 20°C / 101.3 kPa	*In vivo* skin sensitisation*
Melting/freezing point	Acute toxicity: oral
Boiling point (if applicable)	
Relative density	
Vapour pressure (if applicable)	
Surface tension (if applicable)	
Water solubility	
Partition coefficient	
Flash-point	
Flammability	
Explosive properties	
Self-ignition temperature	
Oxidising properties	
Granulometry (if applicable)	
In vitro skin irritation/corrosion	
In vitro eye irritation	
In vitro gene mutation in bacteria	
Short-term toxicity on invertebrates	
Growth inhibition study aquatic plants	
Ready biodegradability (if applicable)	

Know what REACH requires from your registration

- If you manufacture or import 10-100 tonnes of the substance per year, you need to provide up to 13 additional endpoints

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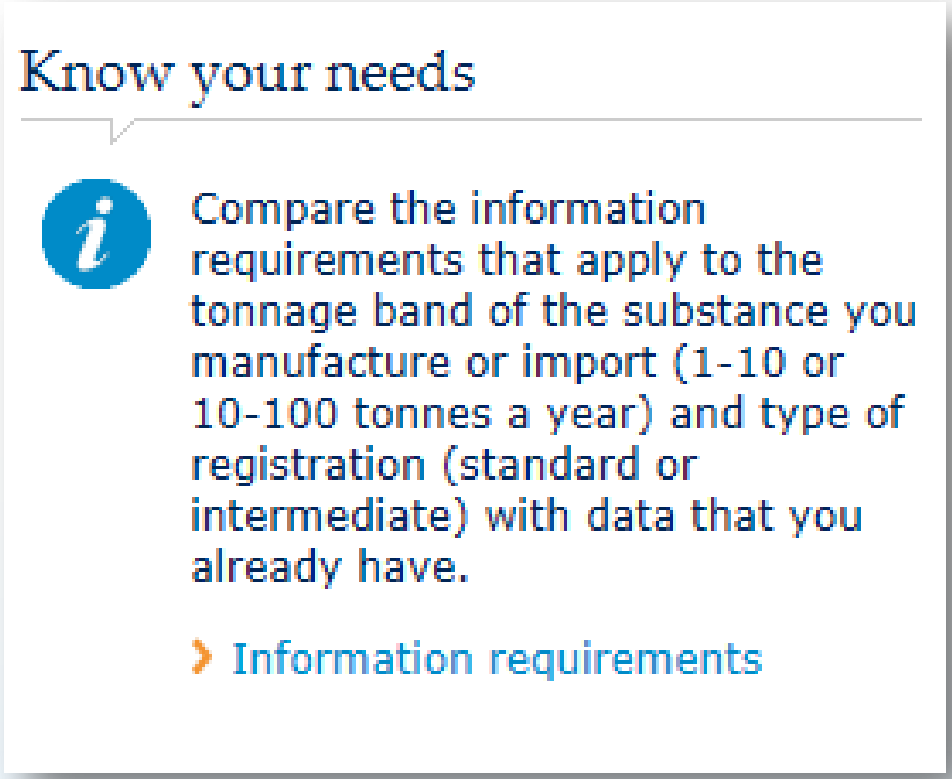
Information requirements: 10-100 tonnes a year

Information required for standard registration of 10-100 tonnes a year (Annex VIII of REACH)
Note: this is to be provided in addition to the information which is listed above

Non-vertebrate animal endpoints	Vertebrate animal endpoints
In vitro mutagenicity study in mammalian cells or *In vitro* micronucleus study	*In vivo* skin irritation*
In vitro gene mutation in mammalian cells	*In vivo* eye irritation*
Activated sludge respiration inhibition test	Testing proposal for *in vivo* genotoxicity (if applicable)
Degradation	Acute toxicity: dermal* or inhalation
Hydrolysis	Short-term repeated dose toxicity (28-day)
Adsorption/desorption screening	Screening for reproductive/developmental toxicity
	Short-term toxicity on fish or testing proposal for long-term toxicity on fish (if applicable)

Know your needs



- You do not have to purchase all of the data if you already own some of them
- You can negotiate access to individual studies or to all the data that was already submitted

echa.europa.eu/regulations/reach/registration/information-requirements

Letter of Access

- Typical way of joining an existing registration
- No data ownership, limited rights
- What does it cover?
- Contractual freedom, but fair, transparent and non discriminatory

Letter of access example	
Study cost	5 000 €
Admin. cost	5 000 €
Total	10 000 €

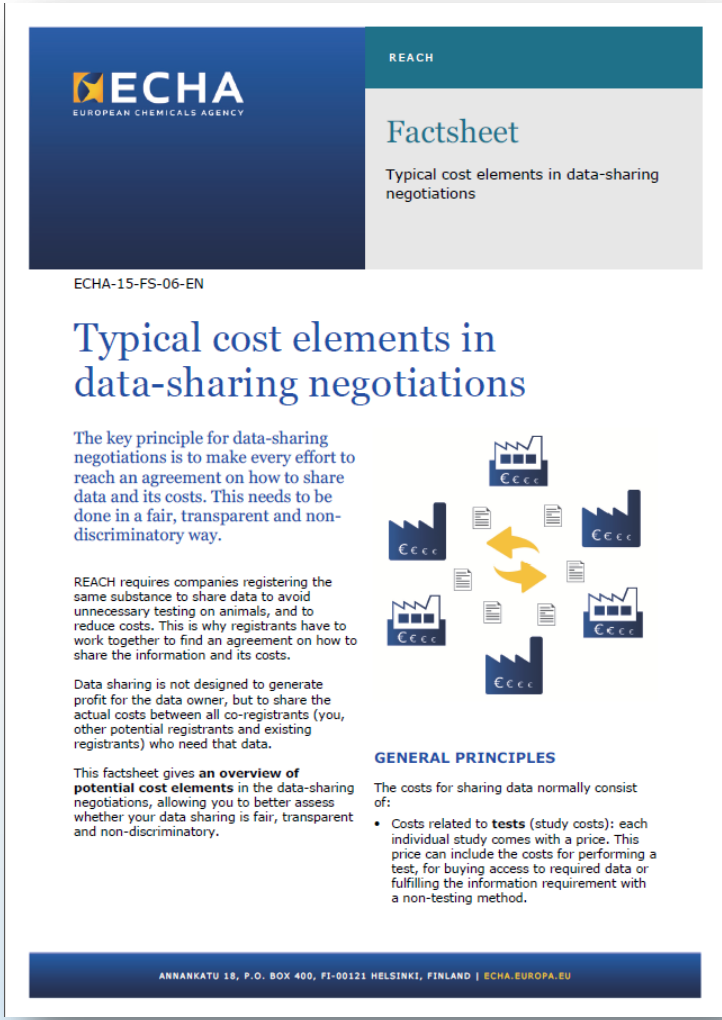
Cost itemisation / breakdown (1)

- You don’t have to pay any additional fees for receiving a cost breakdown
- There are no other preconditions to get it. For example, you cannot be forced to pay a deposit
- Itemisation should list the costs related to:
  - data
  - administrative work
- Itemisation should show the price in relation to the information you require for your registration and contain a justification

Increases/reductions to cost of data

- Cost elements are not admissible or inadmissible as such
- Less rights normally imply that the share of costs to be paid is lower

echa.europa.eu/documents/10162/13631/factsheet_costs_datasharing_en.pdf



ECHA
EUROPEAN CHEMICALS AGENCY

REACH

Factsheet

Typical cost elements in data-sharing negotiations

ECHA-15-FS-06-EN

Typical cost elements in data-sharing negotiations

The key principle for data-sharing negotiations is to make every effort to reach an agreement on how to share data and its costs. This needs to be done in a fair, transparent and non-discriminatory way.

REACH requires companies registering the same substance to share data to avoid unnecessary testing on animals, and to reduce costs. This is why registrants have to work together to find an agreement on how to share the information and its costs.

Data sharing is not designed to generate profit for the data owner, but to share the actual costs between all co-registrants (you, other potential registrants and existing registrants) who need that data.

This factsheet gives **an overview of potential cost elements** in the data-sharing negotiations, allowing you to better assess whether your data sharing is fair, transparent and non-discriminatory.

GENERAL PRINCIPLES

The costs for sharing data normally consist of:

- Costs related to **tests** (study costs): each individual study comes with a price. This price can include the costs for performing a test, for buying access to required data or fulfilling the information requirement with a non-testing method.

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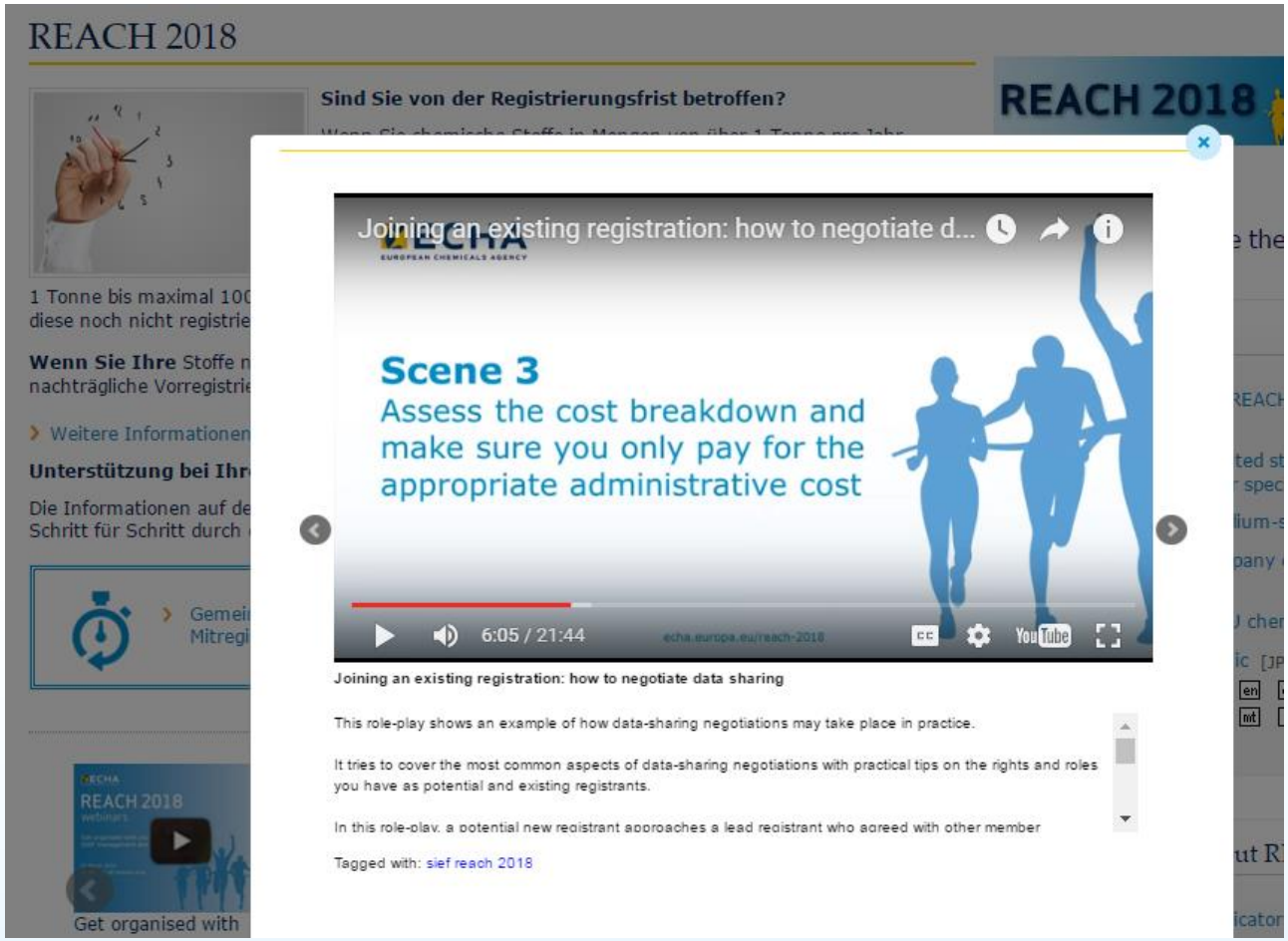
VIDEO



https://youtu.be/e_wZq9ai0Xg?t=6m4s

https://youtu.be/e_wZq9ai0Xg?t=8m46s

The last registration deadline is over, how to proceed?

How to enter the EU market?

- Pre-registration transitional period is over (pending COM clarification March 2018)
- Inquiry for new substances
- Negotiate access to the data within a joint submission
- No registration no market – illegal activities
- Competent Enforcement Authorities

What happens after the last deadline ?

Authorities activities

Retrospective checks

- Your dossier may be checked retrospectively for completeness
  - Enhanced completeness check introduced in 2016
  - Dossiers rarely updated are targeted for retrospective checks to ensure level playing field
  - First campaigns focused on dossiers with ‘on-going’ studies not updated for a long time
  - Registrants were able to fulfil information requirements, e.g. provide a missing study
  - Some registration decisions were revoked (3 out of 39)

Enforcement by national authorities

- Project in **2019** (reporting in 2020)
- All EU countries foreseen to participate
- Scope:
  - Registration obligations after the last deadline in cooperation with customs authorities
  - This includes verification of strictly controlled conditions applicable to substances registered as intermediates

The beginning of a journey

- Your registration dossier is proof of safe use
  - You know the properties of your substances
  - Your clients are informed about how to use them safely
- Authorities look at your registration

•Convinced by the information provided and your assessment?	•Dossier evaluation (compliance check) by ECHA
•Further information to clarify a concern?	•Substance evaluation by EU Member States
•Further risk management at EU level?	•Candidate list of SVHCs, harmonised classifications and restrictions

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Keep your dossier up-to-date

- Updating is a legal obligation
- Proof that you take your responsibilities seriously
- Ensure that you and the authorities assess safe use based on up-to-date and reliable data
- Obligation to all!
- The reality:
  - 67% of all dossiers have never been updated
  - Lead dossiers better off: over 50% updated
  - Dossiers submitted individually even more problematic: 80% never been updated

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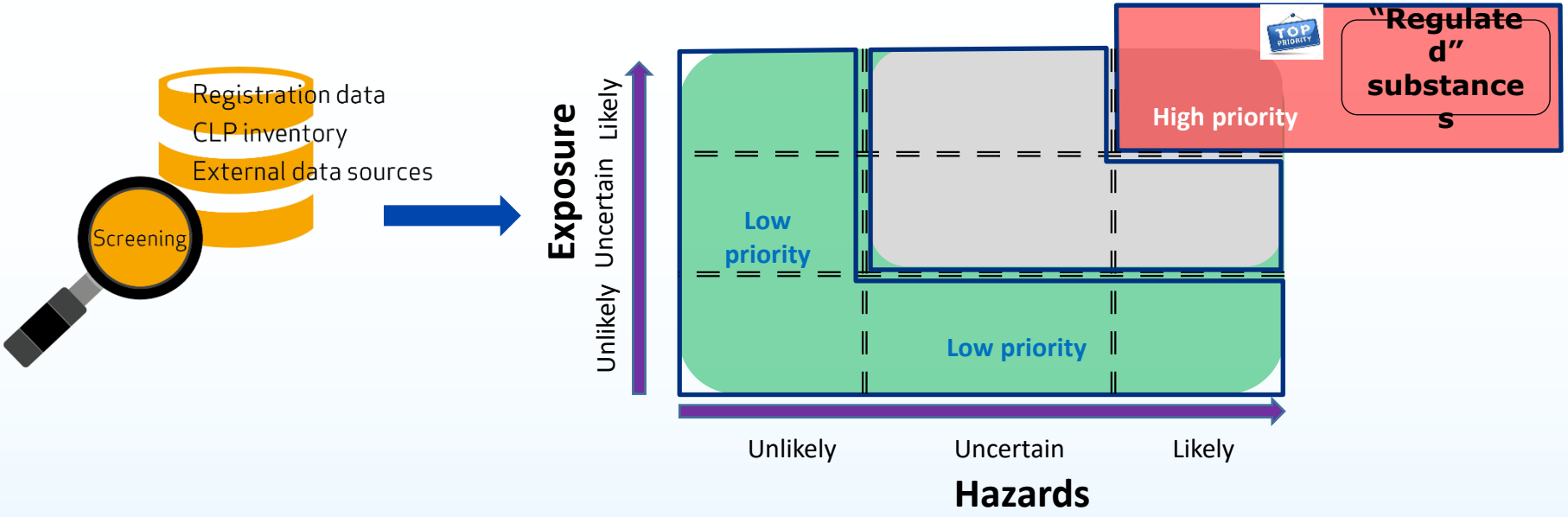
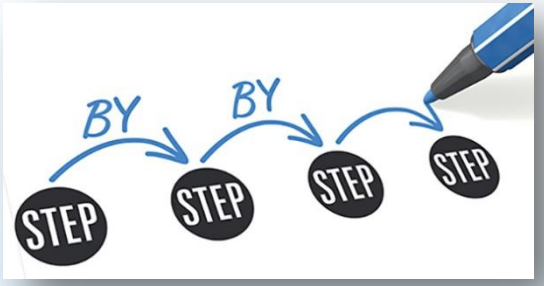
Follow authorities' work

- All dossiers screened and prioritised for further assessment by authorities: evaluation or risk management



Compliance check

- Your dossier may be prioritised if ECHA is not convinced by the information provided
- You normally get a chance to update your dossier before formal process starts
  - Substances potentially picked for compliance check published on our website: echa.europa.eu/regulations/reach/evaluation/compliance-checks
  - Stay informed through our Weekly news
- Recommendations in annual Evaluation reports: echa.europa.eu/evaluation



Recommendations

- Update **new** information without undue delay
  - Changes in company status, substance composition, tonnages, uses and properties
- Make sure you **plan** for dossier updates
  - Keep the 'SIEF' alive: not a legal obligation after 2018 but needed for data and cost sharing
  - Ensure your SIEF agreements cover future costs:
    - New information may need to be generated, e.g. after a request from ECHA
    - Costs must be shared by all members of the joint registration – based on their data requirements obligations

Compliance of your dossier is visible to all

- Compliance and quality give confidence to the public that substances can be used safely

•Non confidential evaluation decisions published

Name	EC / List no.	CAS no.	Decision	Decision date	Further information	
3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	CCH-D-2114356498-35-01/F	05/04/2017		
Trifluoroacetic acid	200-929-3	76-05-1	CCH-D-2114358335-47-01/F	30/03/2017		

•Access to the registration data, registrants' names, frequency of dossier updates

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Substances on authorities' radar

- Substance evaluation and risk management
- Focus on substances that matter
  - Higher-tonnage registrations with important data gaps and with exposure potential
- Common screening in cooperation with Member States
  - Most suitable route to address concern is identified
- Short-listed substances
  - Letter sent to each registrant concerned, with advice and an update deadline before formal process starts
  - Webinar organised for more advice

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Keep up-to-date: PACT

- Public activities coordination tool: echa.europa.eu/pact
- Find out: nature of our concern (CMR, PBT…), on-going activities, authority in charge and outcome

Name	EC/List No	CAS Number	Authority	Activity	Latest update	Scope	Outcome	
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	244-617-5	21850-44-2	Germany	Hazard assessment	05/01/2018	PBT	Substance evaluation under development	Details
Disodium octaborate	234-541-0	12008-41-2 12280-03-4	Sweden	RMOA	05/01/2018	CMR	Appropriate to initiate regulatory risk management action	Details
Methylcyclohexane	203-624-3	108-87-2	Finland	Hazard assessment	09/11/2017	PBT	According to authority's assessment NOT PBT/vPvB	Details

Small and Medium Enterprises (SME)

SME status

- If you are an SME, your status will be verified
  - Systematic check
  - This will run over several years
  - If you are an Only Representative: size of the non-EU company counts
  - Companies are contacted via REACH-IT

- Tips
  - Upload documentary evidence in REACH-IT before submitting your registration
  - Keep your contact details up-to-date in REACH-IT
  - Check your account regularly: you may have requests from ECHA

SME – simplified approach: assess hazard and risk

- Info required depends on tonnage and uses
- 1-10 tonnes: possible reduced data requirements for less hazardous substances
  - Verify Annex III inventory – ECHA website
  - Justification needed in IUCLID
- Chen safety report needed if above 10 tonnes
  - Chesar
  - ECHA Cloud Service for SMEs an option
- Reduced registration fees

Substances in articles

(SiA)

Substances of very high concern (SVHC) – 181 substance

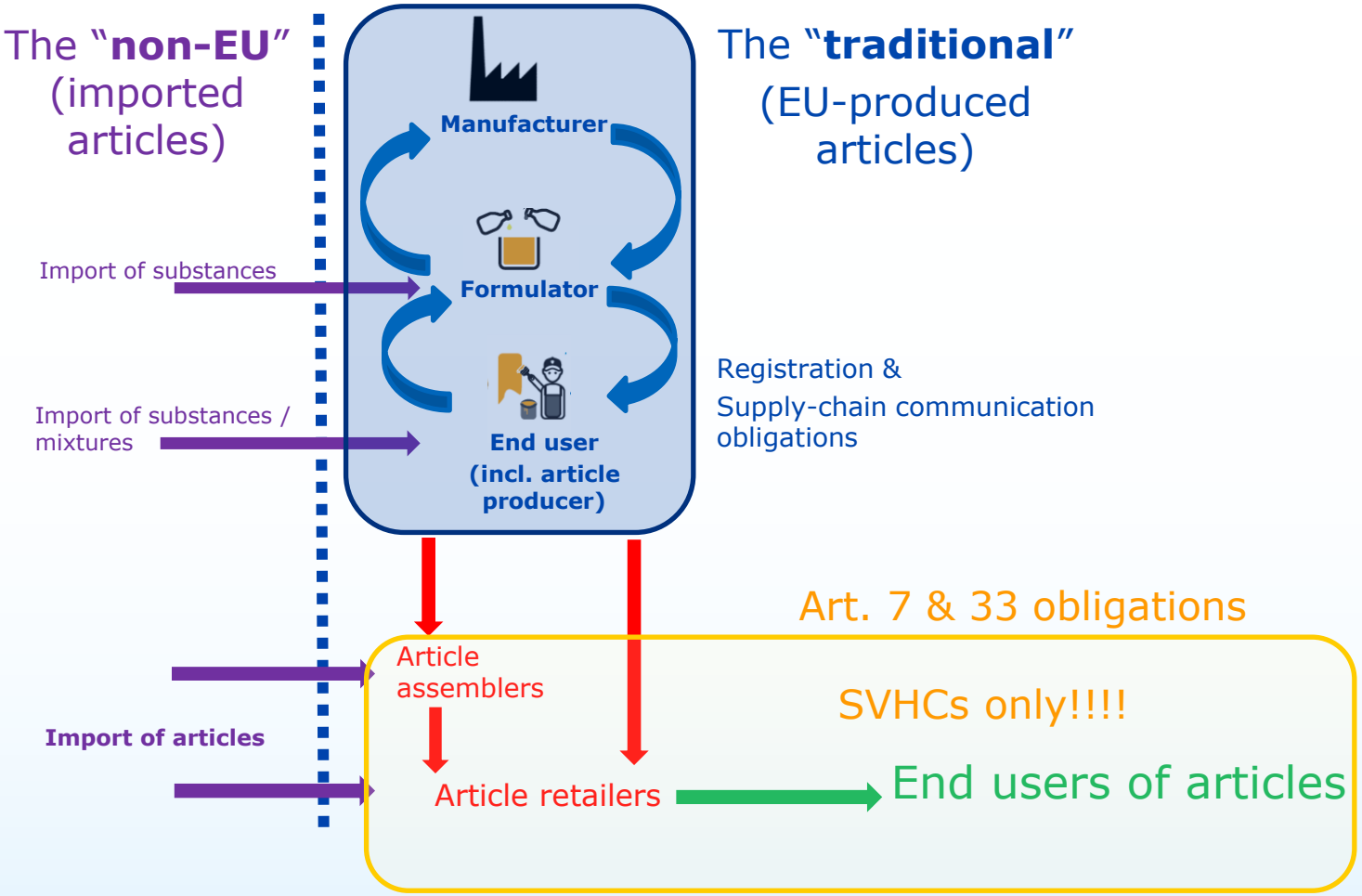
- Substances with the following hazard properties may be identified as SVHCs:

✓ Classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.

✓ Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.

- Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.
- Preliminary step before the authorisation
- The authorisation process aims to ensure that (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.
- The route to authorisation starts when a Member State or ECHA proposes a substance to be identified as an SVHC.

How it works?


The "non-EU" (imported articles)
The "traditional" (EU-produced articles)
Manufacturer
Formulator
End user (incl. article producer)
Import of substances
Import of substances / mixtures
Import of articles
Registration &
Supply-chain communication obligations
Art. 7 & 33 obligations
Article assemblers
Article retailers
SVHCs only!!!!
End users of articles

How are SiA addressed under REACH? - The legal provisions

- **Gathering knowledge/information**:
  - Art. 6 (registration): main mechanism
  - Art. 7.2 (notification): to complement information on substance in articles on the EU market (imported articles)
- **Communication**:
  - Art. 33 (communication): to allow all actors in the supply chains (incl. consumers) to implement the necessary risk management measures, and make an informed supply choice
    - **Safety Data Sheet and Exposure Scenarios (Annex II)**
- Public authorities **regulatory action**:
  - Art. 69 (restriction): restrictions on the placing on the market/use of substances, incl. in articles

How to ensure safe use of chemicals in articles?

a) **Information** on which substances are present in an article, where, and at which level
   - Impacts the exposure potential during the service life, and hence the necessary risk management measures for the safe use of the article and its disposal

b) Effective and focused **communication** within the supply chains
   - Across the EU border and within the EU
   - Throughout the supply chain from manufacturer/importer of chemicals, materials or articles until the final customer and waste management

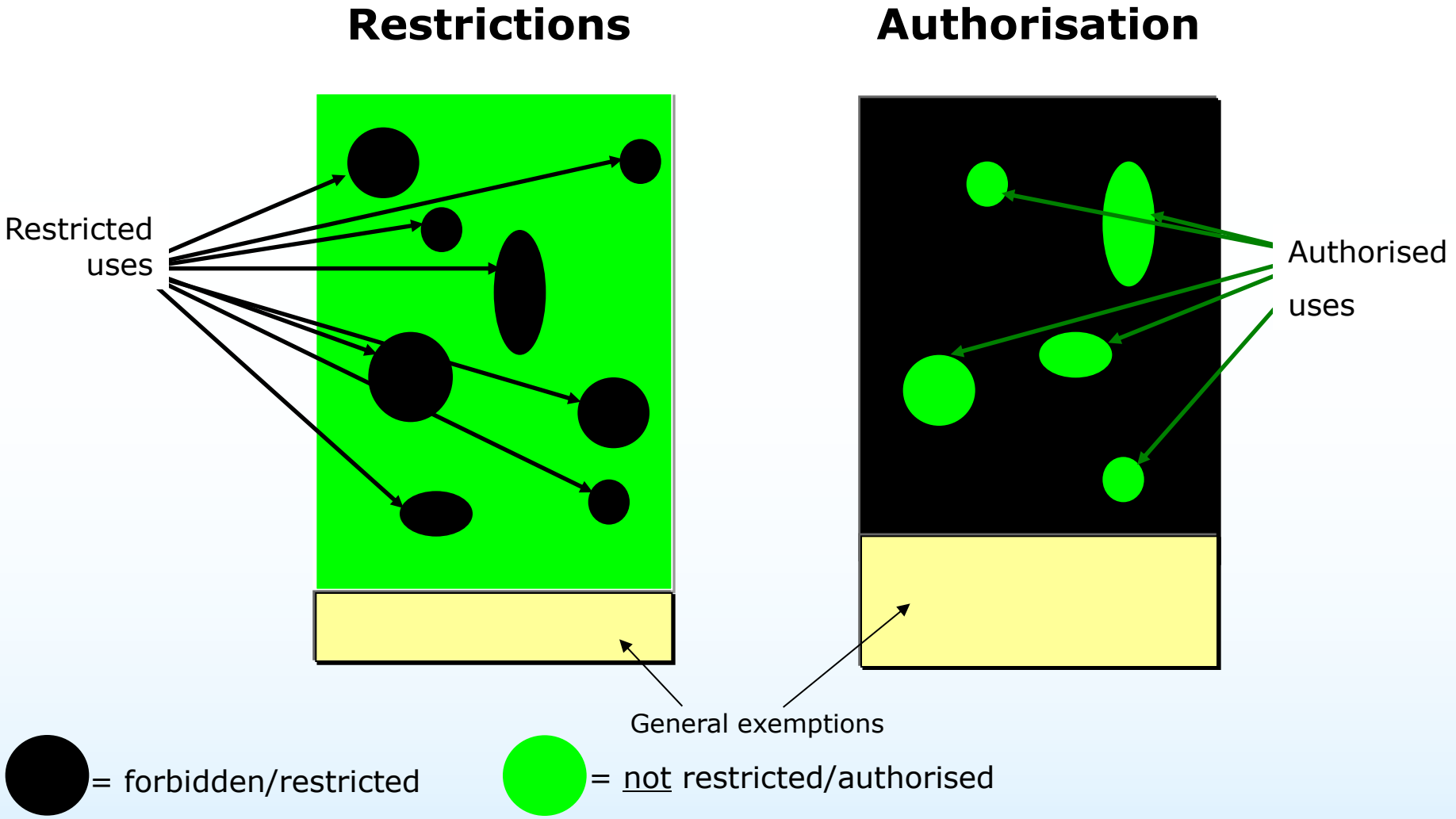
c) Targeted (regulatory) **action from authorities**, where needed

Main (practical) challenges for Industry

- To **know** about the presence of a SVHC substance in an article, in particular:
  - when involving very complex supply chains
  - when incorporated in a bigger, very complex article

- To **communicate** the presence of the SVHC in an appropriate and efficient way

Difference between Restrictions & Authorisation



Authorisation

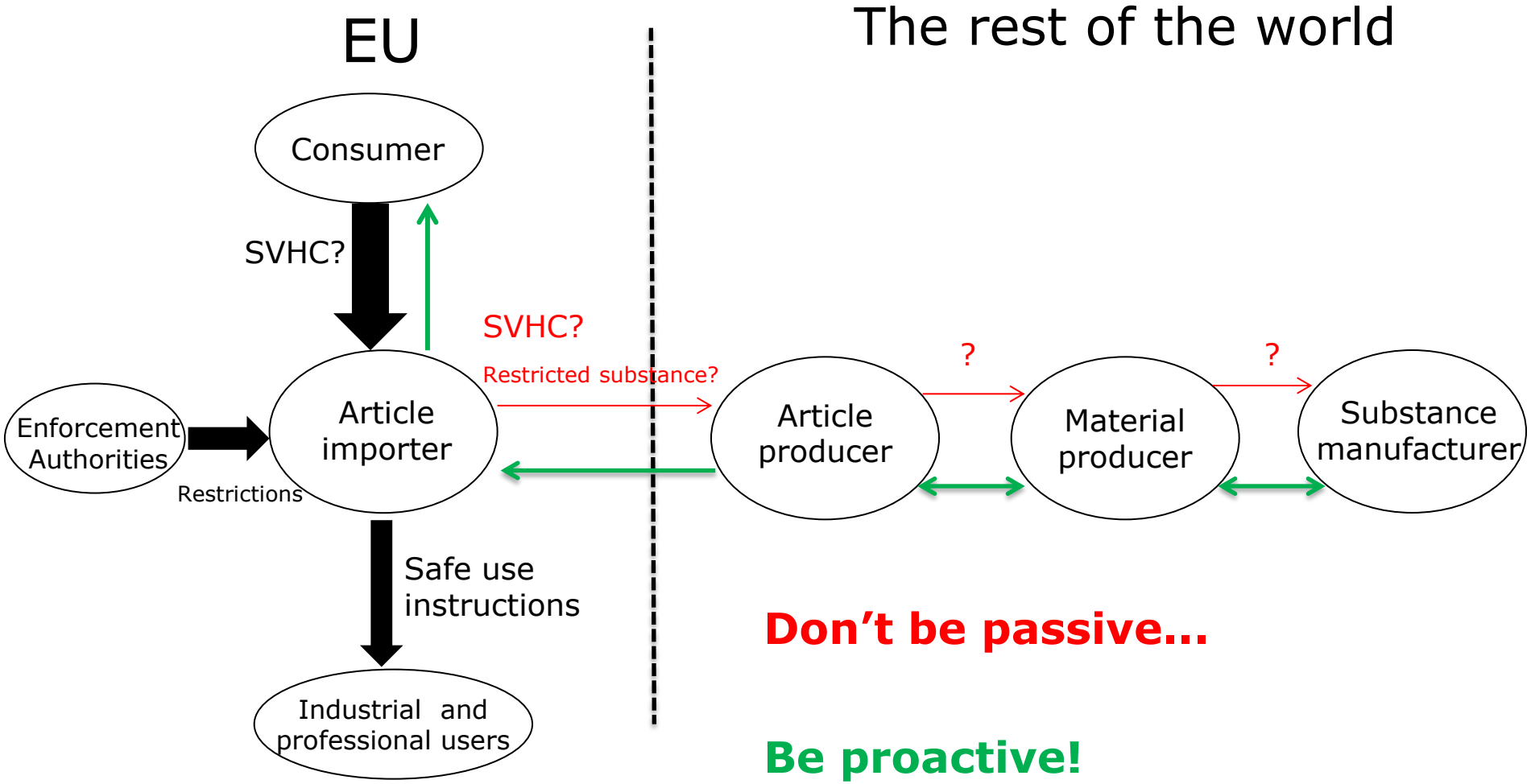
- Focus on:
  - most hazardous substances = Substances of Very High Concern (**SVHC**)
    - Carcinogens, Mutagens and toxic for Reproduction: CMRs → Human Health
    - Persistent, Bioaccumulative and Toxic for the environment: PBTs → Environment
    - very Persistent and very Bioaccumulative: vPvBs → Environment
    - Substances of "*equivalent level of concern*" (e.g. endocrine disruptors, potent respiratory sensitisers)
  - for which uses may lead to **significant exposure**

- Principle: after a certain date "***sunset date***" the use of an Annex XIV substance is forbidden unless specifically authorised (or exempted)
- Ultimate goal: **substitution** by safer alternatives

Check REACH obligation

- **Authorisation**
  - Is the substance included in Annex XIV?
    - ✓ Authorisation as such or substance in the mixture required
  - Always check candidate list as a pre-step for authorisation and SVHC communication for articles
- **Restriction**
  - Are there any restrictions in Annex XVII?
- **Don’t forget classification and labelling (CLP Regulation) and the information in the supply chain (SDS; SVHCs in articles).**

Information flow in (global) supply chains



Being aware and getting involved in possible future regulatory measures

What else to expect?

REACH review

- Report published on 5 March 2018
- ECHA's input to the Commission on registration
  - Dossier quality is a concern
    - → Consider means for ensuring dossier updates
    - → Compliance checks of high tonnage dossiers must continue to ensure that objectives of safe use are met
  - Dissemination
    - → Effective and powerful tool
    - → We will continue to improve and make information available
    - → Reward for good dossiers: confidence to the public

Nanoforms: review of REACH Annexes

- Ongoing review will clarify existing REACH requirements for nanoforms of substances
- Commission proposal currently being discussed by Member States in REACH Committee
- Changes not expected to enter into application until January 2020
- We will develop guidance to ensure sufficient support for industry in fulfilling the requirements

UK withdrawal from the EU

- Prepare for withdrawal date: **30 March 2019**
- UK-based registrants obliged to register under REACH, subsequently subject to UK law
- All registrants (within EU-27/EEA and UK) will be affected in various ways
- See details and follow developments on ECHA's website: echa.europa.eu/uk-withdrawal-from-the-eu

Roadmap for SVHC – annual report

Update on the SVHC roadmap

Information on ECHA website

- Screening:
  https://echa.europa.eu/screening
  Screening Webinar for Industry of 14 February 2017 (presentations and video recording available)
  https://echa.europa.eu/-/how-are-substances-screened-and-shortliste-1

- Compliance check
  https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

- Substance evaluation and CoRAP
  https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
  https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

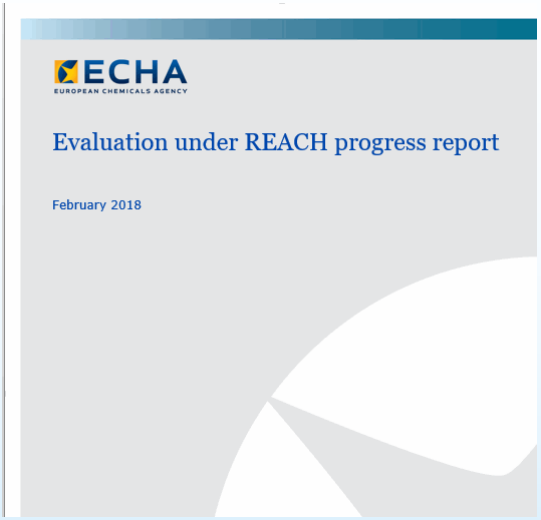
- SVHC Roadmap to 2020
  - Substances of potential concern: https://echa.europa.eu/substances-of-potential-concern
  - Annual report: https://echa.europa.eu/svhc-roadmap-to-2020-implementation
- PACT: Public Activities Coordination Tool
  https://echa.europa.eu/pact

Information on ECHA website

- Also:
- **Registrant's guide - How to act in substance evaluation**
- **How to communicate with ECHA in dossier evaluation**
- **https://echa.europa.eu/practical-guides**

Evaluation under REACH progress report 2016
(2017 to be published soon)

- Summary and statistics on main issues addressed by evaluation
- Advice and tips for existing registrants



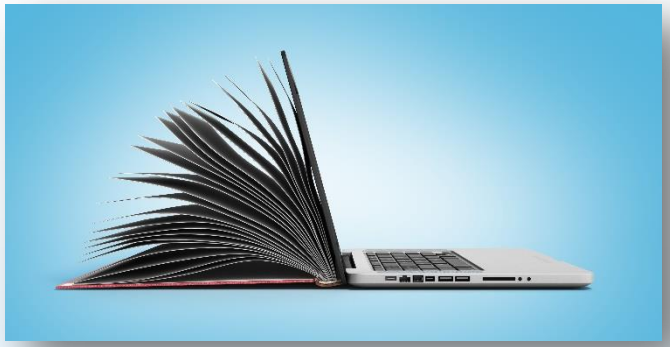
Where to look for help?

- ECHA Helpdesk:
- https://echa.europa.eu/contact

- National Helpdesks within the European Union (EU) and the European Economic Area (EEA):
- https://echa.europa.eu/support/helpdesks

Take home

- Use the available support to secure your registration in May 2018
- Registration is not over by May 2018
- You need to update your dossier – this is the law, and also the proof that you take safe use of chemicals seriously
- Make sure you have a structure in place to handle updates
- Legislation evolves: outcome of the REACH review is around the corner



Thank you!

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