The Biocidal Products Regulation

Key Commission Issues & Next Steps

2 April 2015
Steptoe Seminar
Product Defense for REACH & Biocides
Annual Chemicals Regulation Seminar

Pierre Choraine
European Commission
DG SANTE, Unit E.3

Introduction

- Substance approval
- In-situ generated active substances
- Article 95
- Product authorisation
- Treated articles
- Implementing legislation and guidance documents

Approval of active substances

- Review Regulation
  - Taking over of non-supported nanomaterial forms of existing active substances, of QUATs, of AS/PT combinations in part 2 of Annex II, of PT re-definitions of former food and feed derogation
  - Be aware of deadlines
- BPC opinions
  - Need to establish exclusion and substitution criteria before BPC
  - Discussion on treated articles provisions
- In-situ generated active substances
  - Clarification now available

In-situ generated active substances

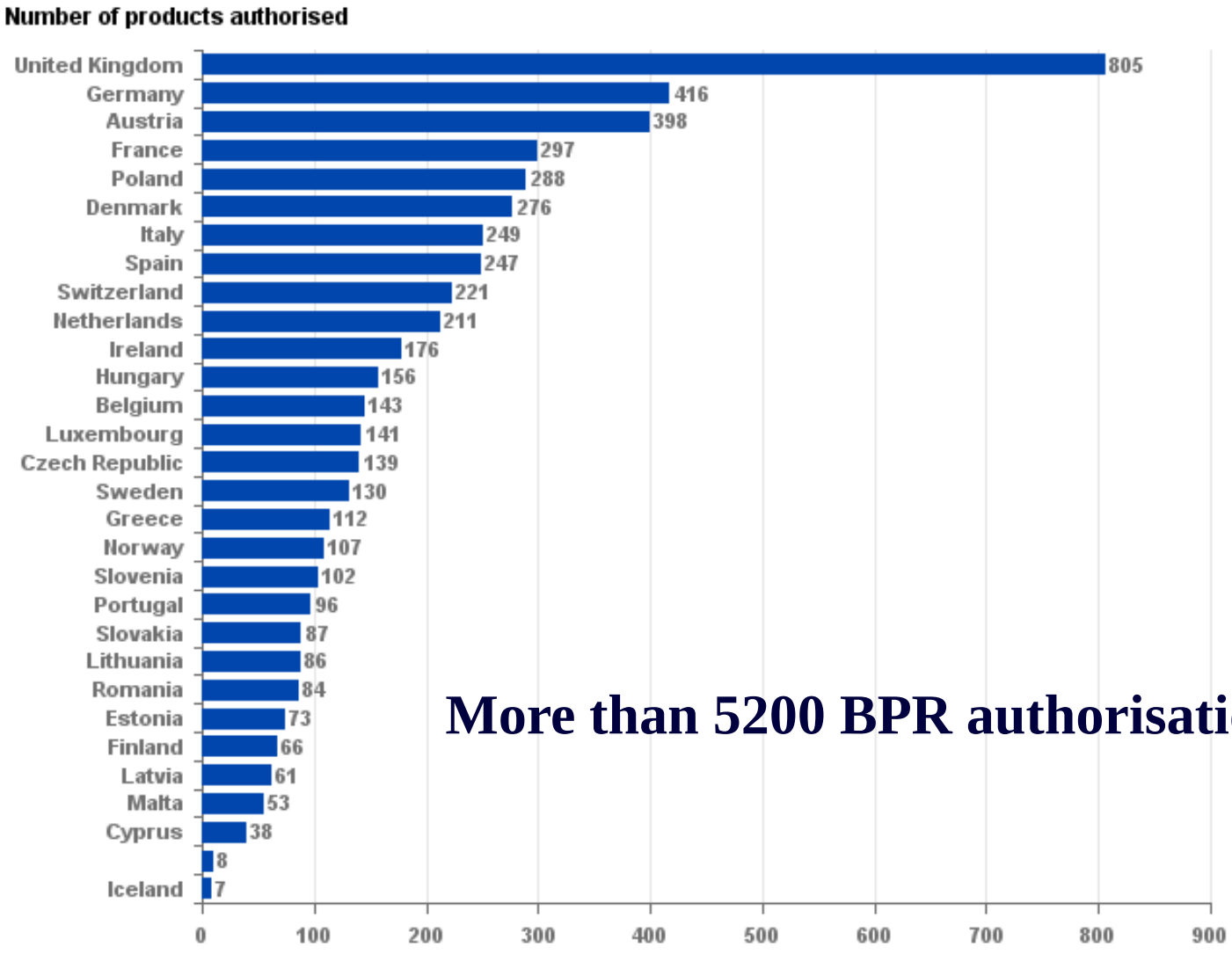
- Clarification on what is included in the review programme and what is not.
- For what is not, list is not exhaustive and two options:
  - Article 13 of the Review Programme Regulation
  - Article 93 of the BPR
- Case of specific substances such as ozone, nitrogen or hydroxylradicals remains to be addressed
- For product authorisation, any company can be authorisation holder (supplier of precursors, manufacturer of devices, the user generating the active substance).

Article 95

- 1 September 2015 deadline
- Practical guides for SMEs
  - Data sharing
  - Letters of access
  - Consortium
- Active involvement to help companies
  - Active chlorine
  - Silver
  - Ozone
- Discussion with MSs on enforcement

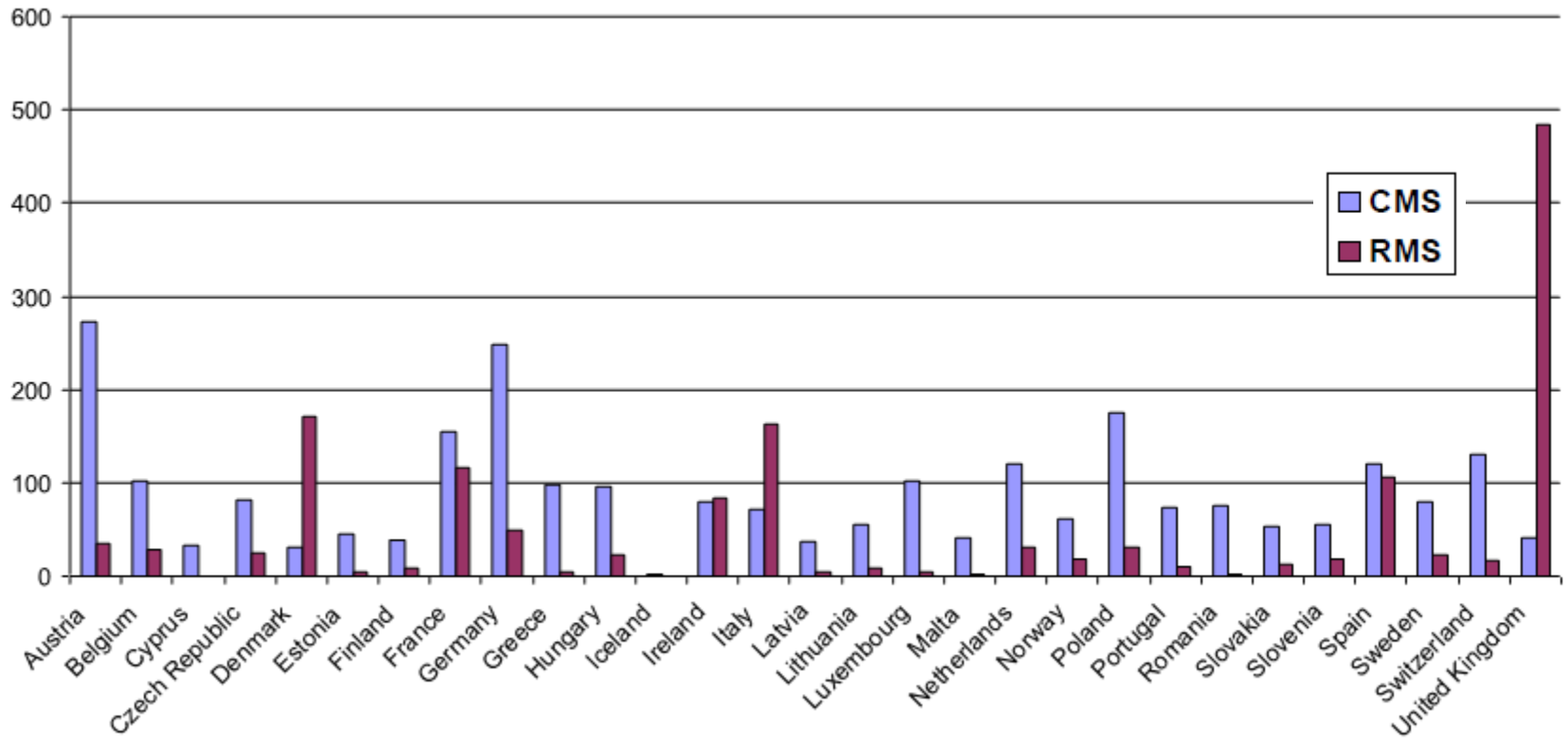
Product authorisations

- More than 5200 authorisations granted in accordance with the BPR
- Very few mutual recognition disagreements
- First product authorised through the simplified procedure
- Applications for Union authorisations expected in 2015
- Additional concepts to facilitate product authorisations
  - Same biocidal product
  - Biocidal products family
  - Consortium



More than 5200 BPR authorisations

Authorisations granted per MS



Revised guidance on Treated Articles

- Clarification on the use of biocides in earlier steps of production chain. Treated article if:
  - The biocidal active substance remains in the treated article, and
  - The biocidal active substance still has an intentional biocidal effect in the final product
  - Example: leather treated with a fungicide which gives a lasting protection from fungal decay even after it has been incorporated in shoes, bags, furniture etc.

Revised guidance on Treated Articles

- Clarification on complex articles of which only parts have been treated.
  - Such complex articles are considered treated articles if the biocidal treatment of one or several components/materials still has an intended biocidal effect in the finished complex article
  - Example: increasing the overall durability of the complex article by protecting a particularly vulnerable component from microbial/fungal decay.

Concluding remarks

- Article 95
- MRLs, SMLs and residual contents
- Renewal of rodenticides
- Sustainable use
- Communication on budget and ECHA fees review

Implementing legislation and guidance documents

Implementing legislation

- ✓ **Regulation on changes to product authorisation :** Reg. (EU) No 354/2013 of 18th April 2013
- ✓ **Regulation authorisation of same biocidal products :** Reg. (EU) No 414/2013 of 6th May 2013
- ✓ **Regulation on fees to ECHA :** Reg. (EU) No 564/2013 of 18th June 2013
- ✓ **Regulation on the extension of duration of review programme to 2024 :** Reg. (EU) No 736/2013 of 17th May 2013
- ✓ **Regulation on the modification on data requirements (proof of technical equivalence in BP applications) :** Reg. (EU) No 837/2013 of 25th June 2013
- ✓ **Regulation on the procedures for the inclusion of active substances into Annex I of the BPR :** Reg. (EU) No 88/2014 of 31st January 2014
- ✓ **Regulation on the procedures for the renewal of authorisations by mutual recognition :** Reg. (EU) No 492/2014 of 7th March 2014
- ✓ **Regulation on the organisation of the review programme of active substances (to replace Reg. (EU) 1451/2007) :** Reg. (EU) No 1062/2014 of 4th August 2014

Commission guidance

- **Work on guidance documents or proposals on various topics :**
  - ***Management of nanomaterials:***

    https://circabc.europa.eu/w/browse/f2d79b34-2f5a-4bb4-97e8-b982c9def765
  - ***Fees payable to Member States*:**

    https://circabc.europa.eu/w/browse/b5c900a2-ef66-4a46-996d-00d5a29aee9a
  - ***Similar conditions of use, for the Union authorisation* :**

    https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e
  - ***Treated articles:***

    https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22
  - ***Comparative assessment :***

    https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e
  - ***Management of in situ generated active substances:***

    https://circabc.europa.eu/w/browse/67bab047-23bc-4edb-a11f-819cb5a5f2da

Thank you for your attention!

For further information:

Commission website on biocides:

http://ec.europa.eu/environment/biocides/

CIRCABC public space on biocides:

https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

ECHA website & Helpdesk on Biocides:

http://echa.europa.eu/regulations/biocidal-products-regulation

Data Sharing Under the BPR and Supply Chain Strategy

Darren Abrahams

Indiana de Seze

Annual Chemicals Regulation Seminar

Product Defense for REACH and Biocides

April 2, 2015 – Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Steptoe
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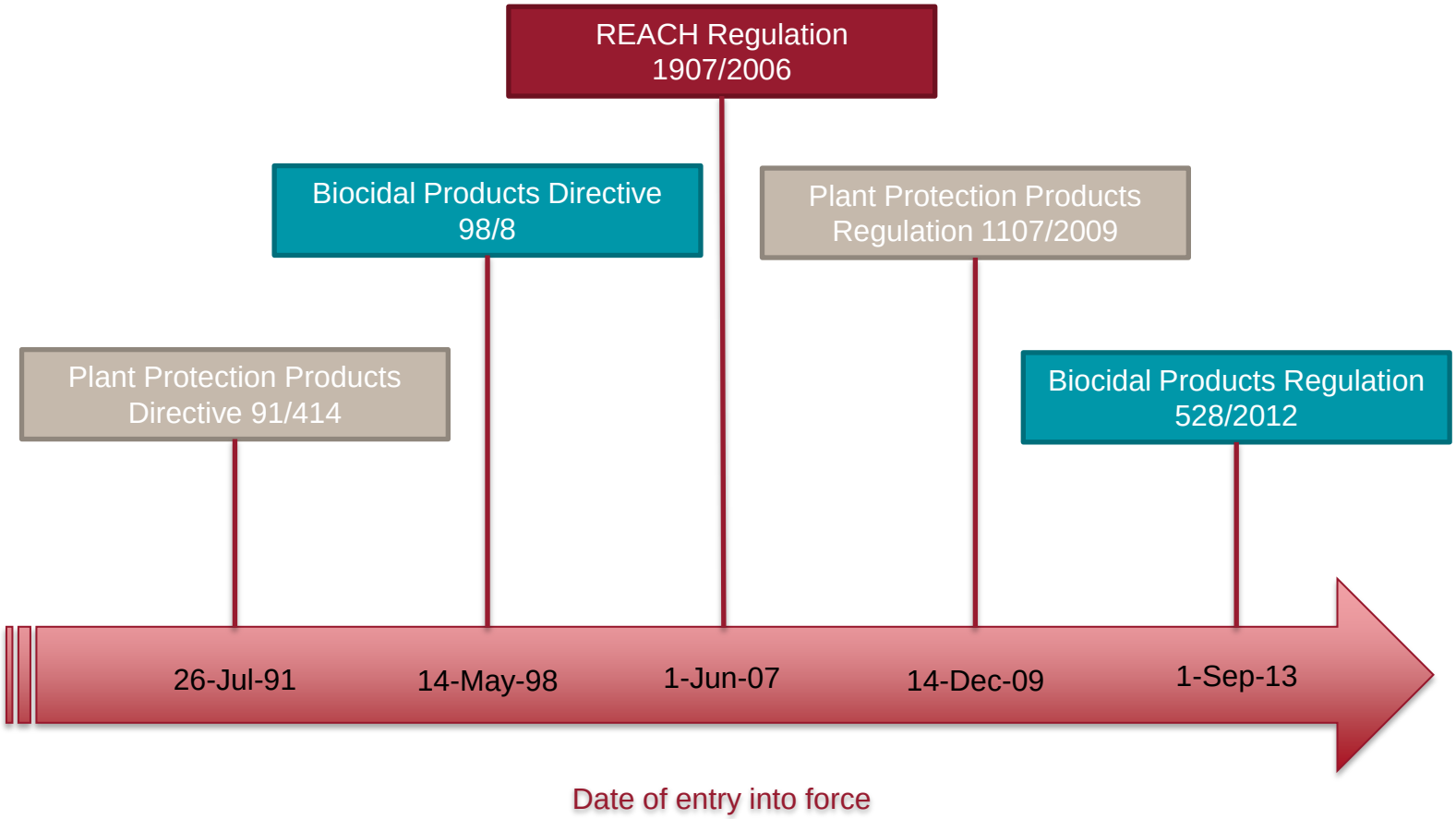
Topics for Today

1. BPR Data Sharing Rules (Article 95 and Chapter XIV)
2. Strategic Options: To be or Not to Be on the Article 95 List
3. Lessons from ECHA Data Sharing Dispute Decisions
4. Lessons from BoA
5. Practical Approach to Negotiations
6. Q & A

BPR Data Sharing Rules

Data Sharing Evolution



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Sharing of Existing Data: Overlap & Differences

	REACH (Art. 30 Phase-In Substances)	BPR (Art. 63)
Standard (and burden)	"Every effort" to ensure that the costs of sharing the information is determined in a "fair, transparent and non discriminatory way" (burden on both parties)	"Every effort" to reach an agreement. Compensation determined in a "fair, transparent and non-discriminatory manner" OR parties may agree to submit matter to binding arbitration (burden on both parties)
Subject to sharing	Study involving tests on vertebrate animals	Tests or studies on vertebrates. Plus all tox., ecotox., env. fate and behaviour studies (for Art. 95 list)
Process Triggered By	SIEF participant	Prospective applicant
Decision maker	ECHA	ECHA
Timelines	No earlier than 1 month after request of proof of costs	No earlier than 1 month after name of data owner provided + 60 day maximum for ECHA decision (Prospective applicant must have paid a share of costs before Decision)
Sub-licensing?	No (Legal entity specific unless otherwise agreed)	No (Exception under Article 95 to an applicant for authorization in its supply chain)
Compensation principles	Costs shared equally	Proportionate share of the cost
Compensation Procedure (Absent Agreement)	Data owner may enforce € claim through MS Courts	MS Courts decide on proportionate share
Remedies Against Decision	BoA + General Court	BoA + General Court

Data Sharing Rules: Objectives

- **Open season for competitors' accessing data since 1 Sept, 2013.** New data sharing and compensation rules for all data submitted under BPD and BPR applied immediately.
- **Stated objectives:**
  - create a *'level playing field....as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of* ***avoiding the establishment of monopolies****, of* ***sustaining free competition*** *between economic operators and of a fair compensation of the costs borne by data owners' (Recital 58)*
  - *'**minimise the number of tests on animals** and for testing with biocidal products, or active substances contained in biocidal products' (Recital 57)*

Data Sharing Rules: Objectives

- **Data owners lose exclusive use but should now be able to exclude 'free-riders'.** During the BPD transitional period, Member States may apply their national rules for placing biocidal products on the market. Free-riders may continue to place existing active substances on the market until the inclusion of the existing active substance into Annex I/IA to the BPD. So companies who had invested € millions in the review programme had the same market access as those who had spent nothing ('1st free rider problem').

Data Sharing Rules: Sharing of What?

- Data protection is distinct from confidentiality:
  - Public information can be subject to data protection
  - Secret information may not be subject to data protection
- No necessary link between data protection and confidentiality

- No definition of 'data protection' in the BPR (as under the BPD and REACH). All protected data submitted for BPD/BPR purposes. What is submitted is not limited to studies alone. Clear intention to ensure nothing slips between the gaps:

  'With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.' (Recital 55)

Data Sharing Rules: What Can Be Protected?

- Data requirements are those for:
  - Existing and new AS data (Annex II and Article 6)
  - Existing and new BP data (Annex III and Article 20)

  submitted for BPD/BPR purposes.

Data Sharing Rules: Protection Periods

- All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95)

ACTIVE SUBSTANCE (AS)	BIOCIDAL PRODUCT (BP)
Approval of a NEW AS **15 years** from the first day of the month following the date of adoption of AS approval decision (i.e. adoption of Implementing Regulation) of each AS/product-type combination	**BP with a NEW AS** **15 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
Approval of an EXISTING AS **10 years** from the first day of the month following the date of adoption of AS approval of each AS/product-type combination If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) **December 31, 2025.**	**BP with ONLY EXISTING AS** **10 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
RENEWAL/REVIEW of an AS approval **5 years** from the first day of the month following the decision on renewal/review of a the approval of an AS	**RENEWAL/AMENDEMENT OF BP AUTHORIZATION** **5 years** from the first day of the month following the decision on the renewal/amendment of a BP authorization

Data Sharing Rules: LoA or Hard Copy?

- **Art. 62(2):**
  - '*Where the data acquired under those tests or studies are still protected… the prospective applicant:*

    (a) shall, in the case of data involving tests on vertebrates; and

    (b) may, in the case of data not involving tests on vertebrates,

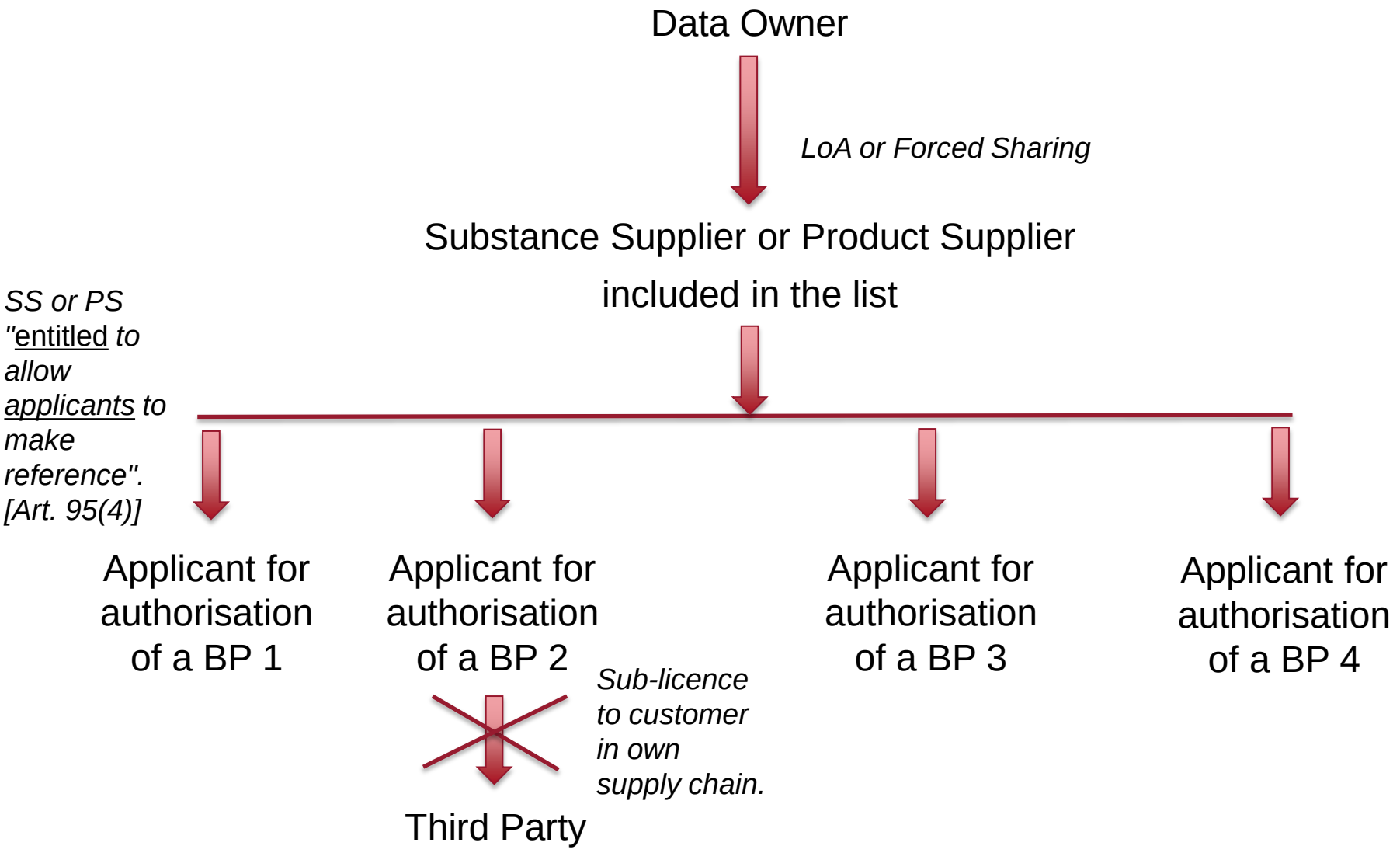
    request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.'

Ambiguity will be used to argue that hard copies are required.

Data Sharing Rules: Scope

- For **existing AS data** mandatory data sharing **not limited to vertebrate animals** but also under Art. 95(3):
  - "*to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to* [Work Programme Regulation]*, including any such studies not involving tests on vertebrates*". (i.e. Exhaustive list of Existing Active Substances to be examined under the Review Programme, which will be replaced by New)
- Potential "Alternative Supplier" must calculate whether it is better to:
  - "Cherry pick" from the dossier (using own data where already owned)
  - "Buy in" completely (Fees Regulation encourages a complete buy in)
  - Rely on others upstream in their supply chain and not be listed

Data Sharing Rules: LoAs "With Legs"



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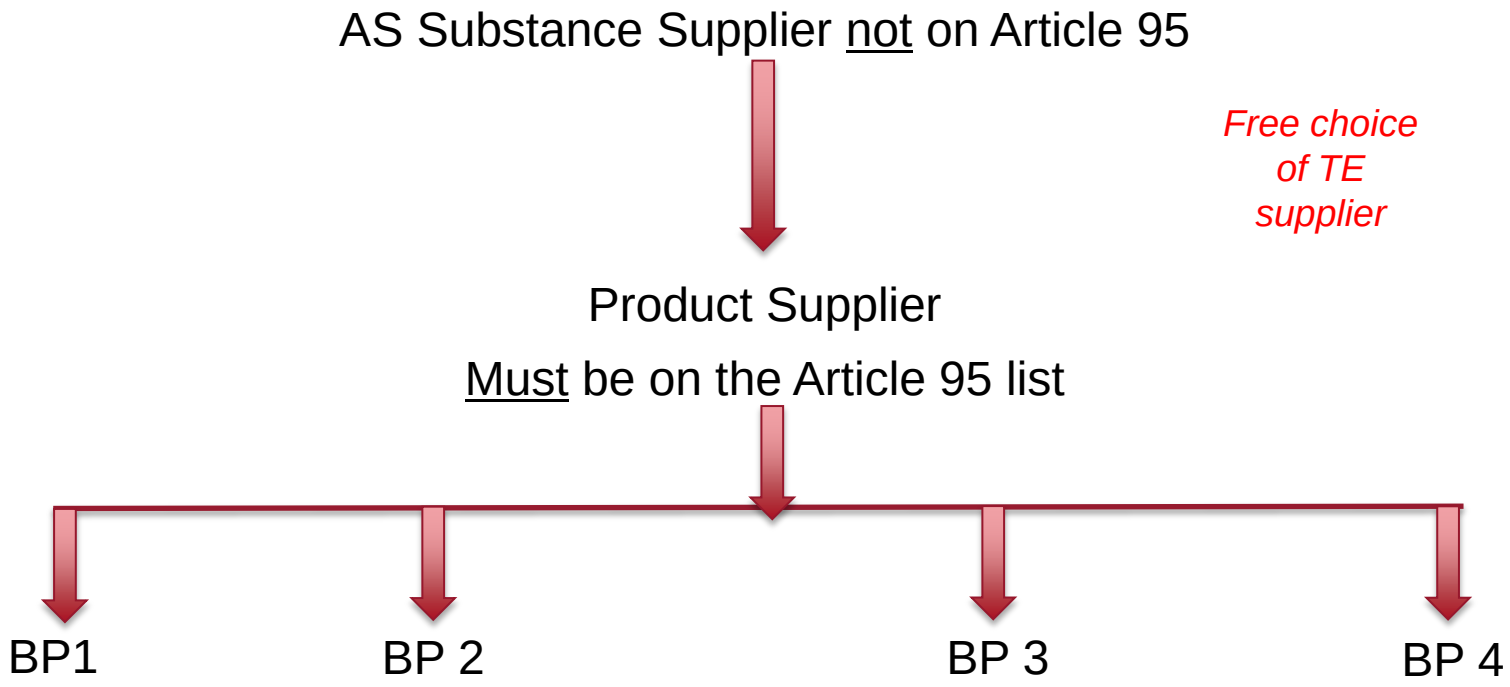
List of Active Substances and Suppliers: Article 95

- **As of 1 Sept. 2015 those who** (i) do not have access to a "complete substance dossier" and (ii) therefore have not been included on the list of **approved sources** drawn up by **ECHA by will be excluded from the market**:
  - **Biocidal products** "consisting of, containing or generating a relevant substance…shall not be made available [i.e. "any supply"] on the market or used unless either the substance supplier or the product supplier is included in the list…for the product-type(s) to which the product belongs".
    - **Data Submitters**: of a "complete dossier" under the Review Programme Regulation (Participants) or Supporters of New AS or "third party" AS dossiers submitted along with a Product authorisation, will also be included in list
    - **"Substance supplier":** "who manufactures [in EU] or imports [into EU] a relevant **substance**, on its own or in biocidal products"
    - **"Product supplier"**: "who manufactures [in EU] or makes available on the market a **biocidal product** consisting of, containing or generating that relevant substance "
- Any one company may fulfill multiple roles
- However, ECHA allows non-EU suppliers to be on the list via an EU-established representative (see press release ECHA/NA/14/36) - **most recent update 31 March 2015.**

Supply Chain Options:
To Be or Not to Be on the Article 95 List

Supply Chain Scenarios: Commodity Active



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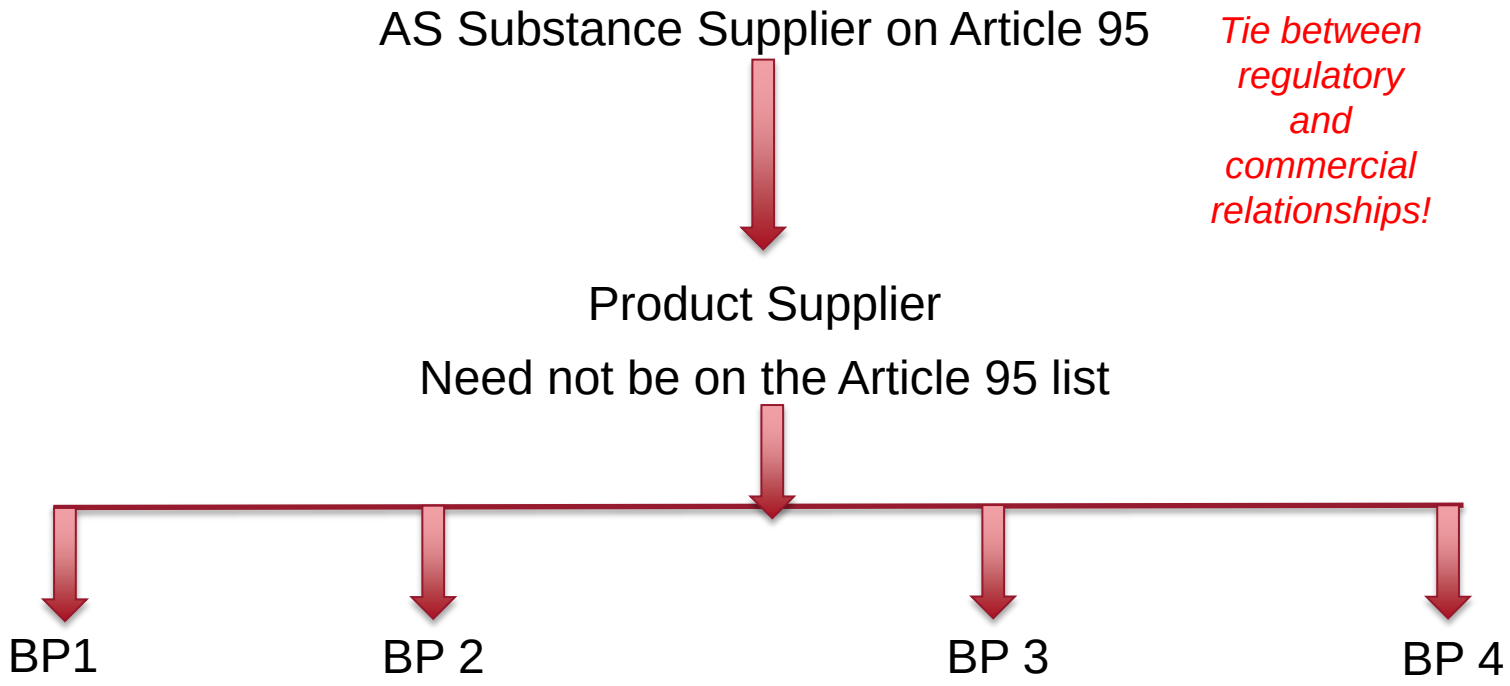
Supply Chain Scenarios: Standard



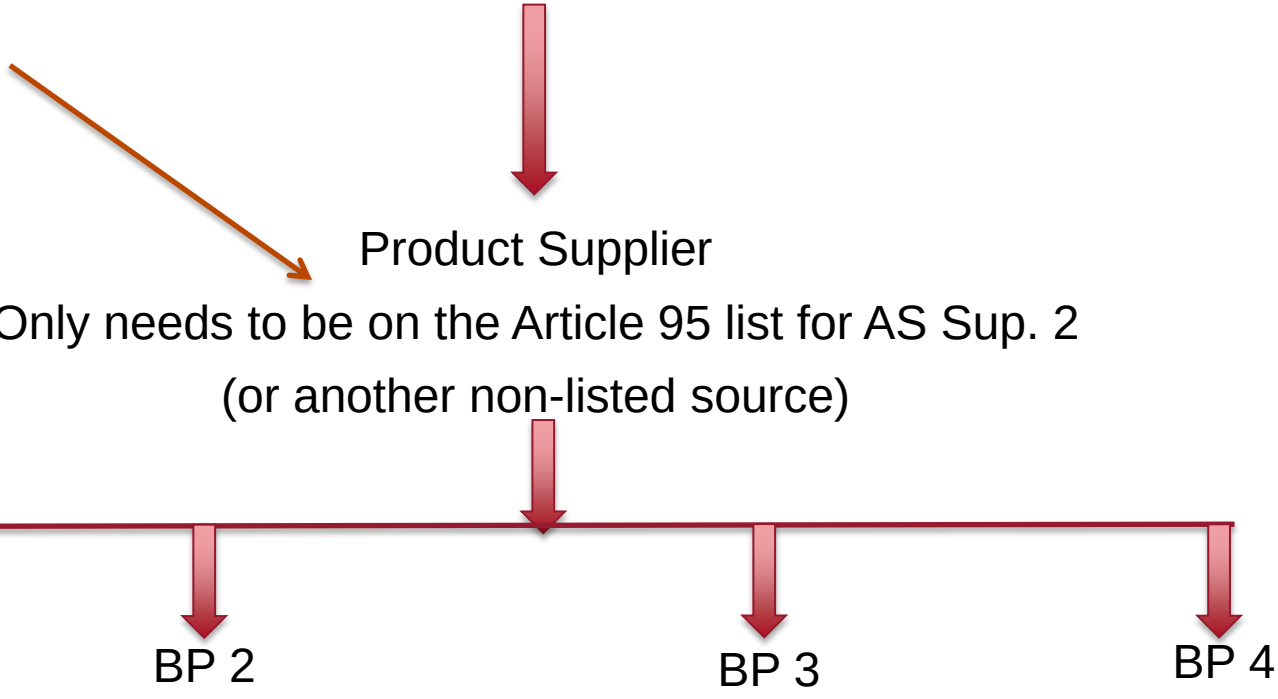
Tie between regulatory and commercial relationships!

Supply Chain Scenarios: Mixed

AS Substance Supplier 2 not on Article 95

AS Substance Supplier 1 on Article 95

Commercial leverage remains



Product Supplier

Only needs to be on the Article 95 list for AS Sup. 2

(or another non-listed source)

BP1 BP 2 BP 3 BP 4

Lessons from Data Sharing Dispute Decisions

Lessons Drawn from ECHA Data Sharing Dispute Decisions to Date

	REACH	BPR
Fav. to claimant	**11**	**1**
(of which:)	*(Art 27(6): 3)*	*(Art 95: 1)*
	(Art 30(3): 8)	*(Art 63: 0)*
Unfav. to claimant	**16**	**3**
Inadmissible	1	-
TOTAL	**28**	**4**

Lessons Drawn from ECHA Data Sharing Dispute Decisions

- Inadmissibility: different substance
  - The data sharing dispute procedure is relative to the substance: not for read-across. What about separate registrations of the same substance?
- Every effort:
  - By both parties: clear requests (opt-out), clear & proactive replies
  - Fact-based: no *a posteriori* explanation – every documented exchange counts
  - Examination of negotiations having taken place between prospective registrant's request and dispute initiation (indication of 6-12 months, 12 days premature)
  - Timeliness: start of negotiations, duration of negotiations, pace of negotiations
  - Responsiveness: number of days count, no holidays
  - One attempt and mere assertions (*e.g.* excessively high price, other substance LoAs are less costly) are insufficient – constructive contributions

Lessons Drawn from ECHA Data Sharing Dispute Decisions

Examples of criteria assessments by ECHA

- Fairness:
  - Lead registrant's proposal to accept instalments to take into account SME status counted as effort
  - SME status must be substantiated to justify reductions sought
  - Decisions to refund previous registrants seen as effort
  - Equal sharing "not manifestly unfair" (proof of costs still required)
  - Pay only data required to be submitted (own data, tonnage band)
- Transparency:
  - List of studies and breakdown of costs (within one month) = first step
  - Cost sharing mechanism
  - Proof of past expenses
  - Future costs not hypothetical
  - Number and capacity of parties (not name)

Lessons Drawn from ECHA Data Sharing Dispute Decisions

- Non-discrimination:
  - Same price irrespective of tonnage band/data requirements
  - Price increase depending on registration date
- Procedural aspects:
  - Duty to inquire if there is alternative data in SIEF only prior to testing
  - DSD must be initiated prior to submission of dossier
  - Submission of an incomplete dossier (by reason of DSD) does not affect the right to manufacture or import a substance
  - Parties invited to continue negotiating:
    - If favourable to claimant, on the price and terms of access to non vertebrate data
    - If unfavourable to claimant, to find agreement
  - Very few appeals

Lessons from BoA

Lessons from the BoA

- **1st decision on a data sharing dispute**, under REACH (Art. 30) issued on December 17, 2014 (Case A-017-2013).
- Key elements giving rise to the dispute:
  - 10% *per annum* increase post-2010 registration deadline (to pre-finance LR's efforts), subject to later reimbursement i.e. deposit (ECHA decision characterized increase as "manifestly discriminatory" but BoA said it did not have sufficient evidence to reach this conclusion, noting the reconciliation)

    No detailed description of what discrimination means in this context.
  - €1,000 handling (one off) (ECHA and BoA held this was not explained with sufficient clarity – did not say it was inappropriate)

Lessons from the BoA (cont'd)

DATA SHARING TERMS

- BoA confirmed that ECHA:
  - Should not assess if the "actual and precise cost of a letter of access is reasonable or justified" (as in Data Sharing Q&A)
  - May make an assessment of whether each of the parties made "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way"
- BoA takes a holistic approach to "every effort" test without separating the three subcomponents:
  - A fact/case driven analysis as to whether every effort is taken based on the "arguments presented during the data sharing negotiations between the parties" (word for word)
  - Only communications between the parties during data sharing negotiations are examined (confirms ECHA practice on DSD, published in August 2014)

Lessons from the BoA (cont'd)

- Reconciliation clauses "may, in certain circumstances, be considered to be an important point in assessing whether every effort has been made" (10% per annum increase was not judged to have been clearly subject to reconciliation)
- Ever-present clarification burden: an effective reversal of burden on data owner to respond to concerns (not fully articulated) and provide unrequested evidence (*e.g. reconciliation mechanism*)?

Lessons from the BoA (cont'd)

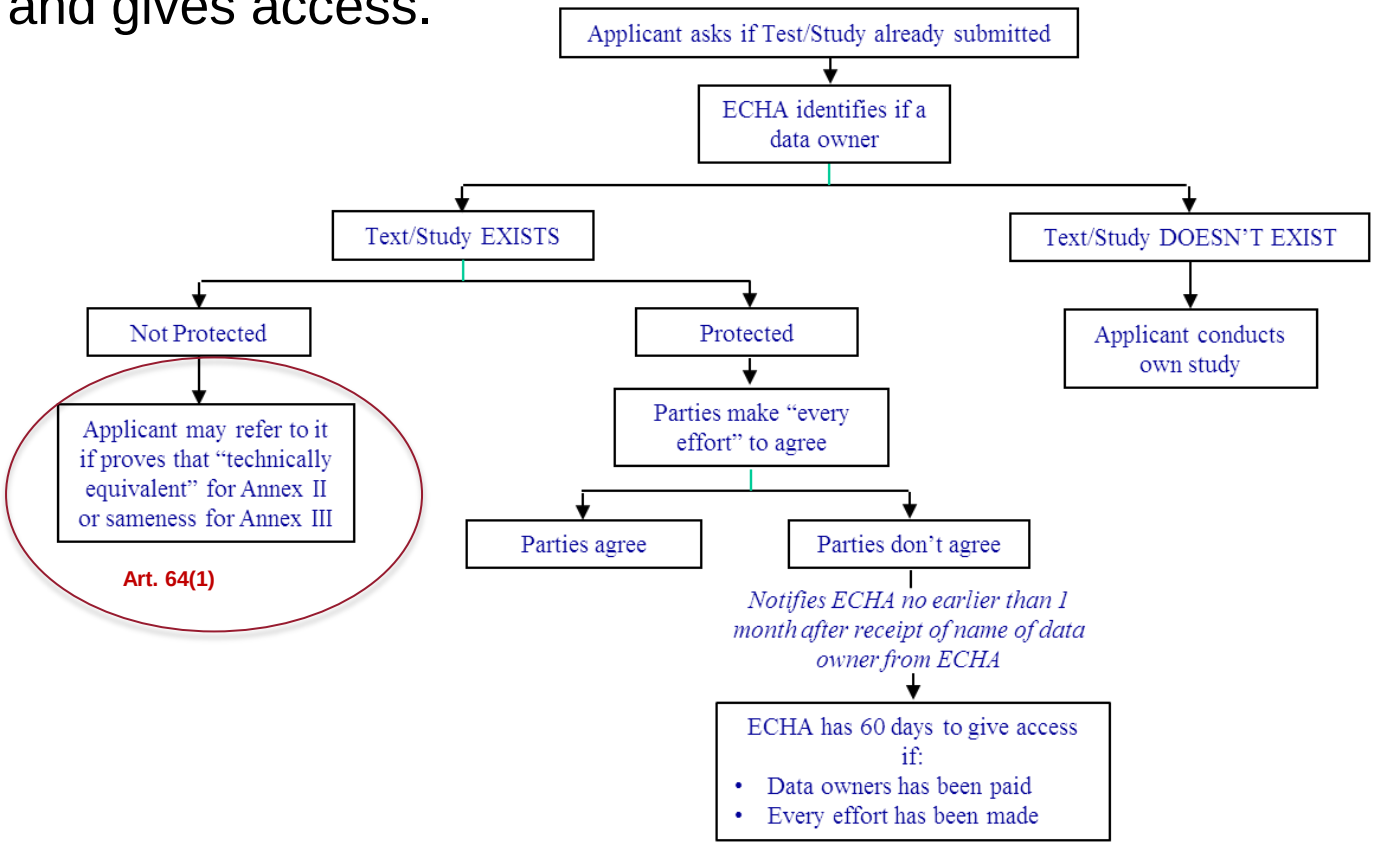
NEGOTIATING PRACTICES

- BoA guidance on other aspects:
  - Early circulation of SIEF agreements is "good practice" but analysis really begins at the moment when active negotiations start (what is stored up for 2018?)
  - Repetition of positions is credited if the response is not judged adequate (after the event/by the data accessor?) When are concerns "adequately addressed?"
  - Negotiations close to a registration deadline are not a per se indication of failure to make "every effort." The reason for failure to agree is more important.

How to Conduct Negotiations

Timelines

- **Timelines for data negotiation potentially very short:** as little as 1 month. ECHA acts within 60 days *after negotiations fail* and gives access.



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Negotiation Process

- **Essential to set in place standard**:
  - Data sharing agreements
  - Negotiation protocols
  - Cost calculation spreadsheets/baseline data

  to allow for rapid responses.

- **Typical stages in process**:
  - Confidentiality Agreement (vanilla or pre-empting negotiations)
  - Agreement on what is sought (list)
  - Delegation of entire process to binding arbitration
  - Exchanges on principles for compensation
  - Review of numbers
  - Review of draft agreement
  - Face to face negotiation
  - Offer to pay

Compensation

Indicative list of issues to consider in negotiations:

- **Scope of rights**
  - Citation or ownership?
  - Geographical spread (EU, EEA, EFTA, EU + US etc?)
  - Purpose (BPR only? BPR + PPP, REACH?)
- **Cost**
  - Distinction between costs & commercial data value
  - Dossier costs versus raw data costs
  - Actual cost (+ inflation) or replacement cost?
  - Management costs (actual or fixed/variable percentage)
  - Risk premium (compare REACH and BPR risk, and nature of study)?
  - Loss of opportunity?
  - Early market access premium?

Compensation

Indicative list of issues to consider in negotiations:

- **Dynamic cost formula or static?**
  - Reimbursement mechanism for overpaying?
  - Claw-back for underpaying and updates?
  - EU only considerations or discounts for other jurisdictions?
- **Other**
  - Are you being asked for commercial information not required by BPR (use of black box trustees)?
  - Bundling?
  - Tying data access to supply contracts?
  - Lump sum penalties for change of supplier? Royalty systems to incentivise loyalty to suppliers?

Take-Home Messages

- Data Sharing:
  - Protocols need to be in place to deal with negotiations. Better prepared parties do well in these procedures.
  - Compensation principles are not just "REACH for Biocides".
  - Dispute procedure appears slanted towards accessors but process is not about cost formulae it is about (demonstrating) efforts.
  - BoA appeals will suspend data access decisions, so there is reason for accessors to remain at the negotiating table.
  - Consortia and task forces face the same data comp. issues which you will face in the bilateral context.

Questions?

2015 Biocides key points

Hugues Kenigswald
Biocides assessment Unit

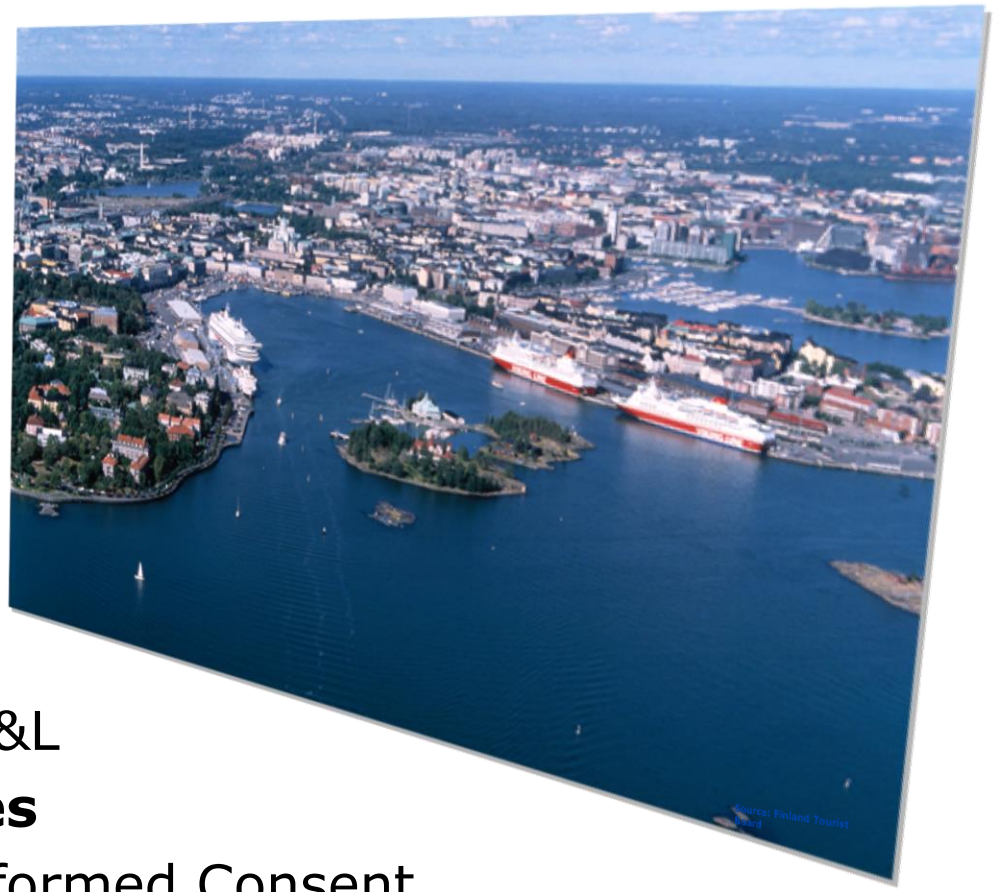
Annual Chemicals Regulation Seminar
2 April 2015

Content

- Role of ECHA in biocides
- Status of biocides applications
- Article 95
- Union authorisation
- IT issues and activities

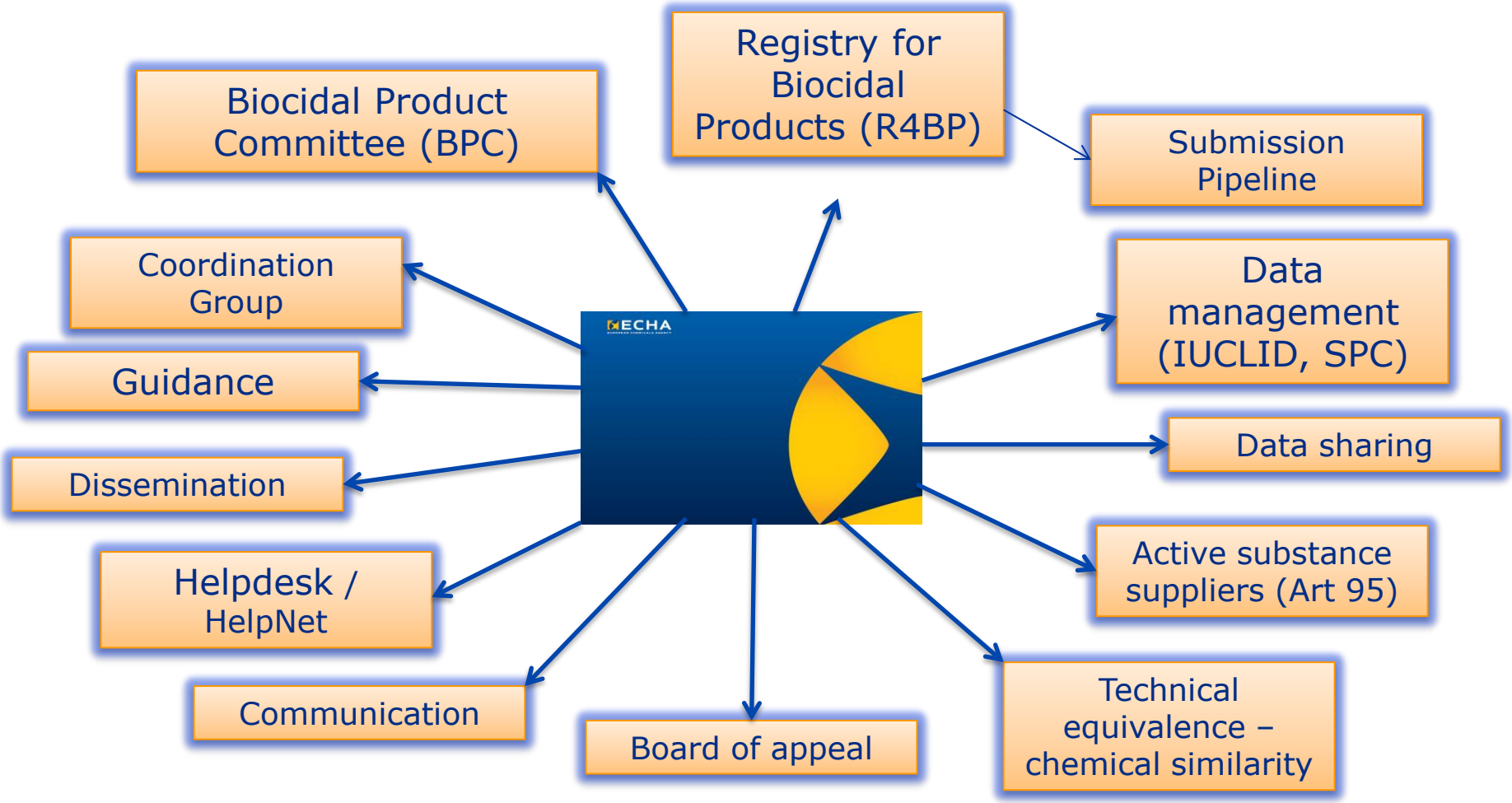
ECHA – almost 8 years old

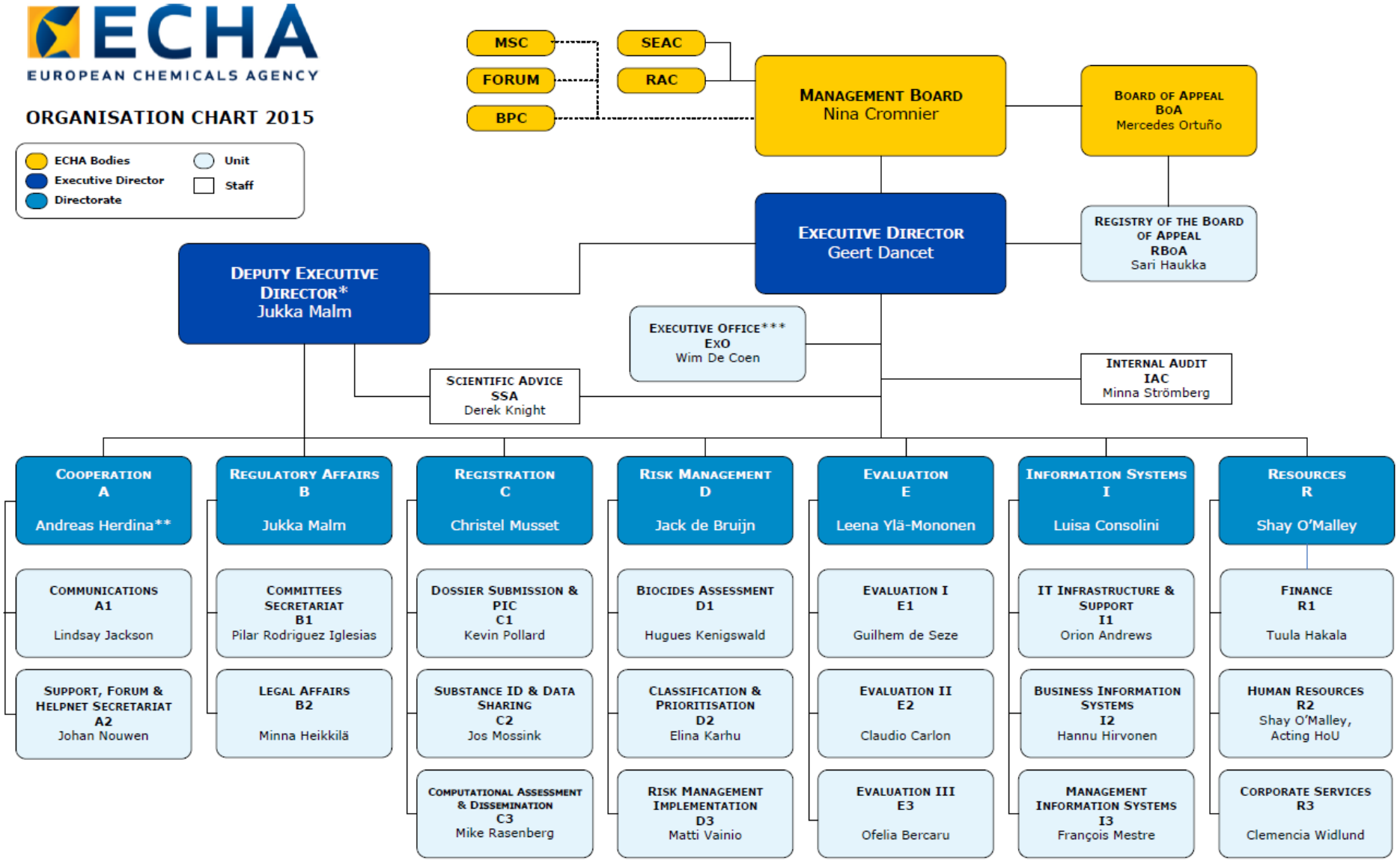
- Based in Helsinki, Finland
- Started on 1 June 2007
- Now about 560 people



- Remit:
  - Originally REACH and C&L
  - From 1/9/2013 **Biocides**
  - From 1/3/2014 Prior Informed Consent.

The role of ECHA in biocides

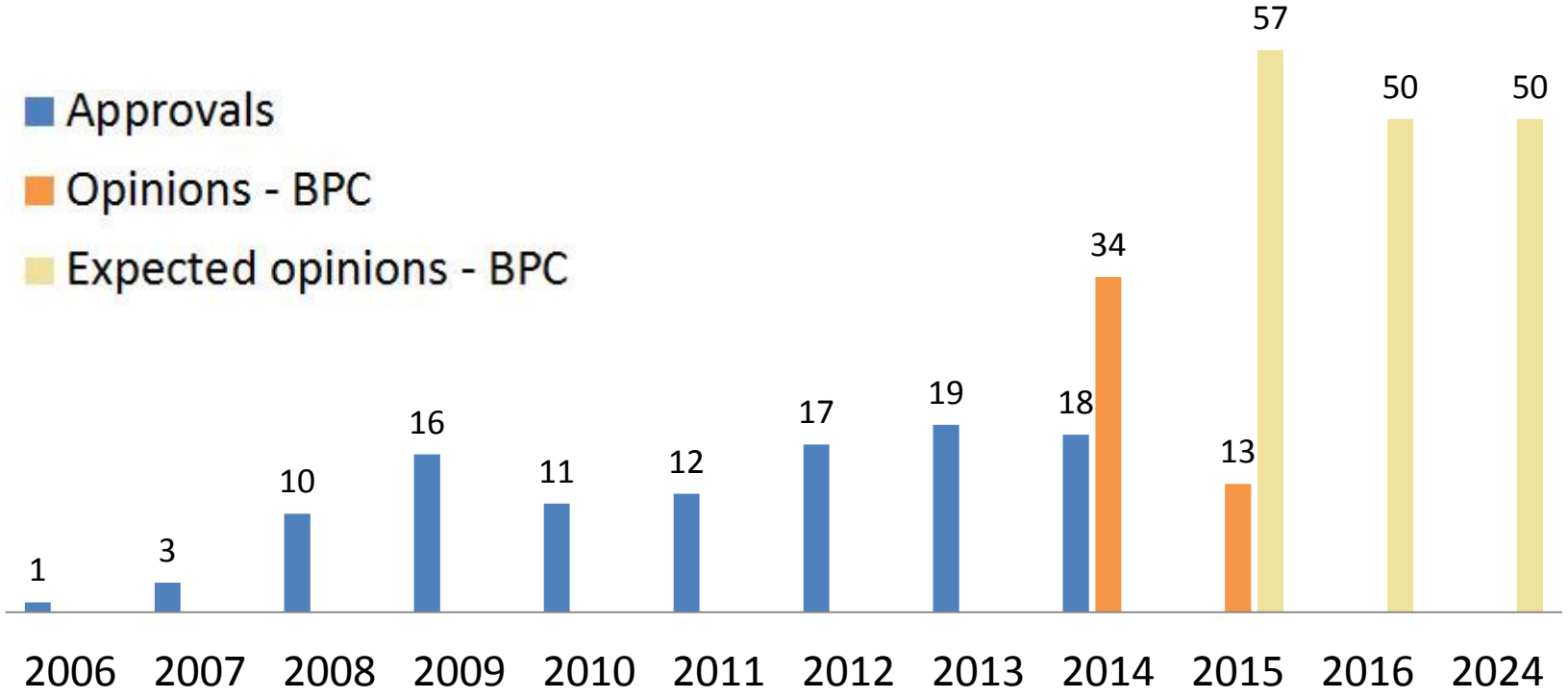




* Exercising also the function of Director of Regulatory Affairs
** Exercising also the function of SME Ambassador
*** The Quality Manager forms part of the Executive Office

Ver 2.0/2015

Progress Review Programme and approval of new active substances (after BPC-9 – February 2015)



Status of biocides applications*

Number of applications made since 1 September 2013*	Received Total	2013 Total	2014 Total	Q1 2015
Article 95	**29**	**4**	**11**	**14**
Active substance approval	**12**	**2**	**9**	**1**
- Annex I	1	0	1	0
- Renewals	2	0	1	1
- New	9	2	7	0
Inquiry to share data (active substance)	**152**	**24**	**90**	**38**
National authorisation	**129**	**35**	**51**	**43**
Mutual recognition in parallel	**588**	**129**	**257**	**202**
Mutual recognition in sequence	**398**	**39**	**287**	**72**
Union Authorisation - pre-submissions	**8**	**0**	**2**	**6**
Assessment of technical equivalence	**13**	**2**	**7**	**4**
SUMMARY	**1329**	**235**	**714**	**380**
* Status on 31 March 2015				

Article 95

- Obligations and consequences
- Which deadline for my products?
- Article 95 list
  - Persons placed automatically on the list
  - Who should apply?
- How to comply?
- First speak with your supply chain
- How to prepare article 95 applications
  - Letters of access
  - Data requirements for complete substance dossiers
- Interaction with applicants during the evaluation

Obligations and consequences

As of 1 September 2015, biocidal products consisting of, containing or generating a relevant substance should not be made available on the market if either the "substance supplier" or the "product supplier" is not included on the list of active substances and suppliers for the relevant product-type(s).

Article 95 list as published

ECHA
EUROPEAN CHEMICALS AGENCY

Article 95 List 34 (144)

Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
Product Type: 6				
Lonza Cologne GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Product Type: 8				
Lonza Cologne GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Product Type: 11				
Akzo Nobel Surface Chemistry AB	Sweden	Substance Supplier	RP Participant	24-Sep-14
Product Type: 12				
Akzo Nobel Surface Chemistry AB	Sweden	Substance Supplier	RP Participant	24-Sep-14
Product Type: 13				
Lonza Cologne GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
2,2'-dithiobis[N-methylbenzamide] (DTBMA)		**EC: 219-768-5**	**CAS: 2527-58-4**	
Product Type: 6				
Rohm and Haas Europe Trading Aps.	Denmark	Substance Supplier	RP Participant	24-Sep-14
1,2-benzisothiazol-3(2H)-one (BIT)		**EC: 220-120-9**	**CAS: 2634-33-5**	
Product Type: 2				
LANXESS Deutschland GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Troy Chemical Europe BV	Netherlands	Substance Supplier	RP Participant	24-Sep-14
Product Type: 6				
Arch UK Biocides Limited	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Clariant Produkte (Deutschland) GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
LANXESS Deutschland GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Lonza Cologne GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Prom Chem Ltd	United Kingdom	Substance & Product Supplier	Art.95 submission	17-Mar-15
Rohm and Haas Europe Trading ApS	Denmark	Substance Supplier	RP Participant	24-Sep-14
Thor GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14

Persons placed automatically on the list

- Participants in the Review Programme
- Supporters of new active substances
- Submitters of “third party dossiers” recognised as complete by a competent authority (alternative active substance dossier submitted within a product authorisation application)

Persons who should make applications

- Alternative suppliers of active substances in the Review Programme
- Alternative suppliers of new active substances after their approval
- Manufacturers of biocidal products consisting of, containing or generating a relevant substance, if the supplier of the active substance used in their biocidal product is not on the list

ⓘ established in the EU or their EU representative if they are not!

ⓘ Non-EU entities can be listed next to their EU representative!

How to comply with Article 95

In practice, for each biocidal product available on the market, the company should be able to demonstrate that:

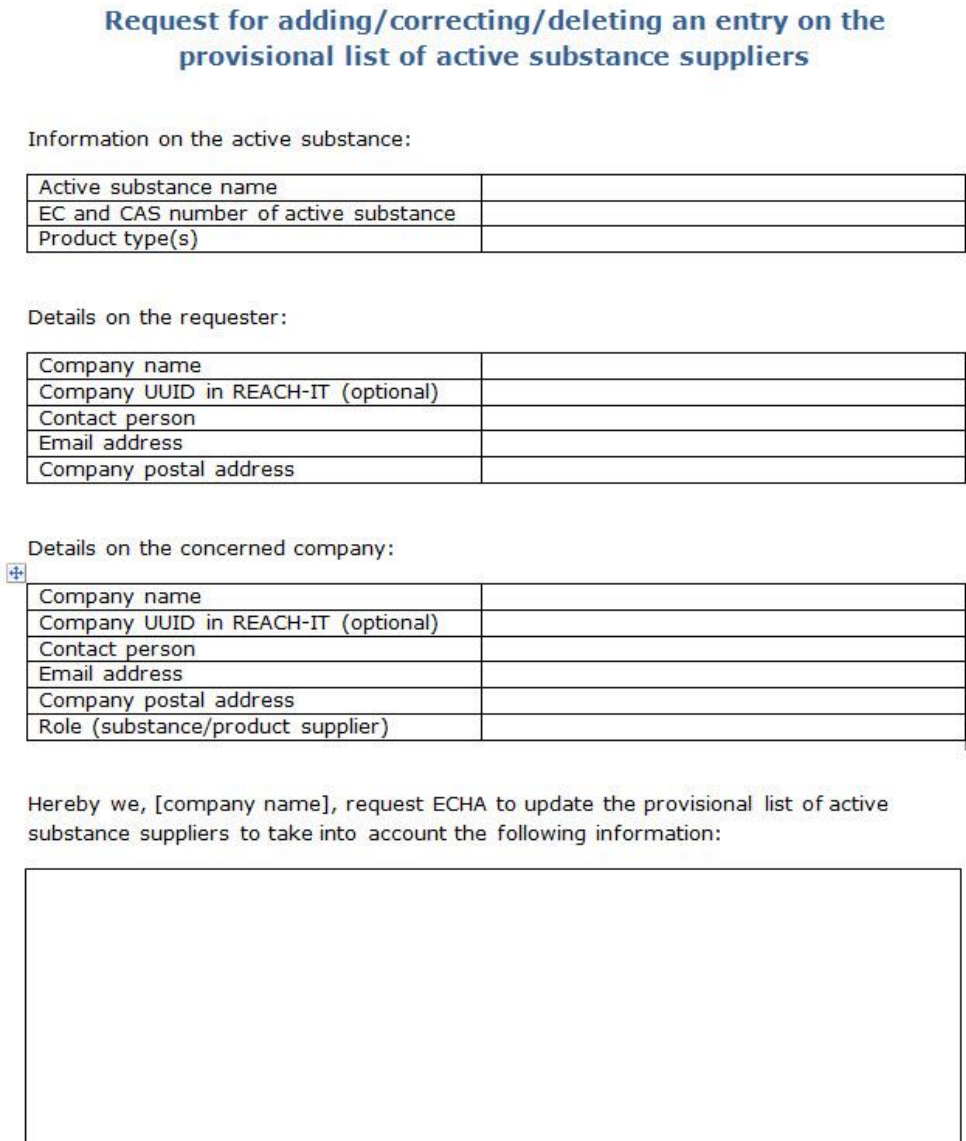
- the product originates (directly or indirectly) from a product supplier included in the list for the relevant product-type(s)

  or

- the active substance(s) originate from a substance supplier included in the list for the relevant product-type(s)

Article 95 list update

- Non-EU companies can appoint an EU representative for the purposes of Article 95, and appear on the list next to their EU representative
- Further correction requests for updating the list are possible using the specific form



Request for adding/correcting/deleting an entry on the provisional list of active substance suppliers

Information on the active substance:

Active substance name	
EC and CAS number of active substance	
Product type(s)	

Details on the requester:

Company name	
Company UUID in REACH-IT (optional)	
Contact person	
Email address	
Company postal address	

Details on the concerned company:

Company name	
Company UUID in REACH-IT (optional)	
Contact person	
Email address	
Company postal address	
Role (substance/product supplier)	

Hereby we, [company name], request ECHA to update the provisional list of active substance suppliers to take into account the following information:

Types of applications

- A letter of access (LoA) to a 'Complete substance dossier'
- A 'complete substance dossier' complying with the requirements of Annex II to the BPR

- [A reference to a 'complete substance dossier' for which all data protection periods have expired]
- ['Mixed application' - both an LoA and data for the endpoints not covered by the LoA]

A specific type of letter of access

- No need for IUCLID 5 - Attach LoA in the submission wizard
- Specific type of LoA originating from a dossier submitter (not necessarily the data owner)
- For the purposes of an Article 95 application, a list of submitted data is not necessary if the LoA refers to a 'complete substance dossier' in its entirety
- For the purposes of an Article 95 application, a LoA can also give access rights to ECHA with the applicant as the beneficiary
- In addition: Product-type(s), applicant's role

Complete substance dossier

- In compliance with Annex II of the Biocidal Products Regulation

Content of dossier:

- All core datasets
- A summary, evaluation and draft risk assessment (section 13)
- PT-specific additional datasets will be required

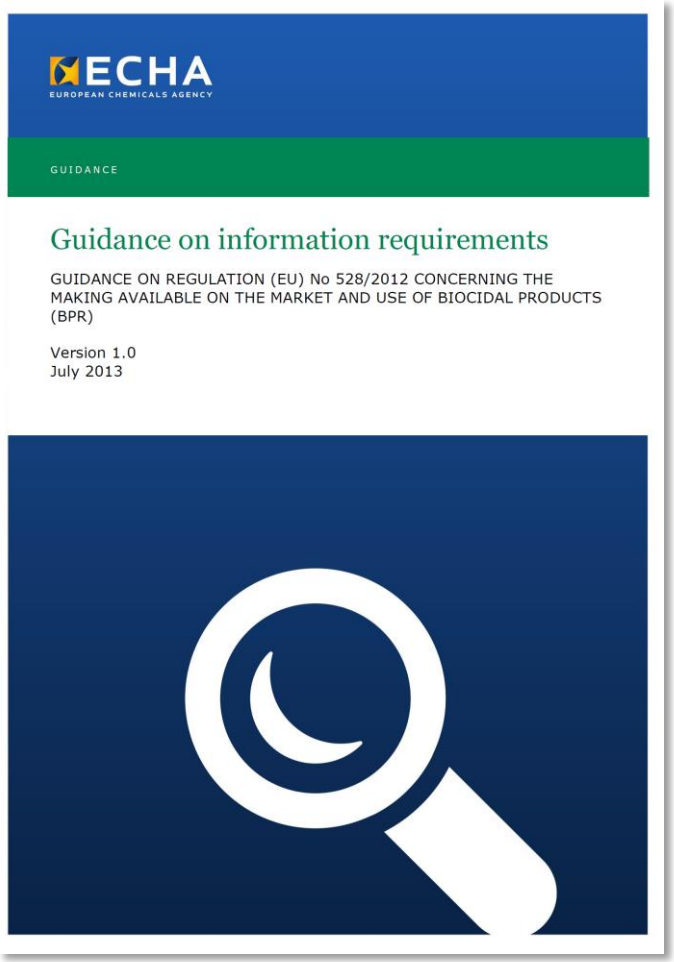
  (Part V of the Guidance on information requirements)

ⓘ Full study reports need to be provided!

Guidance on information requirements

- Information on:
  - Which endpoints to cover;
  - Which tests to provide;
  - Testing protocols;
  - Quality issues;
  - Waivers;
  - etc…

http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf



Evaluation – Interaction with applicants

- Provide with name and contact details of ECHA expert to the applicant
- Time for comments on draft decision 1 (+2) months
- One possibility to update application
- No legal deadline
- Total evaluation time depends on application type, level of complexity and ECHA's workload

Apply as soon as possible!

To ensure inclusion in the Article 95 list before the applicable deadline

(1 September 2015 in most cases)

ⓘ *Provision sufficient time for data sharing negotiations*

Which deadline for my products?

- 1 September 2015
  - currently recognised relevant substances

- 1 September 2016
  - Article 93 BPR

- Other dates (variable):
  - Article 15 Review Programme Regulation

More information on

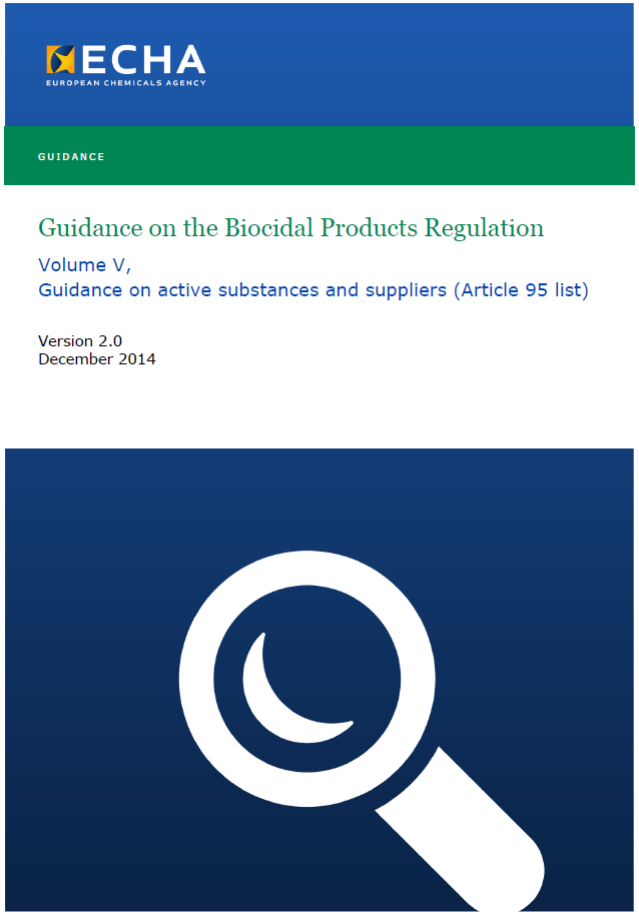
- Active substances and suppliers: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers
- List of active substances and suppliers: http://www.echa.europa.eu/information-on-chemicals/active-substance-suppliers
- Application procedure through R4BP3: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers/application-and-assessment-procedure

Guidance on active substances and suppliers (Article 95 list)

- Available at:

http://echa.europa.eu/documents/10162/15623299/biocides_guidance_active_substance_suppliers_en.pdf

- Updated in December 2014



Practical guides on data sharing

New

- Published in March 2015
- Available at: http://echa.europa.eu/web/guest/practical-guides/bpr-practical-guides

New

LIST OF PENDING ARTICLE 95 APPLICATIONS

Prepared as of 31 March 2015

EXPLANATORY NOTE

In order to increase transparency for industry, in particular SMEs, ahead of the 1 September 2015 deadline, ECHA has decided to publish a list of all the applications made in accordance with Article 95(1), second sub-paragraph, of the Biocidal Product Regulation (BPR) for which ECHA has not yet taken a decision. The list is structured per active substance and includes all product types (PTs) for which a submission has been made. The list includes the names of the applicants and their country, their role as substance supplier and/or product supplier, the date of submission of the application as well as the date of acceptance of the application by ECHA following the payment of the fee. The non-EU companies are listed together with their appointed EU-representatives.

Each entry appears on the list at the time of acceptance of the application by ECHA and remains on the list until the positive or negative decision is taken by ECHA.

WARNING: The list of pending Article 95 applications creates no legal rights or obligations for the entities listed. The list of pending Article 95 applications should not be confused with the list of active substances and suppliers (Article 95 list) and the presence of a company (per substance/PT/role) on the list of pending applications does not guarantee that the application will be successful and that the company will ultimately be included in the Article 95 list.

List of pending Article 95 applications

http://echa.europa.eu/documents/10162/17287015/active_substances_list_of_pending_app_en.pdf

New

LIST OF PENDING ARTICLE 95 APPLICATIONS

Substance Name	EC	CAS	Applicant	Country	Product Type(s)	Submission Date	Acceptance Date	Supplier Type	Other information
2-Octyl-2H-isothiazol-3-one (OIT)	247-761-7	26530-20-1	Lanxess Deutschland GmbH	Germany	6, 7, 9, 10, 13	18-Sep-13	21-Jan-14	Substance Supplier	
			Troy Chemical Company BV	Netherlands	6, 7, 9, 10, 13	19-Mar-15	27-Mar-15	Substance Supplier	
Deltamethrin	258-256-6	52918-63-5	Sharda Europe B.V.B.A (Acting for Sharda Cropchem Ltd. (India))	Belgium	18	17-Feb-15	18-Mar-15	Substance Supplier & Product Supplier	
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)	Mixture	55965-84-9	Vink+Co. GmbH Handelsgesellschaft und Co KG	Germany	2, 6, 11, 12, 13	27-Feb-15	12-Mar-15	Substance Supplier	Awaiting decision from Board of Appeal on related data sharing
			Lanxess Deutschland GmbH	Germany	2, 6, 11, 12, 13	18-Mar-15	30-Mar-15	Substance Supplier	
			Troy Chemical Company BV	Netherlands	2, 6, 11, 12, 13	19-Sep-13	23-Jan-14	Substance Supplier	
Diflubenzuron	252-529-3	35367-38-5	Plank Hygiene KG	Austria	18	11-Oct-13	19-Nov-13	Substance Supplier	
(Benzothiazol-2-ylthio) methyl thiocyanate (TCMTB)	244-445-0	21564-17-0	Laboratorios Miret S.A.	Spain	9	17-Feb-14	10-Apr-14	Substance Supplier	
			Thomas Swan & Co. Ltd.	United Kingdom	9	17-Feb-14	11-Apr-14	Substance Supplier	
2-methyl-2H-isothiazol-3-one (MIT)	220-239-6	2682-20-4	Vink+Co. GmbH Handelsgesellschaft und Co KG	Germany	6, 11, 12, 13	27-Feb-15	20-Mar-15	Substance Supplier	
			Lanxess Deutschland GmbH	Germany	6, 13	18-Mar-15	30-Mar-15	Substance Supplier	
			Troy Chemical Company BV	Netherlands	6, 13	19-Sep-13	13-Jan-14	Substance Supplier	

The presence of a company (per substance / PT / role) on the list of pending applications does not guarantee that the application will be successful and that the company will ultimately be included on the Article 95 list.

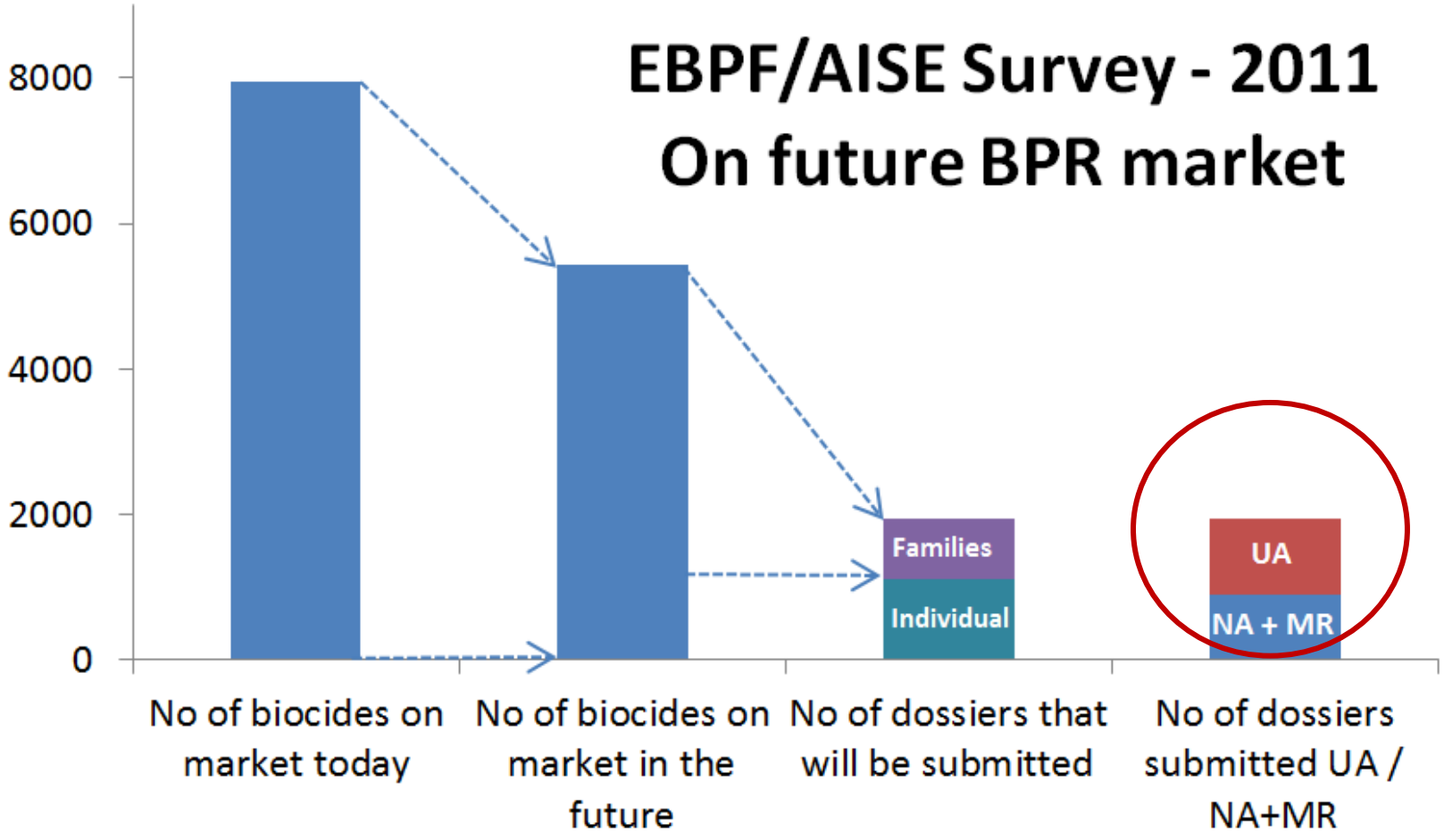
Article 95 – Key messages

- Speak with your supply chain to determine which substance supplier or product supplier is or will be on the Article 95 list
- Don’t underestimate preparation time, especially for data sharing negotiations
- Submit your application as soon as possible – time is ticking; for most products deadline to be on the list is 1/9/2015
- Carefully read ECHA’s updated Guidance on Article 95

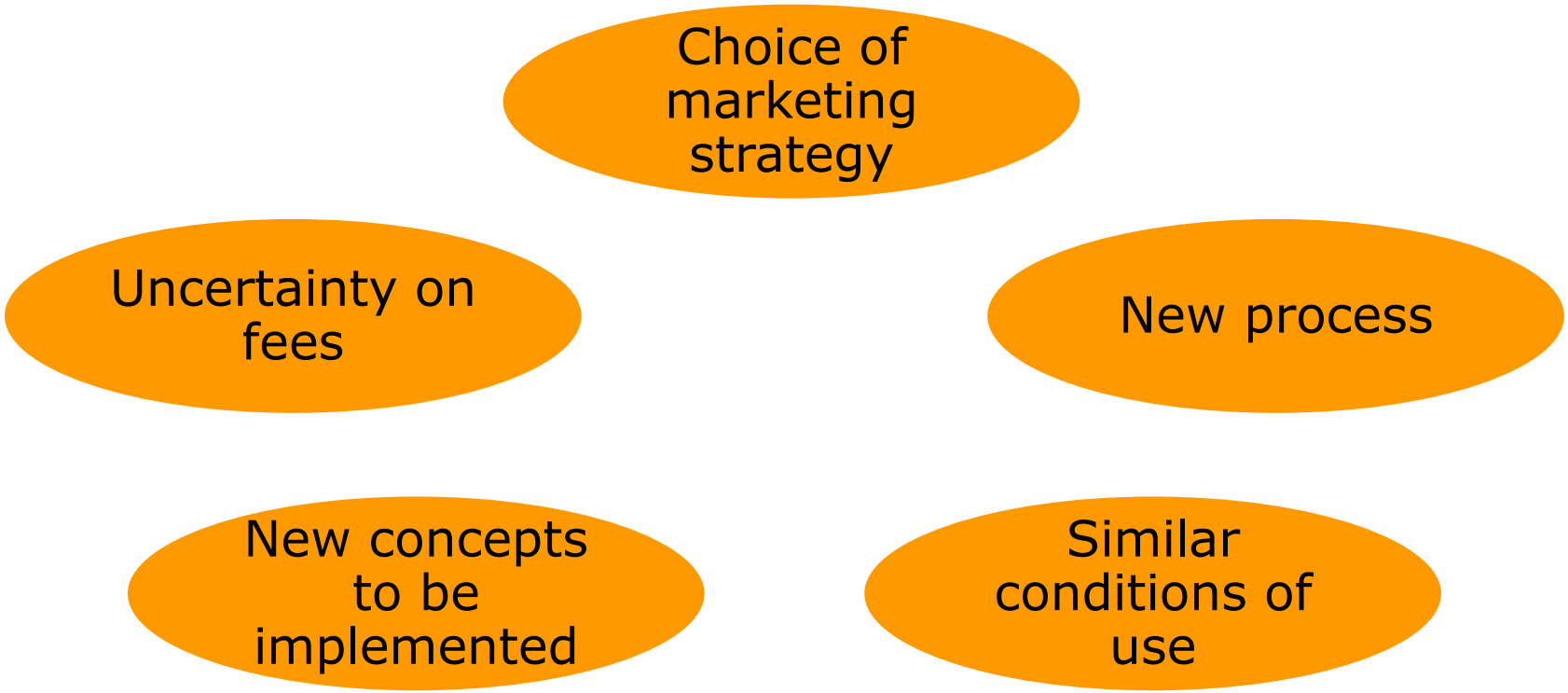
Expectations of Union authorisation

- Single authorisation for the entire EU market
  - Positive impact on product availability
  - Easier procedures for economic operators targeting several Member State markets
- ECHA involvement
  - Fixed deadlines → more certainty for applicants
  - Harmonised procedures → improved consistency in dossiers' assessment

Benefits and Expectations
Union Authorization



Challenges of Union authorisation



Union authorisation
Main roles of ECHA

1. Support to potential applicants
2. Assistance to “pioneering” applicants
3. Involvement in pre-submission consultations
4. Coordination with eCA during the assessment
5. Support to the peer review process

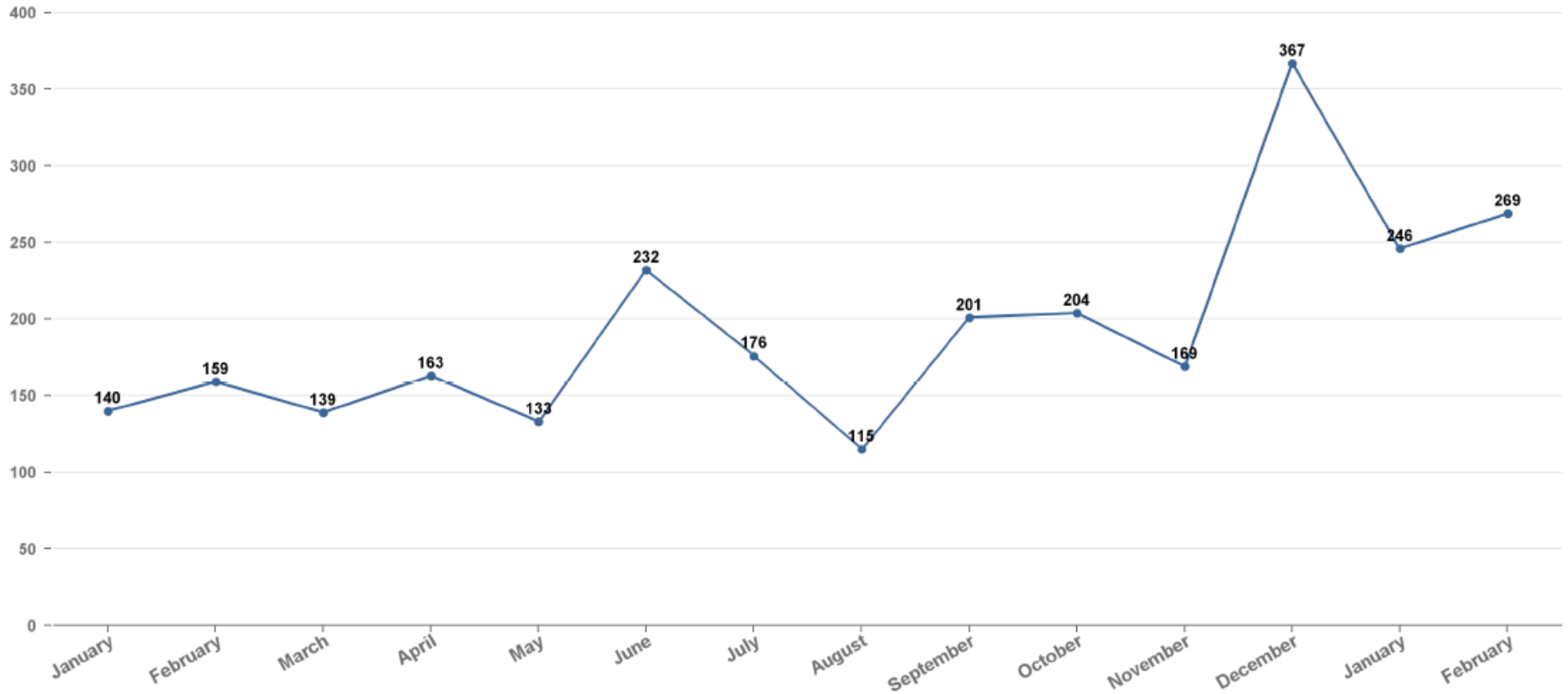
R4BP 3.2 + SPC editor: key issues

- R4BP 3:
  - mutual exclusion rules
  - SPC download
  - Same biocidal product authorisation for same company
  - Follow up of grouped applications
  - Post-migration corrections

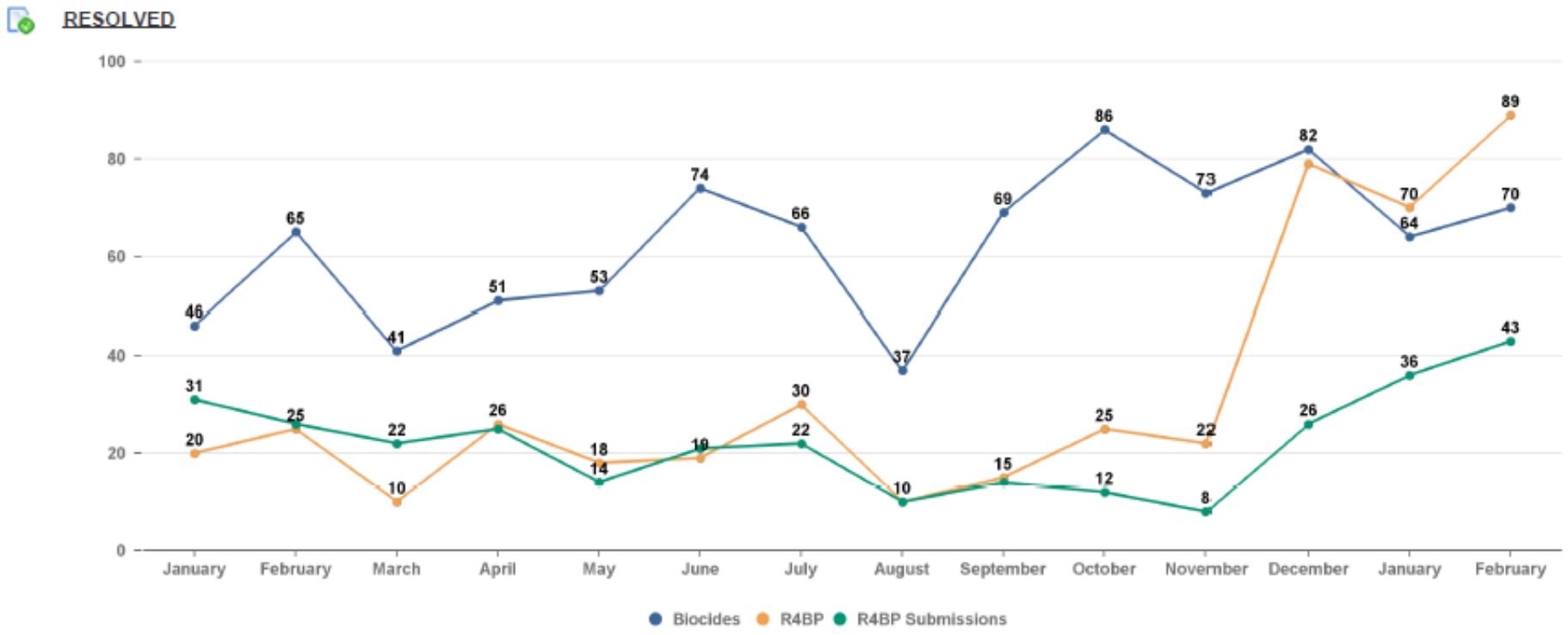
- SPC editor:
  - Incomplete list of active substances
  - Constraints on ranges
  - Copy and paste from word
  - Re-using an existing SPC for another product
  - multilingual version

Trend of overall Helpdesk incidents

ALL BPR INCIDENTS RESOLVED



Trend of Helpdesk IT



Biocides IT activities 2015

a) **R4BP 3 maintenance releases**
   1. **Emergency patch 3.2.1 – RELEASED**
   2. **Emergency patch 3.2.2**
   3. **Maintenance release 3.2.3**
   4. **Maintenance release 3.2.4**

b) **SPC Editor maintenance releases**
   1. **Emergency patch 1.2.0 – RELEASED**
   2. **Maintenance release 1.3.0**
   3. **Maintenance release 1.4.0**

c) **Review Programme migration**
   a) **Initial migration (related with SPC)**
   b) **Review Programme data management (on-going until Review Programme is implemented in R4BP 3)**

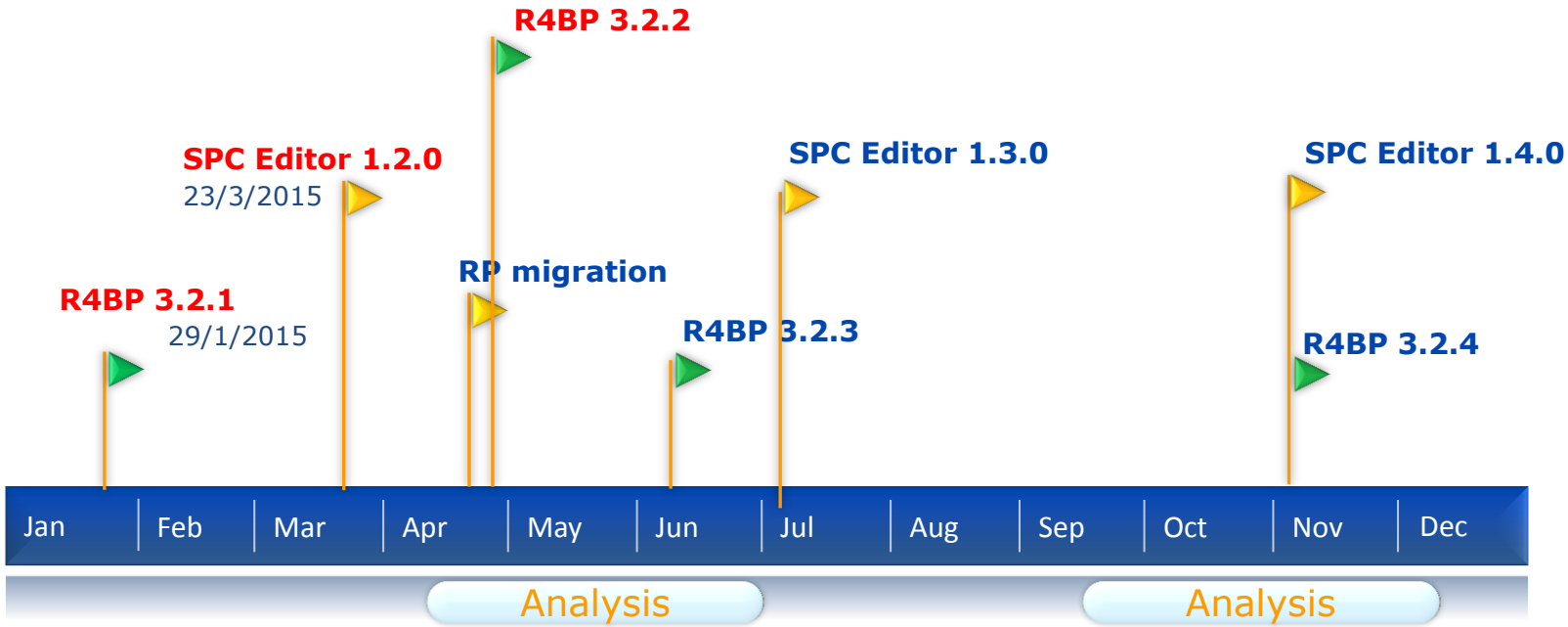
Biocides IT activities 2015

d) Analysis

1) **Meta SPC**
2) **Same Biocidal Product from family member**
3) **NA Same Biocidal product from UA**
4) **Review Programme**
5) **IUCLID 6.1 adaptations**
6) **Simplified authorisation (renewal and notifications)**
7) **Backlog case types and workflows**
8) **Access to national enforcement authorities**
9) **Interface for external/internal systems (e.g. MSCAs)**

e) Data corrections

Biocides IT foreseen activities in 2015 (indicative dates)



Fee Overview under the BPR

Annekathrin Faupel
Registration Manager Europe

2nd April, 2015

Product Defense for REACH and Biocides 2015
Steptoe

Introduction

Focus on Biocide Product Authorisation Fee

Content

1. EU Report on the Fees
2. Industry perspective
3. Some comparisons
4. Conclusions

Report on the Fees

- **EU CA-March15-Doc.7.2.**
- Areas of focus
  - Fees for the evaluation of a.s. per PT and per additional PT;
  - Fees for the authorisation of a BP and of a BP Family;
  - Fees for the mutual recognition of an authorisation for a BP and for a BP Family
  - The annual Fee;
  - Existing measures supporting SMEs in this process

Report on the Fees

- **EU CA-March15-Doc.7.2.**
- Areas of focus
  - Highlight average indicative fee amounts
  - Not included:
    any top-up fee that a wide majority of MSCAs apply to their basic fee

Report on the Fees

- Fees for Biocide Product Authorization

1. More than half of the MSs (16) have established the Fee < 20 000 € **9MSs / 16**
2. Whilst 10 have set it above 20 000 €, among which 6 have set it above 40 000 €

BUT

A large group of MSs: process of adoption/reviewing relevant legislation (12 MSs / 28)

Report on the Fees

- Fees for Mutual recognition of BP Authorization

1. In 19 MSs MR Fee < 5000 € with an average of approx. 4000 € **7MSs / 19**

2. In 10 MSs, MR Fee > 5000 €, among which 4 MSs set it > 10 000 € **2MSs / 10**

BUT

A large group of MSs: process of adoption/reviewing relevant legislation (12 MSs / 28)

Report on the Fees

- BP Family
  - BPF fee are generally higher as single BP authorization
  - Annual Fee
  - 9 MSs are requesting Annual Fees (at the moment) between 100 and 500 € 3 MSs / 9
  - Average ≈ 280 € (2 MSs > 1000 €)
  - ECHA: 10.000 € (PA) / 20.000€ (BPF)
- Support measures for SMEs
  - Only 7 MSs (fee reduction (3) but also other measures)

Report on the Fees

- Final comments from the report
  - Specific fee regulation still has not been adopted in some MS, hence requirements under Article 80(2) of the BPR have not been fully implemented in all MSs
  - Cost of BP National Authorization via MR of BPs *is not significantly different* from those of applying for Union Authorization
  - Similar conclusions can be drawn for annual fees

    However, uncertainty that companies supporting products authorized by the Union might be forced to pay both the ECHA and MS' annual fees

Content

1. EU Report on the Fees
2. **Industry perspective**
3. Some comparisons
4. Conclusions

Industry perspective

- What did we face when collecting information on fee?
  - Information not always available on official websites
  - Help desks not responding
  - Different languages
  - Different currencies
  - Different fee structures

Industry Fee Overview

Industry perspective

- Biocide product Authorisation + Mutual recognition

National Authorization	Average
Biocide Product (2015) 1 a.s. – 1 PT – 1 User Group	~ **41 000 €***
BP – Mutual Recognition (2015) 1 a.s. – 1 PT – 1 User Group	~ **6 000 €***
Total / BP (PA + MR) (2015)	**214 000 €****

* Basis for calculation: 16 MSs where Fees have been updated + NO + CH
** Basis for calculation: 28 MSs + NO + CH

Industry perspective

- Biocide product Union Authorization

National Authorization	Average
Biocide Product Union Authorization *Commission Implementing Regulation (EU) No 564/2013*	**80.000 €***
Biocide Product Union Authorization Evaluation MS Fee	**~ 60 000 €***
Total / BP (ECHA + MS) (2014)	**140 000€**

* Basis for calculation: 12 MSs where Fees have been updated + NO

Industry perspective

- Biocide Product Family

National Authorization	Average
Biocide Product Family (2015) First Authorization 1 a.s. – 1 PT – 1 User Group	~ 75 000 €*
Biocide Product Family (2015) Mutual Recognition 1 a.s. – 1 PT – 1 User Group	~ 9 000 €*
Total / BPF (A+MR) (2015)	**336 000 €****

vs **214 000 €** for a single BP

* Basis for calculation: 16 MSs where Fees have been updated + NO + CH
** Basis for calculation: 28 MSs + NO + CH

Industry perspective

- Additional fees – Top-up fees

	Median
Biocide Product - RMS Additional a.s. 7 Countries	≈ 3300
Biocide Product - RMS Additional PT 12 Countries	≈ 5000
Biocide Product - RMS Additional user group 9 Countries	≈ 4500
Biocide Product - MR Additional a.s. 8 Countries	≈ 2500
Biocide Product - MR Additional PT 11 Countries	≈ 3500
Biocide Product - MR Additional user group 10 Countries	≈ 3200

Industry perspective

- Biocide Product : Basic fee + additional fees

Biocide Product (2015) Authorization sought for all over Europe+NO+ CH PT8 – 1st Authorization + MRs 3 active substances 3 user groups (Industrial-Professional-Amateur	**Basic fee + 2x add a.s. fee + 2 x add. User group** RMS ~ 41.000 + 6600 + 9000 MSs (29 countries) ~ 29x6.000+8x5.000+10x6.400
Total	**334 600 €***

* Basis for calculation: 28 MSs + NO + CH

Industry perspective

- Biocidal product: Administrative change

National Authorization	Average
Biocide Product (2014) Administrative change RMS	~ 500 €*
Biocide Product (2014) Administrative change Mutual Recognition	~ 500 €*
Total / administrative change (2014)	**15 000 €****

* Basis for calculation: 12 MSs where Fees have been updated + NO + CH
** Basis for calculation: 28 MSs + NO + CH

Content

1. EU Report on the Fees
2. Industry perspective
3. **Some comparisons**
4. Conclusions

Some comparisons

- BP : Fee BPR (2015) *vs* Fee BPD (2010)

Biocide Product Fee / BPR / (2014) 28 EU MSs + NO + CH	~ **214 000 €***
Biocide Product Fee / BPD / (2010) 28 EU MSs + NO + CH	~ **100 000 €***

X 2

Some comparisons

- Authorization + MR *vs* Union Authorization

BP /BPR (2014) First Authorization + MR	**214 000 €**
BP /BPR (2014) Union Authorization	**140 000 €**

Basis for calculation: 28 MSs + NO + CH

- Union Authorization (Article 42)
  - Phase-in approach
  - Exclusion for BP containing a.s. falling under Article 5 and those of product-types 14, 15, 17, 20 and 21

Some comparisons

- BP : Difference between MS fees

	Average
Biocide Product Fee BPR / 2015 ***Finland FIN***	**96 000 €**
Biocide Product Fee BPR / 2015 ***Belgium BE***	**15 000 €**

~ X 6

Some comparisons

- BP : Evaluating Member State fee - First authorisation *vs* Union Authorization

	Average
Biocide Product Fee / **First** Authorization BPR / 2015 **28 EU MSs + NO + CH**	**~ 41.000 €**
Biocide Product Fee / **Union** Authorization - eMS BPR / 2014 **28 EU MSs + NO + CH**	**~ 60.000€**

~ X 1.5

Some comparisons

- BP Fee *vs* Plant Protection Product Fee

Biocide Product Fee / BPR / (2015) 28 EU MSs + NO + CH	~ **214 000 €**
PPP Fee / PPPR/ (2010) 28 EU MSs + NO + CH *(information received by ECPA)*	~ **185 000 €**

BUT

Biocide market *vs* PPP market: **3.5 X lower**
(source: market survey)

Content

1. EU Report on the Fees
2. Industry perspective
3. Some comparisons
4. **Conclusions**

Conclusions

- Fee have drastically increased under the BPR
- Fee will highly impact the Biocide business
- All the actors of the supply chain will be impacted
- Biocide sector is in transition - Fewer variability in terms of products
- Disproportion with other markets (PPP)

Conclusions

What is needed?

- Revision of the Fee Regulation (January 2015) should consider the impact for our Industry → Status?
- Same when MSs review their fee legislation
- More SMEs measures (ECHA + MS levels)
- Reasonable Annual Fee (mainly in case of cumulative MS fees and ECHA fee for UA)

Conclusions

What is needed?

HARMONISATION

- PA/MR
  - ? differences between MS
  - ? fee update on which basis – recommendations?
  - ? MS in adoption/review process → fee increase very likely
- Top-up fees
  - ? Intention to add top-up fees?
  - ? Big impact on industry

Thank you

The Gold Standard for Performance

Evaluation of Active Substances:

The Industry Experience

Dr. Samantha Champ
Head of Regulatory Affairs - Biocides
Home Care and Fomulation Technologies Europe
2nd April 2015

150 years

BASF
We create chemistry

1 | Status Quo – where are we are where do we need to go?

2 | Industry experience - qualifications

3 | Extra requirements now in place for A.S. manufacturers

4 | Public consultations

5 | Article 95 – importance of being on the list

6 | Summary

Status Quo

- 1998 - Directive addressed the need to regulate the biocidal products market
- 2002 – confirmation of participation
- 2006 – first wave of dossiers submitted
- 2009 – first approvals
- 2010 – first extension to programme
- 2013 – ECHA take over running of programme
  - Aim of making 50 PT/AS decisions per year
- 2024 – programme to be completed

Status as of end of March 2015

source: source: CA-March15-Doc 5 2 - Progress of the RP of AS

150 years

BASF
We create chemistry

- Number of AS/PT decisions:

112

- Number of active ongoing AS/PT evaluations by ECHA:

100

- ECHA effect – AS/PT decisions since 1st September 2013:

34

- Number of AS/PT decisions still to take (approx):

450

Communicated timelines to completion

150 years

BASF
We create chemistry

Priority List	Product Type	Evaluation	Start BPC opinion
1	8, 14, 16, 18, 19, and 21	31/12/2015	31/03/2016
2	3, 4 and 5	31/12/2016	31/03/2017
3	1 and 2	31/12/2018	31/03/2019
4	6 and 13	31/12/2019	31/03/2020
5	7, 9 and 10	31/12/2020	31/03/2021
6	11, 12, 15, 17, 20 and 22	31/12/2022	31/09/2023

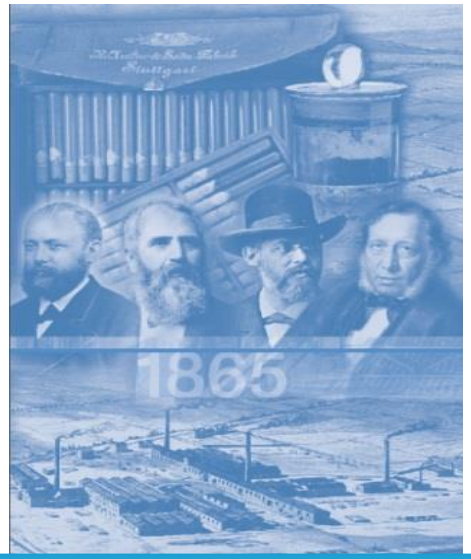
Challenges

- For industry and member states in continuing approach
  - Retention of expertise
- Market distortion in the PTs
- Heavy fee burden for some biocidal product manufacturers
- Negative decisions – impacting business

BASF is celebrating its 150th anniversary in 2015

150 years

BASF
We create chemistry

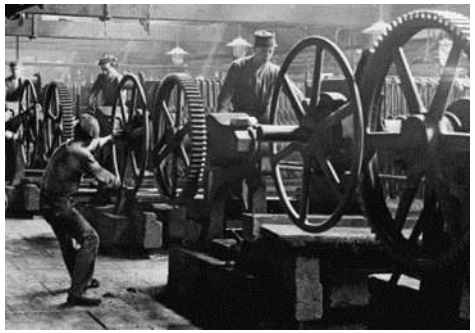


1865 2015 The future…

Chronology of BASF history

150 years

BASF
We create chemistry



1865 – 1901
The age of dyes

1902 – 1924
The Haber-Bosch-Process and the age of fertilizers

1925 – 1944
New high-pressure syntheses

1945 – 1964
From new beginnings to the plastic age

1965 – 1989
The road to becoming a transnational company

1990 – 2015
Sustainable start to the new millennium

Chronology of BASF history

150 years

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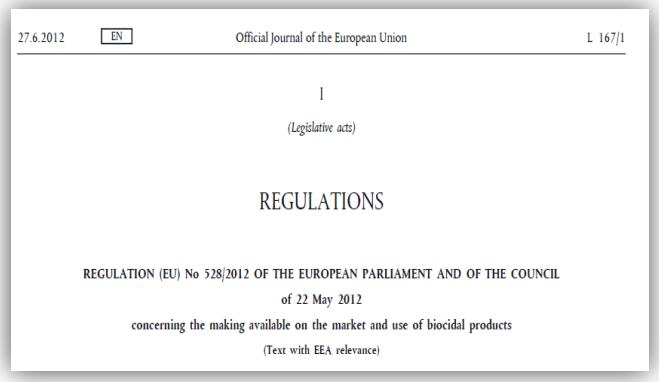
2002 – 202? The Age of Biocides



27.6.2012 EN Official Journal of the European Union L 167/1

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(Legislative acts)

REGULATIONS

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 May 2012
concerning the making available on the market and use of biocidal products
(Text with EEA relevance)

BASF Biocide Curriculum Vitae

- Number of Active Substances supported: 13 (18 in total for Group)
- Number of Product Types: 9
- Number of AS/PT approvals granted: 9 (still opinions)
- Number of AS/PT decisions still be made: 28
- Start of workprograme: 2002
- Expected date of completion: 2024

Extra Challenges for AS manufacturers

- New exclusion criteria and substitution criteria
- Evaluation or consideration of use in Treated Articles
- Harmonised classification and labelling
- IUCLID
- Age of submitted data
- Data sharing and negotiations
- Agreements and contracts
- Documentation of negotiations
- Importance of the 1st of September 2013 in the dossier evaluation

Substitution/Exclusion Candidate – what does this mean?

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- Aim is to encourage the use of active substances with a better tox and environmental profiles
- A new requirement under BPR

Exclusion Criteria (Article. 5)

- Active Substance will not be approved if:
  - CMR 1A and 1B
  - Endocrine Disrupters
  - PBTs (persistent, bioaccumulative and toxic) and vPvB
- If no alternative for PT exists and non-approval would be detrimental to human health, animal health or the environment - AS can be authorised for up to 3 years only.
- Not to be approved for consumer uses

Candidate for substitution (Article 10)

- A substance will qualify as a candidate for substitution if certain criteria are fulfilled, for example:
  - One of the exclusion criteria but may be approved due to lack of alternative
  - 2 out of 3 PBT criteria
  - is a Respiratory sensitisers (R42)
  - Acceptable Daily Intake, Acute reference dose or acceptable operator exposure level significantly lower than other AS for same PT and use.
  - Significant proportion of non-active isomers or impurities
- Length of initial approval for active substance will not be the full 10 years
  - Substances do not qualify for Union Authorisation

Extra steps in the Active Substance Evaluation: Public Consultation

- If the conclusion of the evaluation of any active substance shows that it meets the substitution criteria, according to Article 10, more information is necessary
  - These substances must be further evaluated before approval is granted.
- The further evaluation will take place as a public consultation, whereby any interested third party can submit information to ECHA (European Chemicals Agency) on viable alternatives or substitutes to the active substance under review.
  - 60 day consultation
- This process is very new but it will be increasingly used should more active substances progress through the BPR review programme and qualify as either a substitution

Public Consultation: Experience

- Suitable data is to be submitted – different approach to REACh SEA analysis
  - ALL alternatives are considered for that use
- As of March 2015:
  - Number of public consultations that have occurred: 12
  - Number of PTs involved: 14
  - Amount of data submitted: varied – for 4 substances no data was submitted
  - Percentage of BPC Opinions affected: 34%

(Ref: ECHA doc on experience in public consultation, Nov 2014, BPC-8-2014-06)

Implications for a substitution candidate at Product Authorisation

- If Active Substance is a substitution candidate – a comparative assessment **will** take place
  - Comparison of the product vs other approved products on the market
- A comparative assessment can **only** be done if:
  - Other BPS have already been approved in that country for that PT
  - The BPs on the market must show more than 3 modes of action in killing bacteria/fungi/moulds/yeasts etc.
    - If answer is no – evaluation can not be done for risk of developing antimicrobial resistancy
- The product approval will not be 10 years – most likely shorter than the AS approval
- Fees!
  - More frequent reapproval and comparative assessment fees

Implications of comparative assessment

- BPR timelines have been brought in line with the original submission deadlines
- Aim under BPD – to review the most urgently needed AS and PTs
- Review of remaining AS has been brought in line with the original submission deadlines
- Aim under BPR – to make comparative assessment easier for the PTs

Reality of comparative assessment

- HOWEVER, not all Member States worked according to this logic!
  - Some Member States were quick and have reviewed all AS/PTs
  - Some of the substances have now been branded as Substitution Candidate
  - For some products there are no alternatives in the product type
  - AS will no longer receive the full 10 years approval
  - BPs will not receive the full 10 years
  - Some active substances, which are ‘fortunate‘ to be with slower MSs will qualify but much later in the programme
- Skewing of the market

Pragmatic approaches to comparative assessment

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- Due to the way in which Member States approached the review – not straightforward to evaluate all PTs together
  - PT6 substances are starting to come through
  - Each A.S. is being evaluated independently
  - 50% of sensitising AS s are in this group
  - Deadline for PT 6 review is 2020
  - By 2020 the choice for PT6 may be considerably smaller
  - If some groups of substances are removed – not many alternatives
- For this group of actives an alternative approach needs to be considered to ensure that the market can still work!
- Approach already proposed for PT 14 and PT 21

Important confirmations:
Importance of the Article 95, Manufacturers of Active Substances List

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- Article 95 is an overview of all active substance suppliers and product suppliers who have submitted a valid dossier and are allowed to stay on the market
- All biocidal product manufacturers need to use authorised substance suppliers at the latest from 1st September 2015
  - An approved supplier has to be used even if the Active Substance is not approved on the 1st September 2015

What do Biocidal Product Manufacturers need to have?

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- Transparency of supply chain to supplier in Art. 95 List
- Confirmation of supplier status
- Do not necessarily need a Letter of Access
- Otherwise Member States will police and cancel registrations

Example from UK:

EU Biocides Regulation 528/2012 (EU BPR) – Impact of the Article 95 list on biocidal products made available on the UK market under the Control of Pesticides Regulations (COPR)

From 1 September 2015, a biocidal product cannot be made available on the EU market unless either the substance supplier or the product supplier is included in the Article 95 list for the product type to which the product belongs. Have you checked your supplier is listed?

By 1 September 2015, **all** companies making biocidal products available on the UK market must have evidence their supplier is included in the Article 95 list. This evidence should include written confirmation of the source of the active substance formulated within the product and a link to the source's entry on ECHA's Article 95 list.

HSE does not intend to be prescriptive as to exactly what that evidence should comprise as we believe industry should have a degree of flexibility on this issue, but you should have documentation demonstrating a clear, auditable trail showing the supply of the active substance used in your product is from a specific Article 95 listed company – for example that could be a Letter of Intent to Supply or a similar document from the Article 95 listed company; copies of paperwork such a contract between the companies for the supply of that substance; or invoices/delivery notices etc. If a company is making the biocidal product available on the market and also the Article 95 listed company for the active substance in the product, a simple written confirmation of the fact that they will only be using their own source of the active substance will suffice.

ALL COPR Approval Holders need to submit evidence to HSE to prove that the supplier of the active substance in their product(s) or the product supplier is included in the Article 95 list.

If HSE DOES NOT receive this information on your product(s) by 1 September 2015, the approval conditions relating to the advertisement, sale and supply of your product(s) will be REVOKED.

NO phase out period for the advertisement, sale and supply of your product(s) on the UK market can be granted.

The approval conditions relating to the storage, use and disposal of your product(s) will continue subject to the provisions of Article 89(2), 3(b) and 4(b) of EU BPR.

All other companies making biocidal products available on the UK market must have the required evidence and must provide it to HSE or Enforcement Authorities if requested.

Have you submitted your evidence yet? If you haven't send it to our usual address.

BPR – a life enhancing experience?

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- BPR is and will remain a challenge - need to focus on the positive:
- Work-life Balance
- Health
  - ECHA now in lead – more resources, tighter time lines – need to keep up!
- Learning
  - new documentation, data sharing – develop new skills
- Patience
  - Time lines have been extended - not over soon
- Security
  - Biocides is a job for life!

Thank you for your attention!

150 years

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Transitional Measures Under the BPR: In-situ Generated Active Substances and Food Contact Materials

Dr. Anna Gergely

Annual Chemicals Regulation Seminar
Product Defense for REACH and Biocides
April 2, 2015 – Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Steptoe
STEPTOE & JOHNSON LLP

Extension of the Scope of the BPR

	BPD	BPR
Active substance	A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.	A substance or a microorganism that has an action on or against harmful organisms.
Biocidal product	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or **generating** one or more active substances**, with the intention of** destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action. **A treated article that has a primary biocidal function shall be considered a biocidal product.**
Treated article	None	Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**.

Extension of the Scope of the BPR

	BPD	BPR
Food Contact materials and articles	**Article 1(j):** The Directive **shall exclude products** that are defined or within the scope of Council Directive 89/109/EEC (now Regulation 1935/2004) on materials and articles intended to come into contact with foodstuffs	**Article 2(2) ..**this Regulation **shall not apply** to biocidal products or treated articles that are within the scope of the following instruments: …[**Regulation 1935/2004]** **No exemption for FCM**

In-Situ Generated Active Substances

In-situ Formed Active Substances: Definitions

- Biocidal product definition is expanded: also covers substances or mixtures **generating** active substances. But the emphasis on **intention** to destroy etc. remains unchanged
- On the basis of the BPD definition precursors were not considered biocidal products. The MoD interpretations – further confused the situation. As a result, applicants have submitted dossiers for the authorisation of
  - Precursors
  - Generated active substances
  - Both
  - Neither
- The extended BPR definition clarified this situation – however, no clarity whether some precursors had to already be covered by the BPD – issue of "biocidal intention"
- Direct impact of the interpretation – confusion whether the transitional measures under Article 93 of the BPR apply or not for in-situ generated substances

In-situ Formed Active Substances: New Requirements

- Under the BPR it is foreseen that both the precursor and the *in-situ* generated active substance would go through approval
- Commission's Call for information on in-situ generated active substances (published January 2014) has requested feedback from companies on:
  - Active substances (AS)/PTs supported under the review program
  - New authorisation requests for other precursor/AS pairs – whether or not the company is participant already in the review program
  - Other precursors for the same AS
- Based on input from industry the Commission issued its revised position on the management of in-situ generated substances in Nov 2014; updated in March 2015 focusing on active substances under the Review Program
  - Substances generated in-situ (and their precursors)
  - Active substance releasers
  - Specific substances (ozone, $OH^{\bullet}$) are not yet addressed in the final document

March 2015 Commission Note (Final)

- In-situ generated substances need to be defined by reference to the precursor(s). The precursor is a biocidal product.
- Precursor is already in the Review Program – Article 95 listing is required by September 2015 (need MS review as well?)
- Active substance is on the Review Program but needs to be redefined – Article 13 of the new Review Regulation (Regulation 1062/2014) applies (any deadline for review?)
- New Precursor/AS combinations need dossiers to be submitted during the transition period – as per Article 93 (need to select MS to review?)
- The biocidal product subject to authorisation is
  - EITHER the precursor itself;
  - OR the active substance generated from precursor substances or mixtures, which themselves cannot be authorised as biocidal products (as ambient air or sea water)
- Does the REACH derogation from registration of the active substances cover the precursors as well?

Food Contact Materials

Food Contact Materials and Articles and Biocidal Products

- Products within the scope of Regulation 1935/2004 on Materials and articles intended to come into contact with food (the Framework Regulation) are no longer excluded from the scope of the BPR
- Scope of the Framework Regulation:
  - Materials and articles, including active and intelligent food contact materials and articles, which in their finished state:
    - Are intended to be brought into contact with food; or
    - Are already in contact with food and were intended for that purpose; or
    - Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use
- Annex I of Regulation 1935/2004 lists 17 groups of materials covered by its scope; including Plastics, Paper, Rubber, Glass, Ceramics, Silicones, Textiles, Wood; but also Printing inks, Adhesives, and Coatings

Framework Regulation

Specific Measures

- For the groups of materials and articles in Annex I specific measures may be adopted
  - Positive list with specific restrictions – as the Union list for plastics
  - Specific provisions protecting human health
  - Basic rules for checking compliance
  - Rules for sampling and methods of analysis
  - Specific provisions for traceability; publicly available Community Registers
  - Individual authorization, if necessary
- National measures
  - In the absence of specific measures, Member States may maintain or adopt national provisions (subject of the Principle of Mutual Recognition)

Framework Regulation

General Requirements

- **Article 3: General requirements**:
  - Manufacture in compliance with good manufacturing practice so that under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities which could:
    - Endanger human health - OR -
    - Bring about unacceptable change in composition of food - OR -
    - Bring about deterioration in the organoleptic characteristics
- The labeling, advertising or presentation of a material or article shall not mislead the consumers.

Plastics Regulation

Union list of Authorized Substances

Article 5: Union list:

- Only substances included in Union list may by intentionally used in manufacture of plastic layers in plastic materials and articles
- Includes:
  - Monomers and starting substances
  - Additives excluding colorants
  - Polymer production aids excluding solvents
  - Macromolecules obtained from microbial fermentation
- List may be amended

Article 6: Derogations for substances not included in Union List:

- Polymer Production Aids; Salts; Polymeric additives; Aids to polymerization and NIAS
- Substances in the Provisional List (remaining **only surface biocides**)

Food Contact Materials and Articles and Biocides

- Potential Biocide Product Types (PT) in food contact applications in any material category:
  - Surface biocides (PT4) – intended technical effect in the food contact article;
  - Process biocides (PT 6, 7, 9, 11, 12) – not intended to have an effect and to be present in the final food contact material or article;
  - Food preservatives (in active packaging applications) – intended to be released from the packaging into food, for a technological effect in food;
- All these were previously exempt from the scope of the BPD; now they are covered by the BPR; either as Biocidal Product (BP) or Treated Article (TA)

Regulatory Considerations for Biocides in Food Contact Plastics Materials and Articles

- Plastics Regulation 10/2011 has a positive list for all authorised additives (with some important derogations) – the Union list
  - 'Additives' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article
  - 'Polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article
- Surface biocides are considered additives, so for plastics applications they should be listed on the Union list
- Process biocides may still be used as Polymer Production Aids (PPAs) are under derogation from the Union list
- (Food preservatives still excluded from the scope of the BPR, as covered by Regulation (EC) No 1333/2008 on food additives)

Regulatory Considerations for Biocides in Food Contact Plastics Materials and Articles (cont.)

Multiple regulatory overlap:

- Dual authorization is the proposed approach in Discussion document from the Commission: July 2013:
  - ECHA for authorising the active substance
  - EFSA for establishing use restrictions
- Dual regulation:
  - Under the Food contact legislation:
    - Some surface biocides as additives are under derogation from the Union list: listed in the so called Provisional list, permitted in food contact plastics, their use is subject to national law and FR
    - Process biocides as PPAs are also under derogation from Union list, only subject to national law and FR
  - Under the BPR most of these applications are **considered treated articles**, subject to Article 58 requirements under the BPR, harmonised at EU level

Draft Measure for Setting Limits on Biocides in Food Contact Materials and Articles

- To regulate the overlap between the dual requirements
  - Requirement for the approval of the active substance under the BPR
  - Quantitative restriction on specific migration under the food contact legislation
- Proposal for quantitative restrictions:
  - Migration < 10 ppb; OR
  - QM < 1 ppm; OR
  - Specific limits determined by the new regulation (CMRs, endocrine disruptors, nano: only this option)
- Requires the amendment of the Plastics Regulation (10/2011):
  - Excluding biocides from the Union list
  - Review the Provisional List
  - Requires modification of national measures

Food Contact Materials as Treated Articles

- **Treated articles** were not explicitly covered by BPD - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)
- BPD did **not cover** imported articles treated with an active substance outside the EEA for an internal effect. No requirement to use EU approved actives.
- **BPR introduced changes that explicitly addressed treated articles**
- Specific chapter for treated articles which are not biocidal products
- Article 58(2): A treated article shall not be placed on the EEA market unless all active substances contained in the biocidal product that it was treated with or incorporates are EU approved for the relevant PT and use; and the restrictions are met (exception: fumigation and disinfection of premises)

Treated Articles: Commission's New Approach

Final Note for Guidance on Treated articles - December 2014

- *Article 3(1) (l) of the BPR defines a treated article as '…any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. As indicated in Article 58 (2) to (4), the provisions of Article 58 apply to treated articles in the form in which they are placed on the EU market (in the following also referred to as "finished goods")*, i.e. it does not concern directly components of complex articles or intermediate forms which are not themselves placed on the EU market
- The intentional incorporation of a biocidal product in a component of an complex article seems to imply a beneficial effect for the **finished article**
- In applications where the incorporation of biocidal products into individual components of complex articles was merely in order to perform a specific biocidal function at that stage of the process, but without an intended function in the finished article as placed on the EU market should not be considered as a treated article

Treated Articles: Commission's New Approach

- **Important elements to consider "intention" when making a decision on a treated article:**
  - Claims (both on biocidal function and biocidal property) – no claim does not automatically mean no intention
  - PT of the biocidal product (likely to be intentional or not in the finished article)
  - Concentration of the active substance in the finished article (low concentration, non-effective residues of active substances mean no intention)
- The onus is on the manufacturer or importer of the finished articles to provide justification whether the presence of a biocidal active substance is intentional or not
- If the remaining presence of an active substance in the finished article is not intentional, the article does not qualify as treated and the residual active substance should not be approved.

Summary Conclusions

- Most of the food contact applications falling under the Framework Regulation would be Treated articles under the BPR – with a binding positive list for plastics materials and articles
- To avoid legal uncertainty in a dual approval process - beyond the potential uncertainties related to some complex treated articles - it is necessary:
  - Exclude surface biocides for use in food contact plastics materials and articles from the scope of the Union List under the Plastics Regulation and refer their authorization to their authorization under the BPR
  - Review derogation under Article 6 of the Plastics Regulation for Provisional list
  - Coordinate ECHA and EFSA for the active substance authorisation and restrictions in food contact use (SMLs)
- Transition regulated by the BPR rules – Article 93 applies
- Specific legislative changes in national legislation for incorporating the new biocides measure under the BPR – replacing binding national rules for biocides

Questions?

Issues for Product Authorization: The Industry Experience

Jack Poppleton
Director, Head Global Regulatory Affairs
Arch Timber protection

Content

- Historical Background
- Suppliers and formulators – partnership or competition?
- Technical issues and opportunities
- Procedural issues
- Costs & Timing
- Summary

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Historical Background

- **15 years and counting**
  - BPD programme started in 2000
  - Anticipated 10 year programme
  - BPR now looking to a programme to 2025

- **Major changes**
  - Over this timeline significant fundamental changes have occurred
  - Technical and Procedural changes
  - Complexity unravelling

- **How does the formulator keep pace with the change and remain competitive?**

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Suppliers and formulators – partnership or competition?

- **BPD/BPR is a two phase system**
  - Phase 1 – Active substances
  - Phase 2 – Biocidal products

- **Active substances**
  - Prime objective to gain entry onto the Union List
  - One single use to be demonstrated for listing
  - May be based on "dummy product"
  - Some cases where no supplier would support the AI

- **Biocidal Products**
  - Authorisation for every product
  - Authorisation primarily in every country in the Union
  - Limitations to Union Authorisation
  - Link to active substance (Letter of Access)
  - Product Family approach

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Suppliers and formulators – partnership or competition?

- The Inclusion decision
  - Sets an initial envelope for authorisation of Products
- By no means an exhaustive evaluation of the active AND its use in products
  - Certainly not an evaluation of combinations of actives
- Likely to include a set of restrictions which could significantly impact your existing market
  - E.g. Professional or non-professional use
  - May include the need for significant mitigation measures

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Suppliers and formulators – partnership or competition?

- How useful is the Inclusion decision?

- Data gaps
  - In the rush to meet the timetable for completion of the active substance review programme, many decisions are left to Product Authorisation phase

  - Who will provide the data?
  - Who will own the data?
  - How will the data be presented and evaluated?
  - If there are multiple suppliers, does every supplier have a full data set
  - Do they have access to data not yet used that could be useful?

- How useful is the Article 95 List?

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Suppliers and formulators – partnership or competition?

- The AI supporters intent may not fit with your requirements
  - Is their supported use for Inclusion the same as your needs?
  - How did the evaluation process compare with the original intent?
  - Even where data has been examined under national schemes previously, the new interpretation is likely to much more conservative and therefore restrictive to your uses

- **Decision Time**
  - Do you partner with an AI supplier or simply buy on the market?

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Technical issues and opportunities

- Long evaluation time has had significant implications
- Adaptation to technical progress has changed the guidance documents
- ….. and Regulators interpretation of the guidance
- This has also potentially changed interpretation of existing data, exposures etc. or
- …. Set new data requirements at product authorisation phase for both the product and the active substance
- Increasing importance of hazard profiles / classification

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Technical issues and opportunities

- Products are the result of a significant product development programme

- Typically 5 years of development PLUS registration time
  - Efficacy and use pattern
  - Product Stability
  - Specific tox / ecotox data

- Many formulated product are a combination of actives and uncertainty on any active is multiplied at the product phase.
  - The AI supplier will have only considered their substance, not the combinations
  - PEC/PNEC for product = Summation of PEC/PNEC of all substances in the product

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Procedural issues

- New technology
  - Increasing drive towards electronic systems for applications and data submission
  - How many SME's will have the ability to use such systems?
- IUCLID
- SPC Editor
- R4BP3
  - Many teething problems.
  - Caused numerous issues.
  - Prevented applications in some cases.
  - IT updates issued without sufficient testing.
  - Fix a problem but create others.
  - Compatibility/upload issues.
  - MS have similar problems.

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Procedural issues

- Mutual recognition
  - One primary application to the Reference Member State
  - MR in other states

- Experience with RefMS and MR
  - Not a simple system
  - Very common for MS to reject MR
  - In some cases even data evaluated at AI stage is re-evaluated at MR stage
  - Experience and Legal developments are improving this

- However…..

- Are Reference MS now being much more conservative in their approach to primary authorisation so as to avoid challenges at the MR stage?

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Procedural issues

- New data
  - Under the AI evaluation programme, new data has not been considered
  - Where data has been developed either to answer existing requirements or to further elaborate on the substance or product profiles, how is it to be submitted?
  - What will be considered relevant ?
  - Will there be an open approach to accepting new data or will the pressure on time reject such new approaches?
  - How will the Assessment report for the Active Substance be updated
  - What are the timelines for all of this

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Costs & Timing

- Companies have to face the commercial reality
  - Suppliers have the costs of active substance investment and commercial operability
  - Formulators have to face the supplier cost, the development costs of their products, and the market acceptability.
  - Authorisation costs are very significant – affordable?

- The charging regimes are onerous and differ State to State and according to the type of application

- Timing is not always as given in the Regulation, issues may arise that change the timescales

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Costs & Timing

- Products are the result of a significant product development programme
  - Typically 5 years of development PLUS registration time
- AI Listings are for a maximum of 10 years
  - Review starts 550 days before actual renewal date
- If experience of the BPD is any pointer to future developments, then what confidence can formulators have to undergo a development programme which may be undermined by the renewal phase?

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Some experiences

Some thoughts on experiences-

- Critical to Understand the IT tools
  - When they don't work, how do you work with your MS?

- Mutual recognition – will it ever work properly?
  - Apparent lack of trust between some MS
  - Too many differences of opinion.
  - Process takes far too long
  - Costs in some MS are unacceptable
    - paying for re-evaluation?

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Some experiences

Some thoughts on experiences-

- Communication with MS.
  - Some are very good.
  - Some do not respond.
  - One way communication in some cases.
  - Applicant should be kept up to date but this is not always the case.

- Timelines not always observed.
  - Can take much longer than those set in BPD or the Regulation.

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So what to do?

- Plan your application well in advance.
  - The whole process is very complicated.
- Read any guidance documents carefully
- Then read them again!
  - Some of it is still not clear and open to different interpretations even between Member States.
- Choose your member state carefully.
  - Is your application for a single MS or multiple MS?
  - If the latter, then which will provide the greatest assurance of Mutual recognition

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So what to do?

- Understand exactly how your product will be used and ensure you cover what you want.
  - Make sure that you explain both the product and its uses clearly in your application
  - The regulator may not know your uses well. He will know your product even less.

- Understand the active reviews.
  - Ensure you fit within active substance approvals or that you cover data gaps/uses etc. in full.
  - Consider your relationship with the AI supplier
  - How much help can they give?
  - How do you protect your Intellectual Property?
  - Insist upon Confidentiality Agreements

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So what to do?

- Explain your product and its use clearly.

- Run risk assessments early to identify areas of concern.
  - Understand your risk assessment and models.
  - Do they really work?
  - Do the answers make sense?

- Would you benefit from a Product Family approach?
  - More complex
  - More expensive
  - Potentially more flexible.

- Anticipate questions.
  - Avoids delays and potential costs.

Talk to the regulator before submission if necessary.

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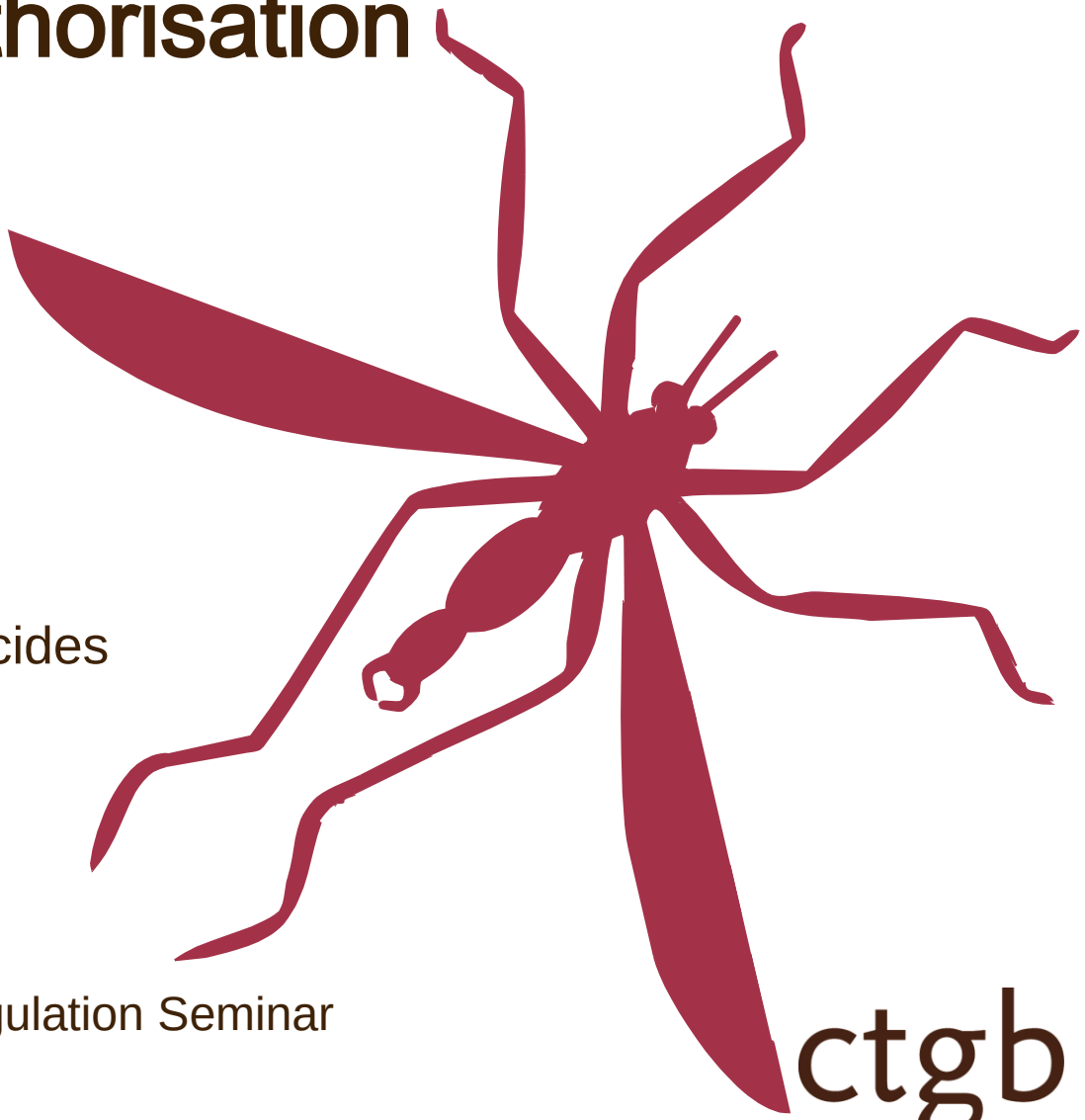
Summary

- The route to product authorisation is NOT paved with gold
- There are many rocks strewn across the path
- Critical to form good relationships:
  - Supplier to formulator
  - Formulator to regulator
  - Formulator to customer
- Critical to understand the process and be able to work within the limitations set
- Some companies will not survive the onslaught

arch TIMBER PROTECTION

Key member state issues for product authorisation



Joost van Galen
Projectmanager Biocides

Annual Chemicals Regulation Seminar

April 2015

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Contents

- Introduction to Ctgb
- Biocides in the Netherlands
- Ctgb's experience with BPR product authorisations
- Transition from national law to BPR
- BPR IT tools

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Board for the authorisation of plant protection products and biocides

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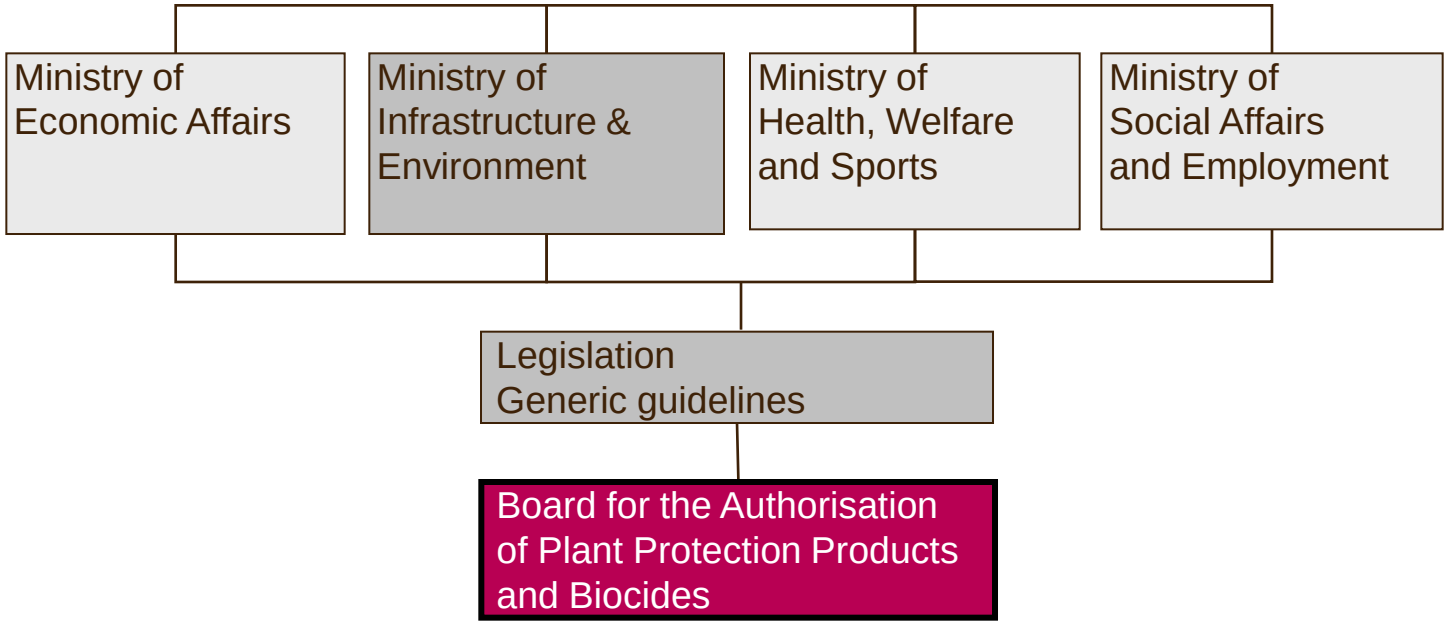
Organisation chart of Ctgb



Ctgb is the independent legal entity for authorisation and a semi-autonomous rate-controlled agency (ZBO in Dutch)

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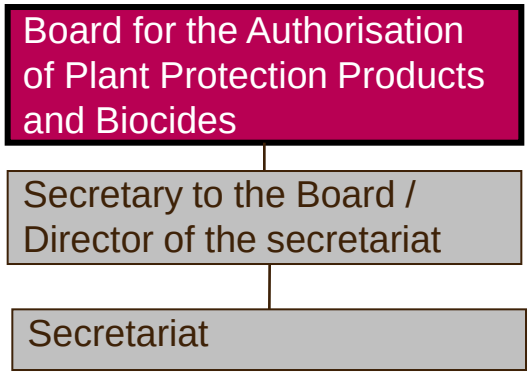
Relation Board and Secretariat



The Secretariat is responsible for the assessment of applications, and drafting the advice to the Board

The Board discusses this advice and:

- adopts or rejects the advice or
- asks for clarification of certain issues

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Biocides in the Netherlands

National legislation and BPR

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Authorisation of biocidal products

- 20+ years of experience in biocide authorisations
- Total of 1400 authorised products

- Dutch (transitional) law
  - Authorisation requirements for all PT's are quite similar to the BPR requirements.

- BPR
  - Authorisation requirements as laid down in BPR.

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Our experience with product authorisation under BPR

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Be prepared

- Avoid surprises at later stage, know what you want/need in advance!

- For example:
  - Union authorisation
  - National authorisation with MR
  - Fees (annual fees), timelines, same biocidal products, specific products per market area

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An SPC for every authorisation

- SPC editor – possibility for database with all authorised biocides
- Biocidal products should be classified, packaged and labelled in accordance with the SPC

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National authorisations (mutual recognitions)

- Build on experience from the BPD
- BPR offers some extra's
- Possibility for MR in parallel
- Disagreements occur in >50% cases
- Most disagreements resolved among MSs (Coordination Group)
- More experience gained per PT: less problems occur

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National experience

- ± 135 BPR/BPD authorisations:
  - ± 35 authorisations as RMS
  - ± 100 mutual recognitions/same biocidal products
- In general we are able to keep to the timelines
- Possibility to deviate for problem resolution
  - Keeping to timelines?
  - Best interest of applicant?

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Same biocidal product

- Straight forward procedure, very useful for SME's and private label companies

- Experience until now:
  - Proof that your product is 'the same' as the reference product
  - When relevant: only administrative changes
  - Letter of Access to all data of reference product and active substance

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Union authorisation

- Pre-submission phase with ECHA
- Discussions:
  - Is product within scope of BPR?
  - The right PT?
  - MSs may have different interpretations

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Union authorisation – the story until now

- Not many applications received yet:
  - High tariff to be paid to ECHA (and eCA)
  - Not available for all PTs yet
  - Limited number of approved active substances

- National same biocidal product from a Union family-member not possible yet

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Biocidal product families

- Defining the family
  - Similar use?
  - Similar composition?
  - Similar levels of risk and efficacy?
- Guidance is final, Q&A documents under development
- Family SPC, Meta SPC, product SPC. IT tools to be adjusted

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Biocidal product family - developments

- SME: consortia formation to share costs
- Advantage to make the family as big as possible?

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Simplified authorisations

- Active substance on Annex I
- Efficacy needs to be proven
- Complete SPC needs to be proven (shelf life)

- No LoA for product approval: no incentive to put new substances on Annex I?

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Transition of biocidal products from national law to BPR

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Approved active substances

- All active substances approved for all PTs a product is intended for → BPR

- Otherwise → national law

- Transition from national law to BPR within 3 years of approval final a.s./PT combination

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After active substance approval

- Products can remain on the market only if authorisation under BPR is applied for
- No new product authorisations under national law

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IT tools take centre stage?

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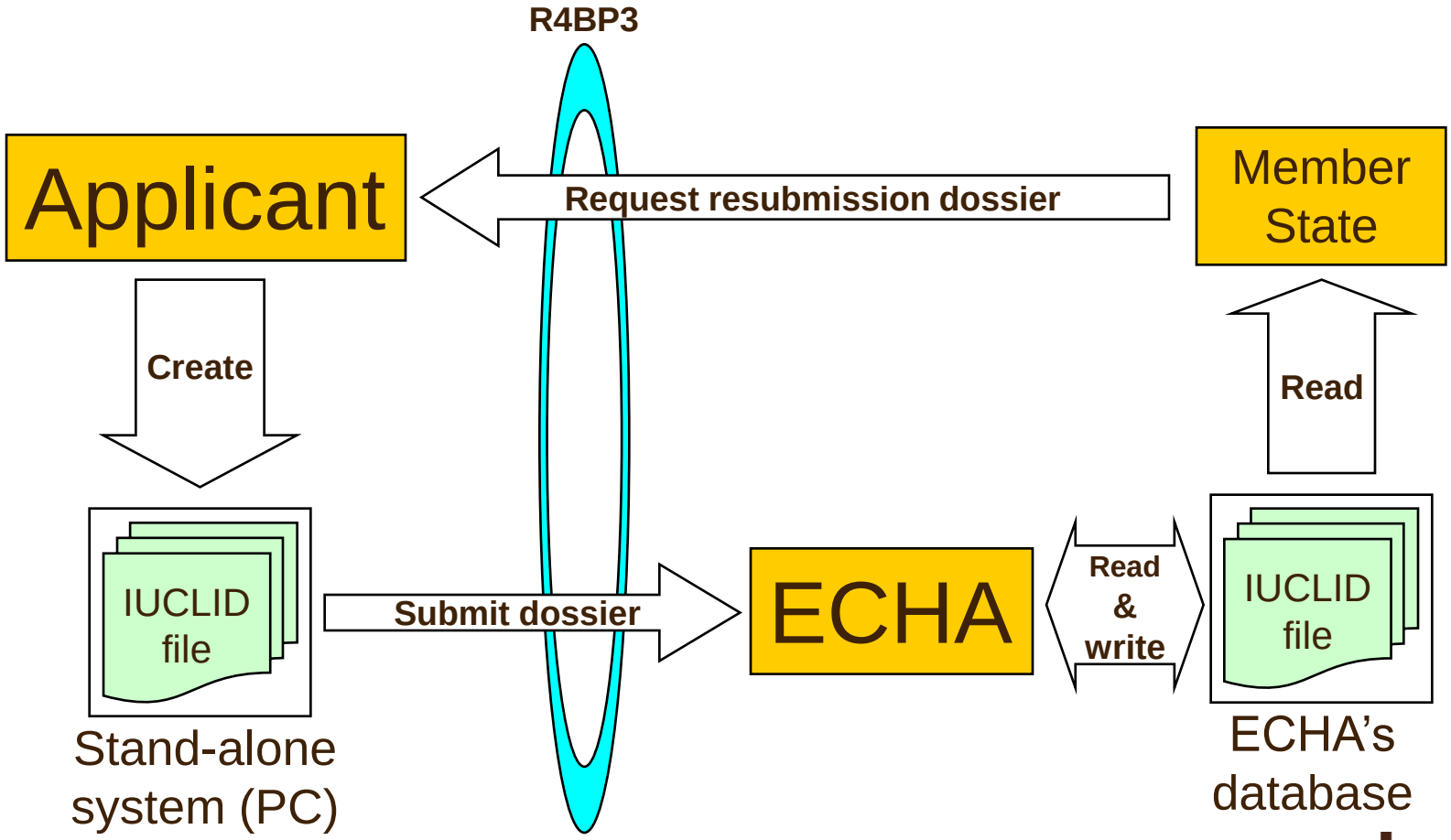
Handling of applications



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Consequence of IT architecture

- CA can not amend the IUCLID dossier
- Applicant is completely responsible for the dossier
- Evaluation of the provided information by applicant

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ECHA provides guidance for applicant's tasks

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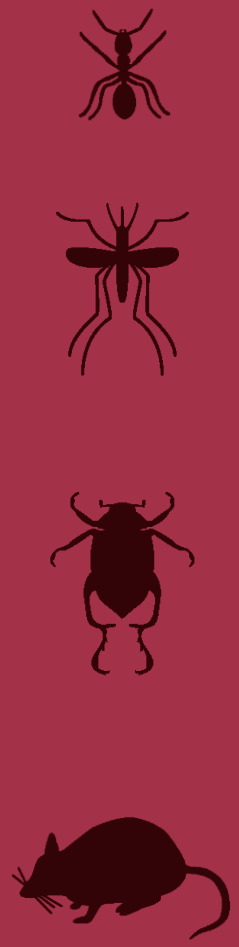
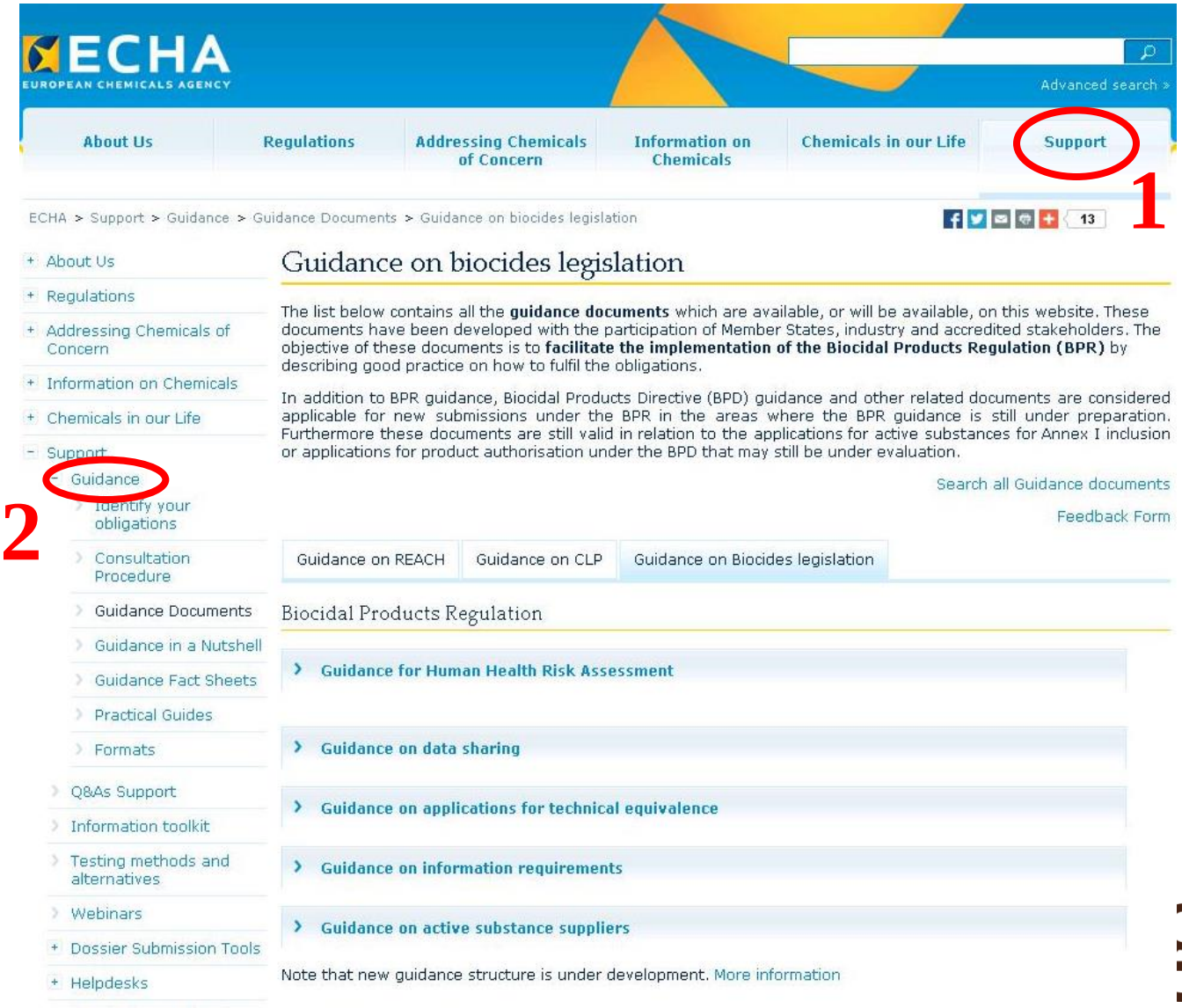
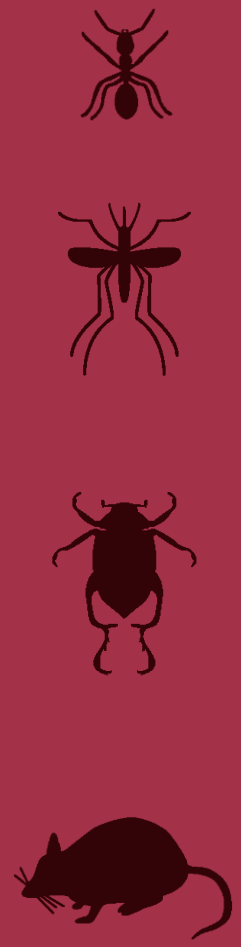
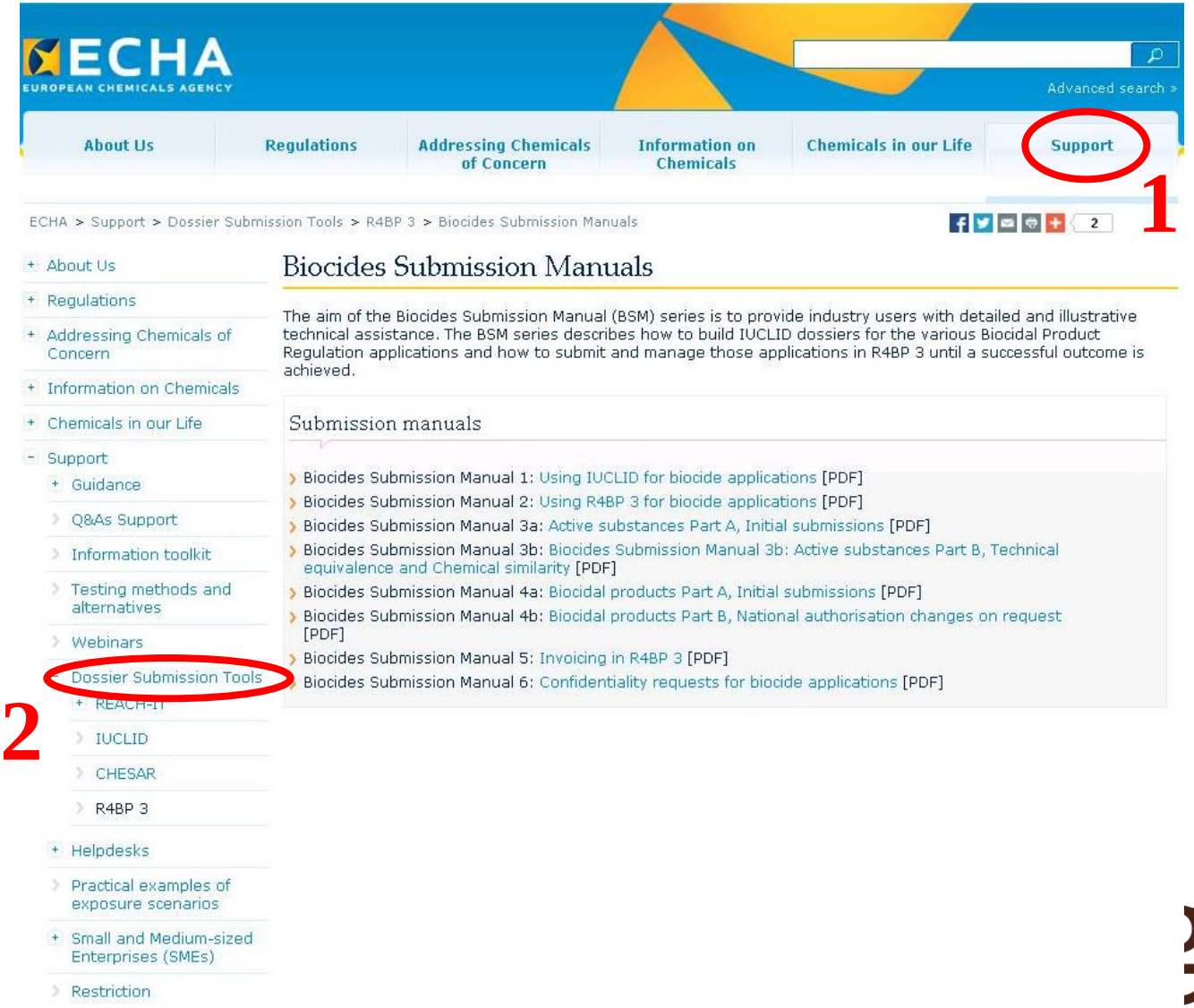
ECHA provides guidance at http://echa.europa.eu/





ECHA provides submission manuals, supporting documents etc.





Questions?

Questions after the meeting:

Contact ECHA at

http://echa.europa.eu/contact/helpdesk-contact-form

Contact Ctgb at

servicedesk@ctgb.nl

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