Article 95, practical insights into a game-changing requirement

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cefic
sector group

Outline

Article 95: how it applies to various actors in the supply chain

Data sharing through the eyes of review programme participants

Inclusion on Article 95 list and beyond

Concluding thoughts

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Article 95: Aim and principles

Purpose: Recitals 8 & 58 of the BPR	Results: Article 95(2) of the BPR
"To ensure the **equal treatment of persons placing active substances on the market"** "A **level playing field** […] on the market for existing active substances"	"As of **1 September 2015**, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless **either the substance supplier or the product supplier** is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs"
• "reducing unnecessary tests and costs to the minimum" • "avoiding the establishment of monopolies" • "sustaining free competition between economic operators" • "equitable compensation of the costs borne by data owners"	

Article 95 listing

Active Substance Manufacturer or Importer	Biocidal Product Manufacturer or Importer	Article 95 compliance
+	-	☺
-	+	☺
-	-	☹

Routes to Article 95 listing

Review Programme Participants

Automatically included

Alternative suppliers

- ✓ Build full Annex II dossier with own data
- ✓ Build part of Annex II dossier + buy LoA to a selection of studies
- ✓ Buy access to complete dossier in review programme

Mandatory data sharing

"For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to *all toxicological, ecotoxicological and environmental fate and behaviour studies* relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates"

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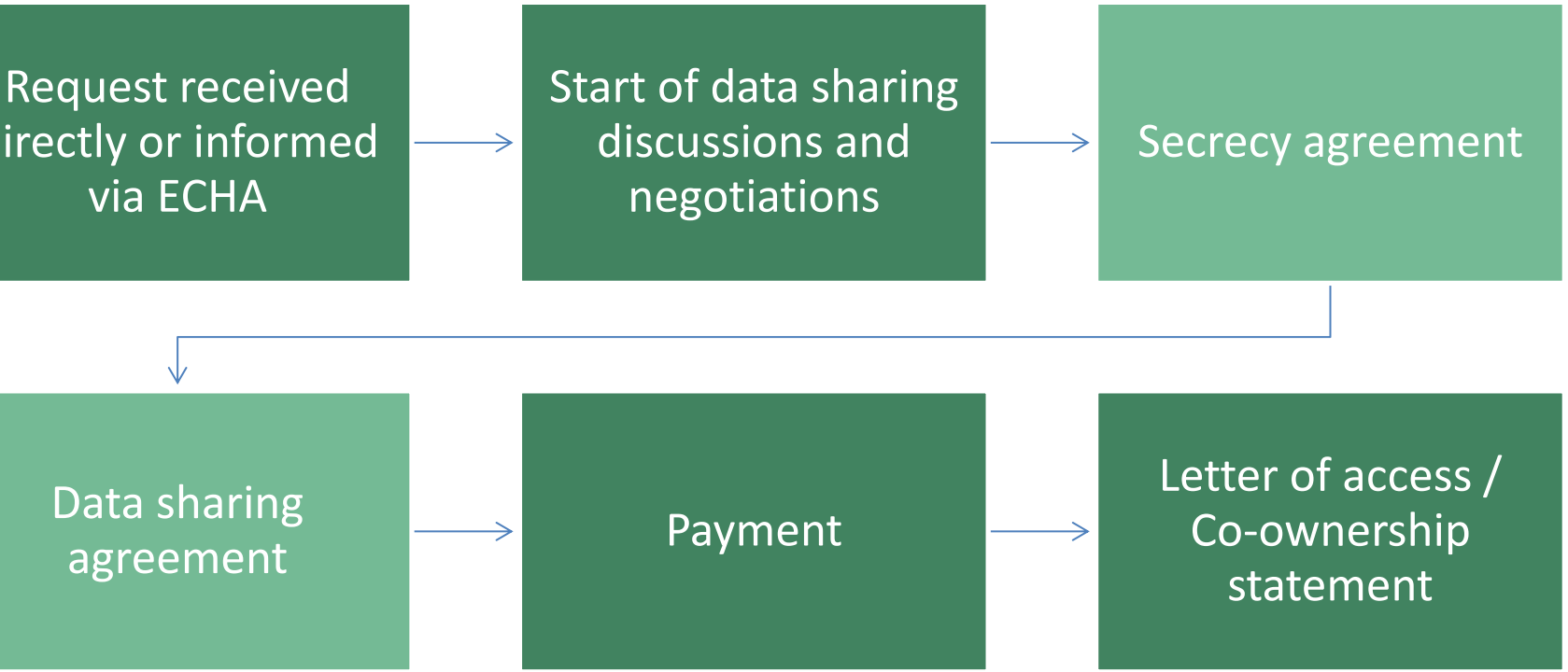
Preparing for data sharing requests

- Is a data sharing request likely?
- Which data?
  - Physical hard copies of the studies/tests or study summaries
  - Selection of studies
  - Data subject to mandatory data sharing?
  - Full dossier?
- Which extent?
  - BPR purposes (Article 95 and beyond)?
  - Right to refer?
  - Ownership rights?

Preparing the procedure for answering data sharing requests



Letters of access for Article 95 inclusion

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

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

[*Date*]

Dear Sir or Madam,

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

[*Name of the Article 95 applicant*] wishes to apply for inclusion as [*indicate role: substance supplier and/ or product supplier*] for the relevant substance [*add name of relevant substance*] in product-type [*add product-type number(s)*] in accordance with Article 95(1) of the Biocidal Products Regulation (EU) No 528/2012.

On behalf of [*name of entity which has the right to grant the LoA*], I hereby authorise ECHA to use [*all the data in the complete substance dossier/the studies listed in the Appendix which are contained in the complete substance dossier*] *(delete as appropriate)* for the above-mentioned relevant substance/product-type submitted by [*name of the entity supporting the approval of the active substance/PT, normally the same entity granting the LoA*] and accepted by the Competent Authority[26] in [*name of Member State whose CA evaluated the dossier*] in support of the application of [*name of the Article 95 applicant*].

I hereby declare that [*name of the entity granting the LoA*] has the right to grant the above-mentioned access.

This letter of access shall be effective as of [*insert date*].

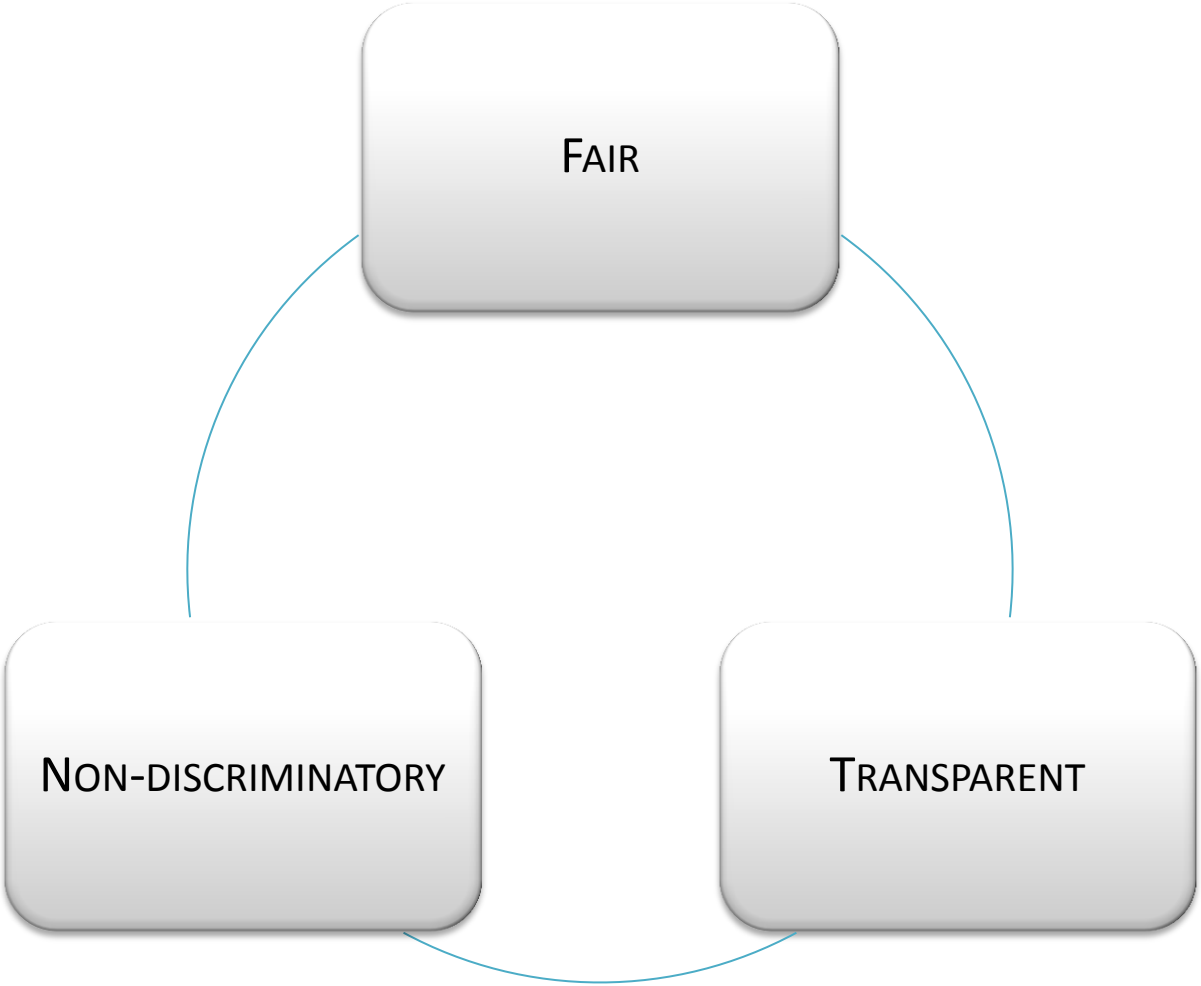
Yours faithfully,

[*name and signature of person authorised to sign on behalf of entity granting the LoA*]

Grantor: [*insert*]	Beneficiary Company: [*insert*]
Contact person:[*insert*]	Contact Person:[*insert*]
Address: [*insert*]	Address:[*insert*]
Phone/email:[*insert*]	Phone/email:[*insert*]

- ✓ Name and contact of data owner and beneficiary
- ✓ Name of active/PT
- ✓ Date
- ✓ Access rights and scope
- ✓ Sub-licencing rights?

Preparation phase: the cost sharing calculation



Cost sharing elements

- **Dossier preparation and evaluation**
  - Studies
  - Consultancy
- **Evaluation fees**
  - Completeness check
  - Evaluation
- **Administrative costs**
  - Internal efforts
  - Management of task force
- **Additional parameters**
  - Risk premium?
  - Inflation?
  - Interest?
  - Scope
  - Sub-licencing rights (95(4))

Cost sharing considerations

- ✓ Consider various scenarios:
  - ❑ Costs for a selection of studies or selection of product-types
  - ❑ Costs for mandatory data sharing
  - ❑ Costs for sharing full active substance dossier

- ✓ How to handle access granted to several parties?
  - ❑ Adjustment in final costs for potential future parties
  - ❑ Put in place a refunding scheme

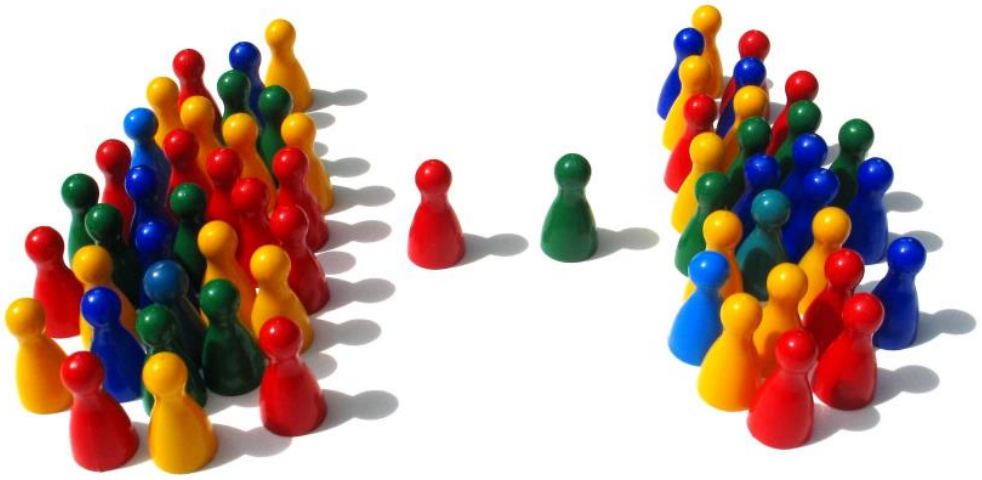
- ✓ How to include future costs generated to obtain final approval of the active substance?

Negotiations and “every effort”

A few observations on negotiations

BE PATIENT

ADAPT



EXPLAIN & UNDERSTAND

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Application to ECHA for inclusion on Article 95 list

Submission to ECHA

Payment of fees

Inclusion on pending list

LIST OF PENDING ARTICLE 95(1) APPLICATIONS

Compliance check

Final decision on inclusion

Article 95 List

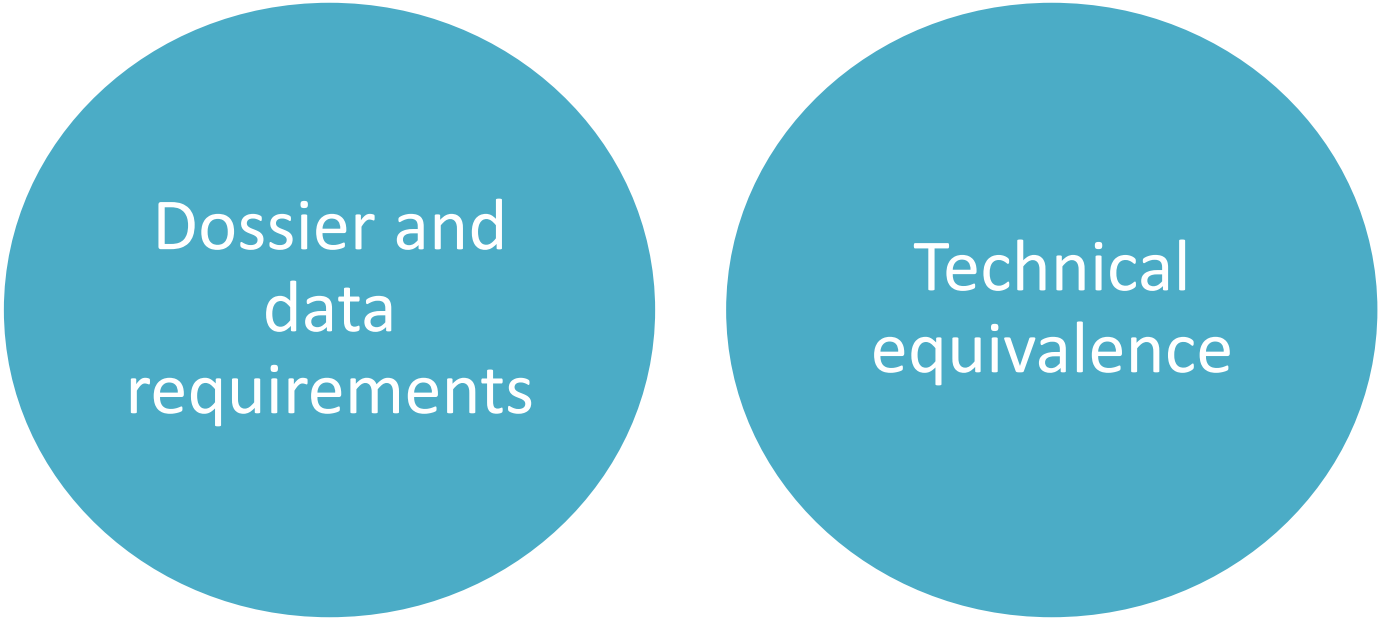
Enforcement of Article 95

"Regarding the overall compliance, enforcement authorities have furthermore some margin of discretion to ensure compliance (...). In case of non-compliance, enforcement authorities could issue ***a warning and require a proof of compliance to be provided within the next 6 months****."*

Note for discussion with Competent Authorities for Biocidal Products (CA-May15-Doc.4.13-Final)

Beyond Article 95…

PRODUCT AUTHORISATION



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Strong principles with loose ends

\+ Justified purpose of a level playing field and sharing costs between actors on the market

\- The devil is in the details:

- Multiple facets of negotiations
- Helpful guidance but case-by-case specific

? How will enforcement be carried out?

To which extent will alternative dossiers be reviewed?

Thank you for your attention

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