2015 Biocides key points

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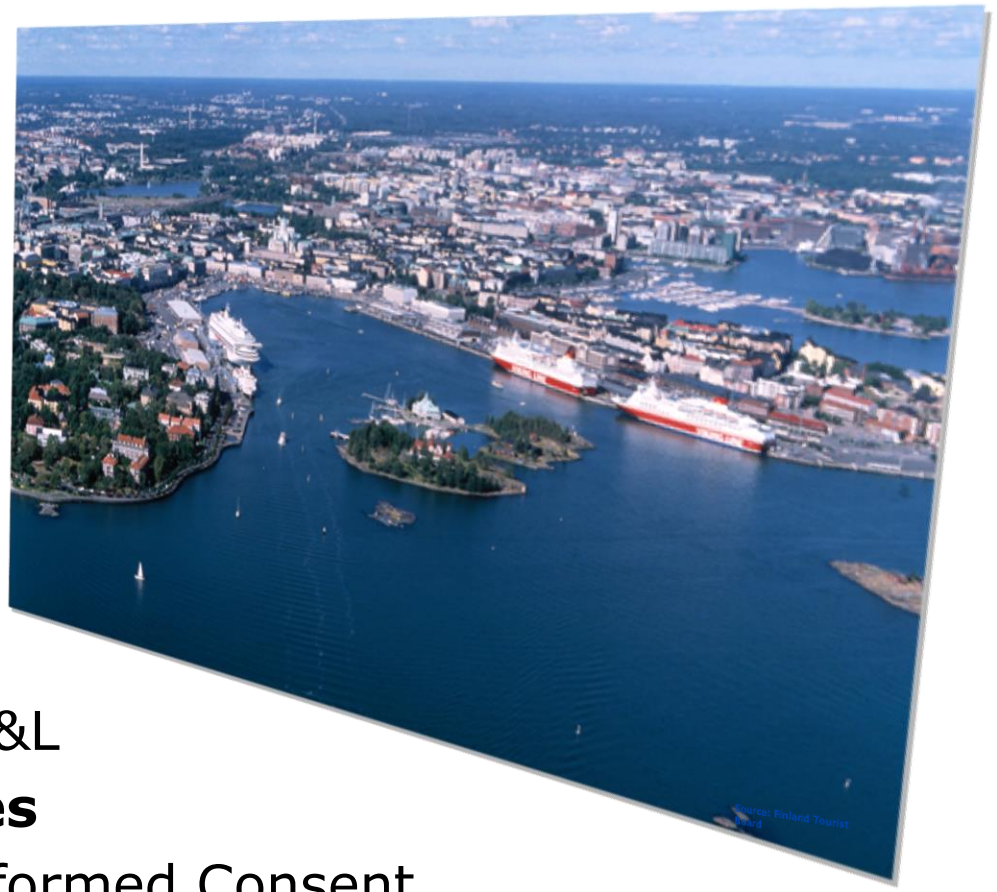
Annual Chemicals Regulation Seminar
2 April 2015

Content

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

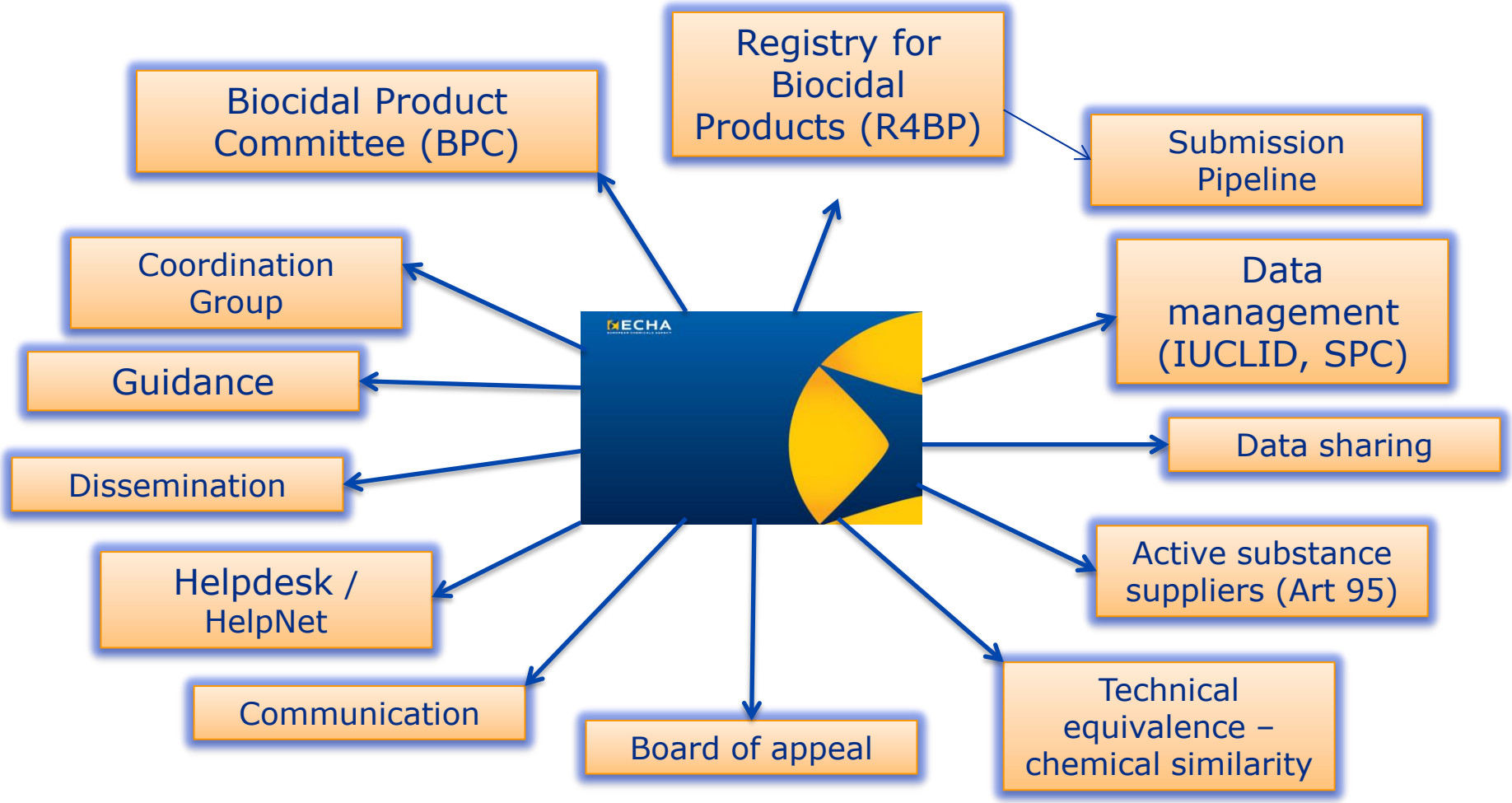
ECHA – almost 8 years old

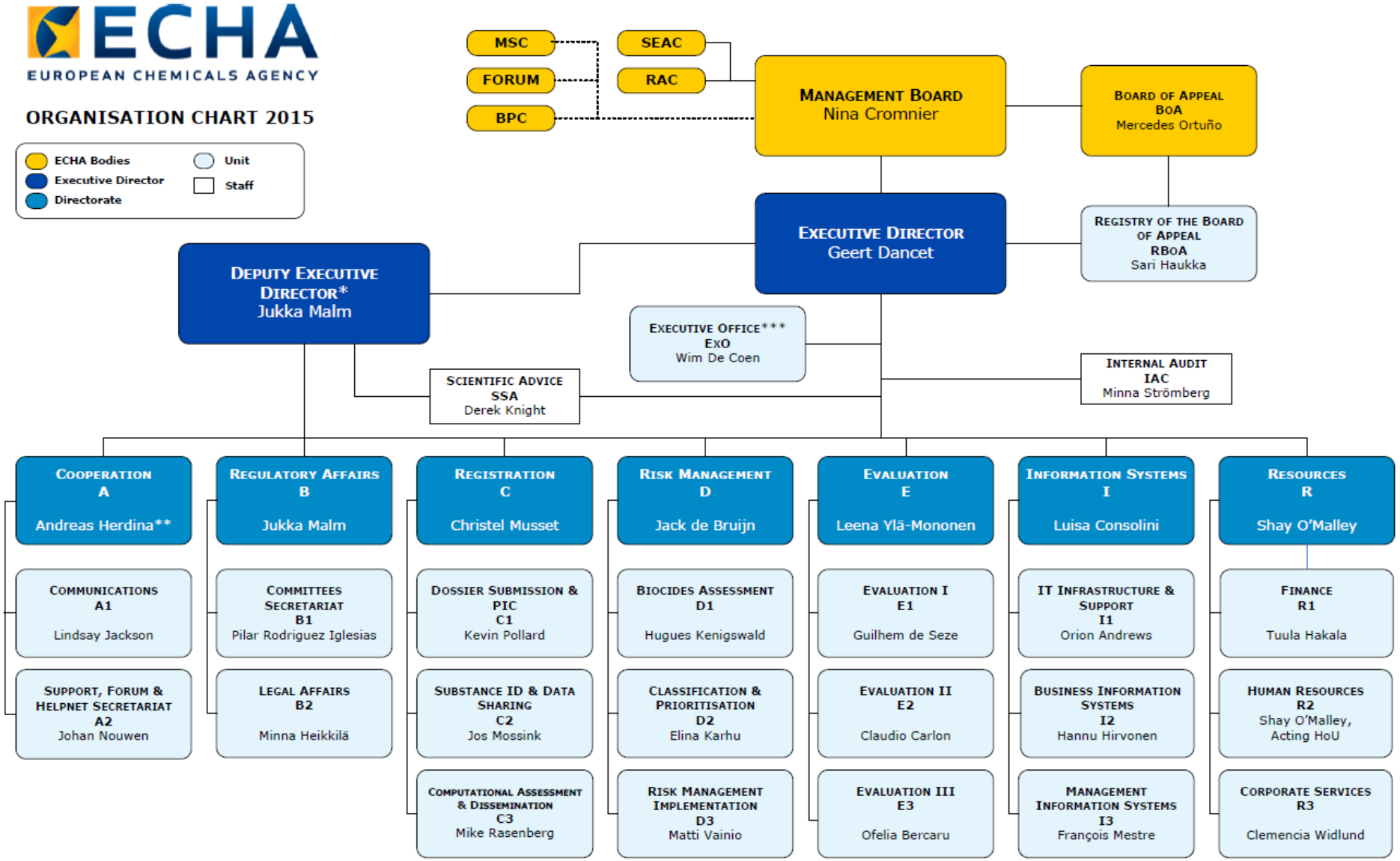
- Based in Helsinki, Finland
- Started on 1 June 2007
- Now about 560 people



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

The role of ECHA in biocides

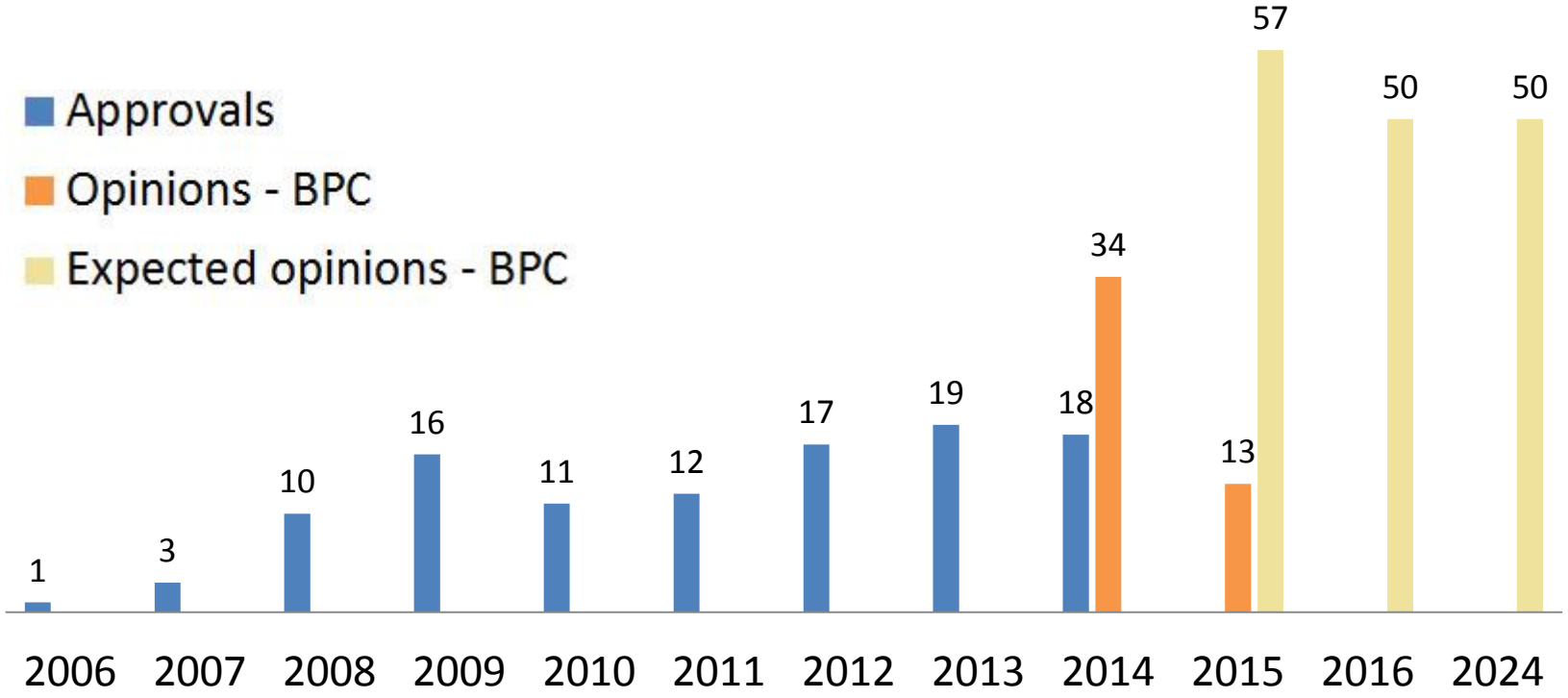




* Exercising also the function of Director of Regulatory Affairs
** Exercising also the function of SME Ambassador
*** The Quality Manager forms part of the Executive Office

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:

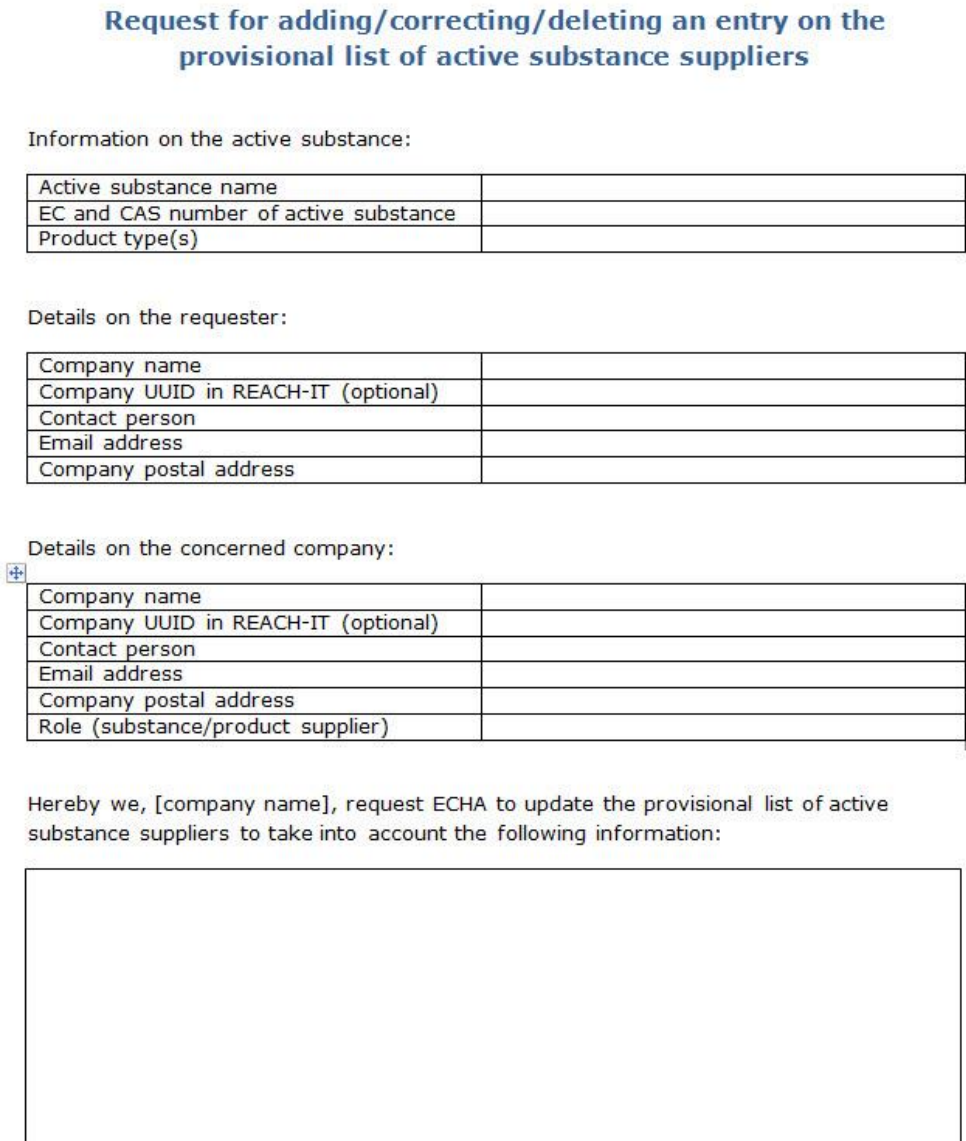
- the product originates (directly or indirectly) from a product supplier included in the list for the relevant product-type(s)

  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

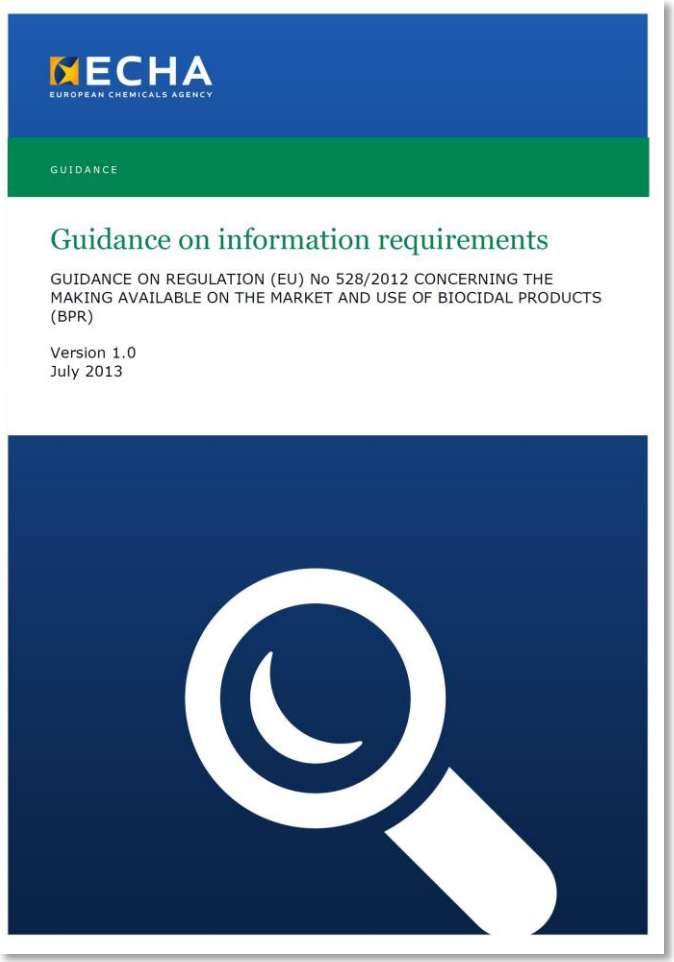
  (Part V of the Guidance on information requirements)

ⓘ 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

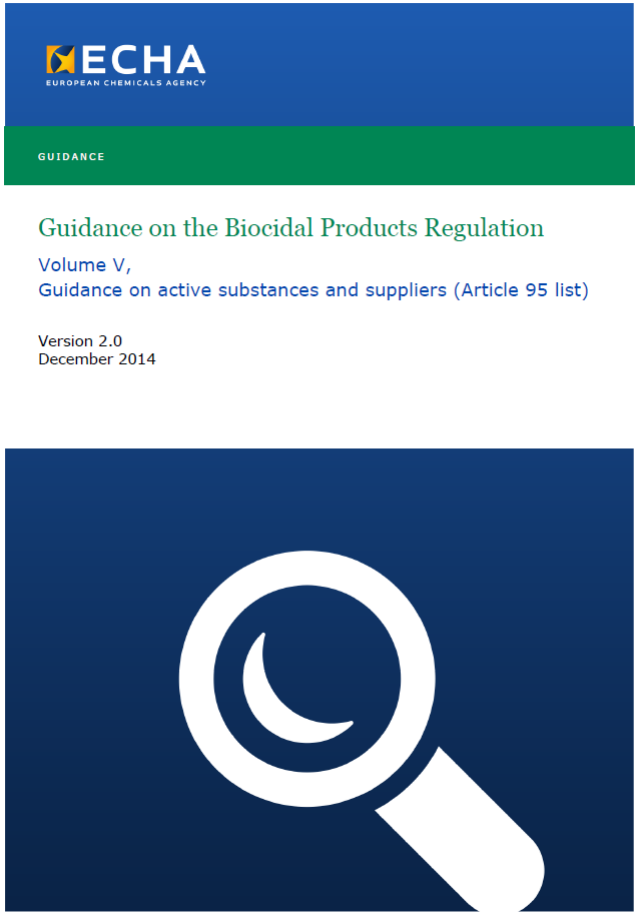
- Active substances and suppliers: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers
- List of active substances and suppliers: http://www.echa.europa.eu/information-on-chemicals/active-substance-suppliers
- Application procedure through R4BP3: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-supplie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

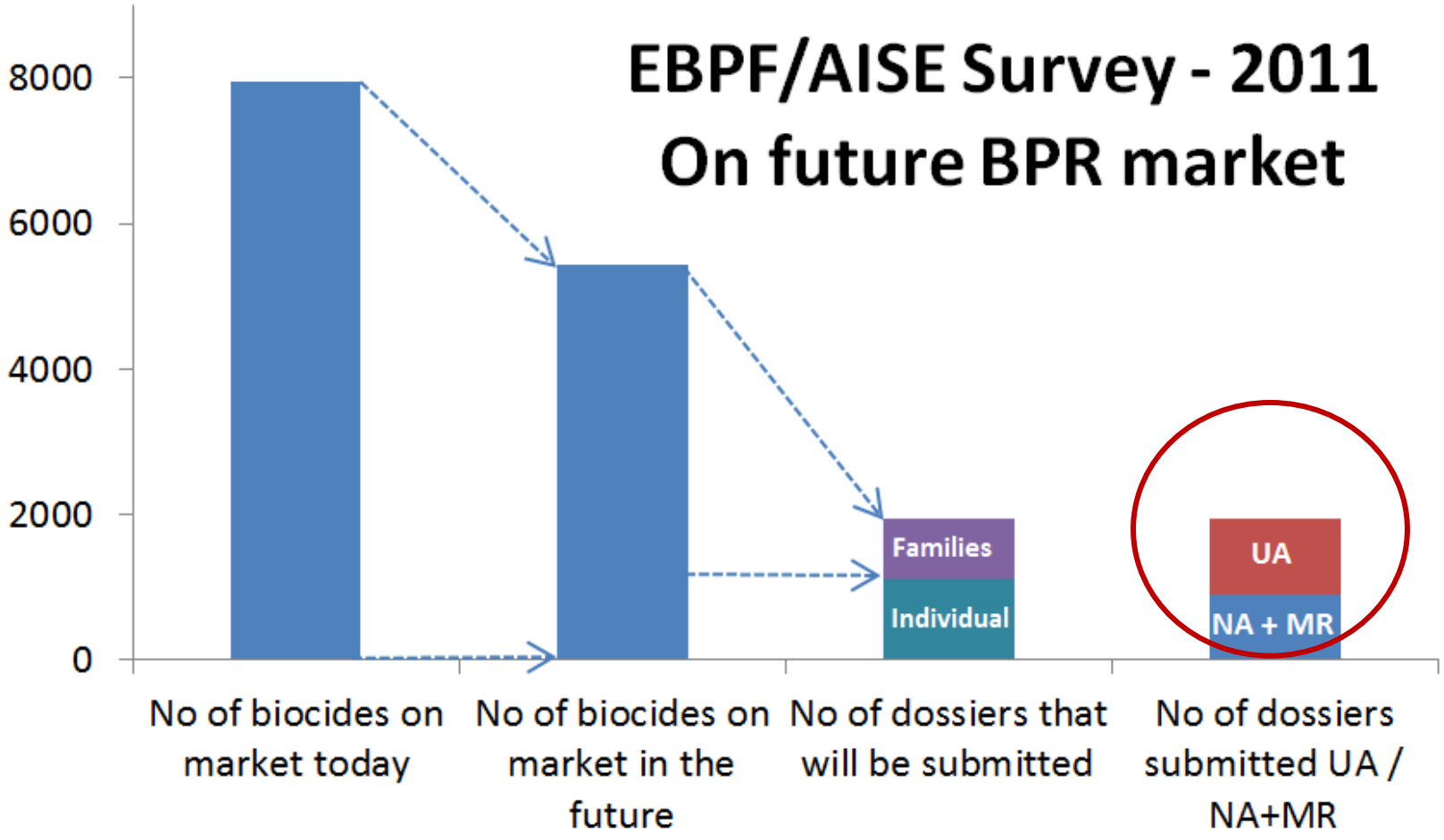
Article 95 – Key messages

- 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

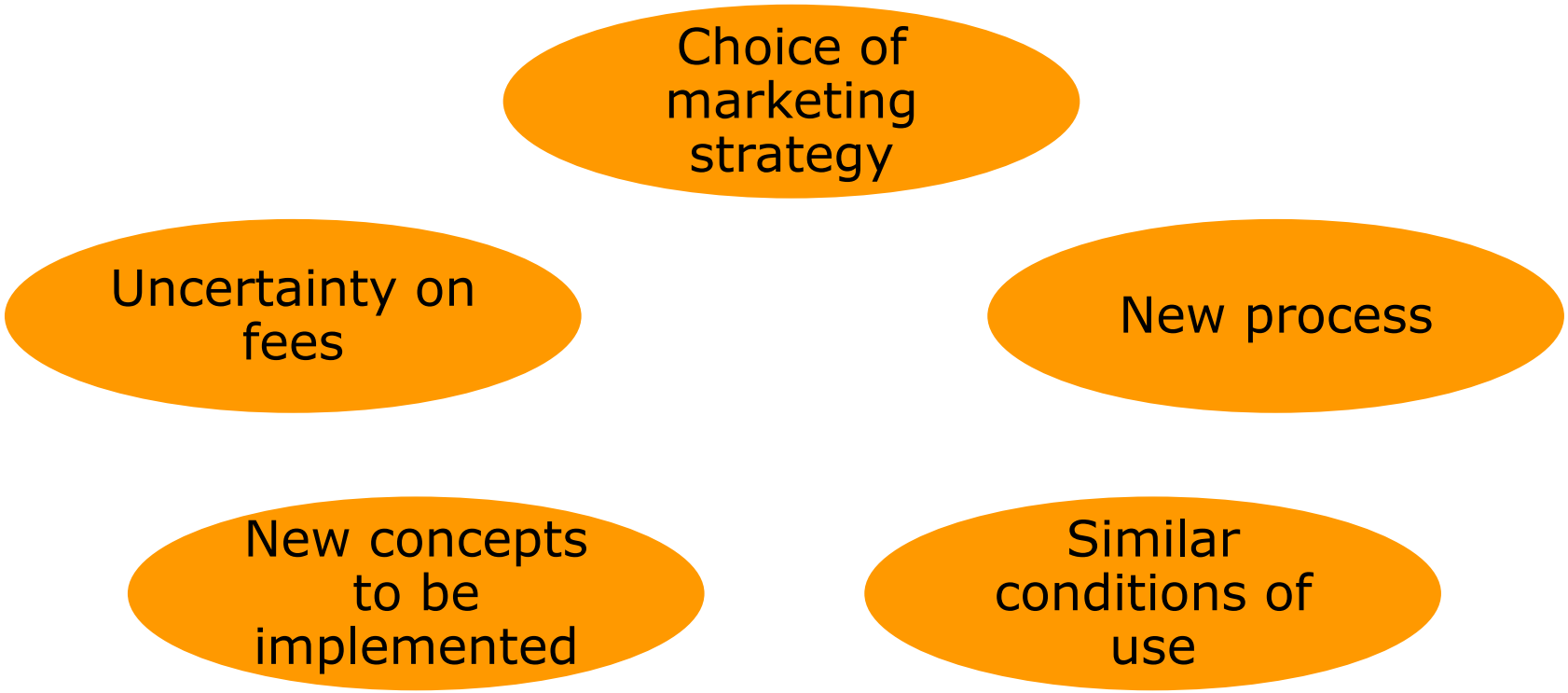
Expectations of Union authorisation

- 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

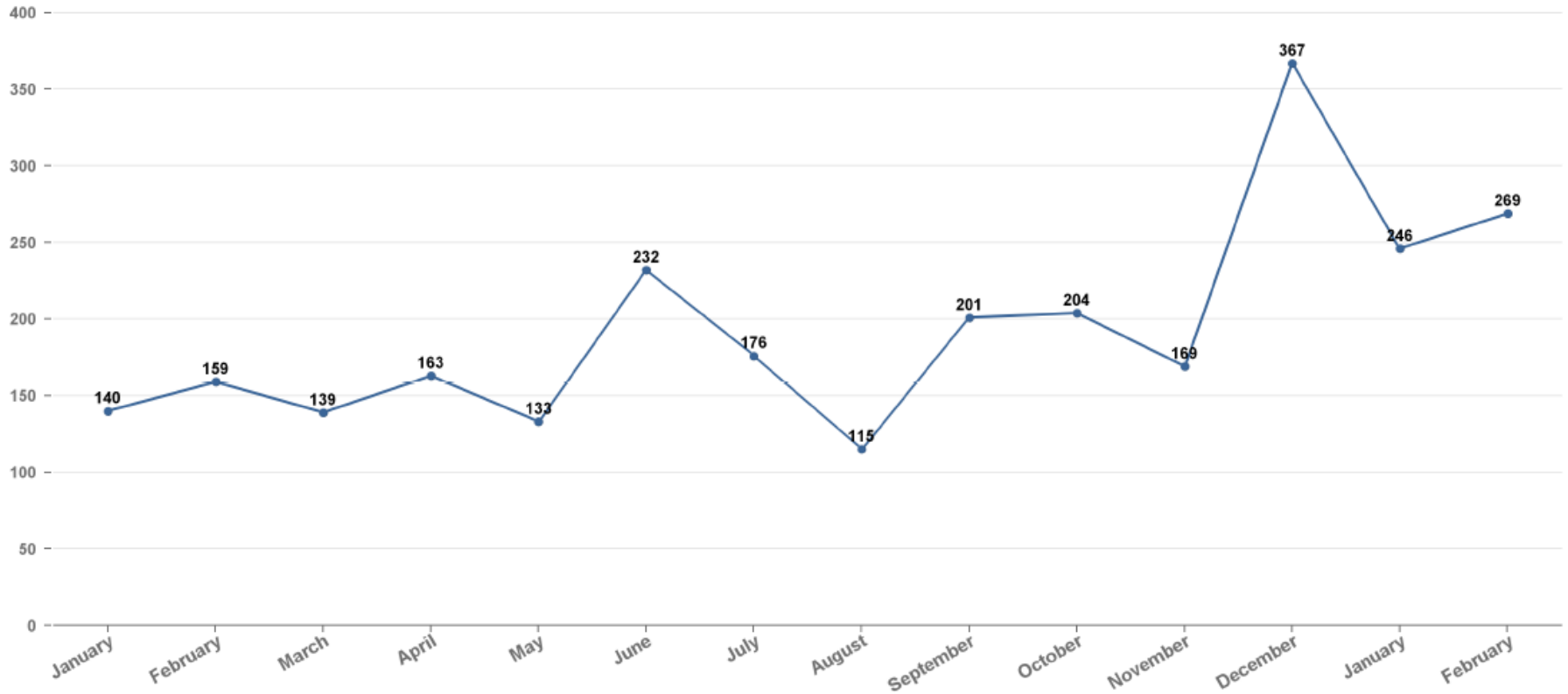
R4BP 3.2 + SPC editor: key issues

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

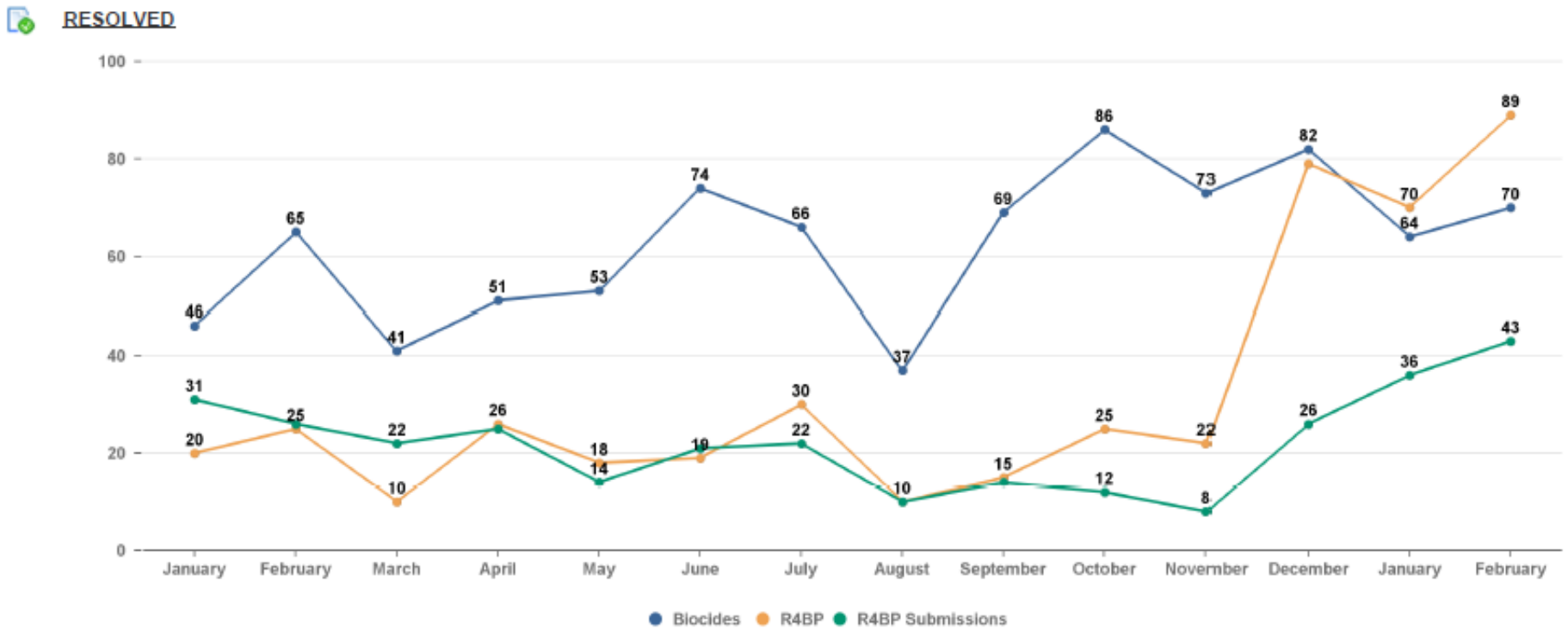
- SPC editor:
  - Incomplete list of active substances
  - Constraints on ranges
  - Copy and paste from word
  - Re-using an existing SPC for another product
  - multilingual version

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)