Taking stock of received, processed and granted applications

Lessons learnt on Application for Authorisation

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Thierry Nicot
Risk Management Implementation Unit
ECHA
With the kind support of Philipp Hennig, Vassilis Kouloumpos and Elina Liopa

Outline

- Overview of received applications
- Lessons learnt from the first dossiers
- Maintain efficiency / areas for improvements
- Take home messages

Overview of received applications

28 applications (56 uses) to date

Broad information on use, comments and responses published

Final opinions published

Commission Decision

Submission

PSIS 6-9 months earlier

Applicant can comment

Draft opinions

Final opinions

Public consultation

Trialogue

2-3 months

8 weeks

max 10 months

1-4 months

~ 6 months

Invoice paid

RAC and SEAC develop opinions

100?

1(1)

12 (17)

13 (36)

2 (2)

Statistics

Substance	Number of received AfAs (applicants)	Number of uses	RAC/SEAC opinions	Commission decisions
			Per use and applicant	
DEHP	**5** (7)	10	11	1
DBP	**2** (2)	4	4	1
[DEHP + DBP]	**1** (1)	3	3	-
Lead chromate Yellow + Red	**1** (1)	12	12	-
HBCDD	**1** (13)	2	26	-
Diarsenic trioxide	**4** (4)	5	5	-
Trichloroethylene	**13** (15)	19	2	-
Lead chromate	**1**(1)	1	-	-
Total	**28** (44)	**56**	**63**	**2**

Outcome of the RAC/SEAC opinions

Substance (Applicant)	Type of applicant (M, I, OR, DU)	Scope (uses and number of DUs covered)	Reasoning (Adequate control vs non-threshold)	Bridging AfA	Review period in years proposed by RAC/SEAC	Additional Conditions proposed by RAC/SEAC
DEHP (Rolls-Royce)	I	Very narrow	AC demonstrated	Bridging AfA	7	No
DEHP (Arkema, Azoty, Deza)	M (virgin)	Very large	AC not demonstrated	-	4; 4	No
DEHP (Vinyloop…)	M (recycled)	Large	AC not demonstrated	-	7; 7	Yes
[DEHP+DBP] (Roxell)	DU	Narrow	AC demonstrated	Bridging AfA	4; 4; 4	No
DBP (Sasol)	DU	Very narrow	AC demonstrated	-	12	No
DBP (Deza)	M	Narrow	AC demonstrated	-	12; 12; 4	No
HBCDD (Ineos…)	DUs (formulators)	Large	Non-Threshold	Bridging AfA	2; 2	Yes
Pb/Cr pigments (DCC)	OR	Medium/Large	Non-Threshold	-	7 (for 4 uses) 12 (for 8 uses)	Yes

Outcome of the RAC/SEAC opinions

Substance (Applicant)	Type of applicant (M, I, OR, DU)	Scope (uses and number of DUs covered)	Reasoning (Adequate control vs non-threshold)	Bridging AfA?	Review period in years proposed by RAC/SEAC	Additional Conditions proposed by RAC/SECA
As2O3 (Linxens)	DU	Very narrow	Non-Threshold	Bridging AfA	7	No
As2O3 (Boliden)	DU	Very narrow	Non-Threshold	-	12	Yes
As2O3 (Nordenhamer)	DU	Very narrow	Non-Threshold	-	12	Yes
As2O3 (Yara)	DU	Very narrow	Non-Threshold	Bridging AfA	22 months	Yes
TCE (Wlisco)	DU	Very narrow	Non-Threshold	Bridging AfA	12	No
TCE (12 AfAs)	2 by M 10 by DUs	Very narrow to Large	Non-Threshold	Under evaluation by RAC and SEAC		
Lead Chromate	DU	Very specific	Non-Threshold	Under evaluation by RAC and SEAC		

Lessons learnt from the first dossiers

Application costs

- 24 responses (submissions between 05/2013 and 10/2014)
- Average cost of preparing an application (per applicant/use): approx. 230,000 €
  - Includes consulting fees, expenses, application fee and internal staff time multiplied by monthly tariff (8,000 €)
  - Approx. half of the total cost accounted for by consulting fees (application fee: 15% of total cost)
- Trend indicates declining costs
  - Average cost of AfAs submitted in 2nd half of 2014: <200,000 € per applicant/use
- 60% of the total cost driven by assessment reports
  - Relative effort: AoA: 40%, SEA: 35%, CSR: 20%

Pre-submission phase

- **Notifications to submit/PSIS since 2012:**
  - **186 notifications**
    - All 'current applicants' have notified ECHA
    - All notifications accompanied by a PSIS request
  - **24 PSISs**: useful for applicants and ECHA
    - Almost all applicants asked for it
    - Very positive feedback
  - Very useful for ECHA-Secretariat and Committees to plan the work → ECHA will maintain notification/PSIS process

Submission phase

- **Submission windows**
  - Almost all applicants submitted within windows
  - ECHA has been flexible in some specific cases
- **Business rules are not a show stopper**
  - 2-3 technical issues solved very quickly
- **Conformity check**
  - All applications were in conformity (legal check not a quality check)
- **Invoices**
  - All paid on time

Public consultations

- **Broad information on Uses** 
  - Lot of CBI in the first AfAs 
    - 1 Access To Documents (ATD) request
    - situation has improved a lot (new AoA/SEA formats) 

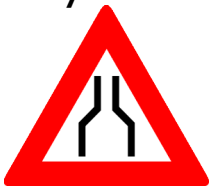
- **Public consultations**
  - Large variety of comments: 
    - from 0 to 400 per application
    - RAC vs SEAC topics
    - 'quality' and relevance
    - submitted by competitors, DUs, authorities/universities, NGOs… from EU, USA, Japan…
  - Novelty
    - comments were made public already during the consultation
    - possibility for applicants to respond

Opinion making

- **Questions to applicants from RAC/SEAC**
  - All applicants have received questions from RAC/SEAC
  - Applicants worked hard to provide answers on time
  - Workload is high!

- **Trialogues**
  - **13** organised so far
  - Very useful both from RAC and SEAC perspectives
  - Not organised if AfA is clear and rapporteurs didn't see the need (first round of Q&As already did the job)

Responses to PC's comments + Q&As + trialogues → heavy traffic and short deadlines !!!!



Opinion making

- **Plenaries**
  - All of them in observed sessions
  - Draft opinions agreed between month 4 and 10 (Average 7.1m/AfA)
- **RAC**
  - Large variety of exposure assessments by applicants: (combinations of) modelling, air measurements, bio-monitoring
  - Strong preference from RAC for measured data
  - Short review periods and/or additional conditions used by RAC to address uncertainties with review process firmly in mind
- **SEAC**
  - Overall applicants have done a thorough job in AoA and SEA… with some shortcomings
  - Short review periods and additional conditions also used
- Both Committees have learned quickly to evaluate AfAs

Opinion making

- **Draft opinions commented by applicants**
  - ECHA aims at having clear draft opinions that don't need to be re-discussed in RAC/SEAC
  - Some applicants had 'minor comments' but didn't send them: market certainty was more important
  - Only one comment by Deza triggered a new evaluation by RAC/SEAC

Decision making

- 2 decisions (DEHP, DBP): Rolls-Royce and Sasol Huntsman
- Discussions about the readibility and enforceability of the conditions (OCs and RMMs)

Substitution

- Substitution is taking place but all substitution activities not visible through the AfA process
  - ~ 50% of substances in Annex XIV with passed LAD → no AfA received by ECHA
- Bridging applications vs long term use
  - ~ 50% of the received AfAs = bridging applications
- ECHA is willing to further work on, promote and monitor/analyse substitution activities
  - Website, Webinars, OECD working group …

Maintain efficiency / areas for improvements

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- **Applicants' feedback**
  - Positive feedback about applicants' experience with ECHA's support mechanisms
    - ECHA staff, PSIS, AfA guidance, workshops/seminars, IT tools…
  - Causes of effort and difficulty in the AfA process identified
    - lack of in-house expertise
    - time and efforts to communicate strategies to customers/stakeholders
    - unpredictability in receiving an authorisation and about the review period

Maintain efficiency / areas for improvements

- **What ECHA has already done**

  - Formats – IT Tools
    - more transparency with the blanking out approach (90/10 ratio)…
    - … more clarity with the combined format for AoA/SEA
    - clearer format for the opinion and justifications
    - pre-configured IUCLID 5 for AfA (pre-filled substance datasets)
    - http://echa.europa.eu/view-article/-/journal_content/title/preconfigured-iuclid-5-available-for-applications-for-authorisation

  - How AfAs are evaluated by RAC and SEAC
    - common approach paper
    - derivation of DNELs/Dose Response Relationships
    - economic feasibility
    - review periods

  - Communication with applicants
    - Personal contact and interaction with the Authorisation team

Maintain efficiency / areas for improvements

- **What ECHA will (continue to) do**
  - Provide additional capacity building
    - To applicants: update of technical guides, best practices etc
    - To RAC/SEAC:
      - derive DNELs/DRRs,
      - specific training on technical/scientific topics as necessary
      - further clarification/definition of the RAC and SEAC interfaces (suitability of alternatives, residual risks, review periods)
      - ensure consistency/ alignment of opinions across AfAs
    - To ECHA-Secretariat staff
      - internal training
      - streamlining of the working procedures/IQMS
    - To the COM, NEAs
      - provide support in the decision making process and to further clarify the scopes of the exemptions

Downstream Users notifications (Art.66)

in brief

- Follows granting of an authorisation
- Requirement for DUs relying on authorisation up the supply chain
- DUs to notify within 3 months of first supply of substance
- ECHA to grant access to national authorities

status

- ECHA has started preparations – webform online in Q2 2015
- Discussion with stakeholders ongoing

open issues

- Submission interface:
  - language(s)
  - information to be requested
  - keeping information up-to-date
- Dissemination of information received:
  - Public registry?
  - To authorisation holder on DU consent? (e.g. to improve communication in supply chains about exposures, substitution activities, in the context of review reports)

Take home messages

Take home messages

- The AfA process works!
- Apply with confidence and be transparent
  - Give sources clearly!
- AfA process had visible positive impacts (better control of exposures at applicants' workplaces, speed up the implementation of safer alternatives)
- We all have gained a lot of experience
- Still on the learning curve but everyone has passed the watershed
- We think it is working well… but have we missed something?

Thank You!