Risk management – get ready

Tenth Stakeholders' Day

27 May 2015

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European Chemicals Agency

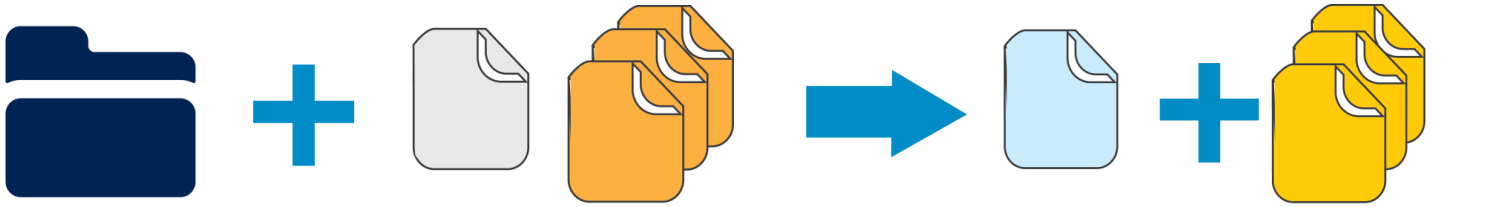
Risk management

- How to help yourself
- What authorities are doing
- Stay ahead of the game

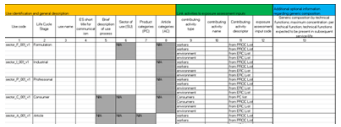
Company risk management depends on supply chain communication

Communication in the supply chain

Registrants



Sector use maps



Information on uses

Safety advice

Downstream users/sector organisations

Help is there

Information on uses

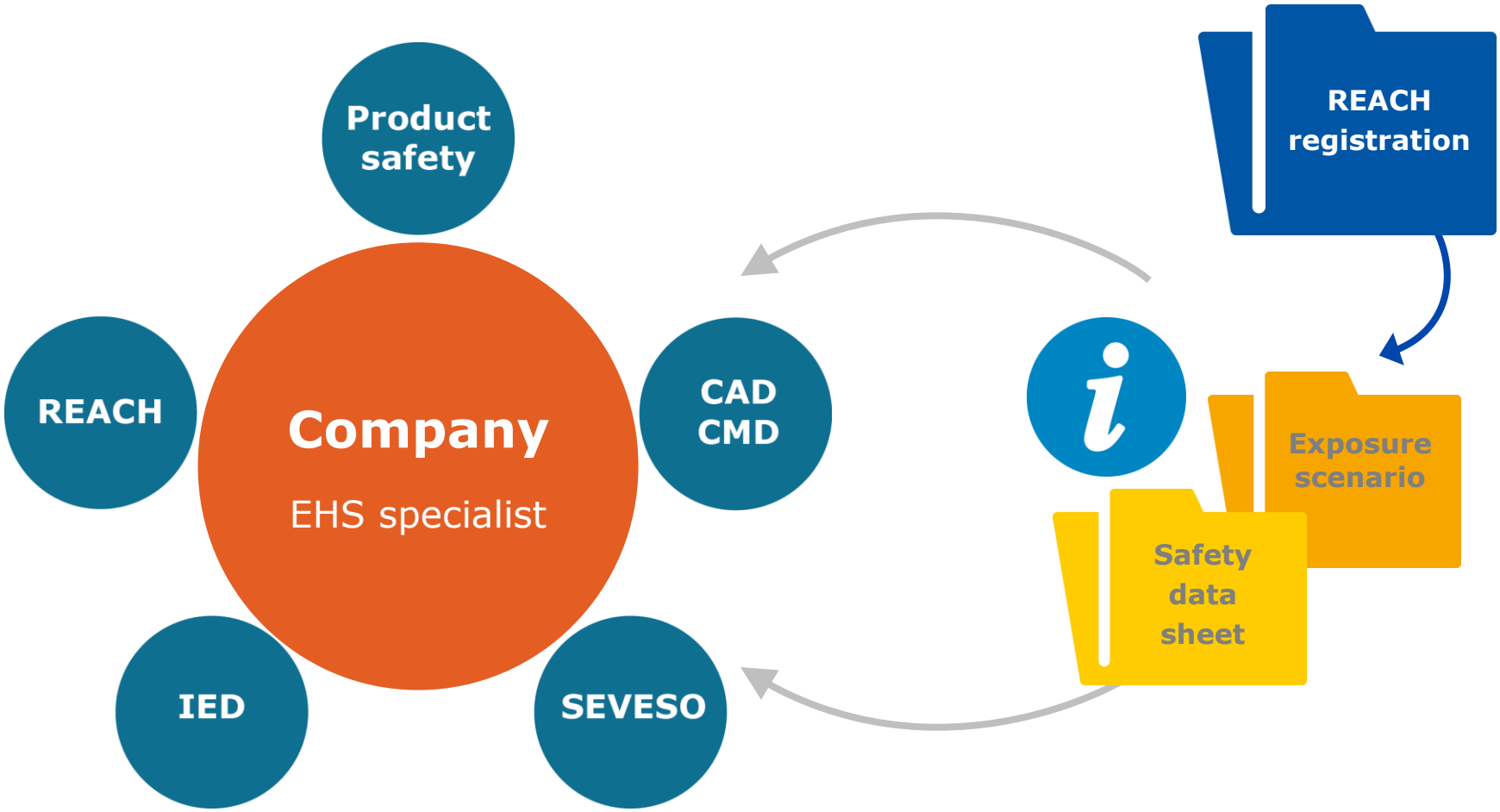
- Guidance, tools and **sector use maps** for chemical safety assessment (CSA)
- Harmonised communication of exposure scenarios (ES)

Safety advice

- Build on existing risk management advice, such as control sheets
- Help formulators provide realistic and relevant safe use information for mixtures
- Use REACH information for other purposes

http://echa.europa.eu/csr-es-roadmap

Making use of REACH in your company



Stay ahead

- Apply the solutions built on experience from the past years – make communication on conditions of use more efficient and more helpful
- Follow the CSR/ES Roadmap activities
  - Work with your sector associations, we need more “end” use sectors to become involved
  - Join in the projects, contact us where needed
- Raise awareness on REACH and the information it brings
  - Integrate REACH into company safety, health and environment systems

Regulatory risk management

What authorities are doing

Priorities

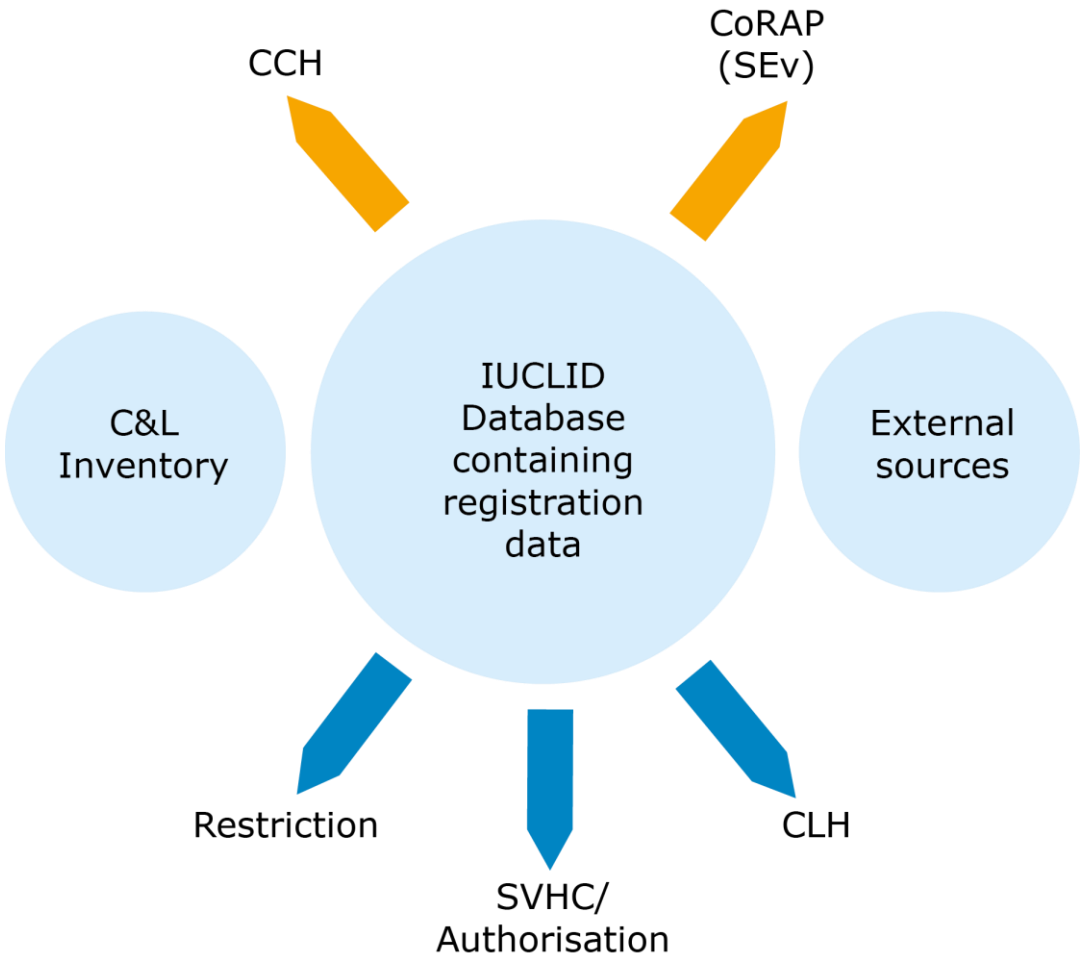
Focus on substances that have the biggest impact on health and the environment

- High potential for exposure of humans or the environment

and

- One or more suspected data gaps in the higher tier human health or environment endpoints and/or
- Indication of hazard in the endpoints of concern

Picking the right substances



State of play

CMRs

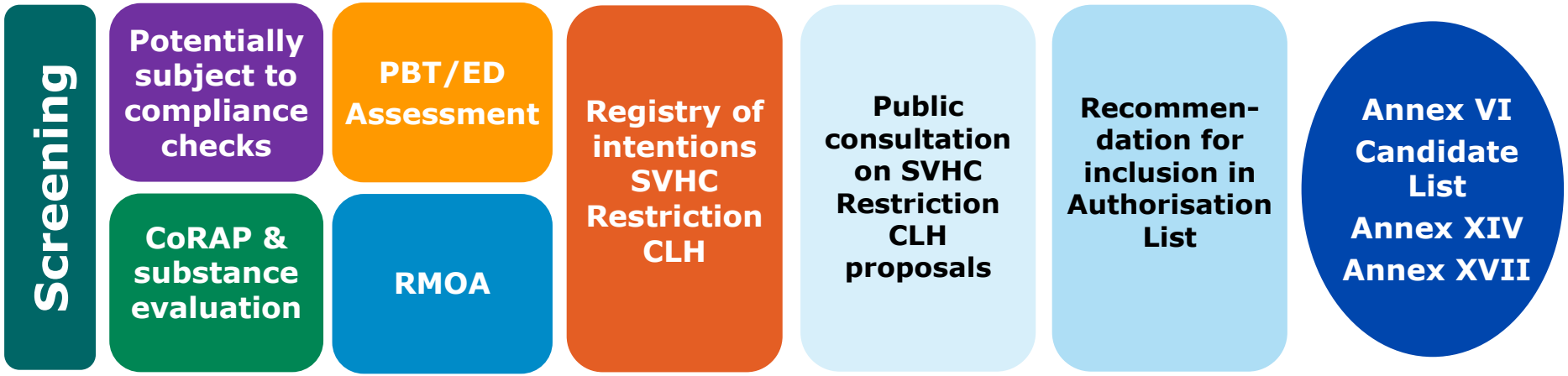
- Vast majority of registered and harmonised CMR substances already being dealt with
  - On the Candidate List, under RMOA or no further action needed
  - Some planned for substance evaluation

PBTs, endocrine disruptors

- Substances with sufficient hazard information already addressed
- Focus is now on further assessment and data generation

http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

Increasing transparency and predictability



Check PACT at:

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

Get ready for regulatory action

- Keep dossiers up-to-date
  - Volumes, uses and hazard/exposure data
  - Transparent and consistent CSR
- Communicate use and use conditions upstream and follow risk management advice through the SDS/ESs

✓ Health and safety concerns can be avoided

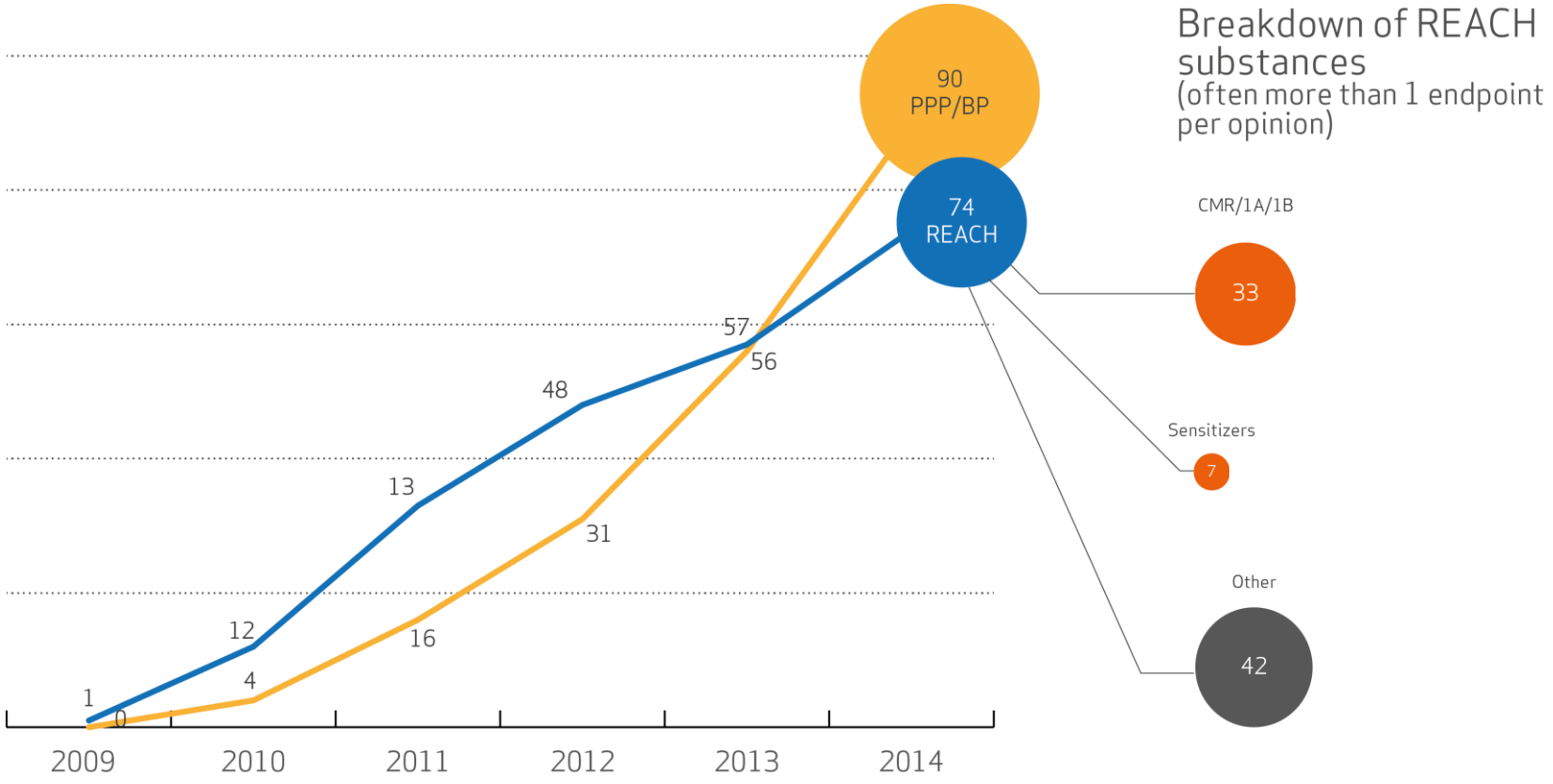
✓ Likelihood of regulatory attention reduced

✓ Helps you to be proactive: Consider possible long-term consequences and innovation

State of play

- CLH
- Restrictions
- Authorisation

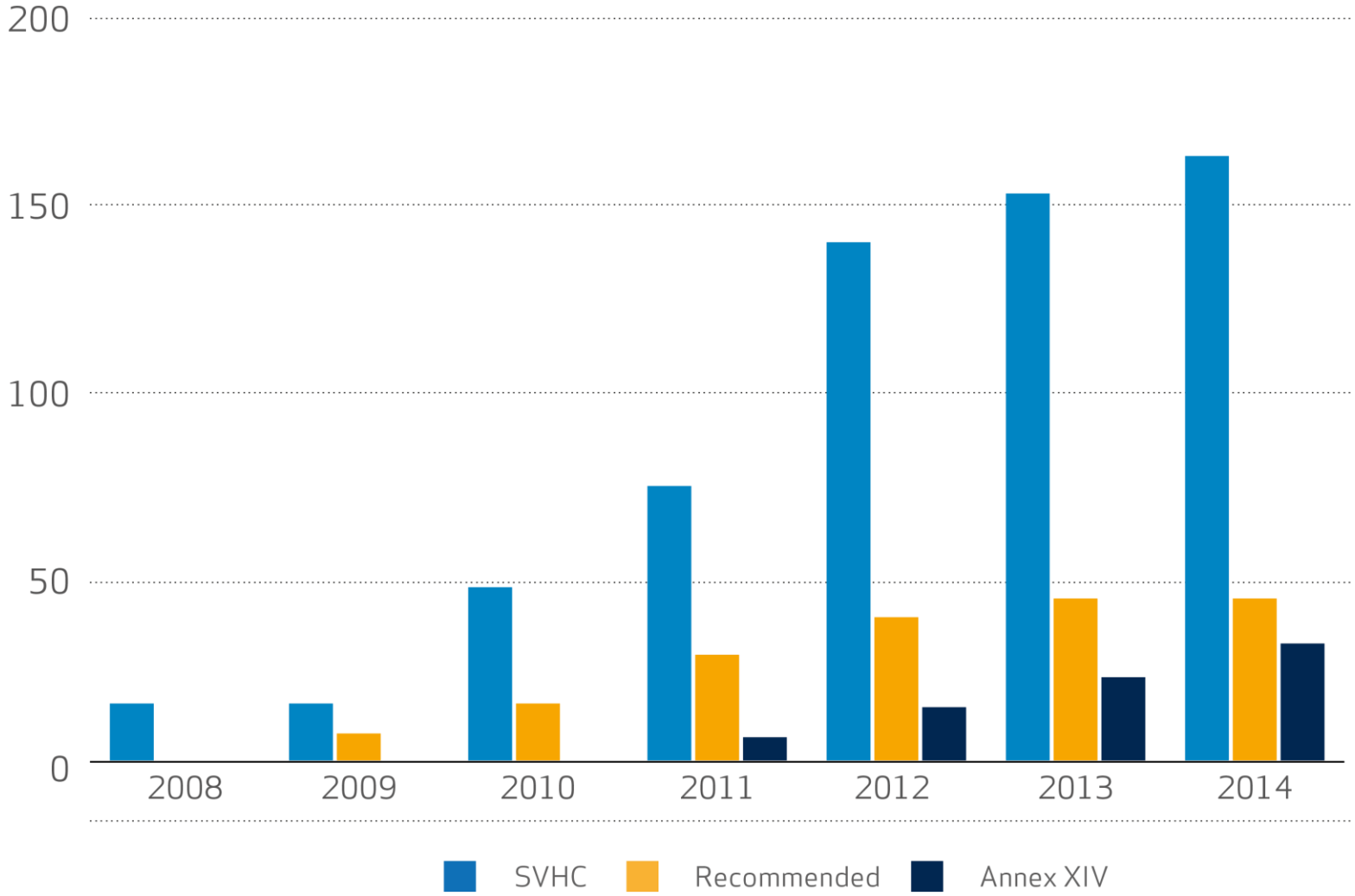
Harmonised classification and labelling



Progress on restrictions

- Process is maturing:
  - Opinions on 13 'substances' sent to Commission; 6 in pipeline
- Efficiency improvements ongoing:
  - Comments received during PC published monthly
  - Working with stakeholders how to better contact downstream users during public consultation
- Work started on restricting the use in articles of substances on the Authorisation List:
  - e.g. Three calls for evidence commenced
  - Phthalates restriction under preparation

Progress on authorisation



Applications for authorisation

- Good progress made with the first applications
- 50 opinions issued supporting the authorisation of justified uses
- Majority of the opinions within seven months, first three decisions taken by COM
- ECHA:
  - Holds pre-submission information sessions and trialogues
  - Improves its tools/formats based on feedback
- Next seminar 29-30 June 2015

Authorisation process

- It is working:
  - Transparent and predictable
  - Public consultations valuable
  - Incentive to substitute
  - Improves risk management measures
  - Well-justified cases will get an authorisation
- Room for improvement:
  - Costs have reduced (by over 30%) but the process can be too burdensome
  - Finding a good balance in “upstream” broad applications

http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation

Next steps on authorisation

- Authorisation taskforce recommends in June on simpler applications for low volumes
- Simplified formats
- Commission will implement legally
- We continue to support other cases that may benefit from streamlined applications

Take away

- Good supply chain communication leads to successful risk management – **activate your sectors**
- Help yourself, be proactive and **use the advance notice** that we provide

  → for smart companies a competitive advantage
- Application for authorisation **is working** and is being further streamlined

Get ready

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