



What effect will grouping of substances have?

ECHA conference - Safer chemicals

22 May 2019

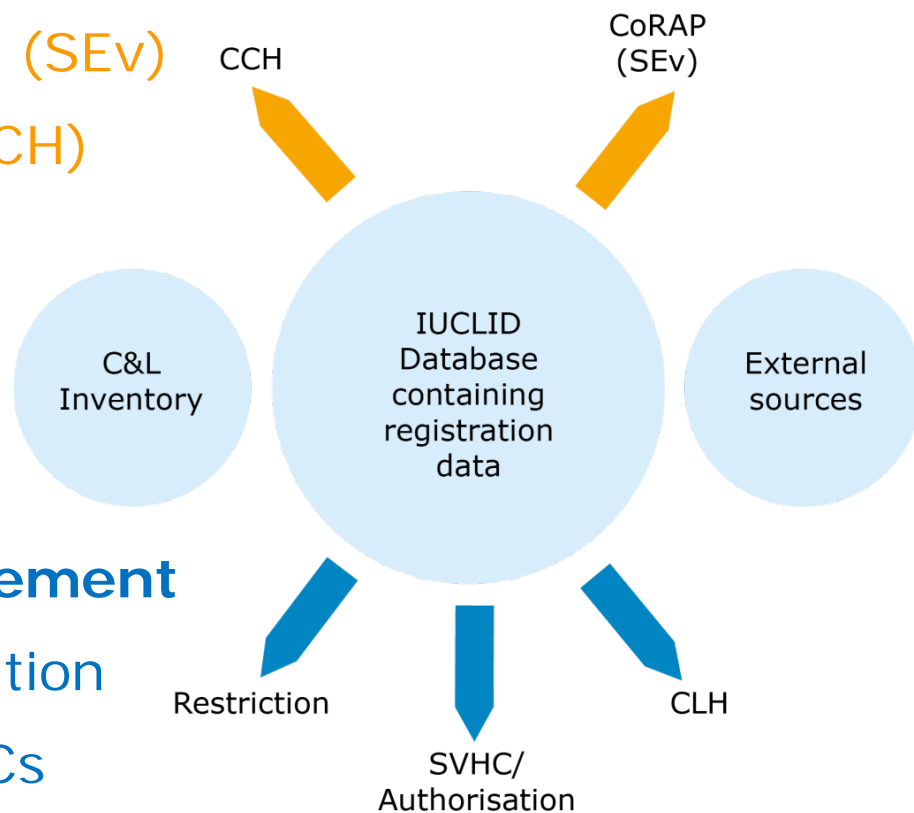
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Head of Computational
Assessment

#SAFERCHEMICALS

EU prioritisation version 0.1

Generation of further information

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



Regulatory risk management

- Harmonised classification
- Identification of SVHCs
- Restriction

Regulatory Strategy for “substances that matter most”



Focus on substances with biggest impact on protection of people & environment through regulatory action

Substances that matter the most

Integrated selection and priority setting

Effective use of the evaluation process

Predictable follow-up with regulatory action where needed

Complementary measures, e.g. sector approach



Focussing on substances that matter

- Higher-tonnage registration dossiers with
- Important data gaps and with
- High exposure potential for:
 - workers
 - consumers, or
 - environment



NOW



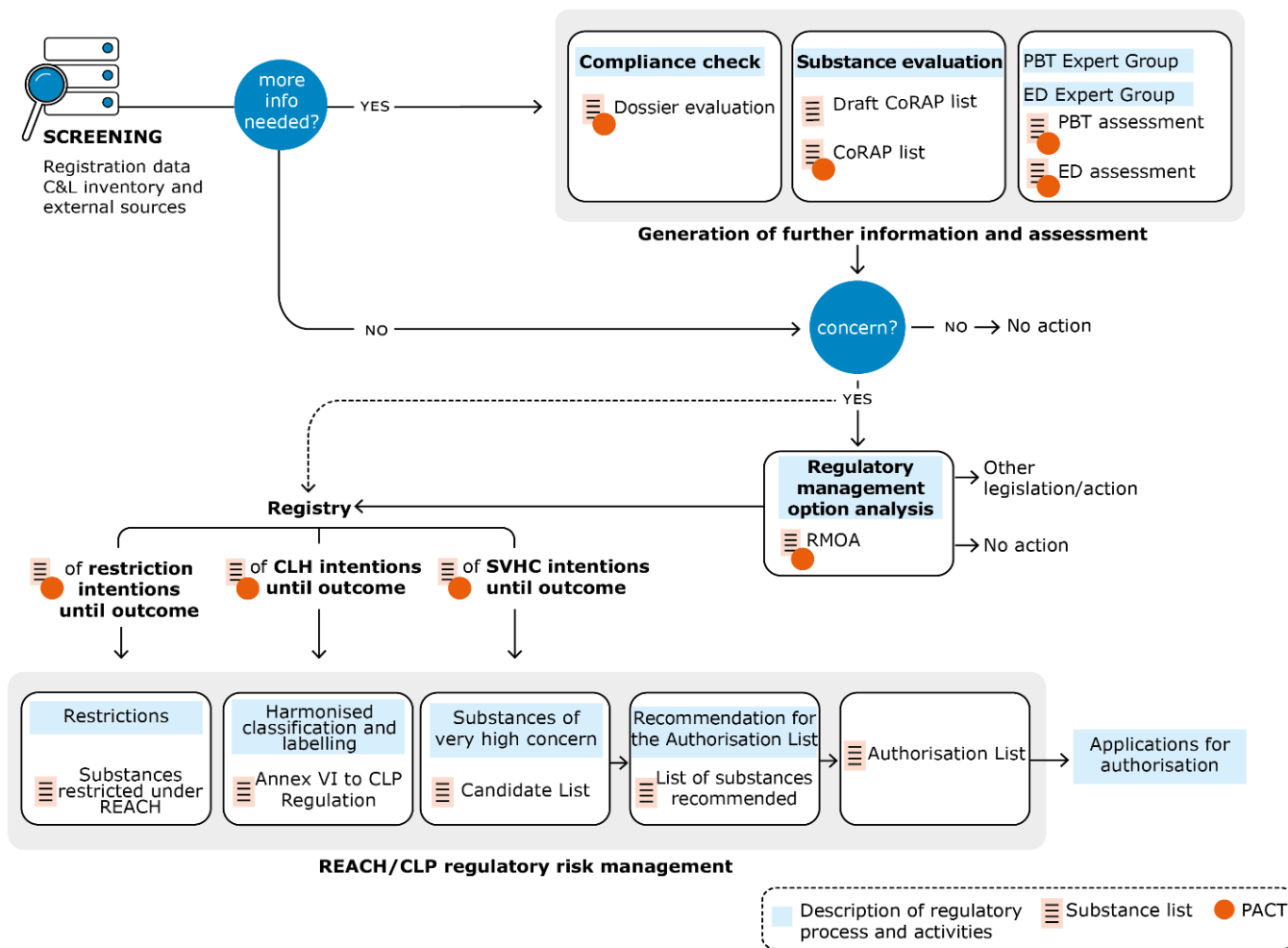
LATER

Further developments

- Less and less cases for regulatory risk management, because of lack of data and compliance:
 - Unreliable use reporting (often over-reporting → everything is prioritised)
 - Many incompliances / data gaps for higher-tier endpoints
- Development of an integrated approach
 - Increased use of information outside the dossier
 - Now also grouping
 - At the same time: increase of transparency for industry with letter campaign, CCH list, PACT etc.
 - Generally few reactions from industry
 - Rate of dossier updating still rather low



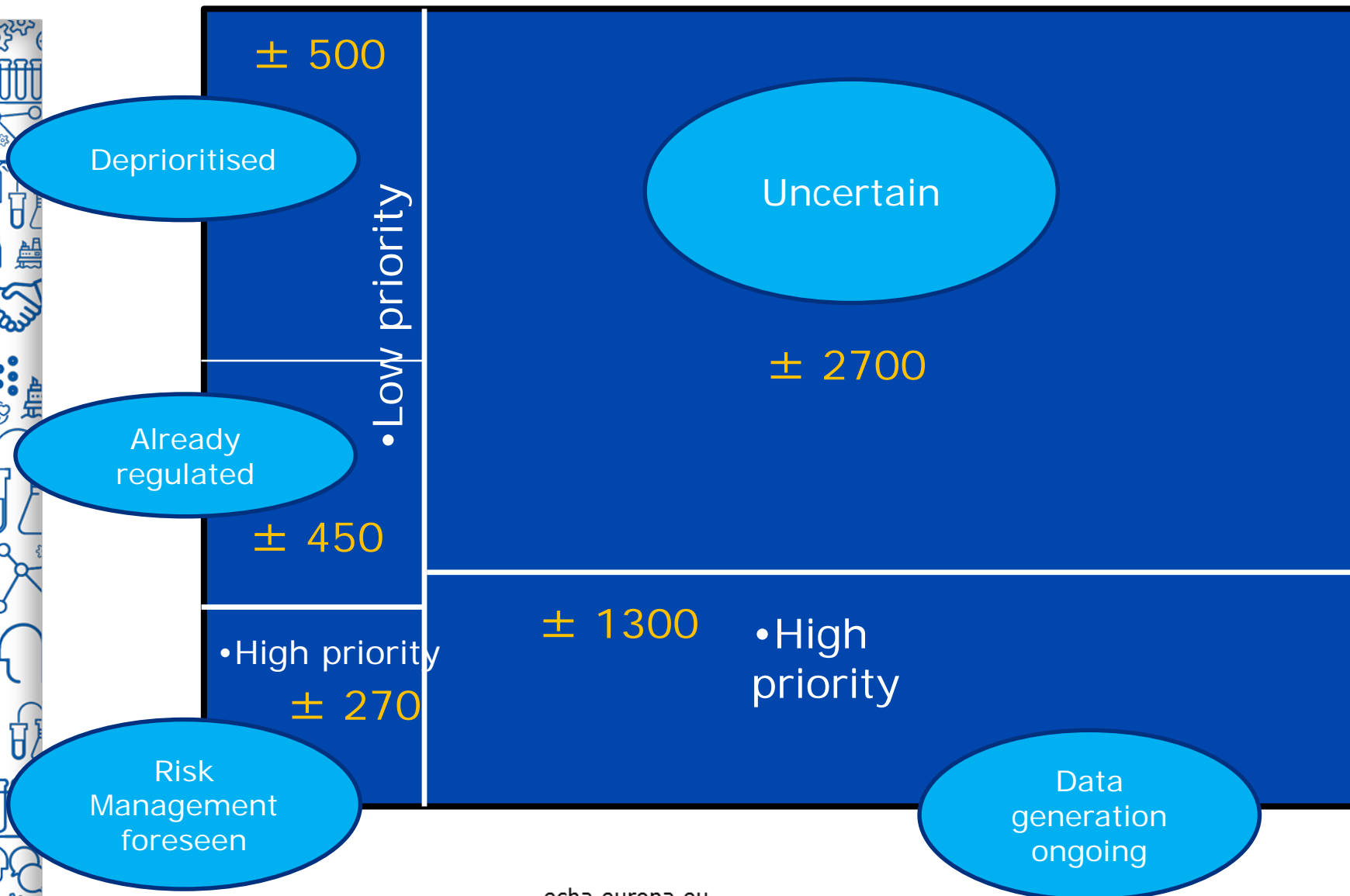
EU prioritisation version 1.0



From ECHA's [Integrated Regulatory Strategy Annual Report](#)

Chemical universe

Chemical universe of Annex IX and X substances as of May 2018





Mapping the chemical universe

What are we trying to achieve?

- Chemical universe gives an estimation of regulatory coverage and the state-of-play of the REACH and CLP implementation (regulatory footprint)
- Chemical universe is not an indication of a single process but an amalgamation of all known information for substances
 - regulatory process data
 - hazard and exposure information in registration dossiers
 - external sources (hazard data, exposure data, regulatory data outside our remit)





Integrated regulatory strategy

By 2020

- Have a sufficient understanding of all remaining substances registered above 100 tonnes/year
- Aim is to conclude for all those substances whether:
 - registrants need to generate more information
 - authorities need to initiate further regulatory risk management actions
 - the substances are currently of low priority for regulatory action

By 2027

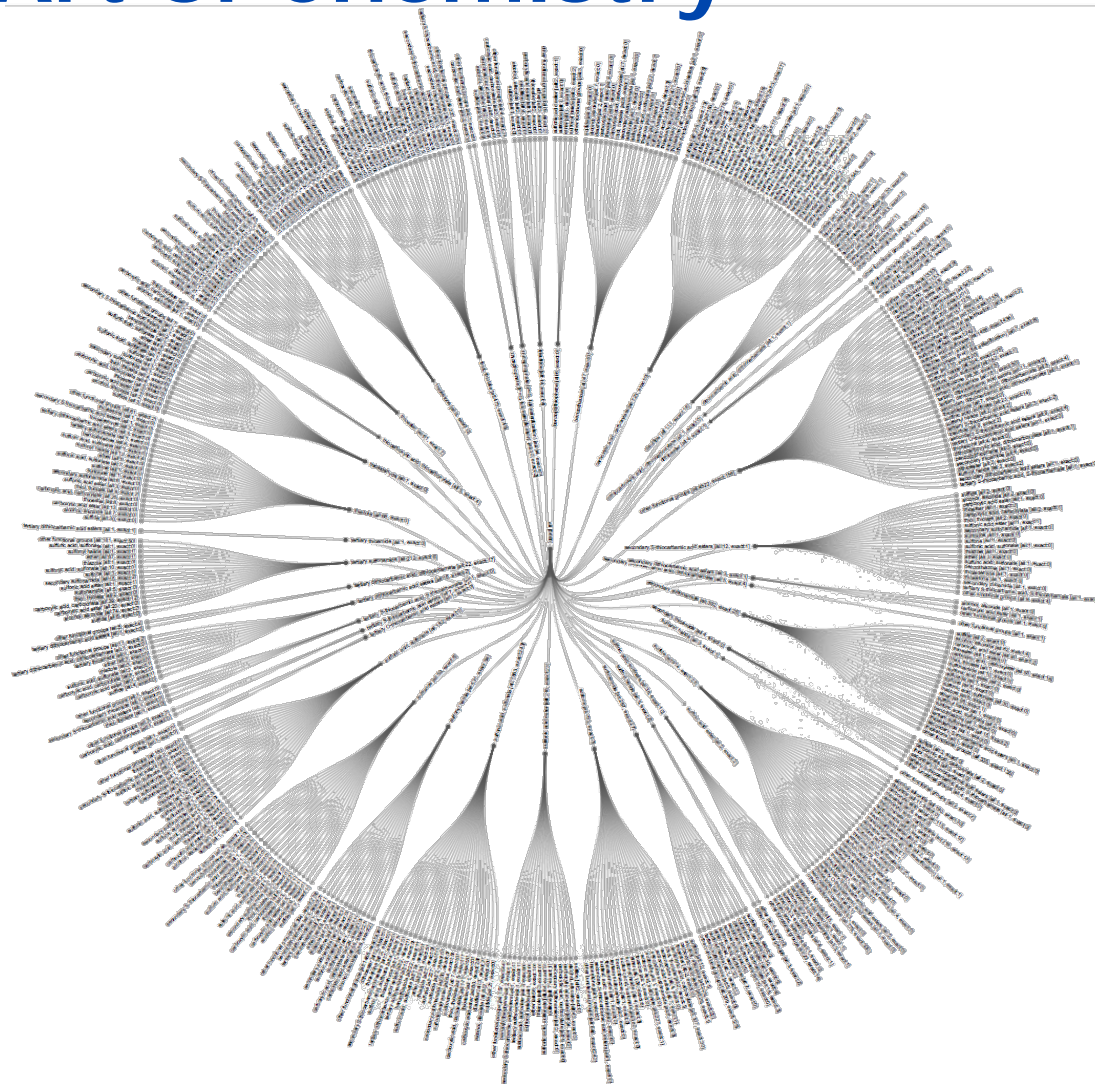
- All substances of concern are identified and **regulatory action initiated**
- Inclusion of low tonnage substances via grouping etc.

How will we get there

- We need to:
 - **accelerate** data generation
 - **intensify** identification of substances of concern
 - **accelerate** regulatory action of substances of concern
 - Time from the identification of concern to (final) regulatory risk management should be as short as possible



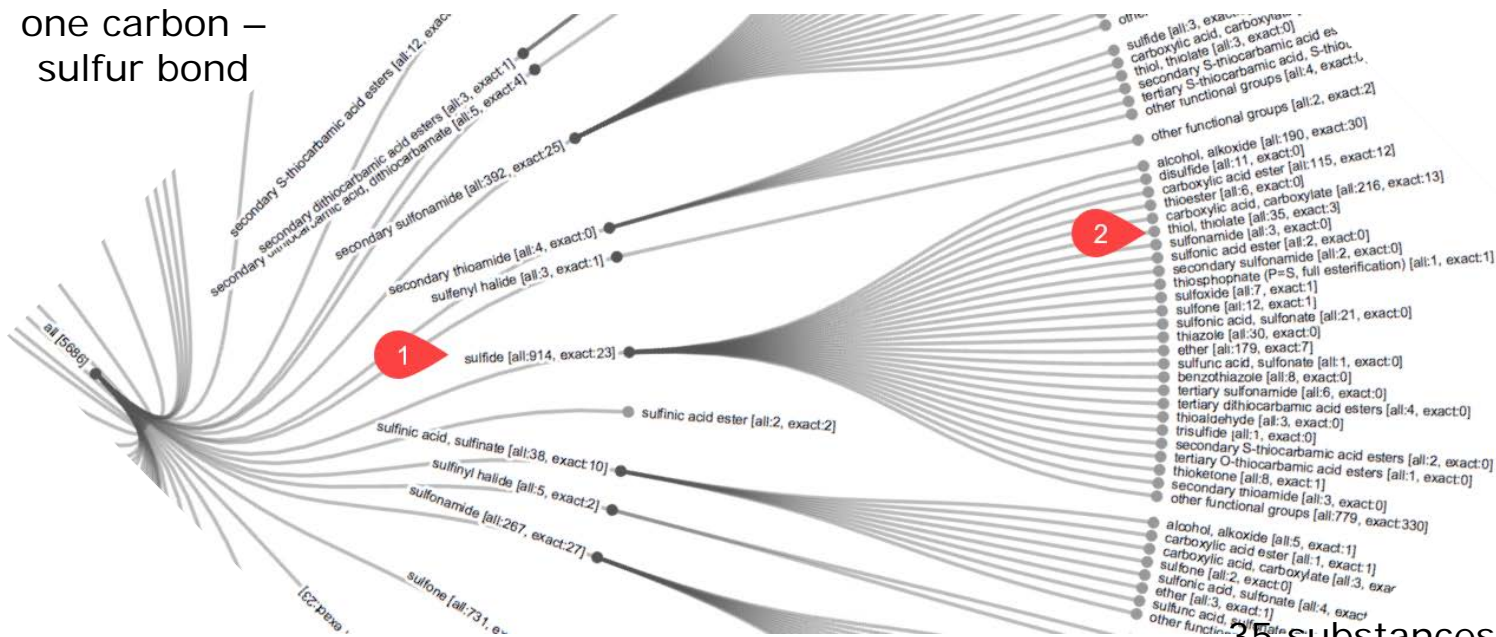
The Art of Chemistry



A closer look...

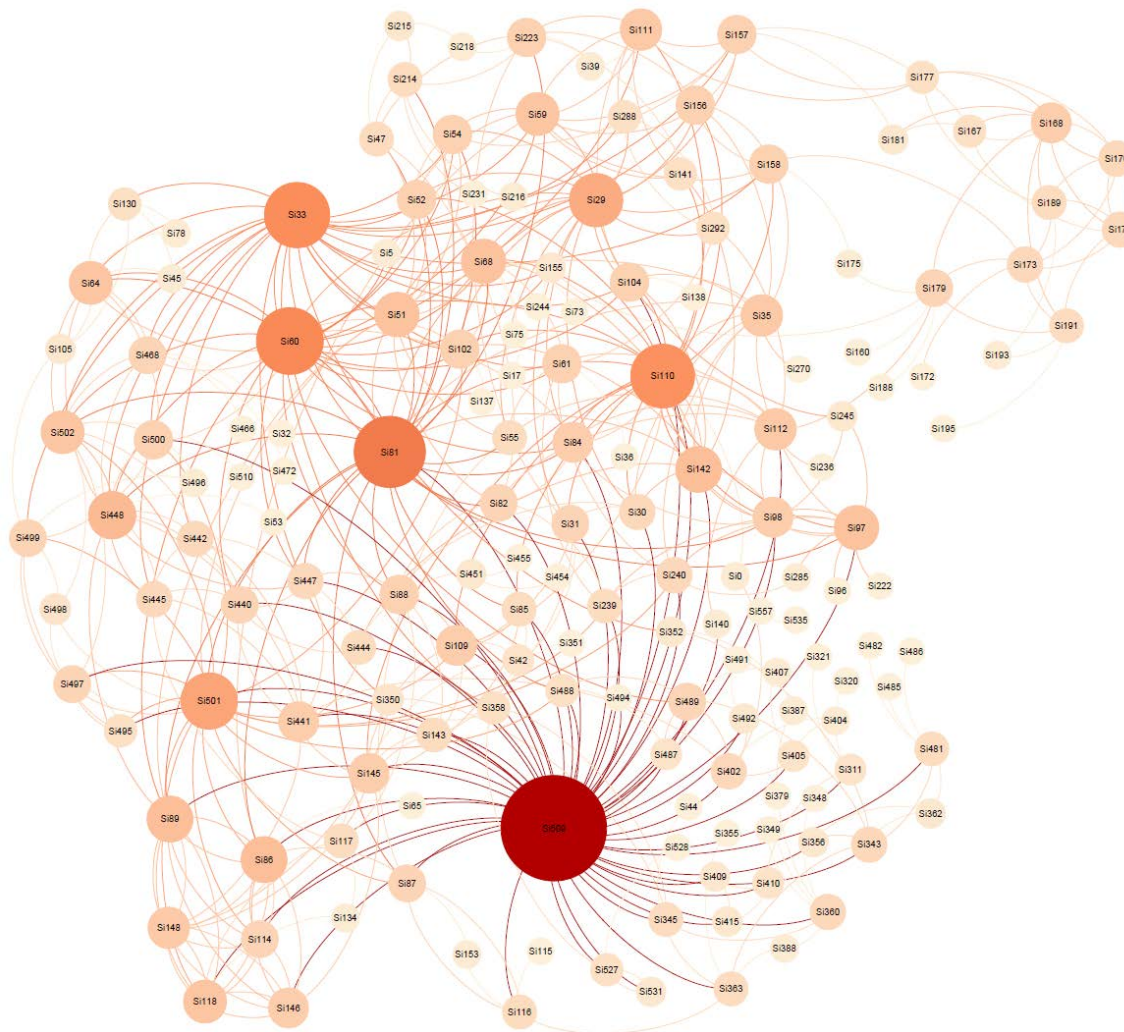
5686
substances
with at least
one carbon –
sulfur bond

914 sulfides, out
of which 23 have
no other
functionality

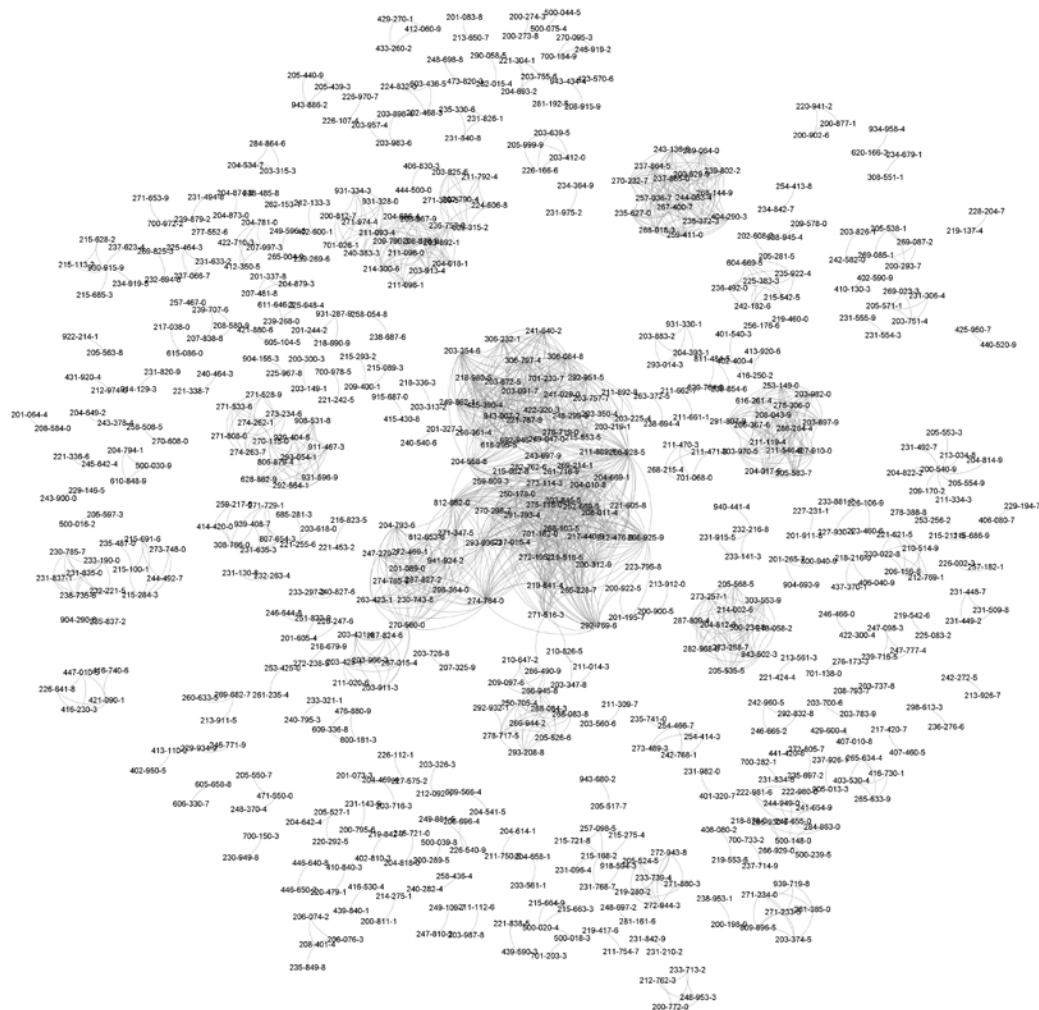


35 substances are
both
thiols/thiolates
and sulfides, out
of which 3 have
no other
functionality

Example of grouping by industry

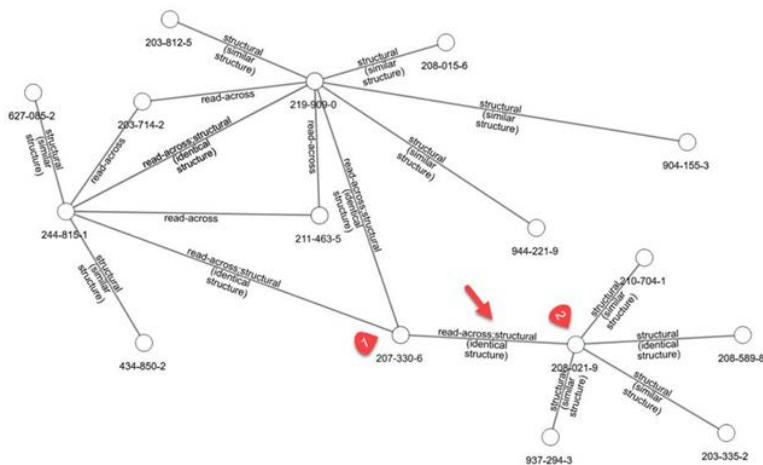


Groups in the grey zone



Forming groups for regulatory scrutiny

- First step is to identify a single substance or a set of related substances that will act as “seed”
- We have built an elaborate machinery that allows identifying all other substances that are related to the seed(s) through *associations* of various types
- Putative group members that are algorithmically identified are *manually* screened for their suitability for inclusion into the group
- We strive to start publishing these groups as soon as feasible, by end of 2020 a complete overview for the grey zone (>100tpa) should be available



Addressing the uncertain area

For most identified substances, action is already ongoing on it or a related substance, by grouping we:

- Bring consistency in how related substances are treated
- Target the right substance at the right time
- Pool which information may allow faster action – despite data gaps
- Increased predictability of authorities' actions
- Support informed substitutions, or avoid regrettable substitutions

We will address all the substances, taking the grouping and existing knowledge into account



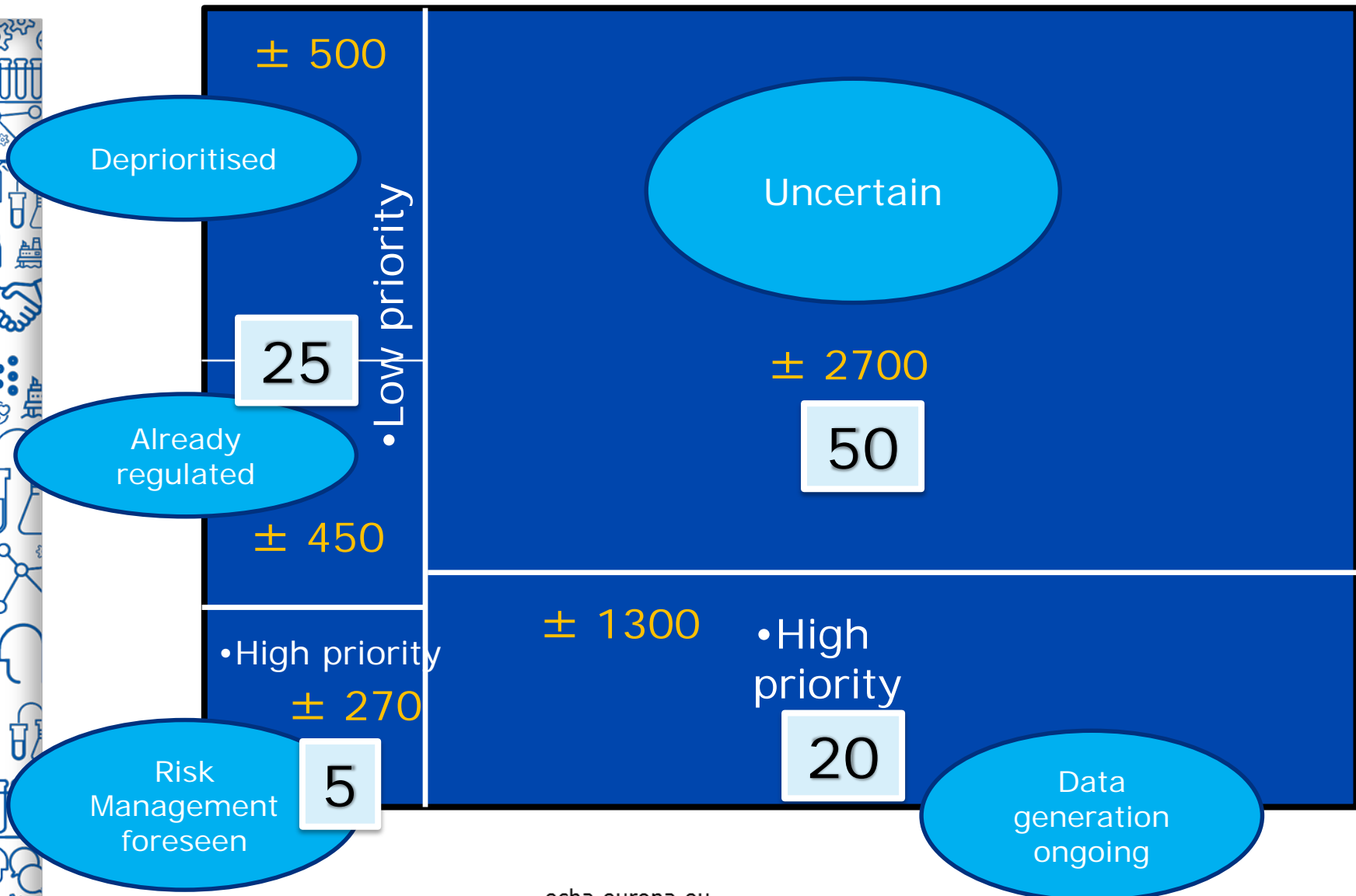
Your position in the chemical universe

...and how to be in a better place



Position in chemical universe – typical large company with 100 registrations

(Chemical universe of Annex IX and X substances as of May 2018)



Following up your chemicals

- **Volume** and **use** information remains relevant for our (prioritisation) approach
 - Updating use information and consequently updating your CSR is 'easier' using Chesar
- Where you have **waived** standard information requirements, it is very likely that work is needed to ensure compliance and safe use
 - Be pro-active and realise that improving waiver statements without additional data generation is hardly ever sufficient
 - Make sure that your company is aware of the increased pressures on the portfolio
 - Have the appropriate staff and funding available
- Grouping is one way to accelerate our work, but not the only one...



Thank you!

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