Update from ECHA

REACH Information and Experience Exchange Forum (RIEF IV)

CEFIC

19 June 2015

Sheraton Brussels Airport Hotel

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World Summit on Sustainable Development 2002

International goal to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment

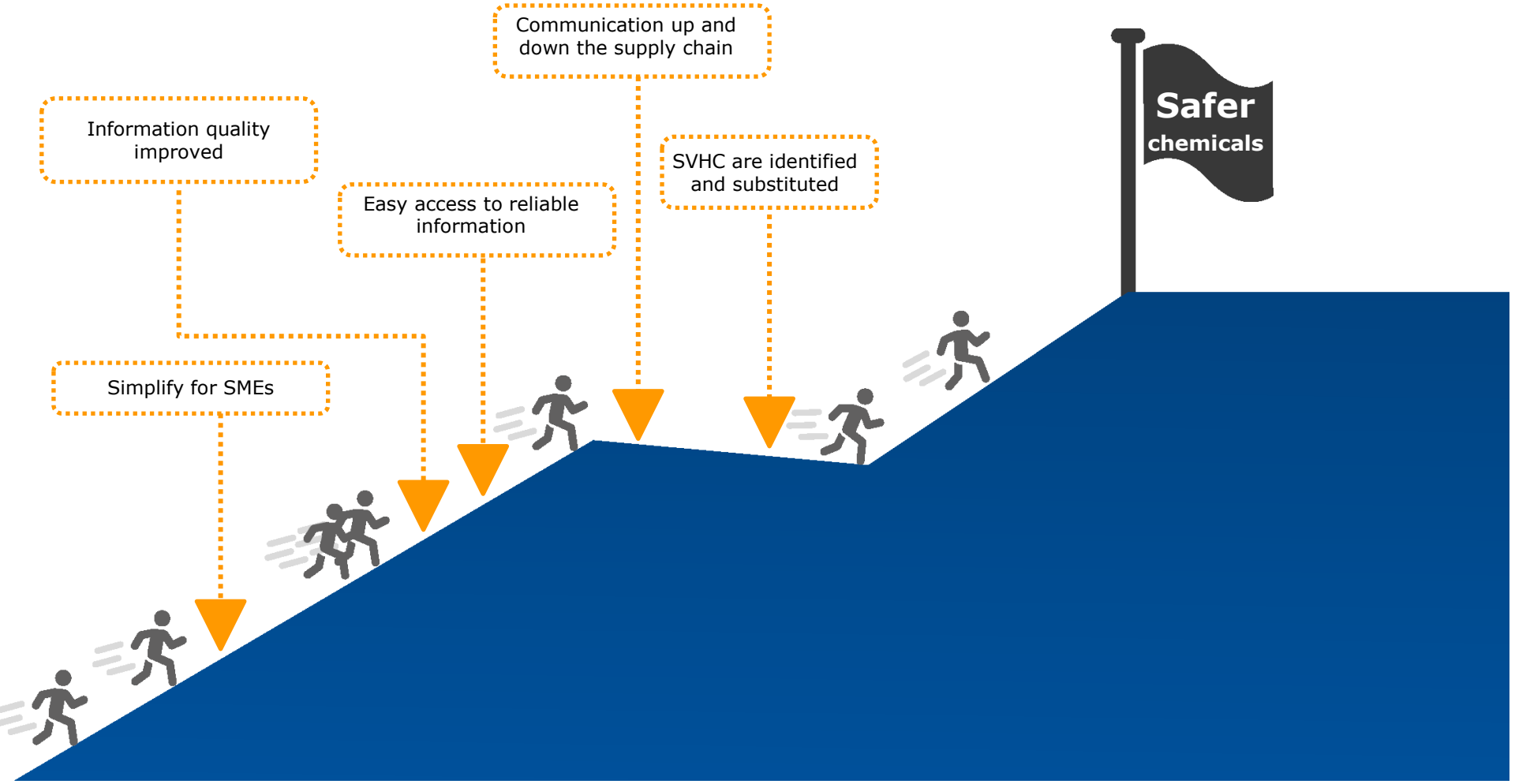
Europe

- REACH and CLP (GHS implementation) are the machinery to deliver the 2020 target. The (non-confidential) information made publicly available contributes to the worldwide goal

Some key principles

- Industry responsible for demonstrating that their substances are used safely throughout the supply chain
- Public right to know

Road to… 2020


Communication up and down the supply chain
Information quality improved
Easy access to reliable information
SVHC are identified and substituted
Simplify for SMEs
Safer chemicals

Update on ECHA activities

- Integrated screening
- New CCH strategy
- Read Across Assessment Framework
- Dissemination
- Registration deadline 2018
- CSA/ES Roadmap

Integrated screening of substances of concern

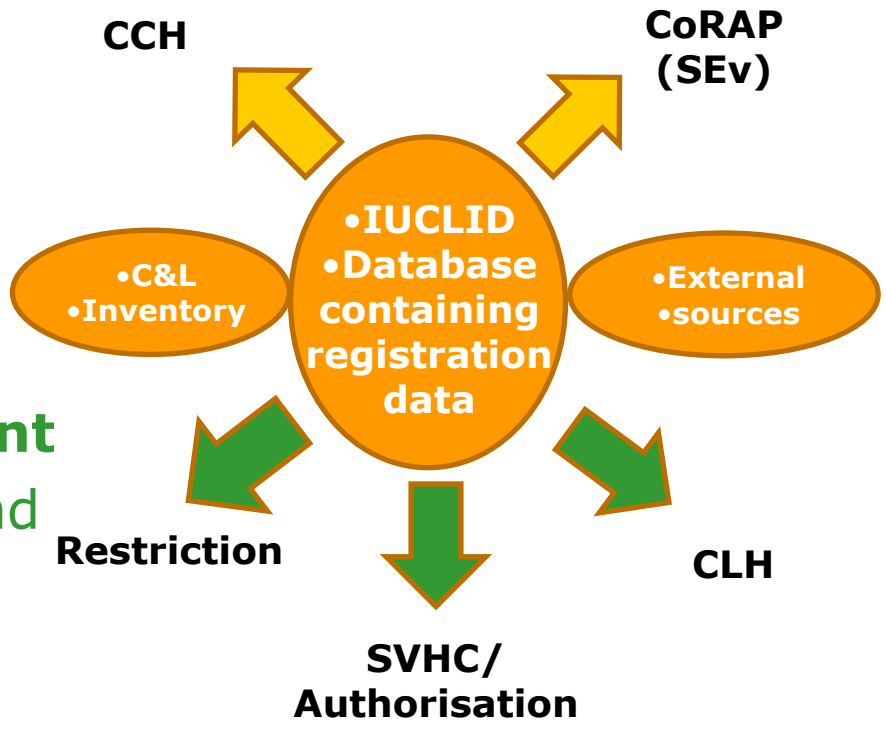
- Use of all available data
- Allocate identified substances to the appropriate REACH / CLP process:

Further information generation

- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction



New compliance check strategy

- The substances / dossiers are selected for action based on screening of the hazard information in the registration dossiers or based on estimation of hazard using external data

- The high potential for exposure to humans or environment leading to high selection priority
  - For potential exposure, data in the dossier as well as external data is used

- Ensure level playing field: random selections continues as well

Read-across Assessment Framework (RAAF)

- Read-across (RA) is one of the most commonly used alternative approaches for filling data gaps in registrations
- ECHA has developed the RAAF to ensure that assessing grouping and read-across is consistent and transparent
- Six scenarios including assessment elements that can support registrants in deciding and justifying RA and grouping appropriately
- Focus on human health endpoints. Environment will follow
- No new concepts, no change in guidance

http://echa.europa.eu/en/support/grouping-of-substances-and-read-across

Dissemination

- ECHA's database contains over 13,000 unique substances and information from more than 50,000 Registration dossiers*

- Upcoming tiered approach to dissemination:
- Info card (1st tier)
  - Substance identity and high-level information (classification, uses and exposures)
  - Overview of main regulatory processes on-going for the substance
- Substance Brief Profile (2nd tier)
  - Additional information on Physical chemical properties, Human Health effects and Environmental effects
  - Information in downloadable format and links to the source data
- Source (raw) data (3rd tier)

*as of 1 June 2015

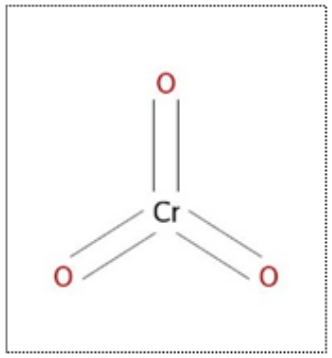
Dissemination – tier 1: Infocard

Chromium (VI) trioxide — DRAFT — *Infocard* – last updated 18/02/2014

Chromia (CrO3); chromium (VI) oxide; Chromium oxide; chromium oxide; chromium trioxide; Chromium (VI) trioxide; chromium, trioxo-; Trioxochromium...

Substance Identity

EC Number	215-607-8
CAS Number	1333-82-0
Molecular Formula	CrO3



Safety classification & labelling

EXTREME CAUTION! This substance is extraordinarily hazardous! This substance is fatal if inhaled, may cause genetic defects, causes damage to organs through prolonged or repeated exposure, may cause cancer, is toxic in contact with skin, causes severe skin burns and eye damage, is very toxic to aquatic life with long lasting effects, is toxic if swallowed, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility or the unborn child, may cause allergy or asthma symptoms or breathing difficulties if inhaled, and may cause an allergic skin reaction.

The above is based on the Harmonised Classification and Labelling approved by the European Union.

Critical properties and Regulatory actions

Substance of very high concern (SVHC) and included in the *candidate list for authorisation.*

Substance of very high concern requiring authorisation before it is used (*Annex XIV of REACH*).

About this substance

This substance is a High Production Volume chemical; per year 10 000 to 100 000 tonnes are manufactured and/or imported in the European Economic Area.

ECHA has no registered data indicating the type of article into which the substance has been processed.

This substance is used in the following products: pH regulators and water treatment products, non-metal-surface treatment products, metal surface treatment products , adsorbents, and laboratory chemicals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in for the manufacture of: fine chemicals, bulk chemicals, plastic products, and fabricated metal products.

Release to the environment of this substance is likely to occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), formulation in materials, formulation of mixtures, as processing aid, in the production of articles, and manufacturing of the substance. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners).

Precautions and Safe Use

Precautions suggested by manufacturers and importers of this substance can be found here; Guidance provided by manufactures and importers on the safe use of the substance can be found here.

Chromium (VI) trioxide – European Chemicals Agency Infocard – last updated 18/02/2014

More

DRAFT

Dissemination – tier 2: Brief profile

4,4'-isopropylidenediphenol DRAFT

Brief Profile – *last updated 18/02/2014*

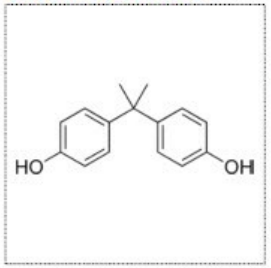
2,2-bis (4-hydroxyphenol) propane; 2,2-di(4-hydroxyphenyl)propane; 4,4' isopropylidinediphenol; Biphenol A; Bisferol A; **BPA**; C006780; DIAN; Ipognox 88

Introduction

The following is a brief profile summarising the non-confidential data on this substance held in the databases of the European Chemicals Agency (ECHA). Please note that this brief profile is generated automatically based on the data available at the time of generation. The data remains the responsibility of its respective owners and ECHA does not assure the quality and correctness of the information. The type of uses and classifications may vary between different submissions to ECHA and for full understanding it is recommended to consult the source data. Regulatory actions information included in the brief profile may not be completed and it is responsibility of the substance manufactures and importers to consult official publications.

More

Substance Identity



EC Number	201-245-8
EC Name	4,4'-isopropylidenediphenol
CAS Number	80-05-7
Index Number	604-030-00-0
Molecular Formula	C15H16O2
IUPAC Name	2,2-bis (4-hydroxyphenol) propane
Smiles	Oc1ccc(cc1)C(c2ccc(O)cc2)(C)C
InChI	1S/C15H16O2/c1-15(2,11-3-7-13(16)8-4-11)12-5-9-14(17)10-6-12/h3-10,16-17H,1-2H3

Type of Substance	Mono constituent substance
Origin	Organic
Registered Compositions	7
Of which contain:	
Impurities relevant for classification	2 compositions
Additives relevant for classification	No compositions
Substance Listed	EINECS (European Inventory of Existing Commercial Chemical Substances)

More

Safety Classification & Labelling

EU Harmonised Classification & Labelling (ATP 1)

Take care. This substance is hazardous. This substance causes serious eye damage, is suspected of damaging fertility or the unborn child, may cause respiratory irritation, and may cause an allergic skin reaction.

More

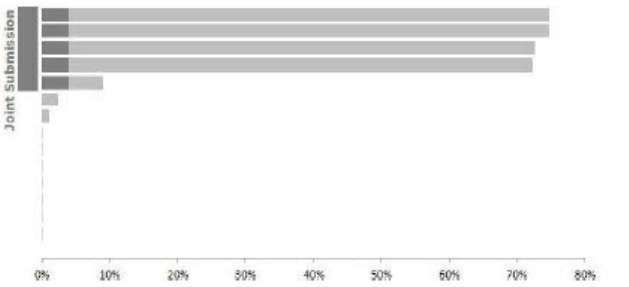
Notified Classifications & Labellings

Caution! This substance is very hazardous. This substance is toxic to aquatic life with long lasting effects, causes serious eye damage, is suspected of damaging fertility or the unborn child, may cause an allergic skin reaction, and may cause respiratory irritation.

More

Breakdown of all 2 605 C&Ls notified to ECHA

Harmonised C&L			
	Eye Dam. 1	**causes serious eye damage**	**H318**
	Skin Sens. 1	**may cause an allergic skin reaction**	**H317**
	Repr. 2	**is suspected of damaging fertility or the unborn**	**H361**
	STOT SE 3	**may cause respiratory irritation**	**H335**
	Aquatic Chronic 2	is toxic to aquatic life with long lasting effects	H411
	STOT SE 1	causes damage to organs	H370
	Aquatic Chronic 3	is harmful to aquatic life with long lasting effects	H412
	Skin Irrit. 2	causes skin irritation	H315
	Carc. 1A	may cause cancer	H350
	Eye Irrit. 2	causes serious eye irritation	H319
	Asp. Tox. 1	may be fatal if swallowed and enters airways	H304
	Acute Tox. 4	is harmful if inhaled	H332
	Acute Tox. 4	is harmful if swallowed	H302
	Muta. 1A	may cause genetic defects	H340



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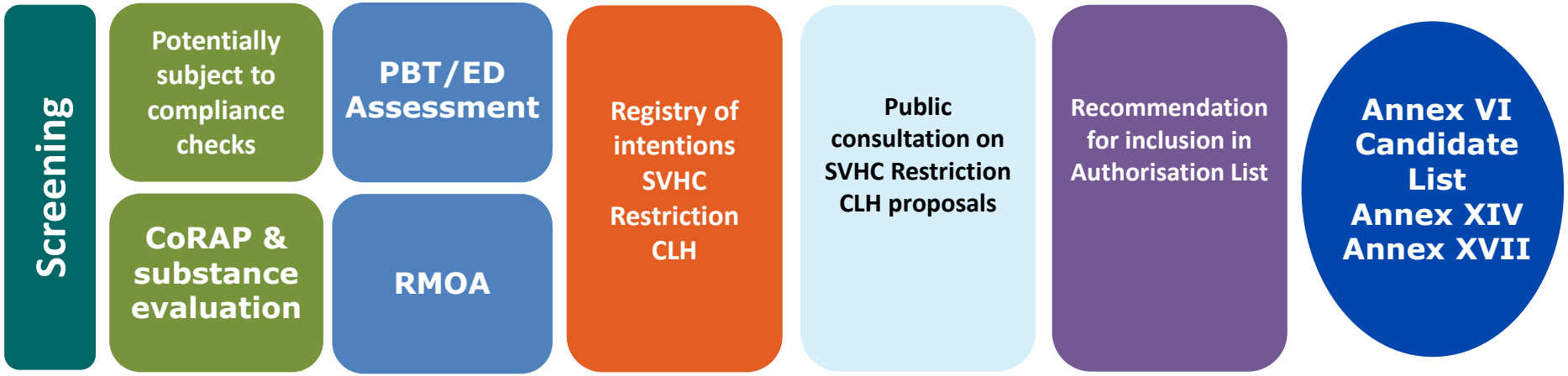
Transparency and predictability

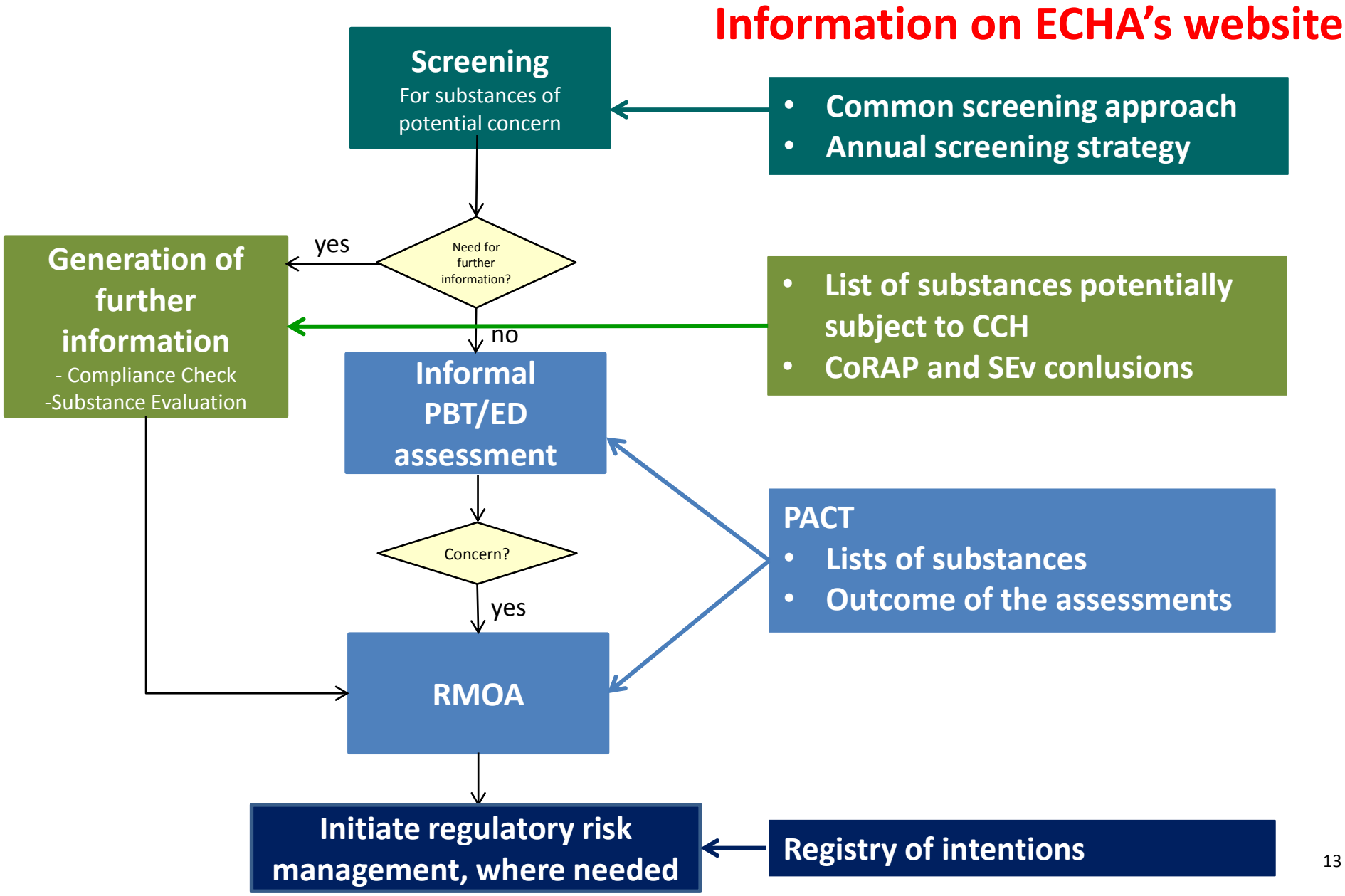
- Transparency
  - What authorities do and why
- Predictability
  - Foreseeable consequences of authorities' work to allow planning by stakeholders
- Measures to increase transparency and predictability
  - Information on ECHA's website
  - Communication to registrants and notifiers

Increasing transparency and predictability

- Information on ECHA's website



Increasing transparency and predictability



Dissemination – future developments

Increased transparency and predictability:

- In the brief profiles Endpoint Summary to be published
  - News alert with more information to follow
- Improvement how Compliance Check activities are disseminated;
- Further automation to publish:
  - Quicker after submission (including updates);
  - Rejected confidentiality claims.

- Make results* of studies downloadable?
  - QSAR/Alternative's development (e.g. CEFIC-LRI's request for data)
  - Improve SDS
  - Support environmental risk and impact assessment

Under Discussion

*Study Results only, not Full Robust Study Summaries

REACH 2018 - Expectations

- Many more registration dossiers
- More small SIEFs
- More registrants alone
- Higher % of SMEs
- More SMEs as lead registrants
- Less information → need to generate new data
- Some very active sectors

Promote the 2018 web pages

- Advice for SMEs for each phase of registration
- Targeted support with three levels of information
  - Getting started - Essential reading - Going deeper
- Practical tips, Do's and Don'ts, Checklists
- Information on events, webinars, new publications

Recently published pages on Data Sharing received a lot of positive feedback: have a look yourself!

http://echa.europa.eu/reach-2018

IUCLID (Q2 2016, beta version available summer 2015)

- Desktop version easier to install
- Improved security, role management for the server version
- Implementation of new OECD Harmonised Templates
- Under discussion:
  - Hosting service offered to industry?
  - Server version and desktop version will continue to be available in any case

Prevent disturbance in your operations:

Install the beta server version now to prepare for the 2016 update!

Chesar 3.0(Release Q2 2016)

- Continue the strong link with IUCLID
- Simplify/improve where possible on the basis of user's feedback
- Start implementing outputs from CSR/ES Roadmap work
  - Alignment with revised Guidance
  - Use maps
  - Possibility to cover more complex assessments

REACH-IT (Release Q2 2016)

- Improved user experience
  - improvements and simplifications on the Usability, Look & Feel and process and text simplification and access to important documents
- Improved contact management – e.g. that Industry can themselves control what address is visible in the CoRP
- Improved user management (via ECHA Account) – e.g. where one user can be linked to many companies (and can access R4BP and ePIC with the same account)
- Upcoming Online dossiers (C&L and Member of Joint submission)
- SME size definition improvements
- Possibility to provide the Substance Identity Profile ('boundary composition')
- Improved process (details in next slides)

SIEF

Under Discussion

- Joint Submissions to become searchable?
- Additional pre-SIEF status to indicate intention to register by 2018?

Data-Sharing / Joint Submission

- REACH-IT enforcement of Article 11 – submitting 'outside' the JS is no longer allowed
- Data and cost sharing strengthened
  - Disagreement to be resolved by data-sharing disputes where needed
- Commission is preparing implementing act in support of this

Completeness check process

- Review done as mentioned in the MAWP/WP
- Based on experience, new formats and regulatory developments a need is identified to improve the technical implementation to
  - Avoid that 'not meaningful' information is submitted
  - Ensure a fair and equal playing field for companies that have collected/generated the required information
- Improvements in technical implementation of some of the rules
- Introduction of manual verification for some items
- Discussed at Management Board meetings and Caracal
- Commission's feedback was sought on:
  - Completeness check on updates
  - Scope of manual verification

Completeness check process – next steps

- ECHA is finalising the technical proposals

- For some rules feedback on impact from industry is highly desirable
  - Technical workshop after summer

- To inform all stakeholders (IND, NGO and MS) about the changes a broader information session will be organised

- Further information will be made available in due time for industry to start preparing

CSR/ES Roadmap

- CSACSR and ES critical for the implementation of REACH
  - Ensure safe use of chemicals through the supply chain
  - Improve insight on use information to improve prioritisation for substances that matter
- Many activities going on (see other topics today)
- More attention needed in some areas, e.g:
  - Ensure the uptake of Use maps
  - Committed management and implementation of ESCom by industry
- ECHA's general observation is that much progress on development is being made, implementation needs to follow

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you!

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