



UPDATE ON THE BIOCIDAL PRODUCTS DIRECTIVE

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Barrister

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sponsored by the American Chemistry Council Biocides Panel, the Consumer Specialty Products Association, and ISSA.

STEPTOE & JOHNSON ^{LLP}

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Arlington, VA

TOPICS COVERED

- 1. BPD refresher**
- 2. Active substance review programme**
- 3. Mini revision**
- 4. Data protection issues**
- 5. Product authorisation**
- 6. Major revision**

1. BPD refresher

SCOPE

- Active substances and preparations containing one or more active substances,
- put up in the form in which they are supplied to the user,
- intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism
- by chemical or biological means.

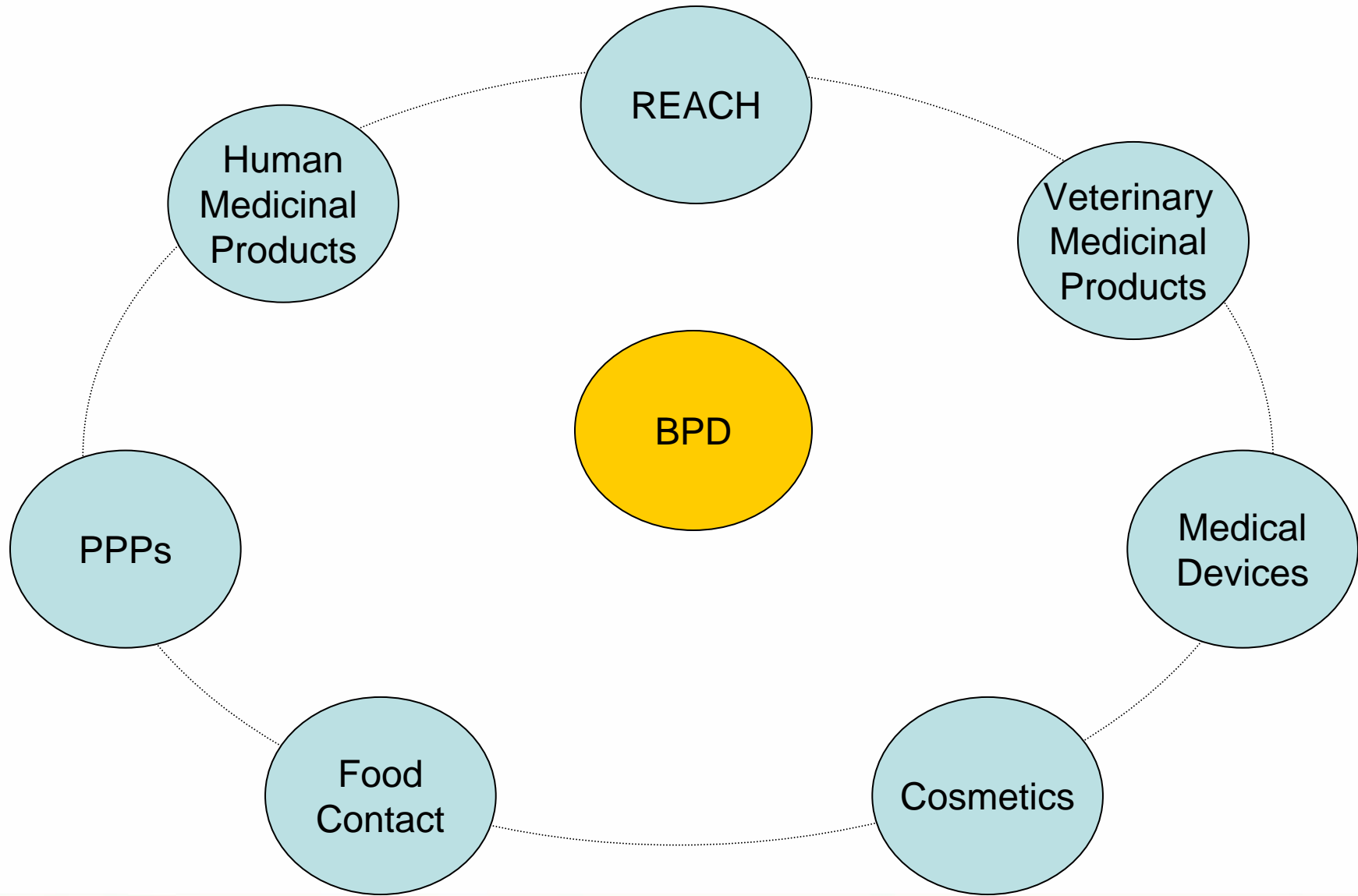
[Art. 2(1)(a)]

Despite “intention”, a focus on inherent properties/main function:

“In case of a divergence of views concerning a particular product between the authorities and the person responsible for placing the product on the market, it is up to the latter to demonstrate that no biocidal effect was intended.”

[[Manual of Decisions](#) para. 2.1.8.1., last modified: 10.07.2008]

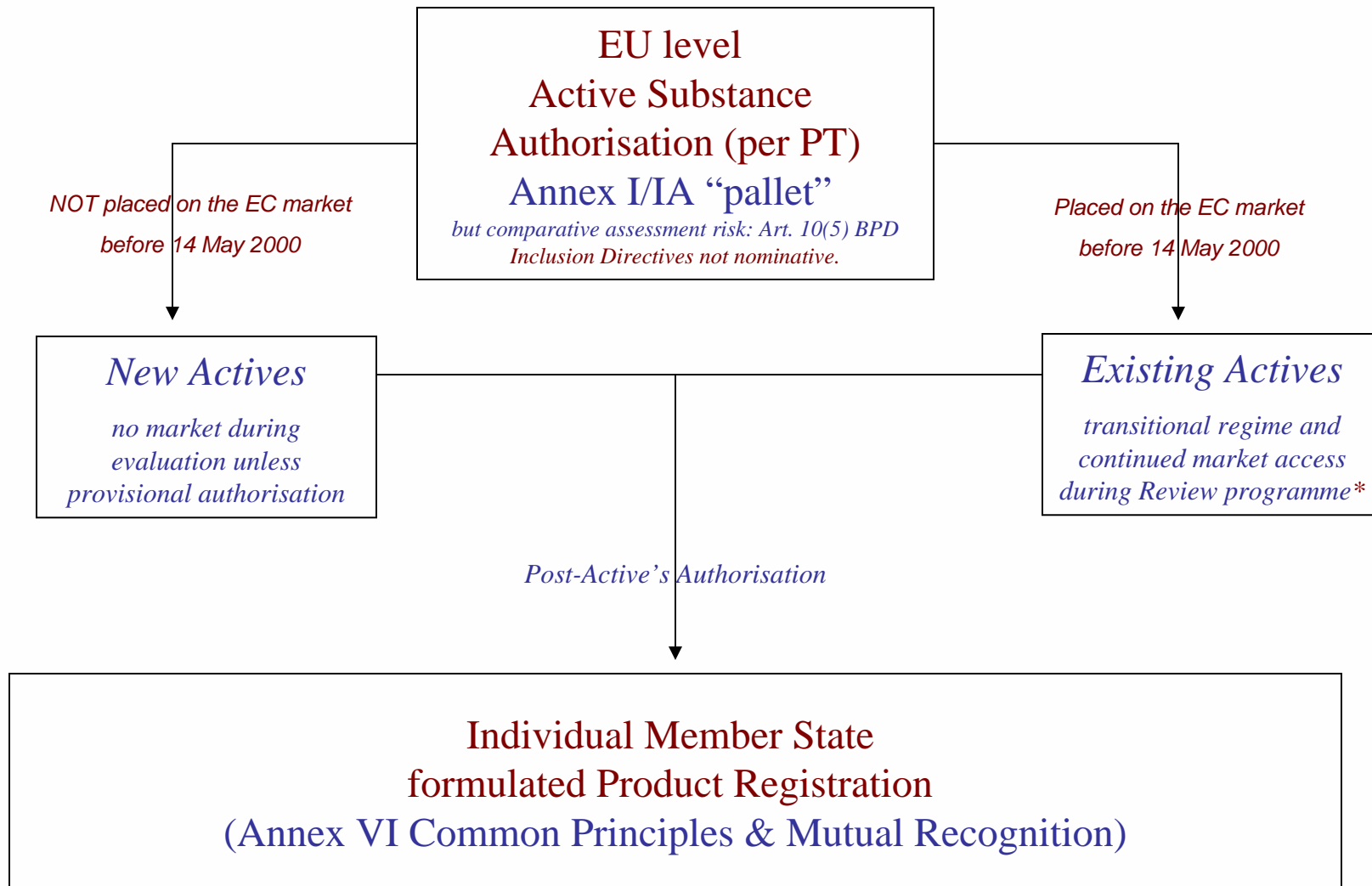
RELATED LEGISLATION



BORDERLINE ISSUES

- Common discussion of biocide/cosmetic borderline.
- Resolution turns on the specific purpose of a product and the exclusions in Article 1(2) BPD.
- Example 1: Preservatives used in cosmetics specifically are not within the BPD scope because covered by the Cosmetics Directive BUT the same preservative in another context would be covered.
- Example 2: Cosmetic product with secondary biocidal activity is not covered by the BPD. A sun lotion containing insect repellent would be covered by the BPD, but antidandruff shampoo and anti-microbial soaps not covered.

2 STAGE PROCEDURE



* Gives rise to the "First Free-Rider" issue.

EXHAUSTIVE PT LIST

<p>GROUP 1 Disinfectants and general biocidal products*</p>	<p>GROUP 2 Preservatives</p>	<p>GROUP 3 Pest control</p>	<p>GROUP 4 Other biocidal products</p>
<p><i>PT 1:</i> Human hygiene biocidal products</p> <p><i>PT 2:</i> Private area and public health area disinfectants and other biocidal products</p> <p><i>PT 3:</i> Veterinary hygiene biocidal products</p> <p><i>PT 4:</i> Food and feed area disinfectants</p> <p><i>PT 5:</i> Drinking water disinfectants</p>	<p><i>PT 6:</i> In-can preservatives</p> <p><i>PT 7:</i> Film preservatives</p> <p><i>PT 8:</i> Wood preservatives</p> <p><i>PT 9:</i> Fibre, leather, rubber and polymerised materials preservatives</p> <p><i>PT 10:</i> Masonry preservatives</p> <p><i>PT 11:</i> Preservatives for liquid-cooling and processing systems</p> <p><i>PT 12:</i> Slimicides</p> <p><i>PT 13:</i> Metalworking-fluid preservatives</p>	<p><i>PT 14:</i> Rodenticides</p> <p><i>PT 15:</i> Avicides</p> <p><i>PT 16:</i> Molluscicides</p> <p><i>PT 17:</i> Piscicides</p> <p><i>PT 18:</i> Insecticides, acaricides and products to control other arthropods</p> <p><i>PT 19:</i> Repellents and attractants</p>	<p><i>PT 20:</i> Preservatives for food or feedstocks</p> <p><i>PT 21:</i> Antifouling products</p> <p><i>Pt 22:</i> Embalming and taxidermist fluids</p> <p><i>PT 23:</i> Control of other vertebrates</p>

*Excludes cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

2. Active substance review programme

REVIEW PROGRAMME

Today biocidal products may only contain active substances that are either:

- under review and listed in the **Review Programme**, or
- already **included in the BPD Annex I/IA**

Review Programme established lists for the evaluation of active substances by Member State *Rapporteurs* over 10 years: **originally scheduled to end on 14 May 2010.**

Currently governed by [Regulation \(EC\) No 1451/2007](#) (so-called “Second Review Regulation”).

REVIEW PROGRAMME

LIST 1 (28.03.2004)	LIST 2 (30.04.2006)	LIST 3 (31.07.2007)	LIST 4 (31.10.2008)
<p><i>PT 8:</i> Wood preservatives</p> <p><i>PT 14:</i> Rodenticides</p>	<p><i>PT 16:</i> Molluscicides</p> <p><i>PT 18:</i> Insecticides, acaricides and products to control other arthropods</p> <p><i>PT 19:</i> Repellents and attractants</p> <p><i>PT 21:</i> Antifouling products</p>	<p><i>PT 1:</i> Human hygiene biocidal products</p> <p><i>PT 2:</i> Private area and public health area disinfectants and other biocidal products</p> <p><i>PT 3:</i> Veterinary hygiene biocidal products</p> <p><i>PT 4:</i> Food and feed area disinfectants</p> <p><i>PT 5:</i> Drinking water disinfectants</p> <p><i>PT 6:</i> In-can preservatives</p> <p><i>PT 13:</i> Metalworking-fluid preservatives</p>	<p><i>PT 7:</i> Film preservatives</p> <p><i>PT 9:</i> Fibre, leather, rubber and polymerised materials preservatives</p> <p><i>PT 10:</i> Masonry preservatives</p> <p><i>PT 11:</i> Preservatives for liquid-cooling and processing systems</p> <p><i>PT 12:</i> Slimicides</p> <p><i>PT 15:</i> Avicides</p> <p><i>PT 17:</i> Piscicides</p> <p><i>PT 20:</i> Preservatives for food or feedstocks</p> <p><i>Pt 22:</i> Embalming and taxidermist fluids</p> <p><i>PT 23:</i> Control of other vertebrates</p>

REVIEW PROGRAMME

Only 45% (716/1577) of substances in the Review Programme are supported today:

LIST 1 (28.03.2004)	LIST 2 (30.04.2006)	LIST 3 (31.07.2007)	LIST 4 (31.10.2008)
<i>54 Dossiers Submitted</i> <i>97 Identified & Notified</i>	<i>84 Dossiers Submitted</i> <i>204 Identified & Notified</i>	<i>350 Dossiers Submitted</i> <i>652 Identified & Notified</i>	<i>228 Dossiers Submitted</i> <i>624 Identified & Notified</i>

In lists 1, 2 and 3 there are 93 active substance/PT combinations where there is more than one dossier.

Source: JRC Presentation 23/24 September 2009

REVIEW PROGRAMME

Multiple dossiers is the result of the legislative framework:

‘...take all reasonable steps to reach agreement on the sharing of information, so as to avoid, if possible, the duplication of testing on vertebrate animals. The competent authorities of the Member States shall encourage data-holders to cooperate... Member States may introduce national measures obliging the applicant and holders of former authorisations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilising information, and the reasonable balance of the interests of the parties concerned.’ [Art. 13 BPD]

‘(1) In the preparation of the complete dossier, all reasonable efforts shall be made, inter alia, to avoid duplication of testing on vertebrate animals and, where appropriate, to establish a collective complete dossier...(5) ...Where, in those circumstances, a collective dossier is not submitted, each individual dossier shall detail the efforts made to secure cooperation and the reasons for non-participation. (6) Details shall be given in the complete dossier and in the summary dossier of the efforts made to avoid duplication of testing on vertebrate animals. [Art. 8 of 2nd Rev. Reg.]

Contrast with REACH...

STEPTOE & JOHNSON LLP

SHARING OF DATA INVOLVING TESTS AND COMPENSATION UNDER REACH

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20/08/200

Data	PROSPECTIVE REGISTRANT		DATA OWNER	Compensation Terms
	Inquire before testing whether a relevant study is available	Request Access from Data Owner (if data is protected)	Provide Access	
Existing Study Involving Vertebrate Animal Tests	Must Art 30(1) para. 1	Must Art 30(1) para. 1	Must ECHA will give access if Data Owner refuses to provide (i) proof of costs or (ii) the study, and block Data Owner's Registration. Art. 30(3)	Calculated 'in a fair, transparent and non-discriminatory way' If agreement cannot be reached on the amount of compensation 'the cost shall be shared equally' Art 30(1) para. 1
Existing Study does <u>not</u> involve testing on vertebrate animals (wider than just animal i.e. non-animal as well)	Must Art 30(1) para. 1	May Art 30(1) para. 1	May ECHA has no power to oblige access but if a study is requested by a SIEF member, and a data owner refuses to share, the other SIEF participants can proceed as if the study did not exist. Art. 30(4)	
Any new study involving tests which is required for Registration and is not available	One SIEF participant conducts one new study (for the purpose of fulfilling a Registration information requirement) on behalf of all other SIEF participants. The SIEF participants need to agree on (or ECHA will impose on them) which party should secure the new testing. Art 30(2) (see Art 29(3) also)			Costs for 'the elaboration of the study with a share corresponding to the number of participating registrants'. (This does not necessarily mean that equal shares will be borne by each of the SIEF members.) Art 30(2)

INCLUSIONS TO DATE

Annex I inclusions

Alphachloralose	Etofenprox
Aluminium phosphide	Fenpropimorph
Boric acid	Indoxacarb
Boric oxide	IPBC
Bromadiolone	K-HDO
Carbon dioxide	Nitrogen
Chlorophacinone	Propiconazole
Clothianidin	Sulfuryl fluoride
Coumatetralyl	Sulfuryl fluoride
Dichlofluanid	Tebuconazole
Difenacoum	Thiabendazole
Difethialone	Thiacloprid
Disodium octaborate tetrahydrate	Thiamethoxam
Disodium tetraborate	

Annex IA inclusions

Carbon dioxide

CLASSIFICATION

Active substances included in Annex I/IA are subject to harmonised classification and labelling - set out in Articles 37(1) and (4) to (6) of Regulation (EC) No. 1272/20036 (the “CLP”).

The BPD underlines that after Annex I/IA inclusion a substance cannot be placed on the market unless it is classified, packaged and labelled. Timing in practice...

The CLP provides that the Competent Authority of a Member State must submit to the European Chemicals Agency (“ECHA”) a proposal on harmonised classification and labelling for a substance. The ECHA Committee for Risk Assessment (“CRA”) is required to adopt an opinion (after “parties concerned” have been consulted) on the proposal. The Commission will adopt a decision on harmonised classification and labelling on the basis of the CRA’s opinion and comments received. The adopted classification and labelling for the substance is included in Annex VI of the CLP.

Commercial impact...

3. Mini revision

MINI REVISION

- Given the low number of substances evaluated to date (and the 14 May 2010 deadline) it **was necessary to extend the Review Programme period.**
- **Directive 2009/107/EC** creates a 4 year extension (until 14 May 2014):
 - for evaluation by *Rapporteur* Member States
 - of transitional regime during which Member States can apply national rules on products (those on actives not yet included in Annex I/IA/)
 - of data protection rules

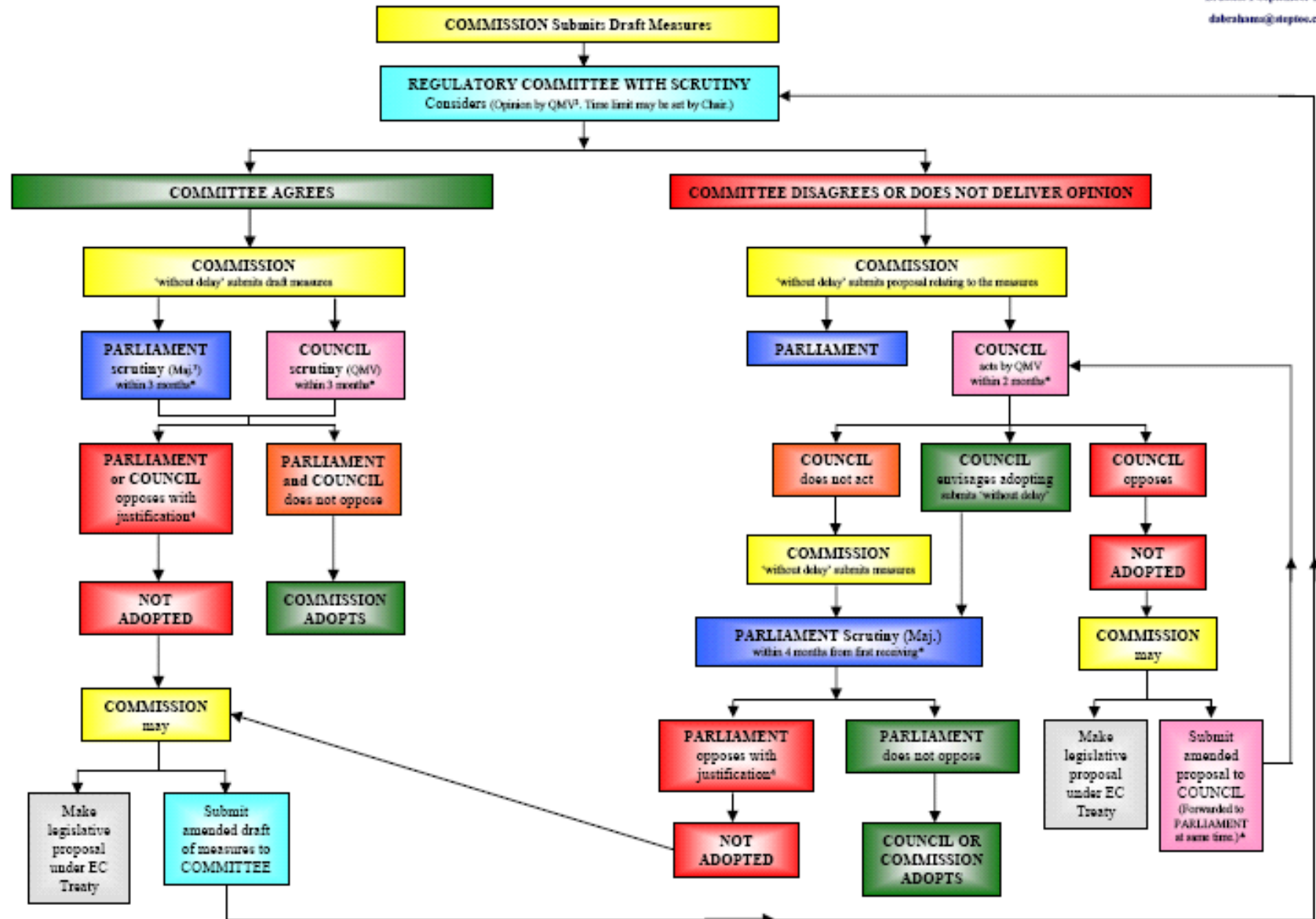
MINI REVISION

Questionable whether 4 years is sufficient:

'The extension of the review programme proposed may not be enough to finalise the evaluation of a number of active substances. On the other hand, a significantly longer extension might work against intensifying the efforts to complete the review programme in a timely manner. Any extension of the review programme and the corresponding transitional period for any remaining active substances after 14 May 2014 should be limited to a maximum of two years and should take place only if there are clear indications that the legal act intended to replace Directive 98/8/EC will not enter into force before 14 May 2014.' Recital (8)

Further extension would be adopted under regulatory procedure with scrutiny.

COMITOLGY: REGULATORY PROCEDURE WITH SCRUTINY¹



1. Council Decision 2006/512/EC of 17 July 2006.

2. Qualified Majority Voting under Art. 205(2) EC Treaty. Committee members may also invoke Article 205(4). It is not clear if this applies in the Council.

3. Majority of its component members.

4. Justification: draft measures (i) exceed implementing powers provided for in the basic instrument; (ii) are not compatible with the aim/content of the basic instrument; or (iii) do not respect subsidiarity or proportionality.

* May be extended by 1 month if complex or stalled if efficient. An abbreviated procedure may be provided for in situations of imperative urgency.

▲ This is not expressly stated but is implicit.

MINI REVISION

The Mini-Revision does not address any of the issues which industry has long complained about/litigated (and was not designed to).

However political undertakings by the Commission (non-legally binding) **concerning data protection, data sharing and free riders** have been made:

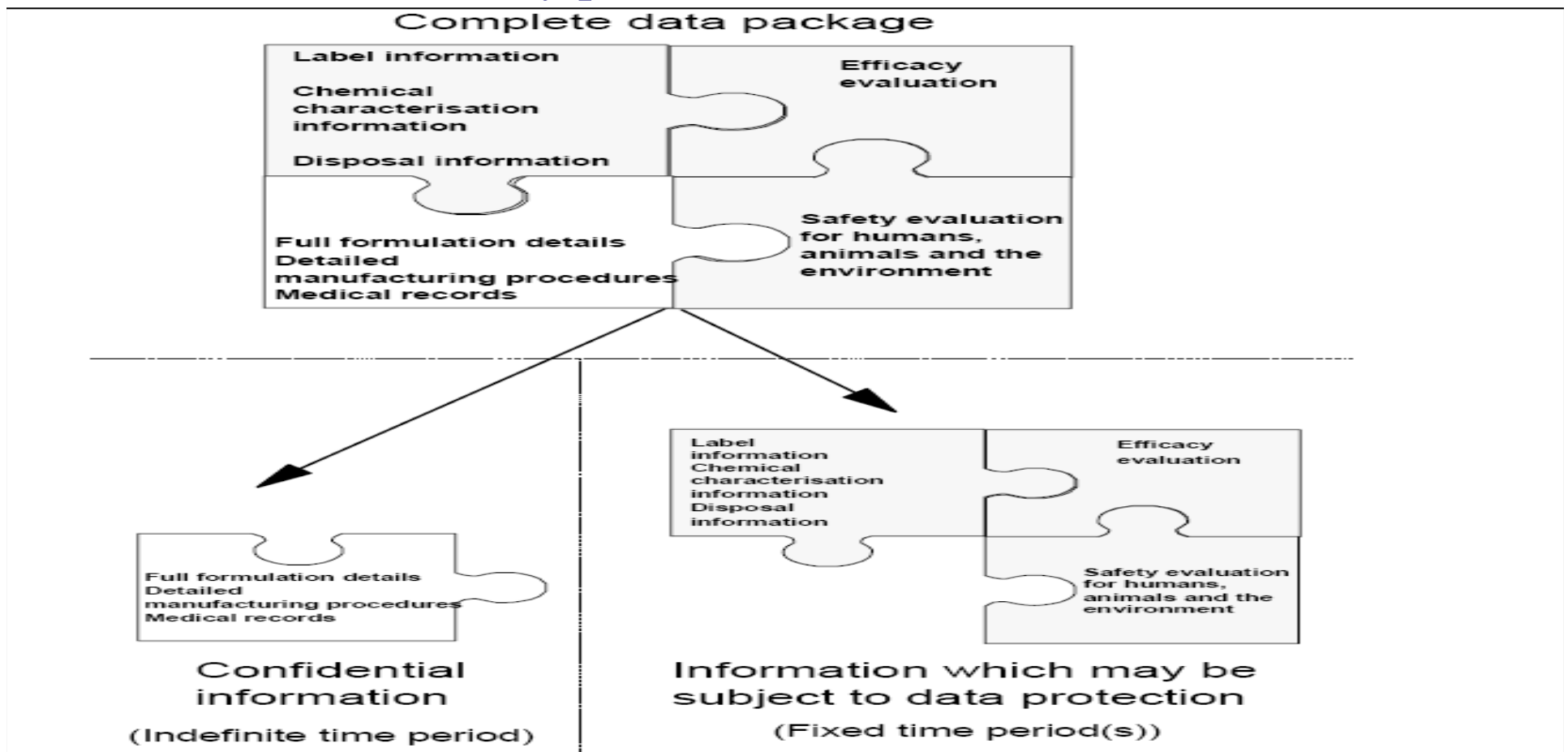
*‘The Commission notes the issues concerning data protection, data sharing and **alleged** free riders‘ that have been raised during the discussions on the proposal for the extension of certain time periods under the Biocides Directive. The Commission will **consider** appropriate solutions to the identified problems in the framework of the substantive revision of the Biocides Directive.’**

**Statement to Permanent Representatives Committee/Council*

4. Data protection issues

DATA PROTECTION

No link between data protection and confidentiality. Data which are protected are not necessarily confidential, and conversely confidential data are not necessarily protected.



DATA PROTECTION

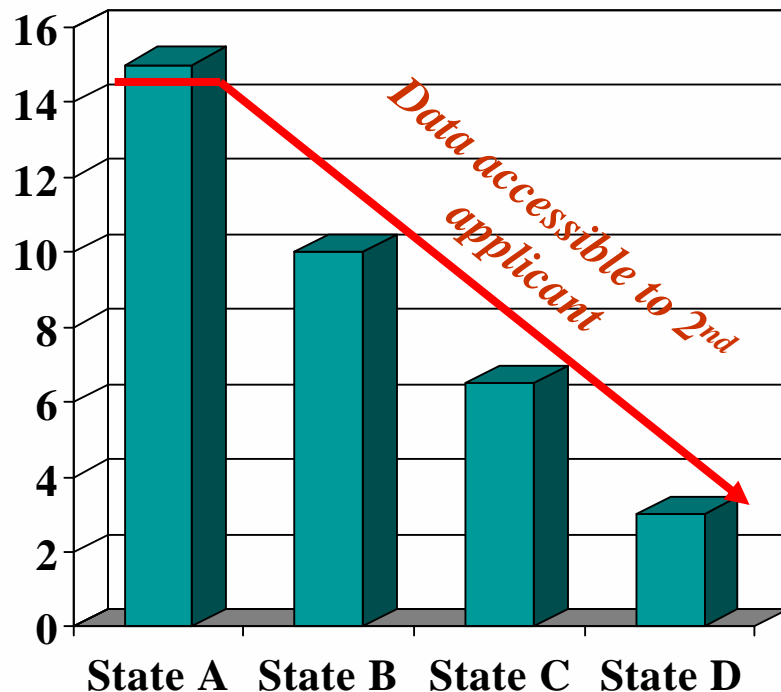
		ACTIVE SUBSTANCE	BIOCIDAL PRODUCT
NEW	1	15 years data protection from date of first inclusion in Annex I/IA [Art. 12(1)(b)]	10 years data protection from date of first authorisation in any MS [Art. 12(2)(b)]
	2	<p>further information submitted for the first time to maintain or vary Annex entry</p> <p>at least 5 years from date of decision</p> <p><i>unless 5 years expires before the 15 (above) in which case expires when 15 years does</i> [Art. 12(1)(d)]</p>	<p>further information submitted for the first time to maintain or vary Annex entry</p> <p>at least 5 years from date of first receipt of information</p> <p><i>unless 5 years expires before the 10 years (above) in which case expires when 10 years does</i> [Art. 12(2)(d)]</p>
EXISTING	3	<p><i>"Any information submitted for the purposes of this Directive" (i.e. for inclusion) data protection.</i></p> <p>[Art. 12(1)(c)(i)]</p>	<p><i>"Any information submitted for the purposes of this Directive" (i.e. for inclusion) data protection.</i></p> <p>[Art. 12(2)(c)(i)]</p>
	4	<p><u>not already protected</u> under existing national rules relating to biocidal products</p> <p>Until 14 May 2014</p>	<p><u>not already protected</u> under existing national rules relating to biocidal products</p> <p>Until 14 May 2014</p>
	5	<p>"Information submitted for the first time in support of the first inclusion" in Annex or additional product type for it.</p> <p>10 years data protection from date of entry in Annex I/IA</p> <p>[Art. 12(1)(c)(ii)]</p>	<p>"Information submitted for the first time in support of the inclusion" in Annex or additional product type for it.</p> <p>10 years data protection from date of entry in Annex I/IA</p> <p>[Art. 12(2)(c)(ii)]</p>
	6	<p>further information submitted for the first time to maintain or vary Annex entry</p> <p>at least 5 years from date of decision</p> <p><i>unless 5 years expires before the 10 (above) in which case expires when 10 years does</i></p> <p>[Art. 12(1)(d)]</p>	<p>further information submitted for the first time to maintain or vary Annex entry</p> <p>at least 5 years from date of first receipt of information</p> <p><i>unless 5 years expires before the 10 years (above) in which case expires when 10 years does</i></p> <p>[Art. 12(2)(d)]</p>

DATA PROTECTION

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 2014

[Art. 12(1)(c)(i) and (2)(c)(i)]



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”...

■ Years of data protection under national law

DATA PROTECTION

“Information submitted for the first time...” 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.**

Free-Rider Issues

- **First free-rider issue:** During the 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.
- **Second free-rider issue:** After inclusion of an active substance into Annex I/IA and when formulators secure a biocidal product authorisation/registration under the BPD, they may switch to another active substance supplier (“free-rider”) and rely on a “letter of access” provided by the person who supported the substance through the review programme. This only applies where technical equivalence can be substantiated. (*See Case C-112/02 Kohlfarma GmbH v Germany: Absence of common origin not a basis for refusal of authorisation.*)

5. Product registration

PRODUCT REGISTRATION

- No product can be placed on the market unless it has been authorised (applying BPD rules).
- Member States authorise a biocidal product only if its active substances are included in Annex I or IA (Art 5(1)).
- BUT transitional period during active substance evaluation for *existing* substances (Art. 16(1)) when national rules apply. (Rules also for new actives – but very few...)
- Post- Annex I/IA inclusion products are governed by BPD principles (applied nationally).
- In case of a non-inclusion decision, products containing existing active substances must be phased out within 12 months of the decision being published.

PRODUCT REGISTRATION

- Different approaches and inaction.

http://ec.europa.eu/environment/biocides/pdf/Post_annex_I_inclusion_procedure.pdf - Microsoft Internet Explorer



WORKING DOCUMENT: DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Protecting the Natural Environment
ENV.B.3 - Biotechnology, Pesticides and Health

HARMONISED TIMELINES AND PROCEDURES TO BE FOLLOWED BY MEMBER STATES, THE COMMISSION AND INDUSTRY FOLLOWING INCLUSION OF AN EXISTING ACTIVE SUBSTANCE INTO ANNEX I OR IA

Introduction

At the 18th CA-Meeting, industry requested clarification of the timescales for action following decisions on Annex I or IA inclusion. Industry also submitted a proposal on possible procedures and timescales, which was distributed for the meeting (Reference CEFIC 05-240).

At the 19th CA-Meeting, the Commission presented a document (Reference *CA-Jul05-Doc 6 A*) setting out a framework of the legal provisions as contained in Directive

MUTUAL RECOGNITION

Existing substances

Step 1: Informal discussions between the Concerned Member State and the applicant about submitting an application for mutual recognition.		
Step 2: Applicant enters details of application in R4BP.		
Step 3: Applicant sends: <ul style="list-style-type: none">• A covering letter confirming that an application is made for mutual recognition of authorisation for the product• A filled in paper copy of the application form generated via the R4BP• One electronic copy of the summary dossier for the product as submitted to the first member state.		
Step 4: Concerned Member State confirms receipt of application (directly to applicant and via the R4BP), declares it incomplete, stops the clock and indicates the date by which the missing data are expected to be submitted.		
Step 4a: Applicant send copy of the first authorisation and of the assessment report from the Reference Member State to the Concerned Member State.		
Step 5: Concerned Member State confirms receipt of application (directly to applicant and via the R4BP) and checks validity of application (copy of authorisation, summary dossier and fee) within 15 days.		

MUTUAL RECOGNITION

Step 6: Concerned Member State confirms receipt of a valid application (directly to applicant and via the R4BP) – the clock starts.	Day 0	
Step 7: Evaluation of the application on the basis of the summary dossier and of the certified copy and of the assessment report of the first authorisation granted.		
Step 8: Concerns on or divergence of opinions with the conclusions of the assessment of the Reference Member State and the summary of the product characteristics to be communicated to the Reference Member State. Concerned Member State to request applicant that certain conditions	Day 90	
referred to in Article 20(3)(e), (f), (h), (j) and (l) of the Directive be adjusted to the different circumstances. ²		
Step 9: Reference Member State to respond to concerns or divergence of opinions.	Day 100	
Step 10: Applicant to respond to request for adjustment to local circumstances to Concerned Member State.	Day 100	
Step 11: If no concerns remain and adjustments are accepted, Concerned Member State to issue the authorisation with a national number and to update the R4BP accordingly.	Day 120	Art. 4.1§1

MUTUAL RECOGNITION

Start of Formal Conflict Resolution Process

<p>Step 12: Concerned Member State officially notifies the Commission, other Member States and the applicant of any remaining concerns or unaccepted adjustments and updates the R4BP.</p> <p>Concerned Member State sends the explanatory document containing the name of the product and its specification and setting out the grounds on which it proposes to refuse or restrict the authorisation to the Commission, other Member States and the applicant</p>	Day 0	Art. 4.4§1
Step 13: The Commission allows a period of 90 days during which the Member States and the applicant can submit comments in writing	Day 90	Art. 27.1.b
Step 14: The Commission prepare a proposal for a draft decision		Art. 27.2
Step 15: The concerns and the comments are discussed in the CA/PA&MRFG meeting		
Step 16: The proposal is voted on in the Standing Committee meeting		
Step 17: Commission adopts decision		
<p>Step 18: In case the decision confirms the refusal/restriction of mutual recognition, the Reference Member State shall take this refusal/restriction into consideration and withdraw/amend the original authorisation, within 3 months of the decision coming into force.</p> <p>If the decision is in favour of the mutual recognition, the Concerned Member State must recognise and grant the authorisation, within 3 months of the decision coming into force</p>		
Step 19: Member States to issue the authorisation with a national number and to update the R4BP accordingly.		

6. The major revision

FEES & IT

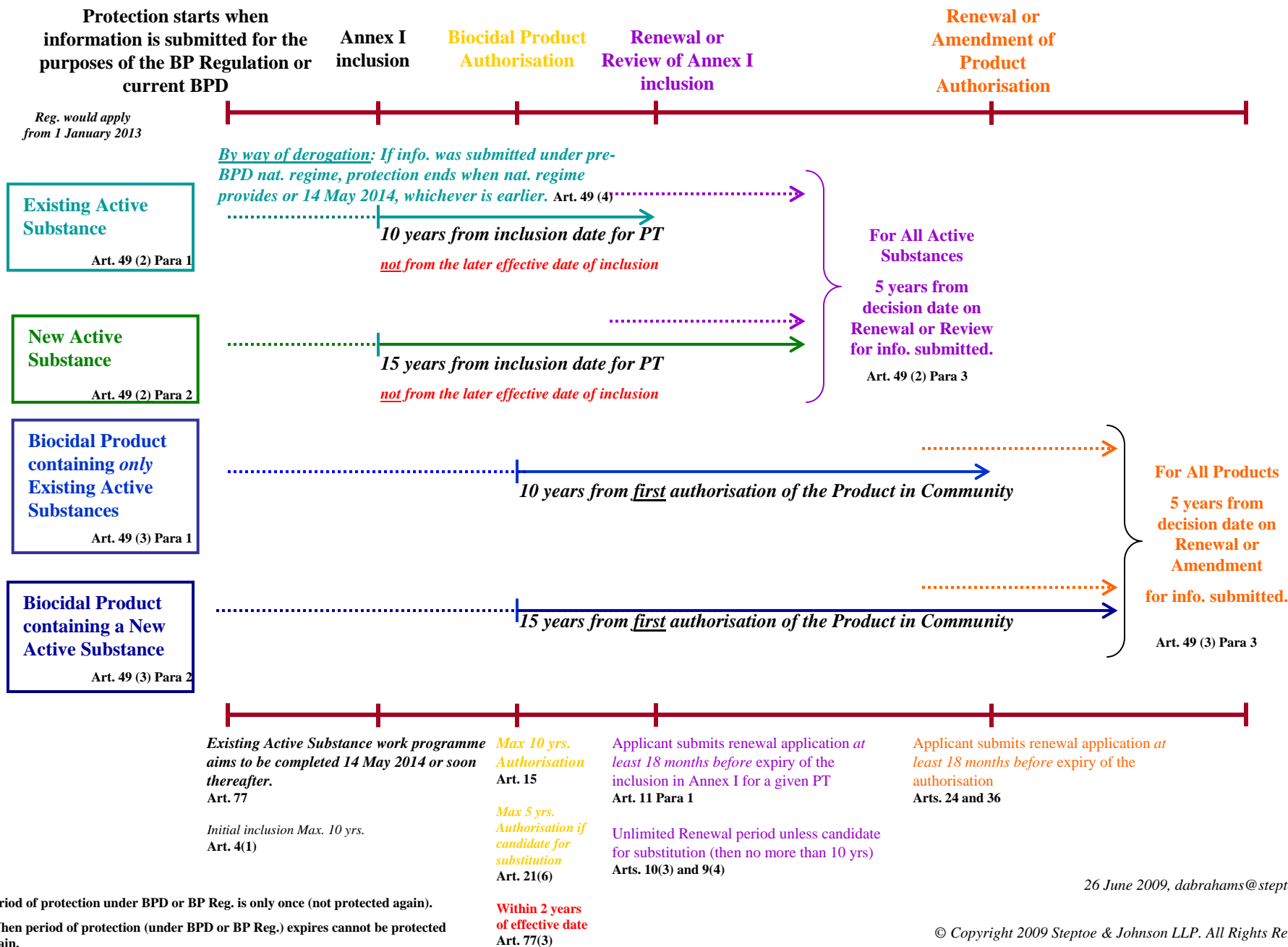
- **Harmonised Fee Structure and Conditions:** Commission would be required to establish a harmonised fee structure **for evaluation of active substances and authorisation of biocidal products**. The fees would be paid to ECHA. A reduced fee would be established for small and medium-sized companies, and would also be adjusted depending upon whether submission is made jointly with other applicants. (The current fee for evaluating an active substance dossier with regard to one PT may range from € 50,000 to €350,000 and different payment modes.)
- **Register of Biocidal Products:** Various types of information will be included in an **electronic database** used for the exchange of information between national competent authorities, ECHA and the Commission. This is designed to facilitate greater consistency of action.

DATA PROTECTION PERIODS

- **Data Protection Periods:** Several new features to the proposed data protection rules e.g. **protection will commence from the moment that information is submitted for the purposes of the BP Regulation** (or the current BPD).
- Of particular concern is the unequal treatment of data in support of an *existing* active substance which was:
 - submitted to an EU member state under a national system or practice for the approval of biocidal products *before* it was submitted for the purposes of the BPD or the proposed Regulation – which would not benefit from 10 years protection post Annex I inclusion of that active substance; and
 - not previously submitted - which would benefit from 10 years protection post Annex I inclusion of that active substance.

It is not clear that this difference in treatment is intentional, and may in fact be a drafting oversight which requires rectification.

INFORMATION PROTECTION PERIODS UNDER PROPOSED BP REGULATION, COM (2009) 267 final



- Period of protection under BPD or BP Reg. is only once (not protected again).
- When period of protection (under BPD or BP Reg.) expires cannot be protected again.

Within 2 years of effective date
Art. 77(3)

DATA COMPENSATION

- Wherever data access is granted (voluntarily or when mandatory) **compensation will be due**, providing that the applicable data protection period has not expired.
- Parties should employ “every effort to reach an agreement” or elect for binding arbitration. If no agreement is reached within 2 months of a request, **ECHA will, within 2 months of being notified, grant citation rights** to tests or studies involving tests **on vertebrate animals**.
- **National courts** would be charged with deciding on the “proportionate share of the costs” that the data access requestor should pay. An appeal against a decision by ECHA in this context might be available under certain circumstances.

DATA SHARING RULES

	PROSPECTIVE APPLICANT		DATA OWNER
Information	Inquire before testing CA OR ECHA WHETHER ALREADY SUBMITTED BY PREVIOUS APPLICANT	Request Access from Data Owner (if data is protected)	Provide Access
Vertebrate Animal Tests or Studies	Must (Authorities will check in Biocides Data Sharing Register) Art. 51(2) 1 st para	Must (for data involving tests on vertebrate animals) Art. 51(2) 3 rd para	Must (ECHA will give access even when compensation not agreed upon) Art. 52(3)
Non-Vertebrate Animal Studies	Must (Authorities will check in Biocides Data Sharing Register) Art. 51(2) 1 st para	May Art. 51(2) 4 th para	May (ECHA does not have the power to give access when compensation not agreed upon) (Title says “ mandatory information sharing” without distinction but recital 51 and explanatory memorandum only refers to mandatory vertebrate data sharing)
Does not involve testing on vertebrate animals (wider than just animal) i.e. non-animal as well	n/a		

COMMUNITY AUTHORISATIONS

A new centralised authorisation scheme would apply for:

- biocidal products containing one or more **new** active substances; and
- “**low-risk**” biocidal products (criteria specified at Art. 17).

For other types of biocidal products authorisation would be sought in a Member State(s) where the applicant intends to supply it.

TIERED DATA & WAIVING

- New tiered approach to data requirements proposed as well as rules on data waiving.
- The proposal explicitly requires consideration of alternative methods to address data requirements:

"Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex."

EXCLUSION CRITERIA

Any active:

- classified as a carcinogen-, mutagen- or reproductive toxin (CMR) Category IA or IB or
- considered as an endocrine disruptor

would *only* be included in Annex I of the Regulation if the particular active fulfilled at least one of the following conditions:

- no or negligible exposure to humans under normal conditions of use;
- active substance is necessary to control serious dangers to public health; or
- use of the substance does not cause any disproportionate negative impacts on the environment or to human health when the biocidal product is used and that there are no alternatives.

SUBSTITUTION

Even where active substances are acceptable, some would be **flagged for substitution** in Annex I.

Biocidal products containing such active substances would be subject to **comparative assessment** and if they present significantly higher risk than alternatives, their authorisations refused or cancelled.

TREATED ARTICLES & MATERIALS

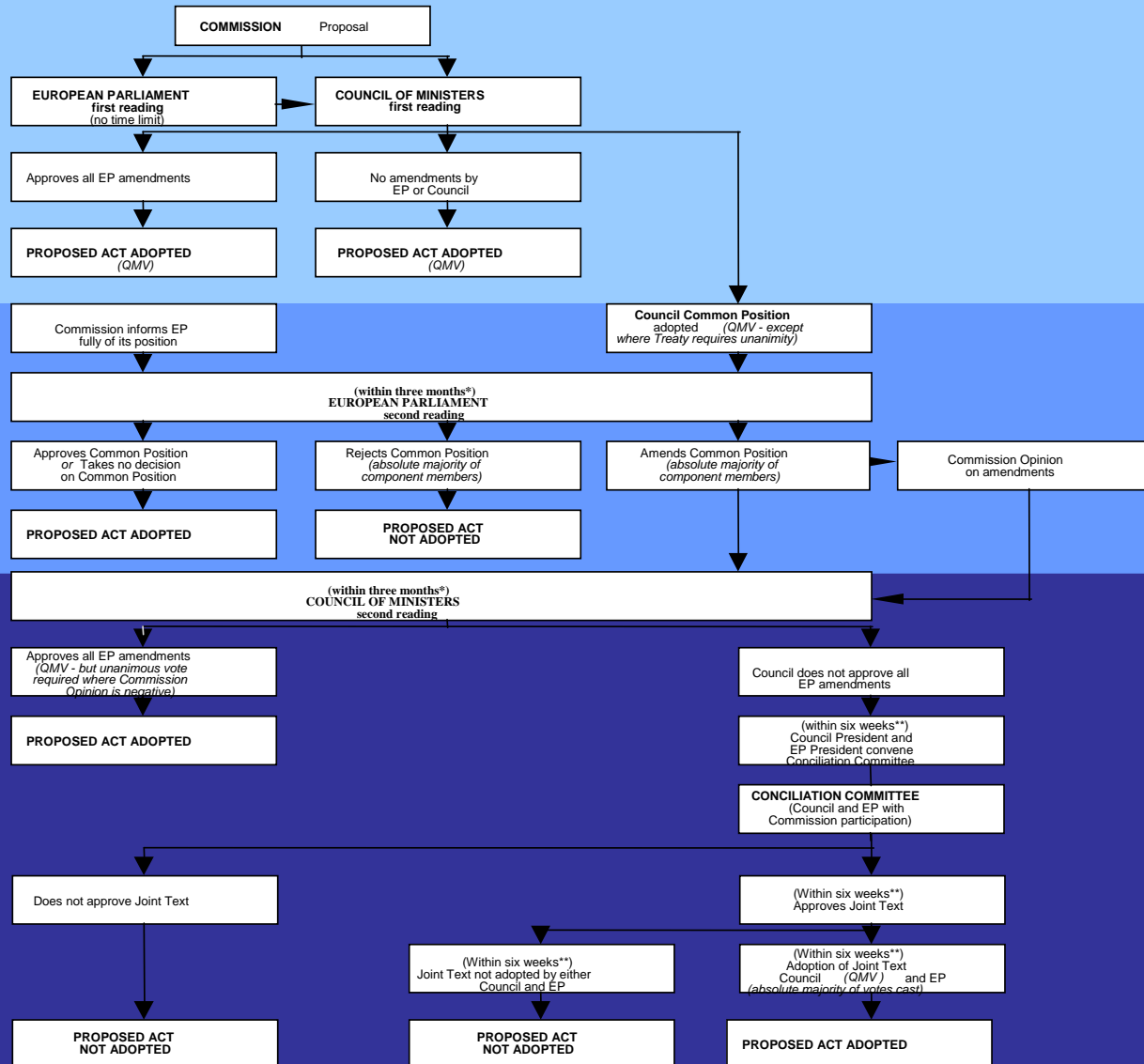
Would only be lawfully supplied within the EU if treated with an EU authorised biocidal product.

This would **close the current gap** in the BPD, which does not regulate articles treated outside the EU and then brought in, even if containing a non-EU approved active substance.

New **labelling requirements** would also apply to treated articles or materials, including the obligation to include “any hazard statement or precautionary statement set out in the authorisation for the biocidal product”.

This provision differs from the US “treated articles exemption”.

CO-DECISION PROCEDURE



"The shortcut"

"The middle way"

"The full works"

*QMV

Qualified majority voting (Council of Ministers): 62 votes out of 87. NB - for certain Proposed Acts (for example, in relation to citizenship and free movement of workers), QMV is not applicable: unanimity is required.

The EP or Council may take the initiative to extend this by a maximum of one month.

** The EP or Council may take the initiative to extend this by a maximum of two weeks.

Questions?

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The *PLC Which Lawyer? Yearbook* consistently recommends Mr. Abrahams in EU Life Sciences and *Legal 500 EMEA (2008)* recognises his "comprehensive understanding" (2008) and "detailed expert knowledge" (2009) of EU environmental regulation. *Chambers & Partners Europe* identifies him as one of the "leading individuals" in EU environmental regulation and reports the market's assessment that he is "exceptionally hard-working and diligent" (2009).