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## General note on data protection in the framework of Directive 98/8/EC

### A. INTRODUCTION

The data protection provisions of Directive 98/8/EC (hereinafter referred to as 'the Directive') are contained in its Article 12. The purpose of these provisions is to allow operators, who invest in generating data for the evaluation of active substances or biocidal products, to recover some of the incurred cost by granting them a period of protection for these data, during which no other operators that also place, or seek to place, substances or products on the EU biocides market may refer to them, unless an agreement is reached about sharing the costs for generating the data. This is done by granting a 'letter of access', that is, a document signed by the owner of the data that gives permission – usually in exchange of financial compensation – to the competent authority to refer to these data for the benefit of a subsequent applicant. Another apparent objective is to protect – for a longer time period – the industry's investment in research, thus giving an incentive for innovation and developing safer products. Naturally, the same provisions set also the *limits* of data protection, i.e. when it should expire; and define the point in time when the data cease to be proprietary and can be referred to by anyone for the purposes of the Directive (public-domain data).

In order to achieve harmonisation of the procedures for the evaluation of active substances and the authorisation of biocidal products, and to facilitate co-operation between the holders of data, it is important that these provisions are implemented in a uniform way. This document attempts to provide guidance to stakeholders on possible interpretations of the provisions of Article 12. It has been conceived as an opinion of the Commission services and has been partly elaborated in co-operation with the Member States. It does not therefore intend to produce legally binding effects.

The very first sentence of Article 12 defines its basic principle, that is, that Member States cannot make use of the information submitted (and presumably owned) by an applicant, for the benefit of a second or subsequent applicant.

The scope of Article 12 – i.e. the data that is to be protected – is defined as "*the information referred to in Article 8*"<sup>1</sup>, which corresponds to the information on active substances (set out in Annexes IIA, IIIA or IVA), and the information on biocidal products (set out in Annexes IIB, IIIB or IVB).

A distinction is made in Article 12 between data protection concerning active substances (Article 12(1)), and biocidal products (Article 12(2)). A further distinction is made between data protection for *new*<sup>2</sup> active substances (Article 12(1)(b)), and for *existing*<sup>2</sup> active substances (Article 12(1)(c)); and for biocidal products containing new active substances (Article 12(2)(b)), and biocidal products containing existing active substances (Article 12(2)(c)), respectively.

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<sup>1</sup> Article 8 of the Biocides Directive sets the requirements for granting an authorisation of a biocidal product or a registration for a low-risk biocidal product.

<sup>2</sup> '**New**' active substances are those that were not used in biocidal products before the date of entry into force of the Directive (14 May 2000). '**Existing**' active substances are the ones that were used in biocidal products before that date.

The protection of data concerning *existing* active substances is also dependent on whether the data are submitted:

- *for the purposes of the Directive* (see Article 12(1)(c)(i) and 12(2)(c)(i)), **or**

- *for the first time in support of the first inclusion in Annex I or IA of either the active substance or an additional product type for that active substance* (see Article 12(1)(c)(ii) and 12(2)(c)(ii)).

Article 12(1)(d) grants protection to data related to active substances *for any further information submitted for the first time*, due to variations in the requirements of the entry in Annex I or IA, or for the maintenance of the entry in these Annexes.

The corresponding protection for biocidal products concerns *any data submitted for the first time* either for a variation in the conditions of authorisation of a biocidal product, or to maintain the entry of an active substance into Annex I or IA (Article 12(2)(d) (i) and (ii)).

## **B. TIME OF PROTECTION**

Data protection for **existing active substances** is granted for:

- Ten years from 14.5.2000 *for any information submitted for the purposes of the Directive* unless data are protected already under national rules. In the latter case, the data protection period granted under national rules will apply in that Member State, but cannot go beyond 14.5.2010;
- 10 years from the date of entry into force of the decision to include an active substance in Annex I or IA, *for information submitted for the first time in support of the first inclusion* in Annex I or IA of either the active substance or an additional product type for that active substance;
- 5 years from the date of entry into force of the decision *for a variation of the requirements of entry* in Annex I or IA of an active substance, or *for the maintenance of that entry*, *for any further information submitted for the first time* (the 5-year period can be extended in order to expire at the same time as the 10-year period referred to in Article 12(1)(c)).

Data protection for **new active substances** is granted for:

- 15 years from the date of entry into force of the decision to include the new active substance in Annex I or IA<sup>3</sup>;
- 5 years from the date of entry into force of the decision for a variation of the requirements of entry in Annex I or IA of an active substance, or for the maintenance of that entry, *for any further information submitted for the first time* (the 5-year period can be extended in order to expire at the same time as the 15-year period referred to in Article 12(1)(b)).

Data protection for **biocidal products containing existing active substances** is granted for:

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<sup>3</sup> Although the Directive does not exactly precise that, by its systematic interpretation we conclude that the protection covers any proprietary information submitted *for the first time* for the purposes of supporting the inclusion of the new active substance in Annex I or IA. It is to be expected that in most cases the information would be newly generated and never used before; however, exceptions may occur.

- 10 years from 14.5.2000 *for any information submitted for the purposes of the Directive*, unless the same data are protected under national rules. In the latter case, the data protection period granted under national rules will apply in that Member State, but cannot go beyond 14.5.2010;
- 10 years from the date of entry into force of the decision to include an active substance in Annex I or IA, *for information submitted for the first time in support of the inclusion in Annex I or IA of either the active substance or an additional product type for that active substance*;
- 5 years from the date of first receipt of *any further information submitted for the first time in order to make a variation of the conditions for authorisation of a biocidal product, or to maintain an Annex I or IA entry of an active substance* (the 5-year period can be extended in order to expire at the same time as the 10-year period referred to in Article 12(2)(c)(i)).

Data protection for **biocidal products containing new active substances** is granted for:

- 10 years from the date of first authorisation in any Member State;
- 5 years from the date of first receipt of *any further information submitted for the first time in order to make a variation of the conditions for authorisation of a biocidal product, or to maintain an Annex I or IA entry of an active substance* (the 5-year period can be extended in order to expire at the same time as the 10-year period referred to in Article 12(2)(b)).

Data protection for biocidal products is in general the same as for active substances. Compared to the situation for active substances, three differences exist for biocidal products:

- (1) data on biocidal products containing a new active substance are protected for 10 years, whereas those for the new active substances are protected for 15 years.
- (2) for data on biocidal products containing *new* active substances, the data protection starts from the date of the first authorisation in a Member State, while for new active substances it starts from the first inclusion of the substance in Annex I or IA<sup>4</sup>;
- (3) for any further data submitted e.g. to address a variation of the conditions for an authorisation of a biocidal product, the data protection starts from the date of *receipt of the data*, while for active substances it starts from the *date of entry into force of the decision* e.g. to make a variation of the requirements for entry in Annex I.

## C. GENERAL QUESTIONS<sup>5</sup>

*1. Data protection for information related to existing active substances that are not evaluated within the review programme established by the Directive*

Article 12(1)(c) specifies the data protection provisions for dossiers concerning active substances on the market before 14 May 2000 (i.e. existing active substances), which may be used in biocidal products.

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<sup>4</sup> Data protection is not relevant for inclusion in Annex IB, as data protection is related to authorisations for placing on the market of biocidal products, and basic substances cannot be placed on the market as biocidal products and consequently do not need authorisations.

<sup>5</sup> Reference to the relevant provisions is generally made to Article 12(1) (active substances), although the same references in most cases (but not all) will also be relevant to Article 12(2) (biocidal products).

These substances had been identified or notified in accordance with the procedures of Commission Regulation (EC) n° 1896/2000 and 1687/2002, but the situation might arise that an active substance was not notified either due to a failure or because of the deliberate decision by producers or formulators not to do so.

In accordance with Article 6(1)(b) of Regulation 1896/2000, only those existing active substances for which a *notification* for at least one product type has been accepted by the Commission were listed for evaluation for inclusion into Annex I or IA to the Directive. In fact, Annex II to Commission Regulation (EC) n° 2032/2003<sup>6</sup> constitutes this review list. Additionally, in accordance with the provisions of Article 4b of Regulation 2032/2003, active substances for which at least one complete dossier was submitted for evaluation to a Member State by 1 March 2006<sup>7</sup> are examined under the review programme and are consequently assimilated to notified active substances.

Other, only-identified existing active substances, have not been allowed on the market for biocidal purposes after the end of the phase-out period (i.e. 1 September 2006, as specified in Article 4(2) of Regulation 2032/2003). The same applies to notified substances in product types not notified, and for existing active substances for which it has been accepted due to socio-economic considerations that they could stay on the market during the phase-out period although, for various reasons, they were not identified by 28 March 2002 (these were listed in Annex VII to Regulation 2032/2003).

In accordance with Article 6(4) of Regulation 1896/2000, applications for inclusion of an existing active substance/product-type combination that is not included in the review list<sup>8</sup>, will be considered as if the substance was not placed on the market before 14.5.2000 (i.e. as if it were a new active substance). One practical consequence of this is that biocidal products containing the active substance in question cannot be placed on the market during its evaluation – this is permitted only for products containing active substances from the review list.

It should be clarified however that, this assimilation to new active substances does not concern the application of data protection rules. Therefore, data protection for a substance which was identified as an existing active substance already on the market on 14 May 2000<sup>9</sup>, *is governed by Article 12(1)(c)*. Furthermore, no provisional authorisations in accordance with Article 15(2) of the Directive can be granted for biocidal products containing such active substances.

The same applies for substances for which, although they were not identified as such, there is evidence that they were used as active substances in biocidal products prior to 14.5.2000. This is justified by the fact that identification of existing active substances was an obligation, so the persons who failed to comply with this obligation should not be rewarded with a longer data protection or the possibility to obtain provisional authorisation for their products. These are benefits that should be reserved only for genuinely new active substances.

## **2. Clarification on Article 12(1)(c)(i) and Article 12(1)(c)(ii)**

Article 12(1) provides that "*Member States shall not make use of the information referred to in Article 8 for the benefit of a second or subsequent applicant:*

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<sup>6</sup> Commission Regulation (EC) n° 2032/2003 on the second phase of the review programme for the evaluation of active substances used in biocidal products has been repealed and replaced by Commission Regulation (EC) n° 1451/2007. Any reference to the repealed Regulation is considered as a reference to Regulation 1451/2007.

<sup>7</sup> This possibility was given by Regulation 1048/2005, amending Regulation 2032/2003 (added Article 4b).

<sup>8</sup> Annex II of Commission Regulation (EC) n° 1451/2007 (which repealed and replaced Regulation 2032/2003).

<sup>9</sup> These substances are found in Annex I of Commission Regulation (EC) n° 1451/2007.

*c) in the case of an active substance already on the market on 14 May 2000<sup>10</sup>*

*(i) for a period of 10 years from 14 May 2000 for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, up to a maximum of 10 years from 14 May 2000;*

*(ii) for a period of 10 years from the date of entry of an active substance into Annex I or IA for information submitted for the first time in support of the first inclusion in Annex I or IA of either the active substance or an additional product type for that active substance."*

Both provisions are cumulative and may apply to the same piece of information.

Article 12(1)(c)(i) grants protection to any (proprietary) information submitted for the purposes of the Directive, i.e. for inclusion of an active substance into Annex I, pursuant to Article 11 of the Directive, or for authorisation of a biocidal product, pursuant to Article 8<sup>11</sup>. In practice, the data will be protected from their submission until 14 May 2010, unless they are already protected in accordance with a national scheme related to the placing on the market of biocidal products. In such cases, the data will be protected until the expiry of any remaining period of data protection provided for under national rules, as long as this time period does not go beyond 14 May 2010.

It is reasonable to expect that during this time span, the evaluation for inclusion into Annex I or IA will be finalised. After that, and in accordance with Article 12(1)(c)(ii), a 10-year data protection is granted, starting from the inclusion into Annex I or IA, for *all data that have been submitted for the first time in support of the first inclusion* of the active substance, or an additional product type for that substance.

The purpose for granting the time-limited data protection of Article 12(1)(c)(i), seems to be to prevent third parties to refer to proprietary data without a letter of access<sup>12</sup>, while these data are being evaluated for the purposes of the Directive, and to avoid that companies that had just submitted new data and obtained protection for them under national authorisation rules would see their legitimate expectations adversely affected during the transitional period; or possibly for both reasons.

During the course of the implementation of the Directive, further clarification was needed on the exception clause in article 12(1)(c)(i), by which information already protected under existing national rules relating to biocidal products would continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, up to 14 May 2010 at the latest.

Clarification was deemed necessary for the following situations:

a) a Member State, acting in compliance with existing national rules, has not granted any data protection, or the protection period has already expired;

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<sup>10</sup> For facility purposes, the phrase "*the date referred to in Article 34(1)*" was replaced with the actual date 14.5.2000.

<sup>11</sup> The provisions of Article 12 do not apply to current national authorisation systems or practices that Member States can maintain in accordance with Article 16(1) during the transitional period. Article 16(1) establishes a derogation from, among others, Article 8 (2), which refers to the information necessary to obtain an authorisation, the same information that is to be protected in accordance with Article 12. Furthermore, it would be illogical to allow the Member States to maintain their current practices or systems for placing on the market (e.g. no particular requirements) during the transitional period, while at the same time imposing a uniform data protection system that could in any case not be applied in Member States which do not require submission of data as a condition for placing biocides on the market.

<sup>12</sup> After all, these are data on substances and products that have already been on the EU market for many years.

b) A Member State, acting in compliance with existing national rules, has granted data protection for a period that expires before 14 May 2010;

c) A Member state, acting in compliance with existing national rules, has granted data protection for a period that expires after 14 May 2010.

In case (a) the first sentence of Article 12(1)(c)(i) applies, i.e. the data are protected until 14 May 2010. The same holds for case (c): even if the protection granted by the Member state would be longer than until 14 May 2010, Article 12(1)(c) last sentence determines that the protection will end at this date. Case (b) seems to be more complicated and the wording of the provision allows for two interpretations.

According to one interpretation, data could indeed be protected for a shorter period of time only and for different periods in different Member States (*in extremis*, anywhere between 15.5.2000 and 14.5.2010). This could lead to rather complicated situations. If Member State A provided data protection up to 2003, while Member State B granted protection up to 2008, the following situation could occur: in 2004, a second applicant could use the no-longer protected data from a first applicant in Member State A to apply for an authorisation there, but he could not do so in Member State B. Still in a given Member State, the conditions for all applicants would be the same, even if they might differ from one Member State to another.

Another interpretation proposed, would solve these complications: data protected under national rules will remain protected until the end of the period determined by those rules. At that moment, the data would be seen as non-protected, in which case the first sentence of Article 12(1)(c)(i) would take effect and protect them until 14 May 2010. The practical result of this interpretation is that all data ends up protected until 14 May 2010, even those that had previously entered the public domain.

The Commission considers the first interpretation to be correct, even though it is somewhat more complicated and Member States will have to maintain very precise records of which data are protected under national rules. It would be otherwise difficult to comprehend why a distinction is made in the provision between two cases, or indeed what purpose would it serve to grant further protection to studies for which the protection given to them under national rules has expired. The first interpretation is also in line with what the Community legislator seems to have intended, as can be seen from the record of the 1939<sup>th</sup> Council meeting.

### **3. Clarification on the scope of Article 12(1)(c)(ii)**

According to the wording of Article 12(1)(c)(ii), "*information submitted for the first time in support of the first inclusion into Annex I or IA of an active substance or an additional product type for that active substance*" is protected for 10 years, starting from the date of entry into force of that (first) inclusion decision.

It follows that data which have already been submitted before, for instance, in the context of national systems for the placing on the market of biocides in any Member State, cannot benefit from this provision. The same applies to data already submitted within national systems in one of the new Member States (even prior to their joining the European Union on 1 May 2004 or 1 January 2007) and to EFTA countries that are members of the EEA Agreement such as Norway and Lichtenstein, as neither the Accession Treaties nor the decision including the Biocides Directive into the EEA Agreement contain any relevant derogation.

On the other hand, it does not seem relevant for the purposes of Article 12(1)(c)(ii) whether the data have been submitted earlier to the Commission or to the Member States for purposes other than authorising the placing on the market of biocidal products, e.g. in the context of authorisations for the placing on the market of plant protection products, or veterinary medicinal products, etc.

As explained, only new data submitted for the first time in support of the first inclusion in Annex I or IA of either the active substance or an additional product type for that active substance are protected for 10 years from the Annex I entry. Consequently, at the time of inclusion of *further product types* for an active substance which is already included in Annex I, *only the additional data* requested due to specific data requirements for that product type will be protected for 10 years.

It has to be noted also that Article 12(1)(c)(ii) is not specifically linked to, and will continue to apply after the finalisation of the review programme.

#### **4. Clarification on consequences of the timing of data submission**

Specifically with regard to the issue of what data may be considered as "*submitted for the first time*" and benefit from the 10-year protection of Article 12(1)(c)(ii), it has to be noted that when the Directive was agreed and adopted, there was no clear view yet on the organisation and timetable of the review programme. Furthermore, in quite a few cases, the 'current national systems or practices' referred to in Article 16(1) that continued to apply during the transitional period were amended – such amendments should be notified before adoption in accordance with Directive 98/34/EC – leading for example to an *extension* of the data requirements under national law.

The issue is particularly relevant in the case of new studies, originally generated in order to support the inclusion of an active substance scheduled for evaluation at the latest stages of the review programme (e.g. active substances of the 3<sup>rd</sup> or 4<sup>th</sup> priority list).

In a representative case, a Member State amended its legislation for placing anti-fouling products on the (national) market, requiring submission of the full data set, as laid down in the Biocides Directive already in 2002, thus obliging companies to generate and submit data that they had not submitted under the previous national system; the same data that they would also have to use when submitting dossiers to support the first inclusion into Annex I or IA of the substances used in anti-fouling products.

Meanwhile, Commission Regulation 2032/2003 on the 2<sup>nd</sup> phase of the review programme provided that dossiers for the evaluation of active substances used in PT 21 (anti-fouling products) had to be submitted no sooner than 1 November 2005 and by 30 April 2006 at the latest. As a consequence, for all anti-fouling substances reviewed in that Member State under the amended national system, data protection under the Directive could not be longer than 14 May 2010. Since the data had already been submitted in order to comply with the amended national authorisation requirements, they would not be considered as "submitted for the first time" when the time came (after 1.11.2005) to submit the same information to support the first inclusion of the anti-fouling active substances in the Directive's positive list. As a result, the protection granted by Article 12(1)(c)(ii) could not apply to such data, although the objective of the Community legislator was to grant the 10-year protection after inclusion in Annex I or IA to these newly generated data<sup>13</sup>.

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<sup>13</sup> As this was an unintended side-effect of the amendment of the particular national legislation and the timing of the Community Review programme, the Member States and the Commission envisaged as a solution to amend Article 12(1)(c)(ii) in a way that data generated **after the entry into force** of the Directive would be eligible for the 10-year protection period after Annex I inclusion, even if they had already been used in a national system before being submitted in view of the first inclusion into Annex I or IA. This would require however the amendment of the Directive in co-decision, and therefore would not provide a timely solution in the particular Member State's case.

However, this unwanted consequence of the review programme, gave also the opportunity to clarify further the issue of what is considered as "*submitted for the first time*". In an opposite example, a company submitted newly generated information to a (Rapporteur) Member State, *first to support the inclusion* of an active substance they were using in their products, and *then* submitted the same information to another Member State to comply with non-harmonised national authorisation requirements that continue to apply during the transitional period (specifically, in order to renew the authorisations of biocidal products that they were holding in that country).

In that case, the data protection from Article 12(1)(c)(ii) for these studies was not affected, since the submission of information in support of the first inclusion of an active substance happened at a point in time preceding their subsequent submission under the national authorisation system.

As a general conclusion, it is evident from the analysis of these provisions (i.e. Article 12(1)(c)(i) and (ii)), that the intention of the Community legislator was to ensure particularly strong protection for data that have been newly generated for the purposes of the Biocides Directive. On the other hand, the correct application of these provisions will necessitate that at the moment of first inclusion into Annex I of an active substance or an additional product type it needs to be clearly established which data are protected until what time. Appendix I to this note contains a schematic view to illustrate better the application of Article 12(1)(c)(i) and (ii).

#### ***5. Clarification on data protection of product dossiers for additional product types***

Data protection of a dossier concerning a biocidal product is governed by Article 12(2)(c) and (d) of the Directive. If the biocidal product contains an existing active substance for use in an additional product type compared to those already included in Annex I or IA, data submitted for the first time is protected during 10 years from the inclusion of the new product type for that active substance. If the biocidal product concerns a product type which is already listed in Annex I, data protection will end at the same time as for the data submitted for the first inclusion of the active substance for that product type.

There will be no further data protection, if a request for authorisation of a biocidal product containing an existing active substance that is already included in Annex I for the particular product type concerned by the request, is made 10 years after the first inclusion.

#### ***6. Protection of data submitted as part of a notification in accordance with Commission Regulation 1896/2000***

The data protection granted by Article 12 concerns information referred to in Article 8 of the Directive (including the data listed in Annex IIA, IIIA and IVA) and starts in practice when information is submitted "*for the purposes of this Directive*" (v. Article 12(1)(c)(i)).

The earliest moment when Article 12(1)(c)(i) could possibly apply is when data were submitted for the notification procedure under Article 4 of Commission Regulation 1896/2000. It is possible that Member States may require that notifiers established in their territory submit simultaneously to their competent authorities the same information as was submitted to the Commission (so the information may get data protection also under national rules). The Regulation requires in its Annex II, point 7, that the information submitted should be based on studies that are available to the notifier and which will be later submitted to the Rapporteur Member State, as part of the dossier referred to in Article 11(1) of the Directive (inclusion of an active substance in Annex I or IA). Article 11(1) refers to requirements of Annex IIA, IIIA and IVA to which provision also Article 8 refers. Hence, studies

submitted with a notification would be protected in accordance with Article 12(1)(c)(i)<sup>14</sup> and, if they were submitted for the first time with the notification of the active substance, they might also get the 10-year protection from Article 12(1)(c)(ii).

### ***7. Protection of data submitted for a provisional authorisation granted under Article 15(2)***

The Directive has no special provisions concerning data protection in cases where a biocidal product is provisionally authorised in accordance with Article 15(2) of the Directive, while the active substance it contains is still under evaluation. Article 15(2) par definition only applies to *new* active substances (i.e. those not used in products marketed before 14 May 2000).

As explained above, the protection until 14 May 2010 for "*any information submitted for the purposes of this Directive*" only concerns the *existing* active substances. It could be argued that one of the reasons it was granted was to prevent third parties from referring to data submitted by their owner for the purposes of the review programme, while the review of the active substance is pending (hence the coincidence with the timeframe of the review programme 14.5.2000-14.5.2010).

*A contrario*, one might also argue that, for new active substances there is no specific evaluation timeframe, and that, during their evaluation stage there will only be the developer company that has an interest – and is technologically and legally in a position – to request already to place a product on the market. Furthermore, new molecules are systematically protected by industrial property rights (patents), to which the human and environmental safety data protection can only be subsidiary.

However, and even if the Community legislator did not provide expressly for data protection during the evaluation stage of a new active substance, in order to obtain a provisional authorisation operators must have submitted<sup>15</sup> to the competent authority of a Member State a dossier for the new active substance with the information referred to in Annex IIA, IIA or IVA, and a dossier on the product with the information referred to in Annex IIB, IIIB or IVB, i.e. "*the information referred to in Article 8*". In accordance with Article 12(1), this information cannot be used by the Member State to which it was submitted for the benefit of a second or subsequent applicant – even if this is a (second) applicant for a provisional authorisation.

## **D. OTHER DATA PROTECTION ISSUES**

### ***1. Consequences for data protection of the non-inclusion decision for an active substance***

The decision not to include an active substance in Annex I or IA does not render the protection under Article 12(1)(c)(i) void. According to the wording of the Article, the information submitted is still protected until 14.5.2010 (or any shorter period of data protection established in individual Member States as explained above), regardless of the outcome of the evaluation.

The submitted data, even if they are submitted for the first time, cannot however benefit from the 10-year protection granted to active substances included in Annex I or IA, as this protection period presupposes - and starts from - the moment of inclusion.

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<sup>14</sup> It has to be noted however that the mandatory information required in a notification – a limited list of endpoints without the full studies – is normally not sufficient to carry out a full evaluation for inclusion of an active substance into Annex I of the Directive or for granting an authorisation for a biocidal product in accordance with the Directive.

<sup>15</sup> In accordance with Article 11(1) which applies to both new and existing active substances.

If the same data are re-submitted later in support of the inclusion of the same active substance<sup>16</sup> and the outcome is favourable this second time, then they may also benefit from the protection granted under Article 12(1)(c)(ii).

## ***2. Data protection for a second applicant submitting data concerning an active substance***

This question refers to the case where one company has submitted a full set of data in support of the inclusion of an active substance, and the data protection that a second company would get if they duplicate (re-generate) the entire data set and submit it also to support the Annex I inclusion.

It has to be said that, in general, the Directive discourages this situation and Member States are even entitled to impose mandatory data-sharing in their territory if both companies are established in the Member State – only at biocidal product authorisation level - in order to avoid the duplication of testing involving vertebrate animals.

The second applicant will get data protection that will expire at the same date as the data submitted by the first applicant. This follows from Article 12(1)(b) and Article 12(1)(c)(ii), which make a reference to the date of inclusion of the active substance in Annex I or IA. If the second applicant's data set results in a different overall conclusion regarding the inclusion in Annex I from that of the first applicant's data, or if the conditions in Article 12(1)(d) are fulfilled, then the provisions of Article 12(1)(d) may apply for the studies being the scientific background for this conclusion.

The answer to the same question is, however, not so easy to provide in the case where the second company re-generates the active substance data to use them for the product authorisation stage (i.e. *after* the active substance has been included in Annex I, on the basis of only the data set submitted by the first company).

While the protection for information on *new* active substances starts from the date of first authorisation (*see* Article 12(2)(b)), information on *existing* active substances submitted for the purposes of product authorisation is protected "*from the date of entry of an active substance in Annex I*" on condition that it was submitted "*for the first time in support of the inclusion*" of the substance (*see* Article 12(2)(c)(ii)). The second company however does not seem to fulfil that condition, as they did not submit the data to support the inclusion of the active substance in Annex I or IA, but only later, to obtain product authorisations.

A different interpretative approach has been suggested to this grammatical interpretation of Article 12(2)(c)(ii), namely, to consider the phrase "*information submitted for the first time*" as a reference to the study *types* for the required endpoints, e.g. a two-generation reprotoxicity study. If a 2<sup>nd</sup> company had to repeat such a study, because the first data owner refused to co-operate, it would still be the 'same information' (i.e. type of study) as the one submitted for the first time in support of the inclusion, and hence the 2<sup>nd</sup> company would also get protection. However, as much as this interpretative approach seems to rime with the logic of the data protection system, it would be difficult to oppose it to the written letter of the law. An amendment of Article 12(2)(c)(ii) would be necessary for reasons of legal certainty.

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<sup>16</sup> This could happen for instance, if a dossier was declared incomplete the first time it was submitted, but was re-submitted later, together with the missing studies. The fact would remain that the new studies *were* submitted "*for the first time in support of the first inclusion*" of the active substance, so the conditions of Article 12(1)(c)(ii) are fulfilled.

## Appendix 1 – Scheme for data protection periods

A full dossier comprises the following studies:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Dossier submission is in 2006, Annex I inclusion in 2008.

- Studies D and E were submitted already in Member State 1 and have data protection under national legislation relating to biocides until 2007
- Studies L and M were already submitted in Member State 2 and have data protection under national legislation relating to biocides until 2009
- Study U was already submitted in Member State 3 and has no data protection (or data protection has already expired).
- Study Z was already submitted in Member State 4 and has unlimited data protection under national legislation relating to biocides.

The following situation emerges:

