



Data Sharing Under the BPR and Supply Chain Strategy

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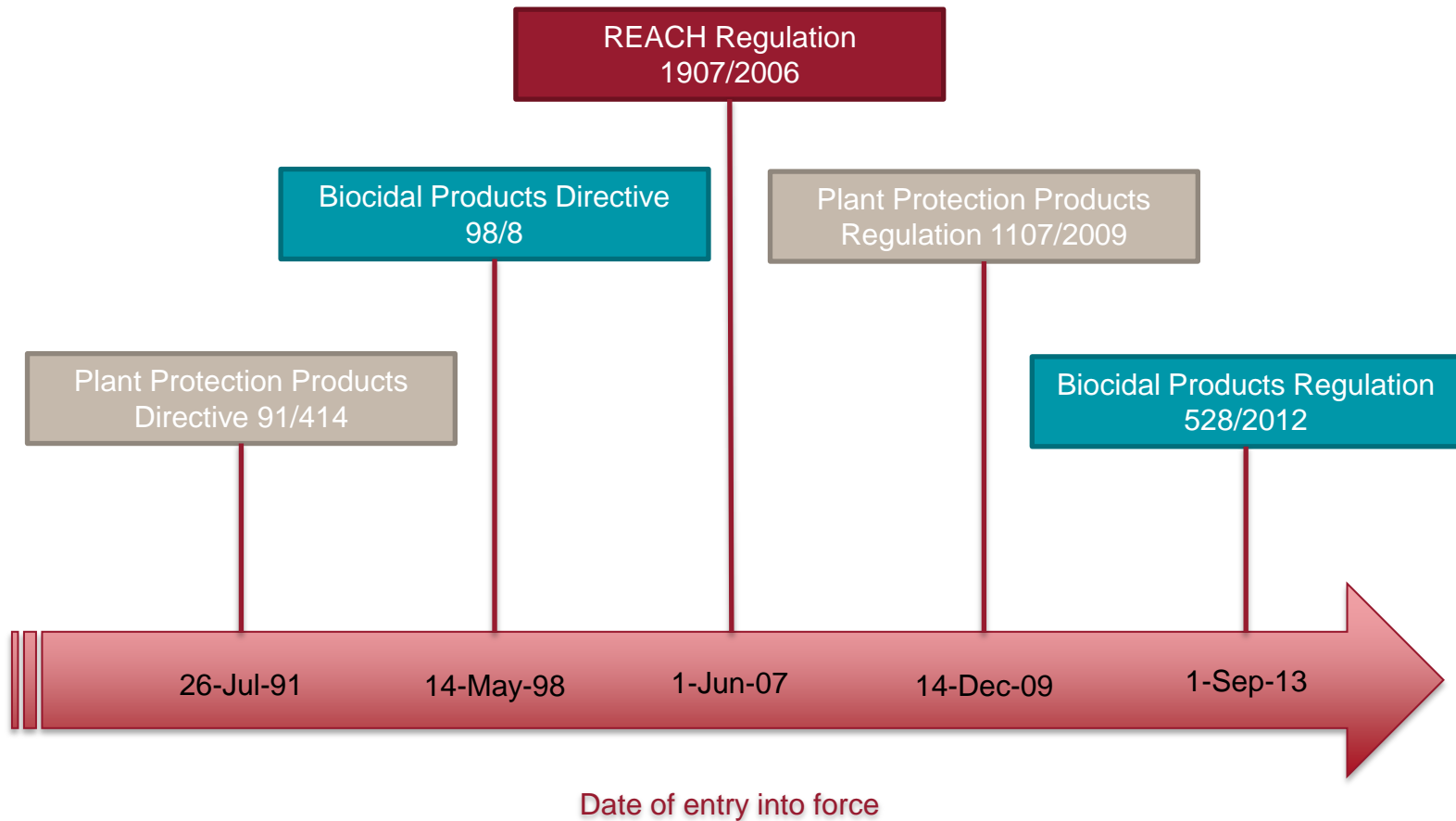
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Topics for Today

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



Sharing of Existing Data: Overlap & Differences

	REACH (Art. 30 Phase-In Substances)	BPR (Art. 63)
STANDARD (AND BURDEN)	<p>“Every effort” to ensure that the costs of sharing the information is determined in a “fair, transparent and non discriminatory way”</p> <p>(burden on both parties)</p>	<p>“Every effort” to reach an agreement. Compensation determined in a “fair, transparent and non-discriminatory manner”</p> <p>OR parties may <u>agree</u> to submit matter to binding arbitration</p> <p>(burden on both parties)</p>
SUBJECT TO SHARING	Study involving tests on vertebrate animals	<p>Tests or studies on vertebrates.</p> <p><u>Plus</u> all tox., ecotox., env. fate and behaviour studies (for Art. 95 list)</p>
PROCESS TRIGGERED BY	SIEF participant	Prospective applicant
DECISION MAKER	ECHA	ECHA
TIMELINES	No earlier than 1 month after request of proof of costs	<p>No earlier than 1 month after name of data owner provided</p> <p>+ 60 day maximum for ECHA decision</p> <p>(Prospective applicant must have paid a share of costs before Decision)</p>
SUB-LICENSING?	<p>No</p> <p>(Legal entity specific unless otherwise agreed)</p>	<p>No</p> <p>(Exception under Article 95 to an applicant for authorization in its supply chain)</p>
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)
<p>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</p>	<p>BP with <u>a</u> NEW AS 15 years from the first day of the month following the <u>first</u> decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)</p>
<p>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</p> <p>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.</p>	<p>BP with <u>ONLY</u> EXISTING AS 10 years from the first day of the month following the <u>first</u> decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)</p>
<p>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</p>	<p>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</p>

Data Sharing Rules: LoA or Hard Copy?

- **Art. 62(2):**

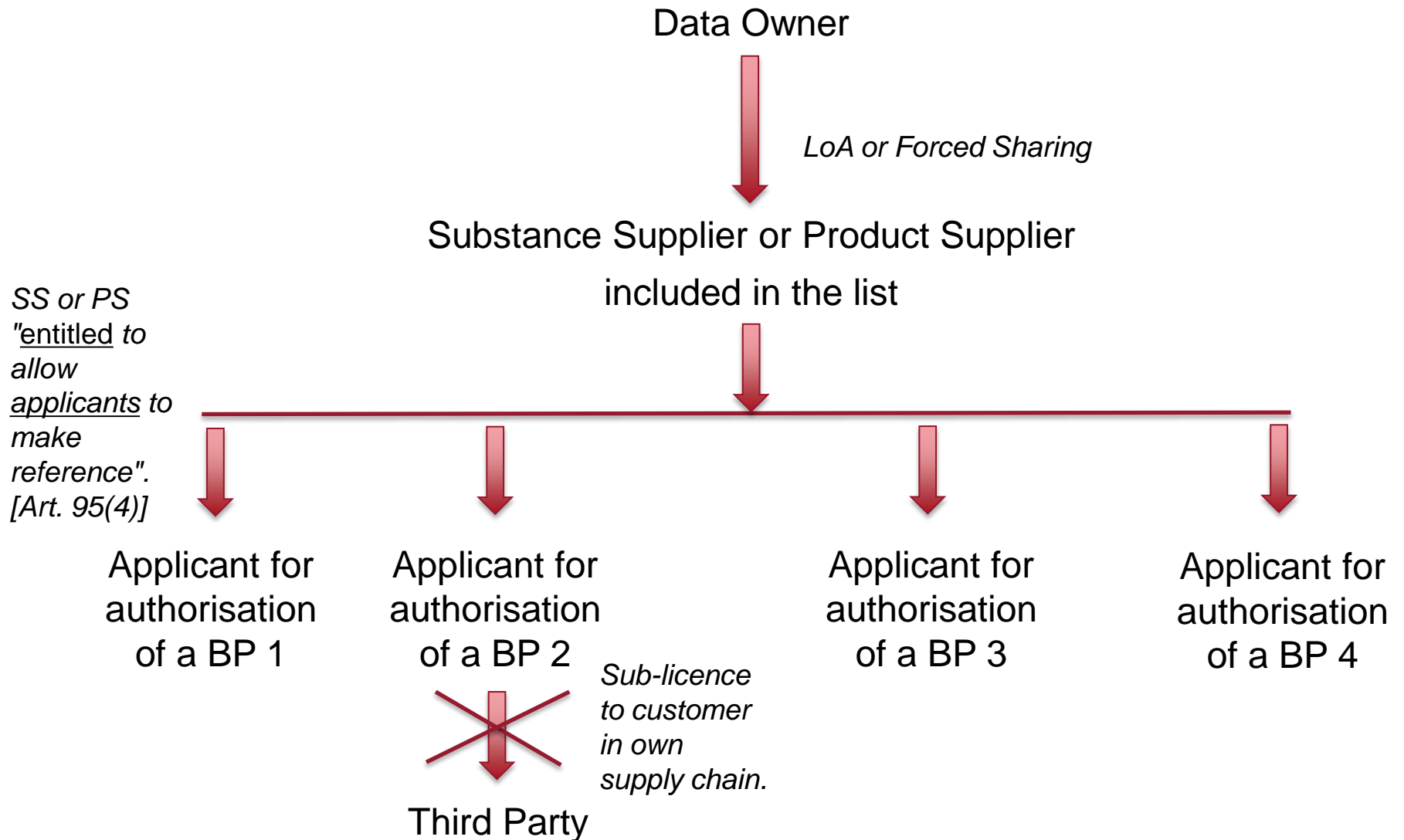
- *‘Where the data acquired under those tests or studies are still protected... the prospective applicant:
(a) shall, in the case of data involving tests on vertebrates; and
(b) may, in the case of data not involving tests on vertebrates,
request from the data owner all the scientific and technical data 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"

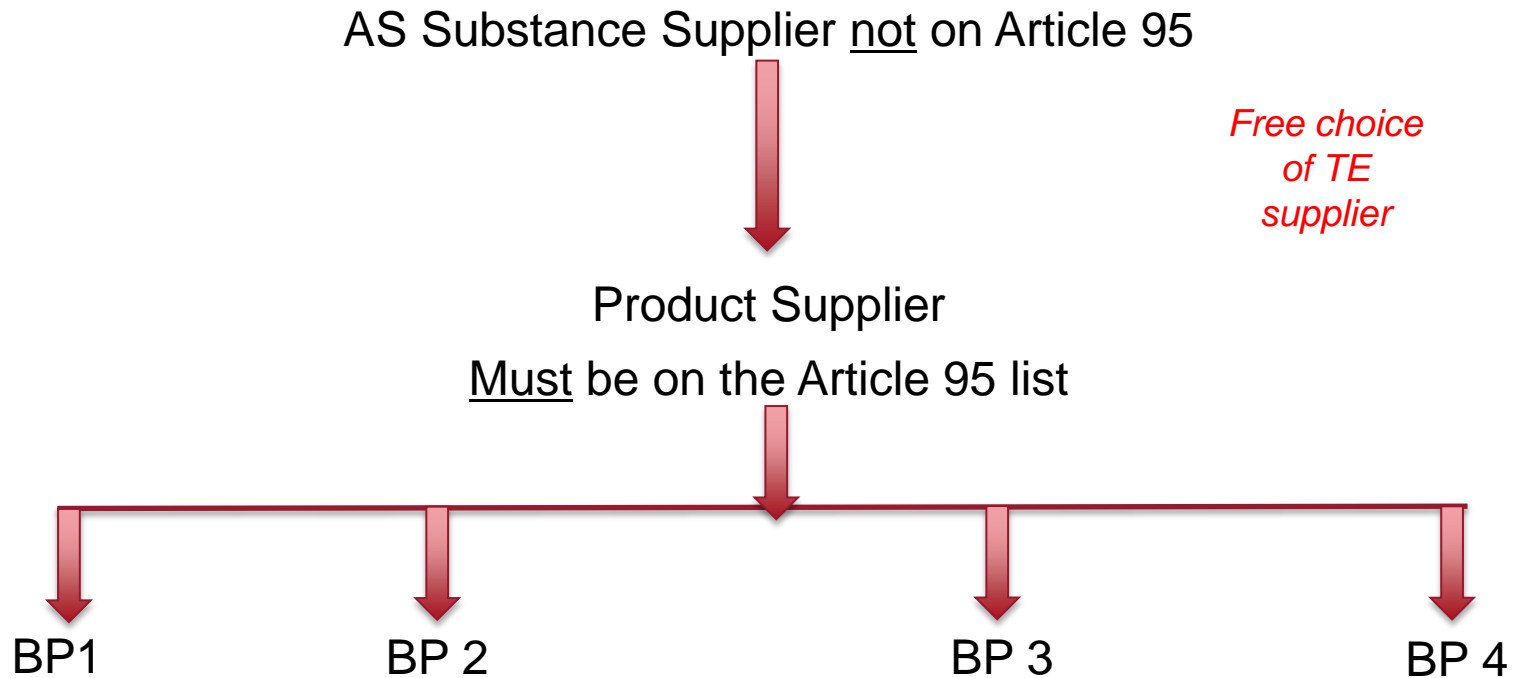


List of Active Substances and Suppliers: Article 95

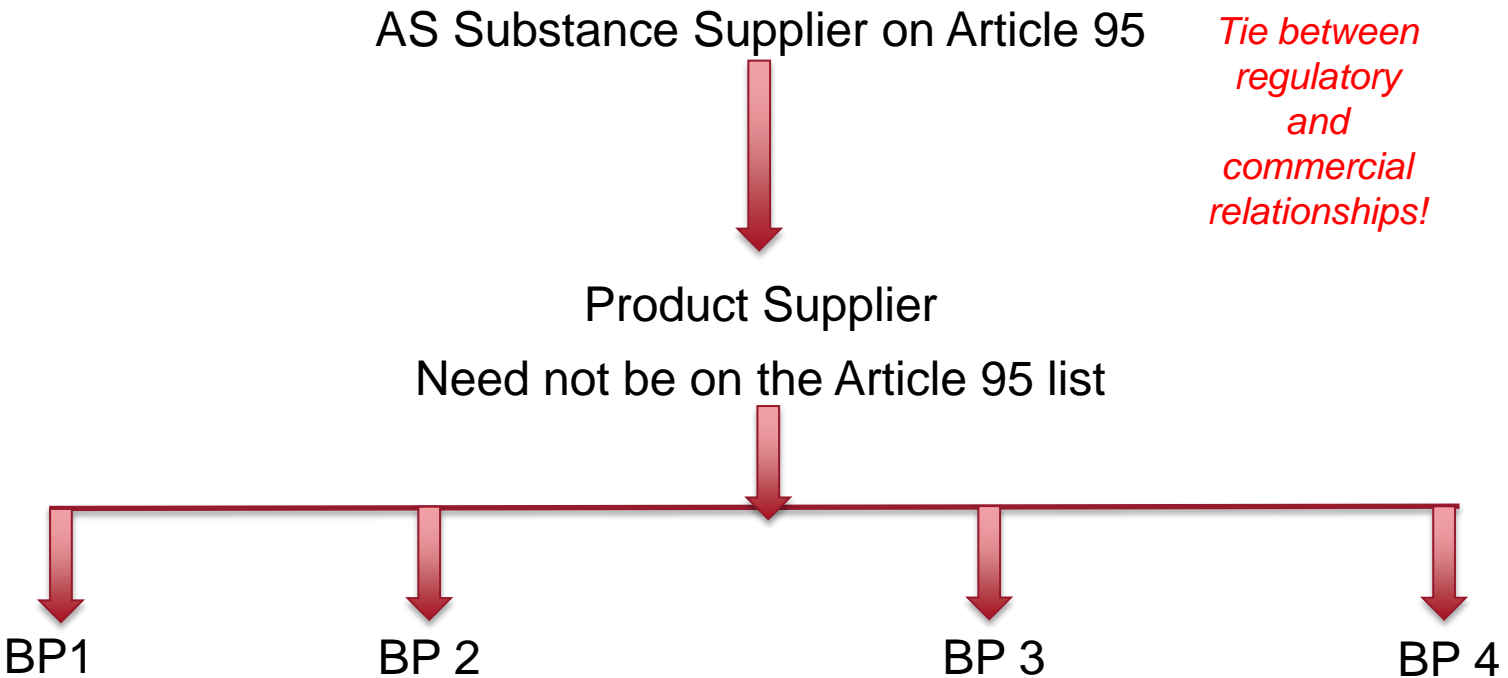
- **As of 1 Sept. 2015 those who** (i) do not have access to a "complete substance dossier" and (ii) therefore have **not been included on the list of approved sources drawn up by ECHA by will be excluded from the market:**
 - **Biocidal products** "consisting of, containing or generating a relevant 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



Supply Chain Scenarios: Standard

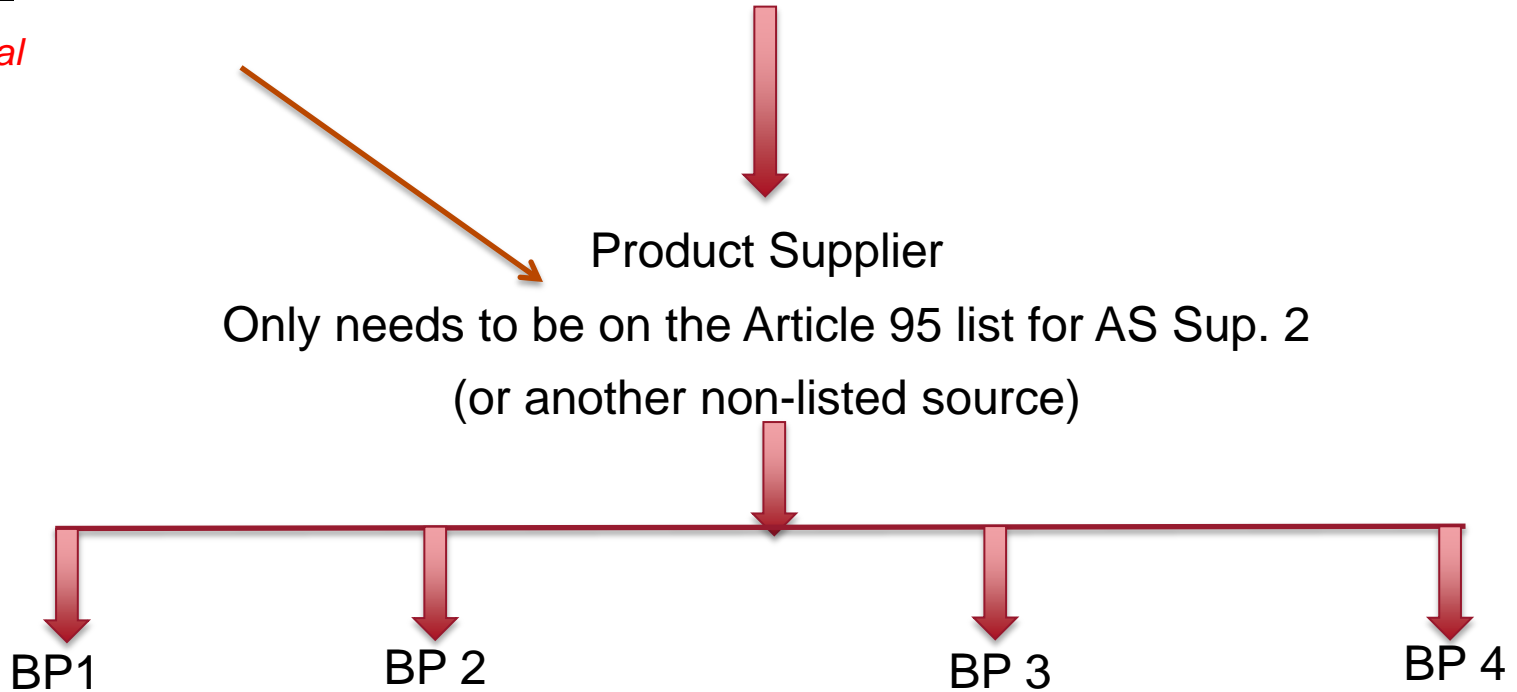


Supply Chain Scenarios: Mixed

AS Substance Supplier 2
not on Article 95

AS Substance Supplier
1 on Article 95

*Commercial
leverage
remains*



Lessons from Data Sharing Dispute Decisions

Lessons Drawn from ECHA Data Sharing Dispute Decisions to Date

	REACH	BPR
Fav. to claimant	11	1
<i>(of which:)</i>	<i>(Art 27(6): 3)</i>	<i>(Art 95: 1)</i>
	<i>(Art 30(3): 8)</i>	<i>(Art 63: 0)</i>
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)

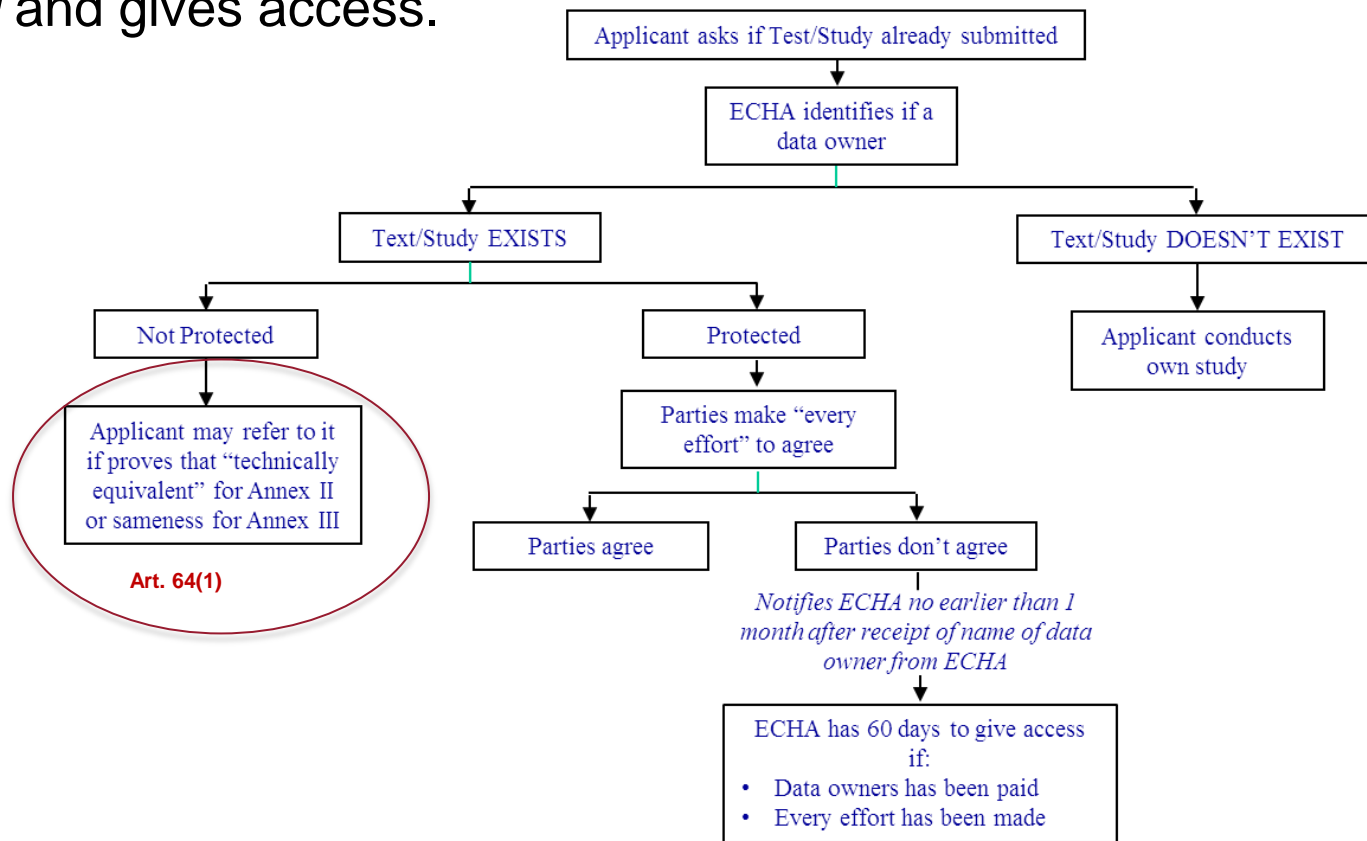
NEGOTIATING PRACTICES

- 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.



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?

