

# Article 95 – update by ECHA

## Biocides Stakeholders' Day

1 September 2015

Hugues Kenigswald  
Biocides Assessment  
European Chemicals Agency



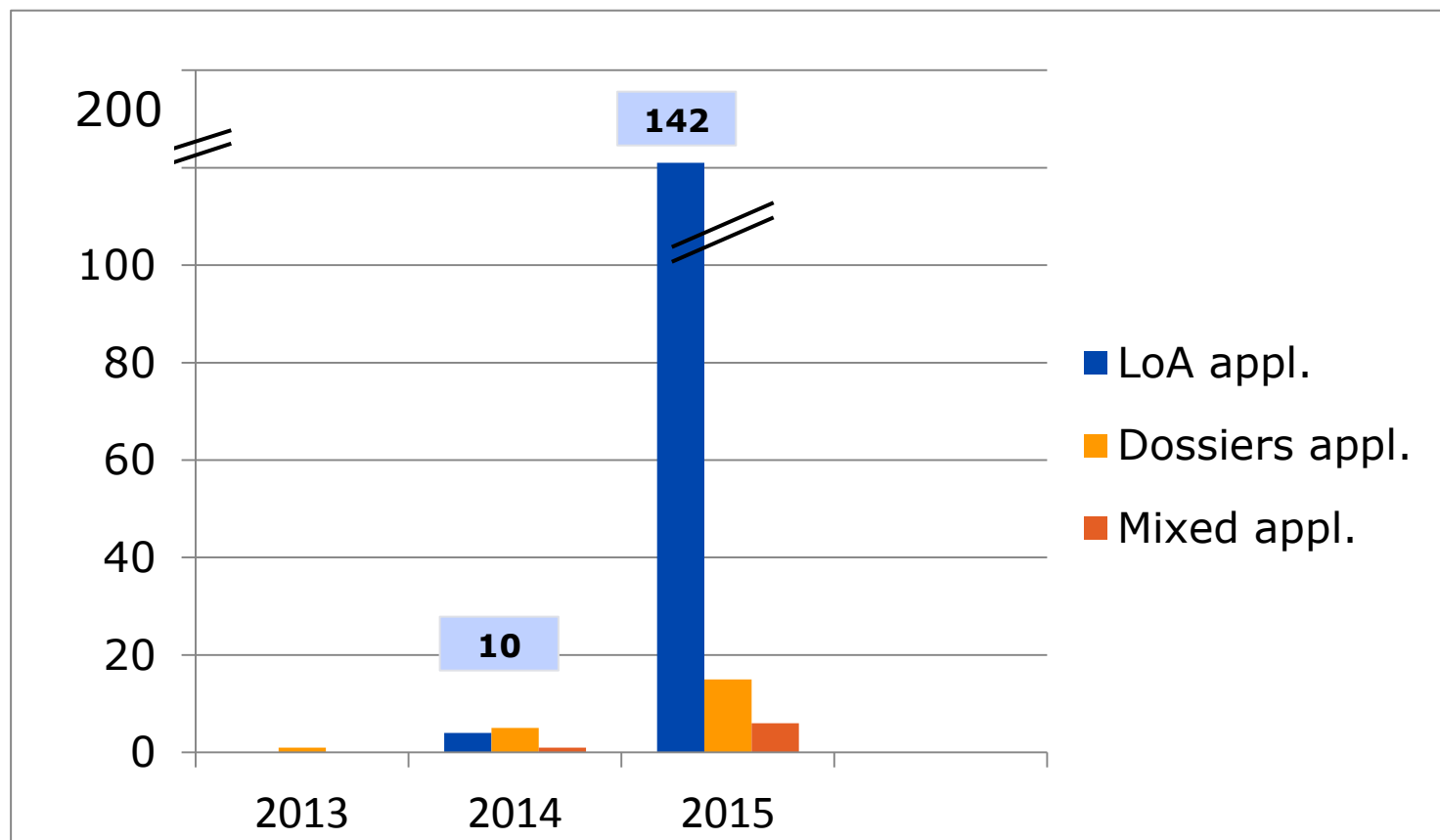
# Overview

- Some statistics
  - Numbers of applications, outcome
  - Distribution of applications and suppliers over active substance/product type (PT) combinations
  - Timelines
- Some hints for successful applications
- Publication of the Article 95 lists
- Article 95 applications after 1 September 2015
  - Active substances covered by BPR but not by BPD
  - New active substances

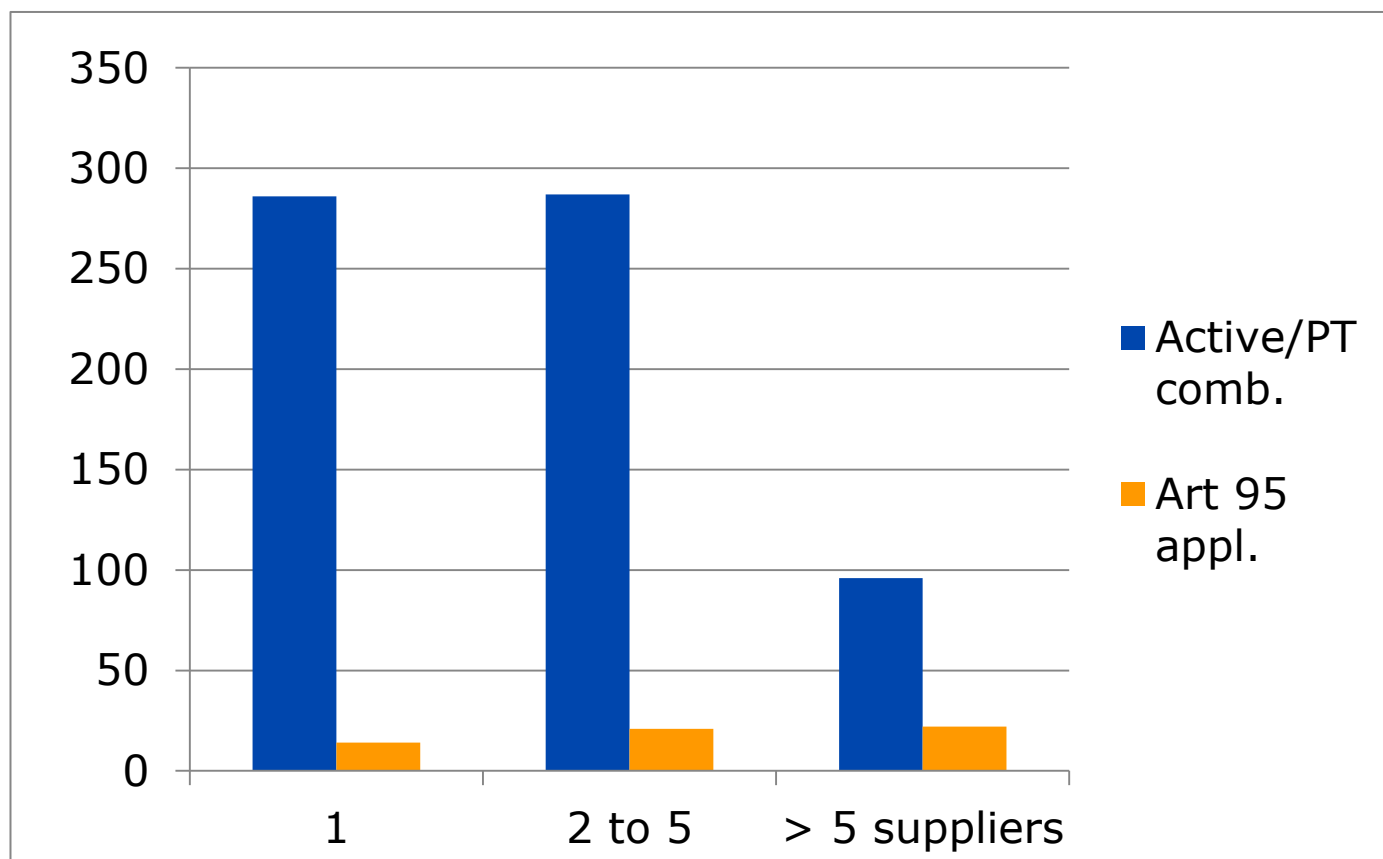
# Some statistics



# Article 95 – incoming applications



## Distribution of Article 95 applications and suppliers over AS/PT combinations

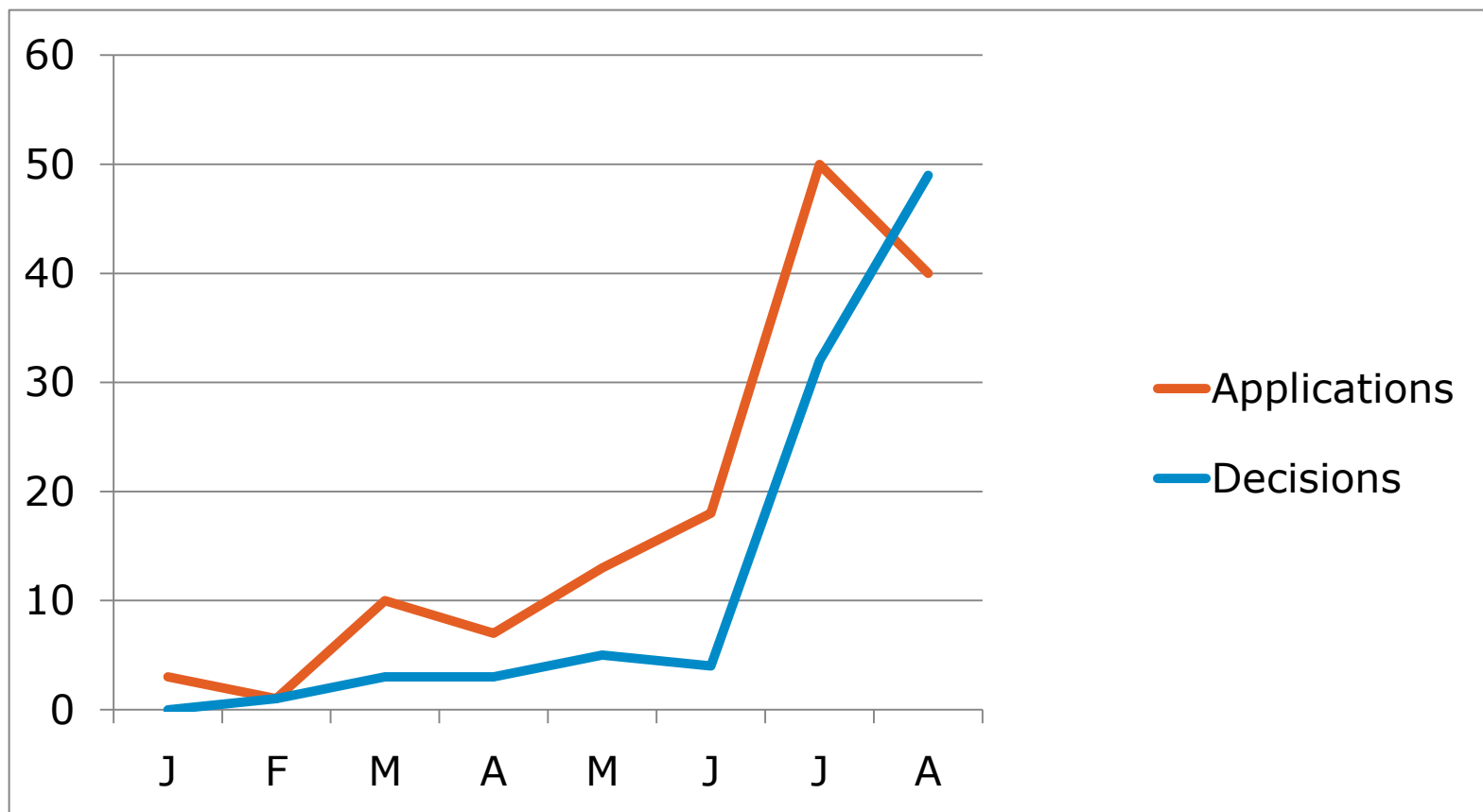


# Preliminary observations

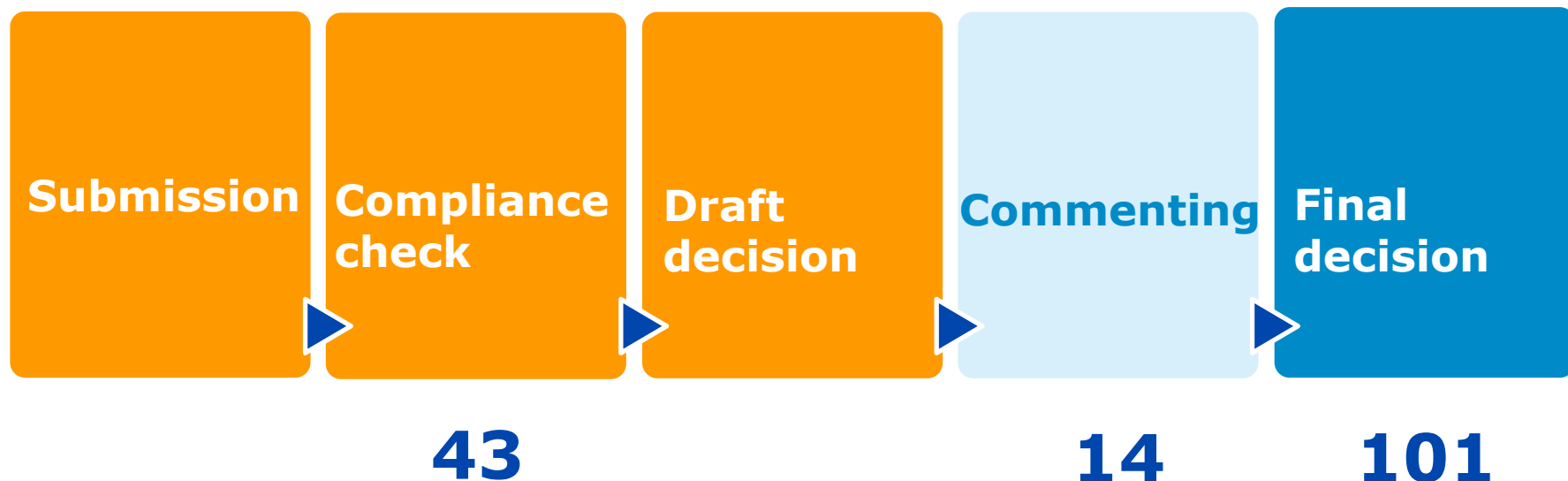
➔ Limited number of alternative suppliers

- Relatively more Article 95 inclusions for active substances with many suppliers
- Only around 15 Article 95 applications for active substance/PT combinations with only one supplier

# Article 95 – incoming applications 2015



# Processing of Article 95 applications



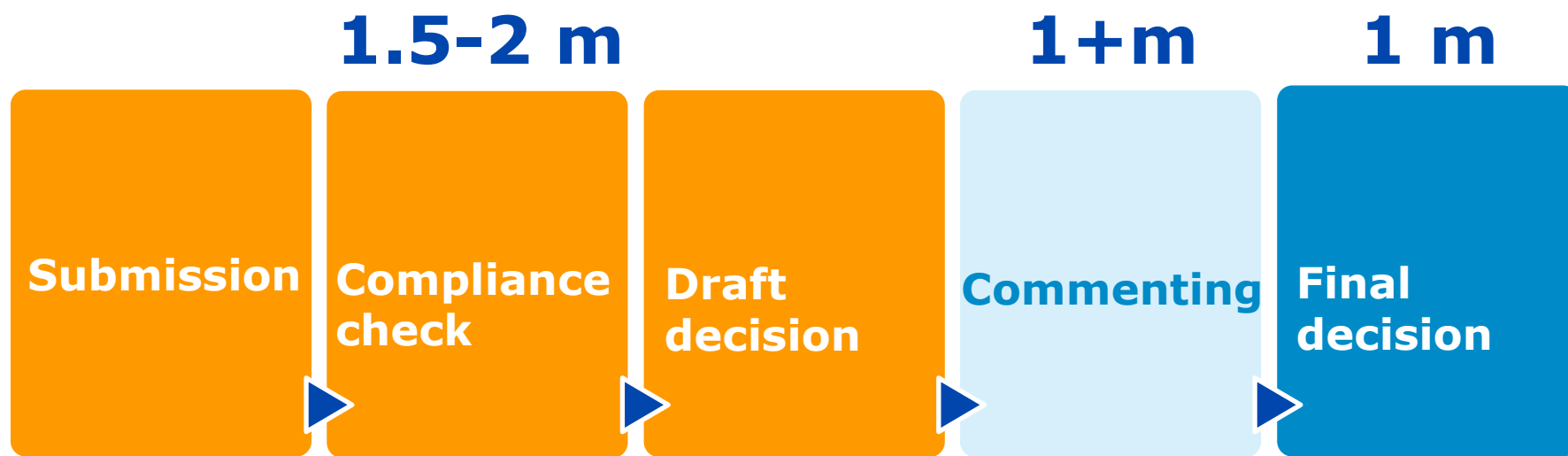




## Decisions

- Draft decisions
  - In general positive for applications based on Letter of Access
  - In general negative for applications based on complete substance dossiers – due to high complexity
- Final decisions – 98 positives & 3 negatives

# Processing of Article 95 applications



# **Common issues with Article 95 applications**



# Validity of Letters of Access (LoAs)

- Must comply with Articles 3(1)(t) and 61 of the BPR
  - Template on ECHA's webpage
- ➔ Also applies LoAs to studies in mixed or complete substance dossiers

**LoA template for Article 95 of the BPR (also for product authorisation in accordance with Article 95(4))**

**NOTE to the reader: The template LoA has an appendix.**

*Please note that any final decision taken by ECHA on a submission for inclusion on the Article 95 list based on a letter of access will be conditional upon the letter of access being valid, with all access rights covered therein approved by the data owner(s). Should the data owner(s) challenge the inclusion of a company on the list on the grounds that the letter of access is not valid, ECHA reserves the right to remove that company from the list.*

*[Letterhead of entity granting the Letter of Access]*

European Chemicals Agency  
Annankatu 18  
P.O. Box 400  
FI-00121 Helsinki

[Date]

Dear Sir or Madam,

**LETTER OF ACCESS FOR THE PURPOSES OF ARTICLE 95(1) OF REGULATION (EU) No 528/2012**

# Waiving of data

- Read the guidance carefully to ensure waiving is possible



# Use of literature data

According to ECHA's *Guidance on the BPR*, public literature data can be used in the assessment if the following conditions are fulfilled:

- The data comply with the BPR Annexes II, III introduction points 5-9. [general provisions]
- The identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the substance addressed in the application.
- The reporting of the study allows evaluation of the quality of the study.

 Data need to be representative for the substance applied for

# **Coming publication dates for the Article 95 list(s)**



# Article 95 List

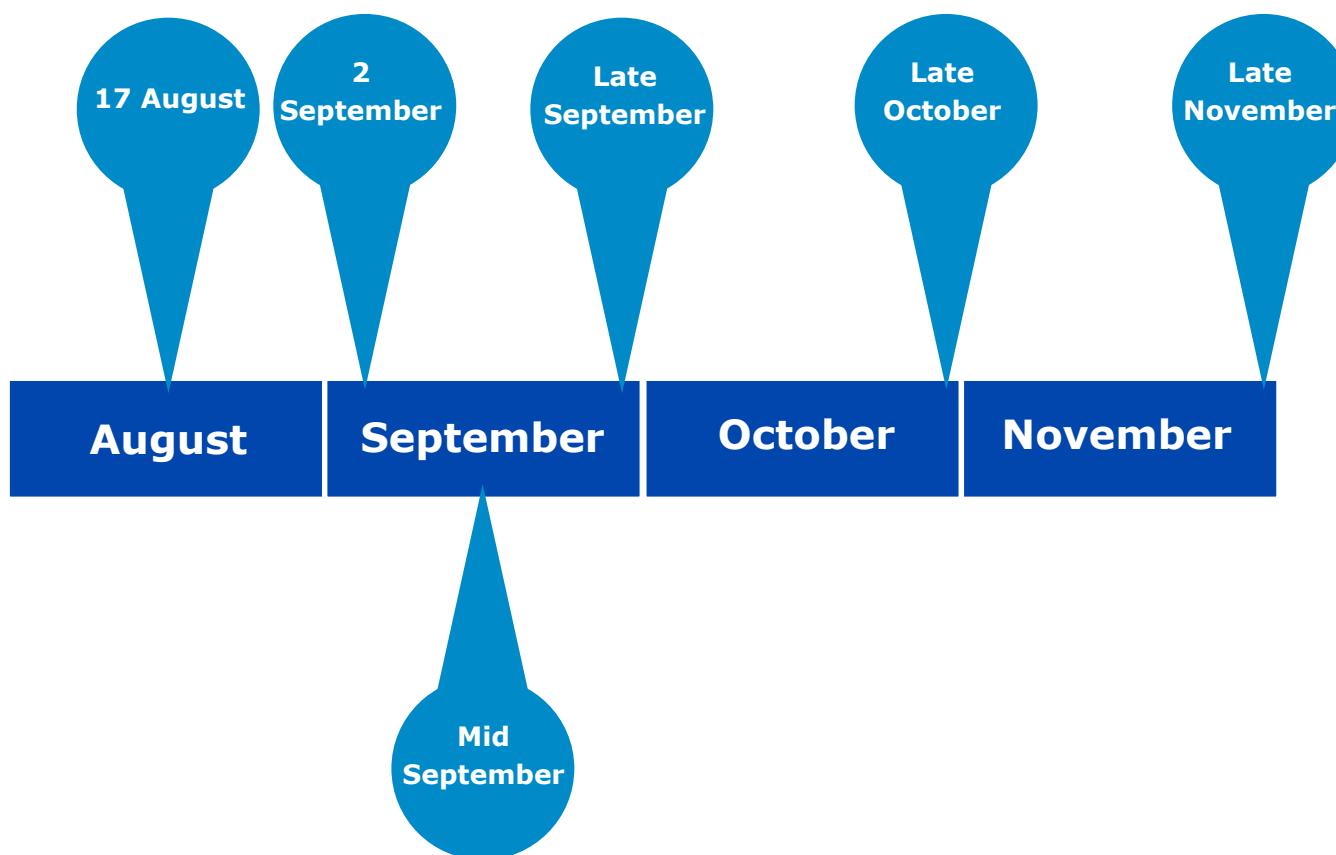
Prepared as of 2 September 2015



# List of pending applications

Substance Name	EC	CAS	Applicant	Country	Product Type(s)	Submission Date	Acceptance Date	Supplier Type
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
(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
Propan-1-ol	200-746-9	71-23-8	BASF SE	Germany	1, 2, 4	05-Mar-15	27-Mar-15	Substance Supplier
(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	222-720-6	3586-55-8	Lanxess Deutschland GmbH	Germany	2, 6, 11, 12, 13	04-Feb-15	11-Mar-15	Substance Supplier
Propan-2-ol	200-661-7	67-63-0	GOJO Industries – Europe Ltd.	United Kingdom	1, 2, 4	10-Apr-15	21-Apr-15	Substance Supplier & Product Supplier
			Brauns-Heitmann GmbH Co. KG	Germany	1, 2, 4	31-Mar-15	8-May-15	Product Supplier
			TENSID-CHEMIE GMBH	Germany	1, 2, 4	14-Apr-15	4-May-15	Substance Supplier & Product Supplier
			CG Chemikalien GmbH & Co. KG	Germany	1, 2, 4	16-Apr-15	20-May-15	Substance Supplier & Product Supplier
			Deb Group Ltd	United Kingdom	1, 2, 4	12-May-15	12-Jun-15	Substance Supplier & Product Supplier

## Publication dates 2015 (both lists)



# **Applications for Article 95 after 1 September 2015**



## Active substances on the Article 95 list are 'relevant substances'


An active substance becomes a relevant substance when a dossier (application) for that active has:

- Been validated by a Member State or ECHA, and
- Found to be in compliance with Annex II of the BPR (or Annexes II or III of the BPD)

## New 'relevant substances' I

- Active substances that are covered by the BPR but not the BPD, for example
  - Some *in situ* generated active substances
  - Substances benefiting from derogation for food and feed in Regulation 1451/2007

## New 'relevant substances' II

- Some can be notified and introduced into the Review Programme
  - Others may benefit from the transitional measures in Article 93 – application 1 September 2016
  - New active substances (application according to Article 4 of BPR)
-  New Article 95 applications possible when new 'relevant substances' have been listed

# Conclusions



## Conclusions

- First major Article 95 deadline reached – and about **98** applications have been approved
- Learn from others – and allow time
- Keep an eye on new ‘relevant substances’ entering the Article 95 list
- Visit our website for guidance





# Thank you

[hugues.kenigswald@echa.europa.eu](mailto:hugues.kenigswald@echa.europa.eu)

Subscribe to our news at  
[echa.europa.eu/subscribe](http://echa.europa.eu/subscribe)

Follow us on Twitter  
[@EU\\_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook  
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)

