REACH – news and developments - ECHA's activities

CHÉMIA 2012
Safe Management of Chemicals

3-5 October 2012, Liptovský Ján, Slovakia

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Dissemination of registered substances

Foreseen updates

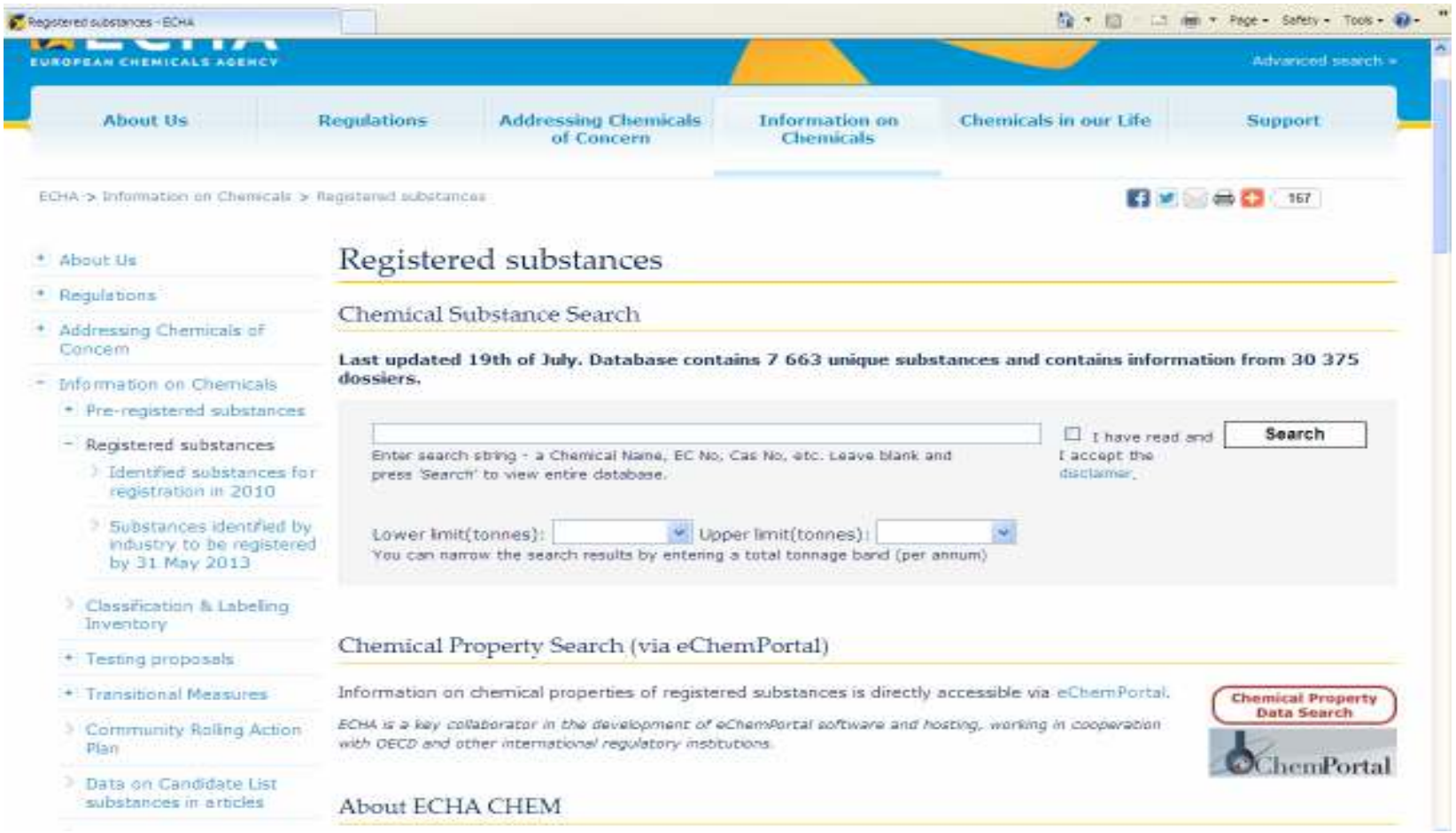
Dissemination of information on registered substances

- According to the REACH Regulation, ECHA has to provide public access to (non-confidential) information on registered substances (Art 119)
  - Accessible and useful also to countries outside the EU
- A dissemination website has been developed in 2010 and is continuously updated
- Other ECHA initiative: hosting the OECD Global Portal

Dissemination

- Search on properties of chemicals
(via OECD eChemPortal link given on ECHA website)

Portal attracts ca. 1500 visits per day



Developments on dissemination

- Increase availability of information
- Decision was taken to also publish (after a transitional period for registrants, i.e. 2012)
  - company name
  - registration number
  - outcome of PBT / vPvB assessment
- Assessment of confidentiality claims is ongoing and should be done in IUCLID 5.4
- The deadline to update confidentiality claims is **31 Oct 2012**
- ECHA will publish all SDS information that has not been claimed confidential (company name, registration number, etc)

Developments on dissemination

- Confidentiality claims for SDS were introduced with new version of IUCLID 5.4
- Fees will be charged for all confidentiality claims
- Use plug-in tools to check what will be disseminated
- Data Submission Manual 16: Confidentiality Claims: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals
- More information:
- http://echa.europa.eu/en/web/guest/view-article/-/journal_content/acde6540-cfbc-420c-b0cf-0b58485c7da9

Biocides Products Regulation

What are biocidal products?

- Biocidal products contain active substances and are used against harmful organisms (e.g. pests, bacteria) to protect human/animal health. For example:
- Estimated around 20,000 biocidal products on market (authorised in MS under national legislation)

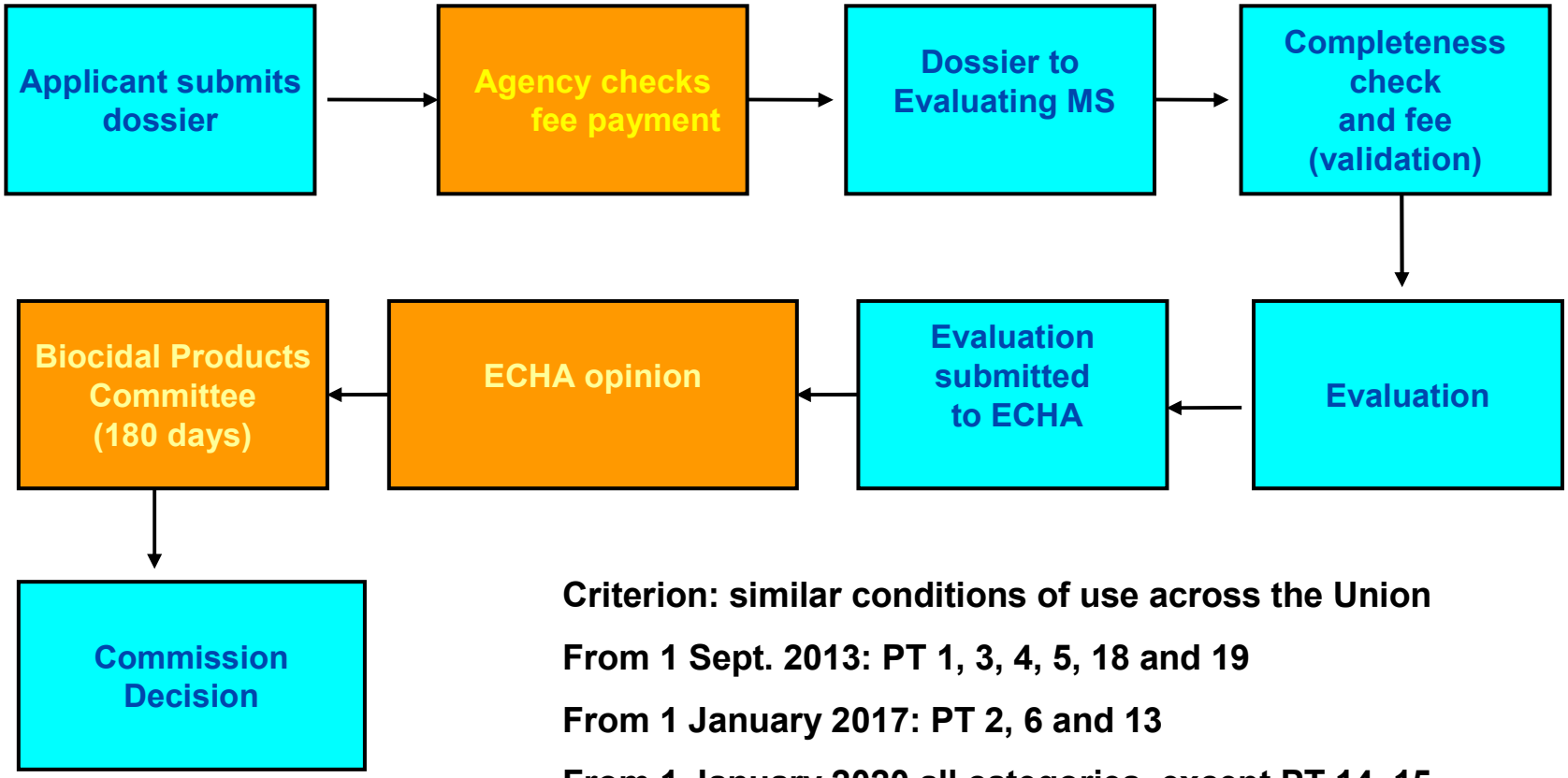
- Active substance = a substance or a micro-organism having an action on or against harmful organisms
- Active substances: around 275 allowed on the EU market

- The total number of opinions to be delivered by ECHA is expected to grow from 80 in 2014 to 300 in 2020

Directive 98/8/EC *vs.* Regulation 528/2012

- Directive 98/8/EC has 2 step approach:
  - Evaluation of the active substance at EU level
  - Product authorisation at MS level
- Regulation maintains 2 step approach but adds possibility for authorisation of biocidal products at EU level
- Other key elements of Regulation:
  - Improve functioning of national authorisations and mutual recognition (e.g. binding deadlines)
  - Reduce animal tests: obligatory data sharing
  - Strengthen rules on data waiving
  - Extend scope to cover articles/materials treated with biocidal products
  - Harmonised conditions/criteria for setting fees in all MS

ECHA and Union Authorisation



Criterion: similar conditions of use across the Union

From 1 Sept. 2013: PT 1, 3, 4, 5, 18 and 19

From 1 January 2017: PT 2, 6 and 13

From 1 January 2020 all categories, except PT 14, 15, 17, 20 and 21

Biocidal Products Regulation (BPR) 528/2012/EU

- Entry into force 17 July 2012, entry into operation 1 September 2013
- Requirement for competent authorities to provide advice to applicants and other interested parties on their responsibilities
- Competent authorities may establish a national helpdesk by 1 September 2013
  - National biocides helpdesks do not exist under the Biocidal Products Directive (98/8/EC)

- In accordance with Article 76 of the BPR, ECHA shall
  - provide technical and scientific guidance and tools for the application of BPR by the Commission and Member States' competent authorities
  - Provide support to national helpdesks

Authorisation

Substances of Very High Concern (SVHC)

- The **identification** of **SVHC** and its **inclusion** to the Candidate List is the first step of the authorisation procedure
- Member State Competent Authorities or ECHA, submit dossiers for the identification of SVHC in accordance with the REACH regulation, **Annex XV**.
- The Candidate List was open from the beginning and up to date contains 84 substances
- Substances in Articles
  - Notification requirement on Candidate List substances in articles is obligatory.
  - Importers, producers and OR of articles have to submit a notification to ECHA if a Candidate List substance is present in their articles above one tonne per year and in a concentration above 0.1% weight by weight.

http://echa.europa.eu

Authorisations

- Annex XIV
  - **First publication 21.02.2011** (EUR-Lex): "*The European Commission has published in the Official Journal the first list of six substances that are subject to authorisation. Without authorisation, their use must end after the specified "sunset date".*
  - The European Commission is responsible for taking decisions on applications for authorisations (grant authorisation for use)

- Up to date contains 14 substances
- Regularly updated by the European Commission
- Authorisation applications must be submitted to ECHA (within 18 month from the inclusion to the Annex XIV)

- http://echa.europa.eu/web/guest/regulations/reach/authorisation

http://echa.europa.eu

Authorisations application

- Annex XVI
  - Socio–economic analysis (financial, environmental, safety, impact, social values and other aspects).
  - The Agency's Risk Assessment Committee will consider each application and submit their opinion to the European Commission.
- A duly mandated OR of a non-EU manufacturer can apply for an authorisation.
  - *Data Submission Manual Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5* is being updated and will be published once the new version of IUCLID is released (summer 2012)
- Risk Assessment Committee assessing the risk of a substance to human health and/or the environment arising from those uses for which authorisation is being sought (Art. 64(4));
- The final decision will be taken by the European Commission.

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Data sharing matters

Recent developments

Campaign REACH 2013 – 2 Lists

- List of lead registrants
  (http://www.echa.europa.eu/web/guest/reach-2013)
  - LR nomination webform
    - voluntary – regular update in 2012
    - Substances for 2013 and for 2018, for which a LR was "nominated"
    - Name of the LR (where authorised) and whether substance is already registered (same or different LR)

Active Lead Registrants as of 28 Sep 2012

EC Number	Substance Name	Registration Deadline	LR is Candidate	LR Name (where ECHA authorised to disclose)	Registered by the LR	Registered by other than the LR

⊘ Information not provided

- LR for substances registered in 2010 → consult the list of registered substances

△ No legitimacy: ECHA does not endorse or reject the information submitted

Campaign REACH 2013 – 2 Lists

- List of substances intended to be registered by 2013 (http://www.echa.europa.eu/web/guest/information-on-chemicals)
  - ECHA Surveys (end 2011) + LR list – monthly update in 2012

✓Information given

- Substances for which one pre-registrant indicated intention to register in 2013
- LR known to ECHA and whether substance is already registered (intermediate/ full)

Substances Identified for 2013 Registration 2 573

NB: Substances which were registered by the 2010 REACH registration deadline (ie before 30 November 2010) are not in this list. *Such substances appear in the Registered substances section of the ECHA website (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances), unless the IUPAC name is claimed confidential.*

EC No	CAS RN	Name	Lead Registrant	Registered
			LR known to ECHA	-
			LR known to ECHA	-
			-	-

⃠Information not provided

- Name of LR → consult the list of LR nominations

△Number of 2013 LR different from 2013 LR list: input from survey

How to facilitate contact between (pre)-registrants

- Contact form will be available from mid October
- Would cover several scenarios given that pre-requisites are fulfilled:
  - If LR nominated himself and agreed to disclose his name
  - If LR nominated himself and did not agreed to disclose his name
- From November names of the existing registrants will be published (unless claimed confidential)
- Be compliant with Data Sharing obligations - Art 11, Art 29(3)

Inquiry process

What is inquiry?

- The word:
  - "An act of asking for information"
- The REACH process:
  - Is also the act of asking for information, but in accordance with Article 26 (1) of the REACH Regulation

- Inquiry should be made by:
  - A potential registrant of a non-phase-in substance
  - A potential registrant of a phase-in substance who has not pre-registered
  - A manufacturer or importer of a substance who had a notification under Directive 67/548/EEC and reaches the next tonnage threshold

How much and how long to process?

- Fee free
- No specified deadlines in the legal text for how long for ECHA to process an inquiry
- We aim to do this as quickly as possible
- Low quality of incoming inquiries still an issue. New and improved Q&A as well as a support IT tool (TCC plug-in) provided to help the inquirers

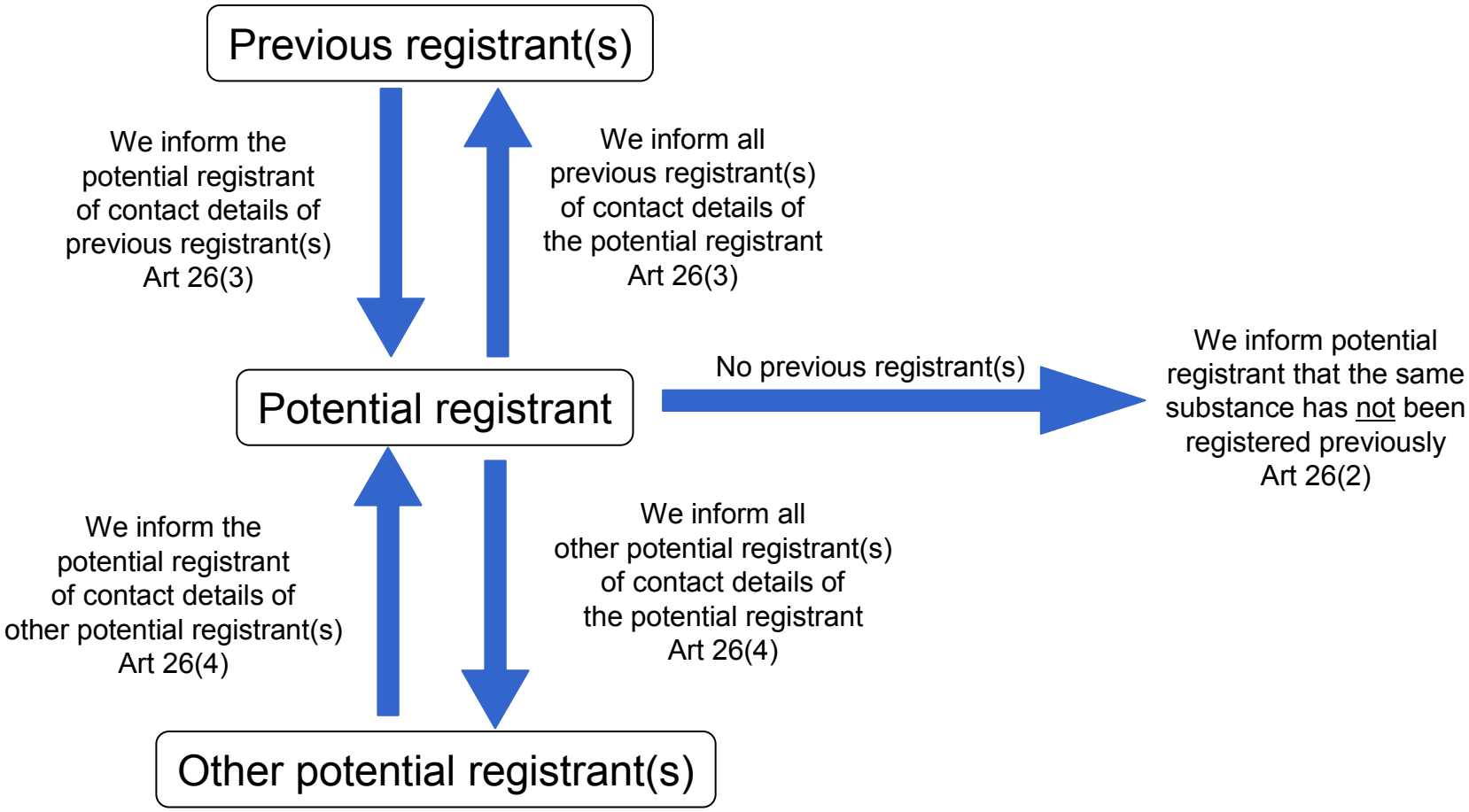
Improvements in the inquiry process

- New REACH-IT version to be launched in November
- New version will offer an enhanced system for processing inquiries
- ECHA will no longer send the contact details in a paper version
- Two weeks ahead of the release inquiries will not be processed
- Improved TCC plug-in tool will be available to increase overall quality prior to submission
- New release will not affect the main requirements to prepare and submit inquiry dossiers

Main pitfalls

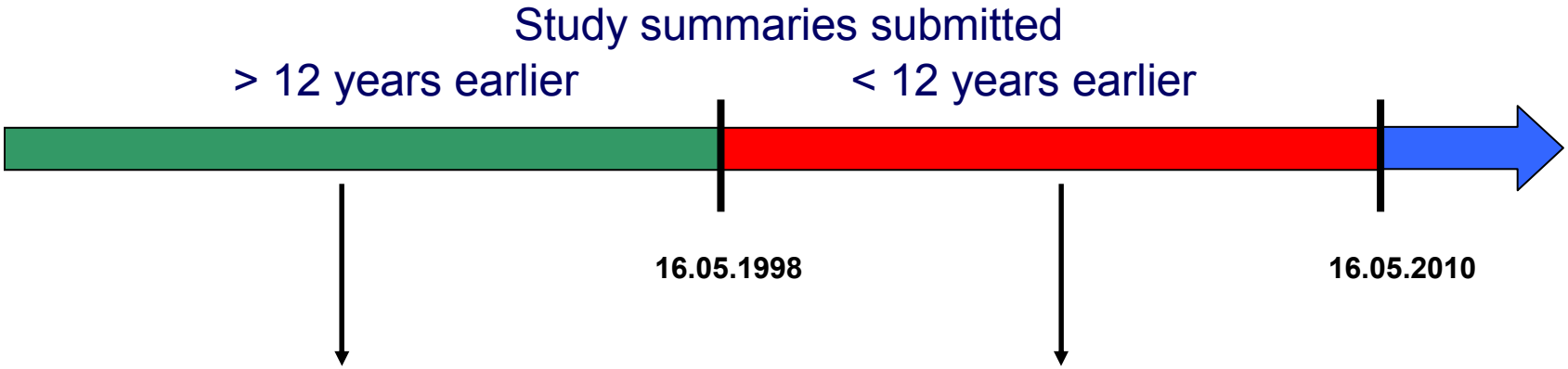
- Quality of inquiry remains low, leading to about 50% rejection rate. Common problems:
  - Inconsistencies in the information provided
  - Failure to provide sufficient information to enable the substance to be identified
  - Absence of spectral data – no justification
  - Absence of chromatographic data – no justification
  - Absence of a description of the methods used to identify the substance
  - More than one substance being inquired about
  - Submitted spectral data is for a different substance
  - Counter-ion in salt substance is not identified
  - Counter-ion is not quantified
  - Stereo-chemistry not accounted for

What are our obligations?



What are our obligations?

We provide a list of studies to the potential registrant available to ECHA
Art 26(3)



Potential registrant should request study summaries from ECHA
and
Make use without paying any financial compensation to the previous registrant.
Art 25(3)

Potential registrant should request study summaries from previous registrant
and
Make every effort to reach an agreement on the sharing of this information and associated costs.
Art 27(2)

Studies involving vertebrate animals shall not be repeated!

Enforcement

REACH Enforcement – Task of the Member States

- **According to the REACH Regulation:**
- Member States appoint competent authorities which are responsible for enforcement
- Authorities ensure that substances and mixtures are not placed on the market unless they are pre-registered or registered in accordance with the REACH Regulation
- Check whether registration requirements of the REACH Regulation are met.
- Apply required sanctions in case of non-compliance with REACH (developed on national level).

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REACH Enforcement: role of ECHA

- Forum for Exchange of Information on Enforcement (Forum) coordinates a network of Member State authorities responsible for enforcement, and has the tasks to:
  - Spread good practice and highlight problems at Community level
  - Propose, coordinate and evaluate harmonised enforcement projects and joint inspections
  - Coordinate exchange of inspectors
  - Identify enforcement strategies, as well as best practice in enforcement
  - Develop working methods and tools of use to local inspectors
  - Liaise with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations,
  - Examine proposals for restrictions with a view to advising on enforceability (Art.77(4))
  - Agree common issues to be covered in the annual reports from the Member States in relation to enforcement (Art. 127).

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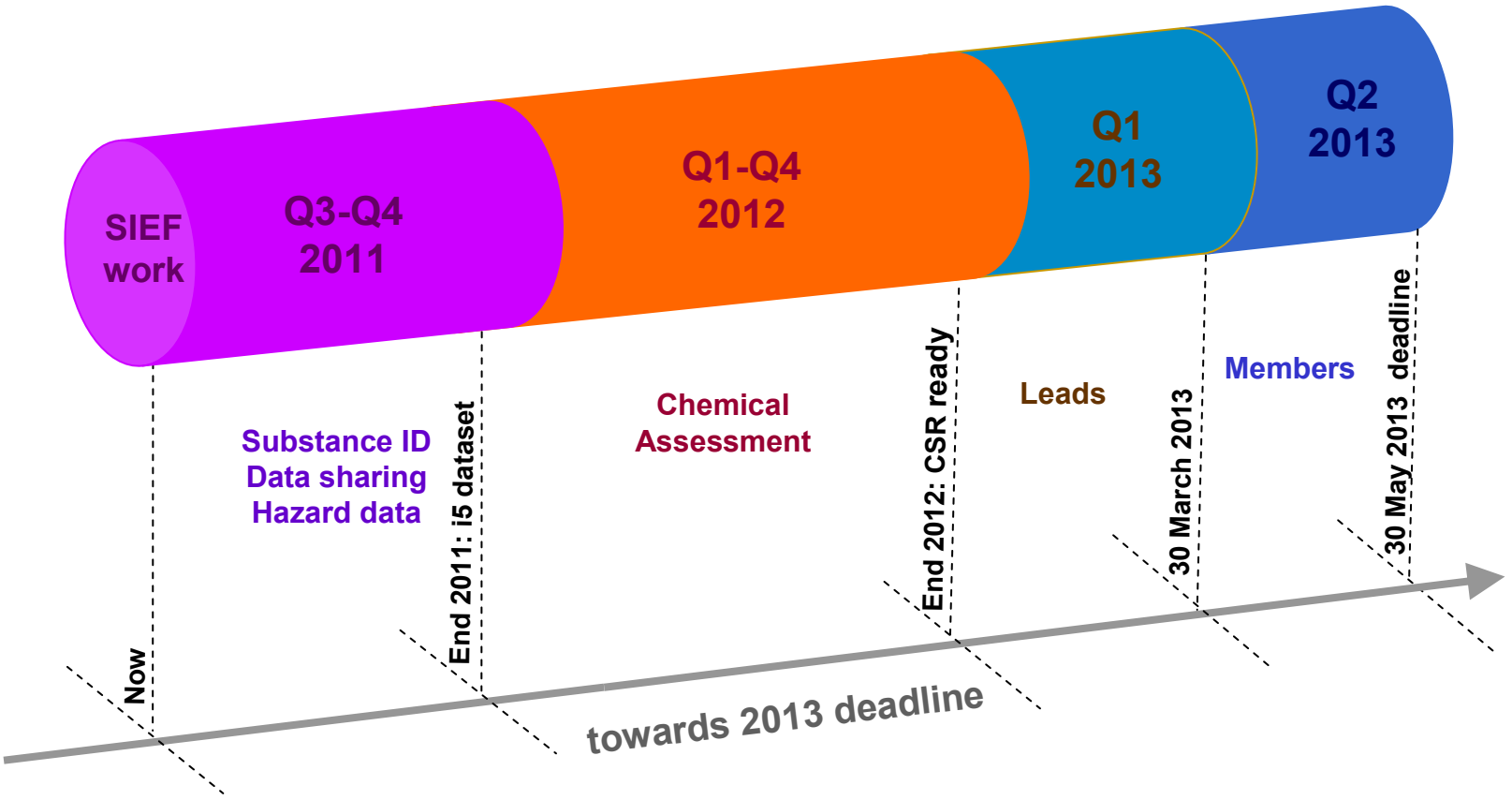
REACH Campaign 2013

Important to know

- Check if your substance is already registered on ECHA website or with Industry organisations
- Less data requirements than for 2010 deadline: cost sharing only for data needed for your tonnage band
- If your substance is not registered:
  - Create/join the SIEF immediately and start discussion on substance sameness and data sharing
  - Refer to Industry organisations to get advice on advice, model agreements and standard letters to manage the SIEF
  - Nominate/find the Lead registrant and make sure that he is known from ECHA to benefit from special services and create transparency for other market players

Countdown: optimal situation



2010 Lead Registrants

- You hold obligations to the next registrants wishing to register the same substance as you
  - You remain Lead of the joint submission beyond 1 June 2018
  - Inform (pre-)SIEF members of your existence
  - Ensure that data sharing conditions are fair, transparent and non discriminatory
  - Newcomers only required to share costs of data needed for their tonnage band: **Annex 10 not required**
  - You will need to distribute the tokens to new registrants
  - Document your communications with the SIEF

2013 Registrants

- Is your substance already registered?
  - ECHA website:
    - http://apps.echa.europa.eu/registered/registered-sub.aspx
    - Some substances may not appear on the list, if the registrant has requested confidentiality on the name
  - Verify within SIEF or industry associations
  - Contact the Lead Registrant
  - Verify whether you have the same substance
  - Start data sharing negotiations
  - Ask for your token to join the "joint submission"

2013 Registrants

- Your substance is not registered yet
  - Most of 2013 SIEFs already exist, the Lead may have been nominated already
    - Verify on ECHA website or with industry associations
  - If not, start the process of SIEF formation
    - Verify whether a SIEF Formation Facilitator (SFF) exists for your substance in REACH-IT (nb. some poor experiences in this area)
    - If not, contact pre-SIEF members to identify those registering in 2013

New Lead Registrants

- Nominate yourselves to ECHA to benefit from special services, e.g. webinars https://comments.echa.europa.eu/Comments/LeadRegistrantNomination.aspx
- Inform the supply chain that your SIEF is functioning and your substance will be registered

Practical recommendations

- Make sure you are aware of all tools and guidance available
  - Some tools are critical to the success of your submission: IUCLID 5, Technical completeness check, fee calculator, & dissemination tools (http://www.iuclid.eu/)
  - Use Chesar for your chemical safety assessment and your CSR (http://chesar.echa.europa.eu/)
  - Dossier submission (http://echa.europa.eu/reachit_en.asp)
  - Data submission manuals (http://echa.europa.eu/reachit/dsm_en.asp)
  - Understanding of the dossier processing by ECHA (http://echa.europa.eu/reachit/dossier_processing_en.asp)

Important events

Interesting upcoming events

- Second Lead Registrant Workshop – 11-12 October 2012
  - http://echa.europa.eu/web/guest/view-article/-/journal_content/2b6c9ef3-b8c8-4ee1-a15d-bee72a3b47ea
- Webinars for the LR registrants of 2013
  - Dissemination and confidentiality claims 6 September 2012
  - General principles of dossier preparation and submission 19 October 2012
  - Registration process I: Business rules 9 November 2012
  - Registration process II: Technical completeness check + Invoicing and payment 22 November 2012
  - http://echa.europa.eu/en/support/training-material/webinars
- Series of webinars for all potential registarnts
- Stakeholder Day (March 2013) will also address Biocides

Thank You.

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