DATA PROTECTION & COMPENSATION

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1. HOW DATA PROTECTION & COMPENSATION WORKS UNDER THE BPD

2. COMPARISON WITH OTHER LEGISLATIVE SCHEMES

3. WHAT “FIXES” ARE NEEDED ON DATA PROTECTION?
HOW DATA PROTECTION & COMPENSATION WORKS UNDER THE BPD
The BPD has provisions on

- CONFIDENTIALITY
- DATA PROTECTION (our topic)

Not to be confused. What is the difference?
WHEN SUBMITTING DOSSIER, applicant may request confidential treatment vis-à-vis the world (except other MS authorities and Commission) [Article 19].

The MS competent authority decides and others must follow its decision.

“Full justification” required in each case [Article 19(1)]. Information must be:

• commercially sensitive and
• disclosure might harm applicant industrially
AFTER authorization granted - even if confidentiality accepted - confidentiality cannot apply to certain information including:

- names and content of active substance(s) / the biocidal product;
- names of other “dangerous” substances [under Directive 67/548]
- physical and chemical data
- the summary of the results of the tests required in the Dossier
- certain methods of analysis [referred to in Article 5(1)(c)]

HOWEVER, confidential information remains so indefinitely or until the applicant/manufacturer decides to disclose it.
Data Protection [Article 12] differs in several important respects:

• not requested but applied as a general rule of law

• only applies to specified types of information (not all)

• time limited after which available to potential users
Commission “Technical Notes for Guidance” (July 2002) encapsulate the issue:

“There is therefore no link between data protection and confidentiality.

Data which are protected are not necessarily confidential, and conversely confidential data are not necessarily protected.

When the time period of data protection has ended confidentiality will still apply.”
(Section. 9.3.1)
DATA PROTECTION

Complete data package

- Label information
  - Chemical characterisation information
- Disposal information
- Full formulation details
  - Detailed manufacturing procedures
  - Medical records
- Efficacy evaluation
- Safety evaluation for humans, animals and the environment

Confidential information
(Indefinite time period)

Information which may be subject to data protection
(Fixed time period(s))

Source: Commission Technical Notes For Guidance: July 2002
DATA PROTECTION

Article 12 sets out rules on “use of data held by competent authorities for other applicants”.

The general rule [Art. 12(1)] is that: “Member States shall not make use of the information referred to in Article 8 for the benefit of a second or subsequent applicant”.

Article 8 information is the Dossier submitted for EITHER Active Substances or Biocidal Products.
“Letter of Access” - second or subsequent applicant has the written agreement in the form of a letter of access of the first applicant that use may be made (by MS) of such information:

Takes form of a document, signed by the owner or owners of relevant data protected under the provisions of this Directive, which states that “these data may be used by the competent authority for the purpose of granting an authorization or a registration of a biocidal product under this Directive.”

This is the mechanism which allows the accessing of data by second comers and therefore allows the first to register a mechanism for recouping its investment. The $ arrangements and negotiations are not regulated by EC law.

Difference between owning data and being granted access is that the owner has the whole package (including raw data). Right for MS to use the data ≠ full access for second comers.
LETTER OF ACCESS

Letter of Access:

• does not compromise the provisions of data protection
• reduces unnecessary testing
• reduces unnecessary evaluations of tests by the CA
• reduces unnecessary copying and delivery of test reports
TIME LIMITS

Periods of data protection depend on whether:

• active substance or a biocidal product

• already on EC market on 15 May 2000 or not

• purpose for which data is submitted

• whether first submission or further information
## TIME LIMITS

### ACTIVE SUBSTANCE

<table>
<thead>
<tr>
<th>NEW</th>
<th>Description</th>
<th>Time Limit</th>
<th>Note</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>15 years from date of first inclusion in Annex I/IA</td>
<td>[Art. 12(1)(b)]</td>
<td></td>
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### EXISTING

| 3   | "Any information submitted for the purposes of this Directive" (i.e. for inclusion) | [Art. 12(1)(c)(i)] |

| 4   | not already protected under existing national rules relating to biocidal products | Until 14 May 2010 |

| 5   | "Information submitted for the first time in support of the first inclusion" in Annex or additional product type for it. | 10 years from date of entry in Annex I/IA | [Art. 12(1)(c)(ii)] |

| 6   | further information submitted for the first time to maintain or vary Annex entry | at least 5 years from date of decision | unless 5 years expires before the 10 (above) in which case expires when 10 years does | [Art. 12(1)(d)] |

### BIOCIDAL PRODUCT

<table>
<thead>
<tr>
<th>Description</th>
<th>Time Limit</th>
<th>Note</th>
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<tbody>
<tr>
<td>further information submitted for the first time to maintain or vary Annex entry</td>
<td>10 years from date of first authorization in any MS</td>
<td>[Art. 12(2)(b)]</td>
</tr>
</tbody>
</table>

| 2   | further information submitted for the first time to maintain or vary Annex entry | at least 5 years from date of first receipt of information | unless 5 years expires before the 10 years (above) in which case expires when 10 years does | [Art. 12(2)(d)] |

| 3   | "Any information submitted for the purposes of this Directive" (i.e. for inclusion) | [Art. 12(2)(c)(i)] |

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**Summary**

Data Protection for Biocidal Products and Active Substances is the same BUT 3 important differences:

1. data on biocidal products containing a new active substance are protected for 10 years whereas those for the new active substance are protected for 15 years

2. for data on biocidal products containing new active substances the data protection runs from the date of authorization in the first Member State while for new active substances it runs from the inclusion into Annex I or IA1

3. for (further) data submitted e.g. to address variation of conditions of requirements of an authorization of a biocidal product, the data protection for biocidal products runs from the date of the receipt of data, while for active substances it runs from the date of decision following the receipt of further information
GUIDANCE


Not legally binding or even the Commission’s view but persuasive because:

• Directive is a harmonization measure (former Art. 100a, now 95) requiring consistent application throughout EU without “gold plating”.

• Commission is the enforcing authority vis-à-vis MSs and interpretation likely to be reflected in future action (to date, judgments against several MSs for non-transposition).
ISSUE 1: HOW NATIONAL PROTECTION INTERACTS

Existing substances and products

"Any information submitted for the purposes of this Directive" protected under existing national law on biocides date under each MS national law BUT maximum cut off date of 14 May 2010

Different protection periods in different MSs.

Necessitates very precise MS records on what data are covered by national rules. Commission acknowledges this to be “complicated”…

GUIDANCE
"Information submitted for the first time in support of inclusion" in Annex or additional product type for it.

10 years from date of entry in Annex I/IA
[Art. 12(1)(c)(ii) and (2)(c)(ii)]

“First time”:

- data submitted to national biocides schemes is not included.
- data submitted to other EC schemes (PPPs etc.) is included.
ISSUE 3: PROVISIONAL AUTHORIZATIONS

Article 15(2): provisional authorizations.

No special additional rules.
ISSUE 4: EFFECT OF MARKET WITHDRAWAL

No necessary effect.

Protection not contingent on ongoing market presence.
Series of cases brought challenging data protection / “free riders”:

Phase I Regulation 1869/2000 cases – rejected on standing alone.

Phase II Regulation 2032/2003 cases – interim measures rejected, judgment pending, same standing issues?
COMPARISON WITH OTHER LEGISLATIVE SCHEMES
Directive 91/414

Accelerated Revision Program. Intention is to make as "similar as possible" with BPD.

Particular focus on data protection – to harmonize rules.

Current rules do not include Letter of Access (though agreement needed) but do include restrictions on use by Member States.

Industry positions generally indicate that periods currently provided are insufficient given the investment which the data represents.

Commission comments to date suggest that mandatory data sharing may be an element of the revised Directive at least at the stage when actives / products are re-evaluated.
Format of REACH remains in flux.

Parliament plenary in November

Moves towards Political agreement in Council by year end.

Mandatory sharing?
Extend to information derived from non-vertebrate animal tests?
WHAT “FIXES” ARE NEEDED ON DATA PROTECTION?
“FIXES”?

- Challenge is that there is not yet a “one size fits all” model for the wide range of EC regulatory authorisations. May be a case for different periods of protection (depending on what is at stake) but no apparent logic for different rules per se?

- Mandatory data sharing is not yet a common notion. Some mixed feelings about this in EU chemicals sector.

- Contrast with US mandatory data licensing under FIFRA (which also includes Exclusive Use for 10 years and Compensation for 15 years for non-protected data).

- This means that insufficient thought has been given to the $ implications of date sharing. i.e. NO EC DATA COMPENSATION RULES!
“FIXES”?

HOW MIGHT DATA SHARING WORK?

• Clear guidance on how compensation is to be calculated to facilitate consensual negotiation (replacement cost, value of early market access etc.).

• Clear rules on what happens when original data submitter refuses access in event that negotiation fails.

• Binding arbitration required (a valid offer of compensation should include acceptance of arbitration).
“FIXES”?

HOW MIGHT DATA SHARING WORK?

• Bar on satellite litigation around arbitration (save where fraud).

• Strict enforcement and sanctions for failing to respect rules for data sharing. (US model includes possible threat of cancelling registration where failure to negotiate, participate in arbitration or pay an award).
1. Holistic approach to data protection and compensation clearly needed.

2. Concerns about protection and free-riders MIGHT be resolved in a piecemeal fashion via litigation.

3. HOWEVER there is a window of opportunity to look at this issue in the round: REACH, revision of PPPs Directive and (later) BPD etc.

4. Greater experience of this in US model. Perhaps a strong basis from which to develop a “global solution”.

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