(Re-)Applications for Authorisation of hexavalent chromium

FME/ION/Metaalunie workshop
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Outlook

- REACH Authorisation process
- Experiences from chromate applications
- ECHA's view on the PANTEIA study
- Some remarks on re-applying
- Take home messages

Key elements of REACH

Registration	• Substances manufactured and imported into the EEA are registered with ECHA • Information for safe use is communicated within the supply chain
Evaluation	• Examination of registrant testing proposals • Compliance check of registration dossiers • Evaluation of substances
Regulatory Risk Management	• **Authorisation** • Restriction • Harmonised classification and labelling

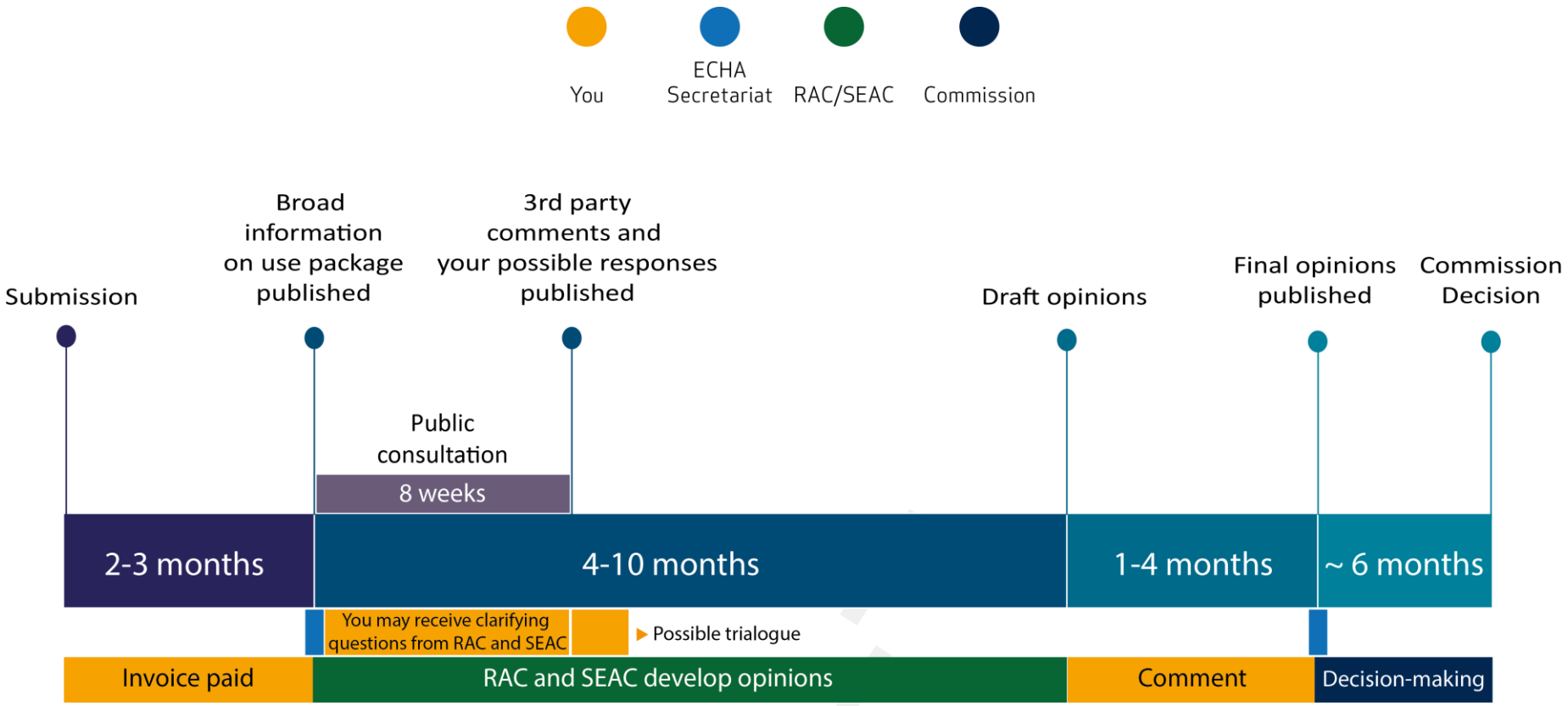
REACH Authorisation title

- Aim is to:
  - use **S**ubstances of **V**ery **H**igh **C**oncern as safely as possible
  - progressively replace SVHC by suitable alternatives
  - guarantee the good functioning of the EU internal market
- After "sunset date", non-exempted uses of SVHC on the "Authorisation List" require authorisation.
- Idea: Authorisation raises awareness of a substance's profile and helps promoting safe use and substitution.

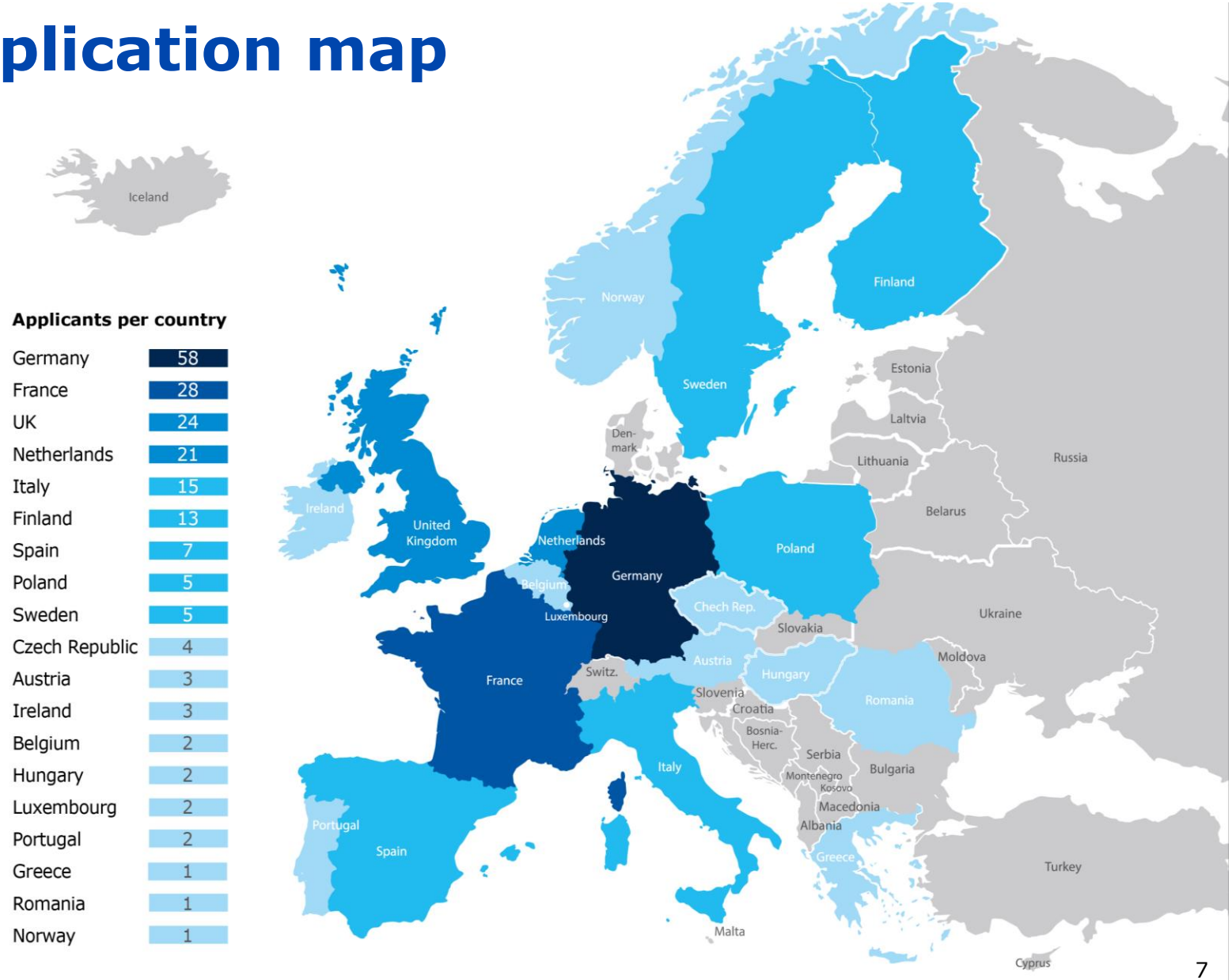
Application process: What ECHA strives for

- Well focused, business-friendly application process:
  - substitution should take place where suitable
  - application effort should be “fit for purpose”
- Appropriate scrutiny of applications:
  - We aim at competent & fast processing of applications
  - We provide clear & well-justified opinions
- Trust among all actors involved:
  - We run a fair & transparent process, which is open to scrutiny by all stakeholders
  - We provide guidance (PSIS, Practical Guide,…)

Application timeline: About 2 year cycle



Application map



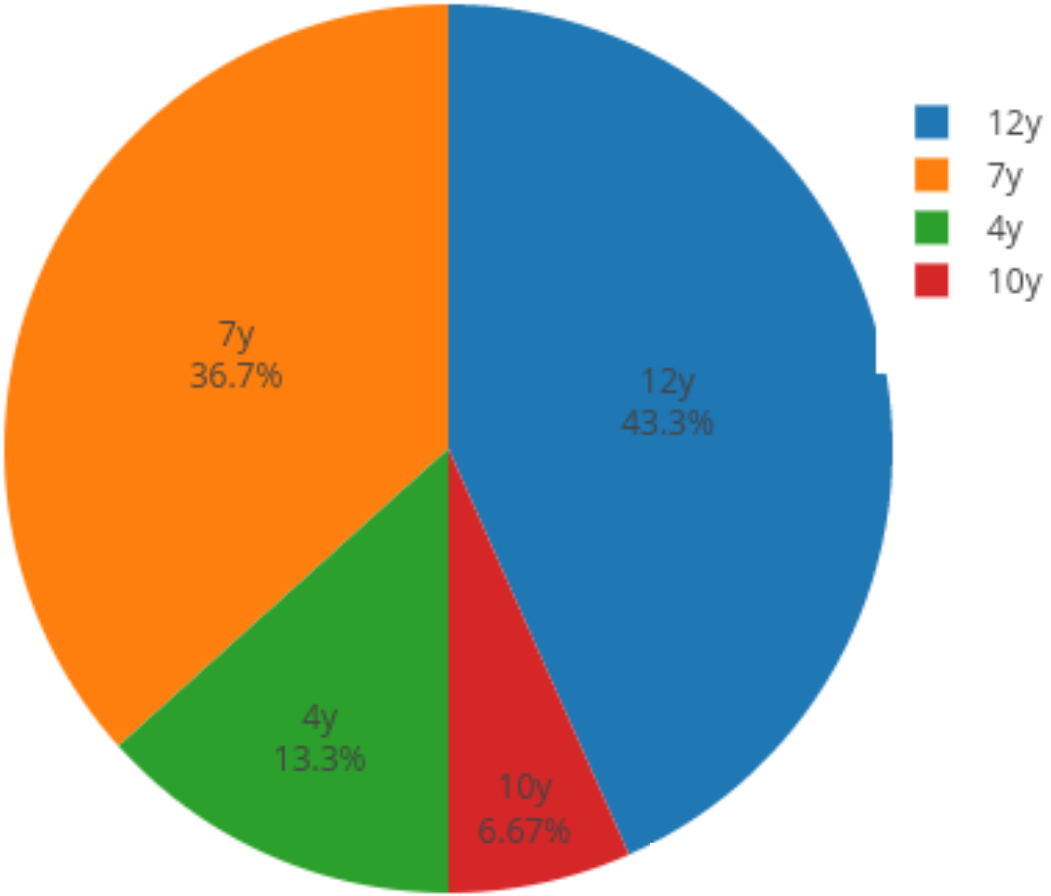
Applicants per country

Germany	58
France	28
UK	24
Netherlands	21
Italy	15
Finland	13
Spain	7
Poland	5
Sweden	5
Czech Republic	4
Austria	3
Ireland	3
Belgium	2
Hungary	2
Luxembourg	2
Portugal	2
Greece	1
Romania	1
Norway	1

Chromate applications

- So far, **57** AfAs for Cr6-compounds received
- **92** uses by **123** different applicants
- Coverage of **~20 000** tonnes of Cr6 compounds in scope of the authorisation requirements per year
- ECHA committees have sent opinions for **~30** uses to the European Commission
- So far, only **one** opinion on a Cr6 upstream application sent to the Commission, **four** more in the making.
- By implication **>50** downstream user applications, many of them obtaining **12 yr** review period!

Chromates—review periods



Chromates—when 4yr review period?

- **4 yr** review period recommended for **four** uses only
- Deficiencies in the application documents:
  - Descriptions of operating conditions and risk management measures too vague
  - AoA unfocussed, ignoring alternatives and economic feasibility assessment
  - SEA did not clearly state what would likely happen when RP is 0, 4 or 7 yrs
- This point relates directly to PANTEIA study!

PANTEIA study (1)

- Interesting study, many pieces of useful information
- ECHA does agree with some of the results, but
- we have **strong reservations** about the conclusions.
- Our main issues with the study:
  - Impacts overestimated—to our reading the possibility of re-applying was not really taken into account
  - Shutdown decisions—did you take into account the response of your competitors/customers/market?
  - Review period of 12y would result in no problems—why?

PANTEIA study (2)

- Dutch platers are covered by CTAC sub, i.e. **7 yrs** for chrome plating and **4 yrs** for decorative plating.
- How many of you intend to shut down because of this?
- At least part of any negative impact is due to weak application strategy (lack of information).
- Relatively small additional investment could have resulted in less uncertainty and longer review periods.
- What about Carcinogens/Mutagens at work directive or the suggested Cr6 OEL of 1 µg/m³? Don't they pose similar problems than REACH authorisation?

Cry wolf

- PANTEIA study stresses uncertainty as prime reason for shutdown and relocation. Who creates this uncertainty?
- ECHA has always emphasised possibility of re-applying.
- Is EU chrome sector helping to create this uncertainty by emphasising how bad authorisation system is?
- What you could do:
  - do not waste time focussing on the outcome of the previous upstream application, instead
  - take stock & analyse learnings from 1st round of authorisations
  - prepare a more focused and better argued review report

Some remarks about re-applying

- In ECHA's opinion, re-applications are **NOT** meant to be a big drag.
- Authorisation should be seen as a **permit** that needs to be renewed every now and then.
- For that, authorisation holders are required to submit:
  - their authorisation number
  - an updated AoA including information on R&D activity
  - if a suitable alternative was found, a substitution plan
  - if other elements of their original application had changed, an update of these elements

Some remarks about substitution

- On 25 Jan, ECHA will co-organise workshop of Finnish chrome sector on innovation in surface treatment
- Goal: promote long-term substitution of Cr6 in plating
- Job platers, customers, providers of alternatives and funding agencies to meet in person and exchange
- Pilot workshop that could be repeated in other EU-countries and with other SVHC and industrial sectors
- ECHA would be happy to support your associations in organising something similar!

Take home message from ECHA

- **Authorisation can be renewed!**
- Application costs should not be a showstopper:
  - Application effort and costs have gone down by ~40%
  - Average review period for Cr6 applications has been ~9y
  - Re-application cost depends on quality of original application
- Application process has had visible impacts
  - Control of exposures to SVHC have improved
  - Safer alternatives have been developed and start to be adopted
- ECHA engages with applicants to improve the process.

Take home message for ECHA

- What do you want me to take home from this meeting?

Back up

Remember, ECHA offers extensive support

- Guidance documents, Q&As, instructions and user manuals, available at: http://echa.europa.eu/applying-for-authorisation
- Pre-submission information sessions for prospective applicants and other seminars/workshops
- Specific help to small and medium sized companies: http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes
- Information on how RAC/SEAC deal with applications w.r.t review period, economic feasibility, dose-response, confidentiality, etc.

  https://echa.europa.eu/applying-for-authorisation/evaluating-applications

Substitution workshop background

- ECHA tries to find ways to support substitution of hazardous alternatives
- E.g. Scoping study performed by Prof. Joel Tickner (U. Massachusetts Lowell) - findings include:
  - Building support for grant mechanisms/private-public partnerships funds to invest in the innovation research
  - Build support for structures providing technical support for SMEs for evaluation and adoption of alternatives
  - Create mechanisms for supply chain collaboration and engagement, including shared performance testing and evaluation, and demonstration sites.

Key messages from RAC

- Provide clear descriptions that illustrate the process and the worker activities covered in the exposure scenarios
- RAC has a strong preference for measured data
  - Supplement limited measured data with modelled values
  - Include contextual information alongside monitoring data and all input parameters for modelling
- Describe all RMM in place to control/minimise exposure
  - OC/RMM (technical, organisational, PPE in appropriate depths)
- When applying for downstream users':
  - Representative data is needed to cover the scale, process, technology and the diverse RMMs in place
  - Explain how the data provided adequately represents the expected variability in exposure and address potential uncertainties

Key messages from SEAC

- Describe your substitution efforts to substantiate the need for a particular review period
  - Impacts should be analysed from society's perspective
  - Lost business of one actor might be the gain of another
- Be clear about data sources, assumptions and methodology
  - SEAC should be able to trace data and reproduce the results
- Focus on demonstrating that the benefits of continued use outweigh the risks
  - The lower and more certain the health and environmental impacts of continued use are, the less effort is required when estimating the costs of the non-use scenario