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COMMISSION NOTICE

Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009

(Text with EEA relevance)

(2019/C 229/01)

The document provides Member States and applicants with guidance on the procedures and policies surrounding various elements of data protection, as related to plant protection products legislation. It considers the practical application of the legal provisions of Articles 59 – 62 and 80 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽¹⁾. Throughout the document references to Articles refer to Regulation (EC) No 1107/2009 unless otherwise stated.

These Guidelines are intended to help Member States to apply the rules in a consistent way, and for applicants to understand those rules. It does not produce any legally binding effects.

This document covers 2 main areas;

- Section 1 – explaining the periods of protection applied to studies under different circumstances – the ‘why, when and how long’;
- Section 2 – clarification of the special procedures and provisions that apply to vertebrate data sharing.

Since the adoption of the first Guidance document ⁽²⁾ in 2013, Member States have gained experience and the document should be updated. The use of these revised Guidelines is recommended for applicants and Member States for any applications for active substance and/or plant protection products submitted after 3 October 2019.

This document is intended to assist businesses and national authorities in the application of the EU legislation, more specifically Articles 59-62 and 80 of Regulation (EC) No 1107/2009. It is without prejudice to interpretation of Union law by the Court of Justice of the European Union.

Revision history

The following parts have been revised compared to the first version of the document dating from 1 February 2013 ⁽²⁾.

When	What
3 July 2019	Change to provisions for protection of confirmatory data. Clarification of general requirements for applying protection via increased emphasis of paragraph 6.

⁽¹⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁽²⁾ Guidance Document on Data Protection (SANCO/12576/2012– rev. 1.1, from 1 February 2013, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en).

When	What
	<p>Clarification of other points of the technical Guidelines which were raised by Member States, thanks to their gained experience and while developing other guidelines, such as the one on Article 43 of Regulation (EC) No 1107/2009.</p> <p>Change of rules for the acceptance of duplicate studies.</p>

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SECTION 1

PERIODS OF PROTECTION AND HOW TO APPLY THEM

Status and scope of this guidance

1. This document provides Member States and applicants with guidance on the procedures and policies surrounding various elements of data protection, as related to plant protection products legislation. It considers the practical application of the legal provisions of Articles 59 – 62 and 80 of Regulation (EC) No 1107/2009. Throughout the document references to Articles refer to Regulation (EC) No 1107/2009 unless otherwise stated.

2. These Guidelines are intended to help Member States apply the rules in a consistent way, and for applicants to understand those rules.

3. This document covers 2 main areas:
 - Section 1 — explaining the periods of protection applied to studies under different circumstances – the ‘why, when and how long’;

 - Section 2 — clarification of the special procedures and provisions that apply to vertebrate data sharing.

Background — the legal provisions

4. Since 14 June 2011, all data protection provisions are legislated by Articles 59-62 (Chapter 5) and Article 80 of Regulation (EC) No 1107/2009 (hereafter 'the Regulation').
 - Article 59 stipulates the provisions for data protection for data submitted as part of an application for authorisation, amendment to or review of an authorisation under the Regulation. It includes provisions for data submitted to support minor uses and for renewal of authorisation.
 - Article 60 outlines the requirements for Member States to prepare, keep and make available to interested parties the lists of studies used to support an authorisation.
 - Article 61 outlines the general provisions for the avoidance of duplicate testing, including the procedures for provision of data lists to third parties to allow informed access negotiations with data owners. Articles 8(1) and 33 (3) also outline the need for justification of steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals.
 - Article 62 outlines the special provisions related to vertebrate studies.
 - Article 80(2) outlines the provisions for data protection for data submitted and considered under the Transitional measures. As specified in these transitional measures, data protection must be applied in accordance with the provisions of Article 13 of Directive 91/414/EEC ⁽³⁾.
5. For some time (until the transitional measures are completed) Member States must reflect the data protection provisions under three possible different data protection regimes:
 - national rules (that were in place prior to Directive 91/414/EEC) – applied at Member State level and varying greatly between Member States, some with no data protection, some with protection in perpetuity. For clarity throughout the remainder of the document these will be referred to as 'old' national rules.
 - national rules transposing Directive 91/414/EEC (Article 13) – applied at Member State level, with Annex II data protection linked to active substance (a.s.) approval at EU level. For clarity throughout the remainder of the document these will be referred to as '91/414 national rules'. Note although the legal provisions were adopted as part of an EU Directive to be applied at 'EU level', the nature of the process required that data protection was applied at a national level. The '91/414 national rules' 'capped' the maximum protection allowed under the 'old' national rules'.
 - Regulation (EC) No 1107/2009 (Chapter 5 and Article 80(2)) – which attributed the responsibility for the granting of data protection exclusively to Member States, linked to the date of product authorisation (or renewal of authorisation).

General considerations before claiming and granting protection for a test or a study

6. The Regulation specifies that in order to be eligible for protection tests and studies should meet the following requirements:
 - a) The tests and studies must be necessary to support the authorisation or amendment of an authorisation (new authorisation, amendment to allow use on another crop, renewed authorisation, reviewed authorisation or extension of authorisation for minor use);
 - b) The tests and studies must be performed to Good Laboratory Practices/Good Experimental Practices (GLP/GEP) standards;

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

- c) The applicant must claim protection for the tests and studies as well as provide reasons for why the test and studies are necessary for the first authorisation or amendments to the conditions of authorisation;
- d) The tests and studies must not have been protected previously (or be subsequently unprotected) in the Member State where the authorisation is sought.

The claim for data protection and whether submitted studies have been previously protected must be specified by the applicant in their approval and authorisation submissions. The applicant must also identify vertebrate studies.

Whether the tests and studies are GLP or GEP and necessary, should be determined by the Rapporteur Member State/Zonal Rapporteur Member State (RMS/ZRMS) (for the approval and zonal assessments respectively), and reflected in the lists of studies produced in accordance with Article 60 of the Regulation.

7. It is critical that Member States consider carefully the *context* in which data have been submitted in order to correctly apply the periods of protection. Below is a summary of several different scenarios for data submission, and the data protection applied in each case:

Active substance data – as defined in Annex II of Directive 91/414/EEC, Regulation (EU) No 544/2011 and Regulation (EU) No 283/2013 ⁽¹⁾		
Scenario – type of data submitted and necessary to support....	Period of protection	Comment
8. Active substance data submitted for a new active substance initially included on Annex I of Dir. 91/414/EEC (NAS under Dir. 91/414/EEC) – see Art 80 (2) b.	10 years from date of first (inclusion in Annex I) approval of the active substance.	Such active substance data protection expires at the same time in all Member States.
9. Active substance data submitted for an existing substance initially included on Annex I of Dir. 91/414/EEC (EAS under Dir. 91/414/EEC). See Art 80 (2) a.	5 years from date of first (inclusion in Annex I) approval of the active substance for the additional data necessary to support first inclusion in Annex I.	Such active substance data protection expires at the same time in all Member States, for data which are essential for Annex I inclusion/approval and which were not used for national authorisation before submission of the dossier. If the tests and studies were used for national authorisations before submission of the active substance dossier, old national rules may apply.
10. Active substance confirmatory data submitted under Dir. 91/414/EEC for NAS or EAS (assessed post-approval).	See Guidance document SANCO 5634/2009 ⁽²⁾ . These data are not protected unless the approval Regulation is amended as a result of the evaluation of the confirmatory data (or <i>critical</i> end points change as a result). In that case data protection for confirmatory data will be protected +5 years from the original approval (not the amended approval).	These data are generally not protected

Active substance data – as defined in Annex II of Directive 91/414/EEC, Regulation (EU) No 544/2011 and Regulation (EU) No 283/2013 ⁽¹⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
11. Active substance data submitted for a NAS considered under Article 80 1 (a) – ‘pending’ NAS under Dir 91/414/EEC (PNAS) which are substances covered by Regulation (EU) No 188/2011). See Article 80(2) b.	10 years from date of approval of the active substance.	Such active substance data protection expires at the same time in all Member States.
12. Active substance data submitted with an application considered under Article 80(1)(b), (c) and (d) – AIR1 actives and resubmissions (substances listed in Regulation (EC) No 737/2007, substances, covered by Regulation (EC) No 33/2008, and listed in Decisions 2008/934/EC and 2008/941/EC). See Article 80(2)(a) and (c).	5 years from date of (re)approval of the active substance.	Data protection expires at the same time in all Member States. For re-submissions data protection applies to the whole dossier (including the ‘old’ data submitted for the first non-inclusion since they were necessary for approval).
13. Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product (Article 33 of the Regulation)	10 years from date of first authorisation of first product containing that active substance in each Member State where the data is necessary for the authorisation.	Data protection may expire at different times in each Member State, depending on date of national authorisation. Studies <i>necessary</i> for the active substance approval are defined by the Rapporteur Member State (RMS) (Member States subsequently define the list of studies that are protected nationally). Note 1: same protection periods apply if active substance is identified as a Candidate for Substitution. Note 2: this also applies in case the first authorisation was granted in accordance with Article 30 (provisional authorisations)
14. Active substance data submitted with an application under Article 22 of the Regulation (low risk NAS) and with the application for authorisation of the corresponding product.	13 years from date of first authorisation of a low-risk product containing that low-risk active substance in each Member State.	Data protection may expire at different times in each Member State, depending on date of national authorisation. Studies <i>necessary</i> for the active substance approval are defined by the RMS (Member States subsequently define the list of studies that are protected nationally).

Active substance data – as defined in Annex II of Directive 91/414/EEC, Regulation (EU) No 544/2011 and Regulation (EU) No 283/2013 ⁽¹⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
<p>15. New active substance data submitted and justified with an application under Article 15 of the Regulation (renewal) and with the application for renewal of authorisation (Article 43) of the corresponding product. Applies also to low risk active substances.</p>	<p>30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation</p>	<p>Data protection may expire at different times in each Member State, depending on date of national authorisation, although renewal timescales are harmonised. Applies only to new data used to support the renewal of approval of the active substance, where the data concerned are also necessary to support the renewal of authorisation of a product containing it. Note same protection periods apply if active substance is identified as a Candidate for Substitution.</p>
<p>16. Active substance confirmatory information submitted for NAS or EAS (assessed post approval) for approvals issued under Reg. (EC) No 1107/2009.</p>	<p>The situation arises when confirmatory information is submitted after the granting of an authorisation. In the case where the confirmatory information is necessary for the authorisation, confirmatory information will be protected in line with the main active substance data package for NAS i.e. for +10 years from the first authorisation), or for renewed active substances, 30 months from the date of amended authorisation or from the date of decision to maintain the authorisation in each Member State.</p>	<p>Generally the submission of confirmatory information will not be necessary for the authorisation (Article 59(1) subparagraph 1 (a)). Where it is necessary, protection timelines as indicated will apply.</p>
<p>17. Active substance data submitted for an application for first authorisation of a new product, or for a new use for an already authorised product, that was not necessary for the renewal of approval of that active substance.</p>	<p>10 years from date of authorisation of the product applied for.</p>	<p>When new active substance data is required for an amendment of a product authorisation, the protection period of that data is counted from the date of first authorisation of the product, not of the new use.</p>

Active substance data – as defined in Annex II of Directive 91/414/EEC, Regulation (EU) No 544/2011 and Regulation (EU) No 283/2013 ⁽¹⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
<p>18. New active substance data submitted and justified with an application under Article 15 of the Regulation (renewal) and with the application for a New product authorisation (Article 33).</p>	<p>10 years from date of first authorisation of the NEW product containing that active substance in each Member State where the data is necessary for the authorisation of the NEW product and the authorisation is granted before an existing product authorisation is renewed under Art.43.</p>	<p>If data protection is claimed for a renewal, as well as for a new product, the data is no longer protected after expiration of the shortest period.</p> <p>The data protection period is linked to the authorisation which comes first:</p> <ul style="list-style-type: none"> — 10 years if the Art. 33 authorisation is granted before the Art. 43 — 30 months if Art. 43 renewal is granted before the Art. 33.

Product data – as defined in Annex III of Directive 91/414/EEC, Regulation (EU) No 545/2011 and Regulation (EU) No 284/2013 ⁽²⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
<p>19. Product data submitted with an application under Article 4 of Directive 91/414/EEC and pending on 14/6/2011 (new product submitted before 14/6/2011).</p> <p>For the active substance data provided to support that authorisation see points 8, 9 or 12.</p>	<p>10 years for product data from the date of the first authorisation in each Member State.</p>	<p>Article 80(5)(a) of the Regulation applies. Data protection is triggered by the decision on a pending authorisation. Therefore once the decision to authorise a product is adopted, Regulation (EC) No 1107/2009 applies, in particular Article 59.</p>
<p>20. Product data submitted with an application under Article 33 of the Regulation (new product under Regulation).</p> <p>For the active substance data provided to support that authorisation see points 8, 9, 13, 16 or 18.</p>	<p>10 years from date of first authorisation of that product in each Member State.</p>	<p>Data protection may expire at different times in each Member State, based on date of first authorisation in that Member State.</p> <p>It should be noted that for any application for product authorisation submitted after 14/6/2011, the Regulation applies, as provided in Article 80(5).</p>

Product data – as defined in Annex III of Directive 91/414/EEC, Regulation (EU) No 545/2011 and Regulation (EU) No 284/2013 ⁽³⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
<p>21. Product data submitted with an application under Article 40 of the Regulation (mutual recognition (MR)).</p> <p>For the active substance data provided to support that authorisation see points 8, 9, 13, 16 or 18.</p>	<p>10 years from date of first authorisation of that product in each Member State.</p>	<p>Protection must be applied to data supporting MR authorisations, noting however that submission of dossier is required for MR only where requested by the Member State concerned. Even if data are not submitted, they are still effectively protected in the mutually recognising Member State. It is the responsibility of Member State to confirm that a period of protection has not been granted for the data or that any period granted has expired in their territory. They may use information submitted by applicants (see paragraph 31)</p>
<p>22. New product/use data submitted with an application for amendment (new crop) under Article 33 of the Regulation (new crop amendment).</p>	<p>10 years from date of first authorisation of that <i>product</i> in each Member State (<i>not</i> the date of authorisation of the new crop).</p>	<p>Note Article 59 1 (a) refers specifically to amendment to allow the use on <i>another</i> crop.</p>
<p>23. New product/use data submitted with an application for amendment (new good agriculture practices (GAP) on existing crop) under Article 33 of the Regulation (new GAP existing crop amendment).</p>	<p>No protection for 'new GAP data', but original dossier data protection remains unchanged.</p>	<p>Note: Article 59 1 (a) refers only to amendment to allow the use on another crop.</p>
<p>24. New product/use data submitted with an application for new formulation of existing product under Article 33 of the Regulation (new formulation).</p>	<p>10 years from date of first authorisation of that product in each Member State (but only for data submitted to support the new formulation). This period is 13 years in case of low-risk products (see paragraph 25).</p>	<p>A significant formulation change requiring the submission of data is effectively a new product submission. See the guidance document ⁽⁴⁾ SANCO 12638/2011 <i>on significant and non-significant changes of the chemical composition of authorised plant protection products</i>.</p>

Product data – as defined in Annex III of Directive 91/414/EEC, Regulation (EU) No 545/2011 and Regulation (EU) No 284/2013 ⁽³⁾

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
25. Product data submitted with an application under Article 47 of the Regulation (low risk products). For the active substance data provided to support that authorisation see point 14.	13 years from date of first authorisation of that product in each Member State.	Data protection may expire at different times in each Member State.
26. Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active substance considered under AIR2 onwards. For the active substance data provided to support that authorisation see point 15.	30 months from date of first renewal of authorisation of that product in each Member State.	Data protection may expire at different times in each Member State (although because of renewal timescales these dates should be similar). Applies <i>only</i> to new data necessary to support the re-authorisation of the product.

Minor use data as defined in Article 51(2)(d)

Scenario – type of data submitted and necessary to support....	Period of protection	Comment
27. Data submitted by authorisation holder to support minor use extension (under Article 51) – e.g. residues data.	Protection in line with product data protection expiry in each Member State (not 10 years from date of authorisation of extension of use). Note active and product data protection granted in accordance with Article 59 is extended by three months for each minor use extension. Note active and product data protection granted under Article 80(2) is not extended.	To extend 'core protection' for data protected under Article 59, minor use may not be based on extrapolation and the application must be submitted within 5 years of original product authorisation. Extension up to maximum of 13 years (15 years for low risk).

Minor use data as defined in Article 51(2)(d)		
Scenario – type of data submitted and necessary to support....	Period of protection	Comment
28. Data submitted by official or scientific bodies, professional agricultural organisations or professional users (not-authorisation holders) to support minor use extension (under Article 51) e.g. residues data.	Protected in line with product data protection expiry in each Member State. Note the 10 year protection for the data supporting the original authorisation remains unchanged (no 3-month extension).	No extension of 'core protection' if application submitted by someone other than authorisation holder. – <i>even if data are generated by the authorisation holder</i>

(¹) Implementing Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013 p. 1).

(²) Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009 (SANCO/5634/2009 rev. 6.1 from December 2013 or later, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en).

(³) Implementing Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

(⁴) Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products (SANCO 12638/2011, November 2012, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en).

29. One general principle of data protection which applies equally to Directive 91/414/EEC and the Regulation is that once a test or study report has been used and protected under the PPP legislation in a Member State, the study should not be protected further via a new submission in the same Member State (⁴).
30. The question of whether a study has been used before (and received protection previously) is a complex issue which raises many practical difficulties for Member States. Whilst the Member State can identify active substance data that may have been protected previously 'at an EU level', they may not be able to easily identify data used nationally to support authorisations. It is thus *crucial* that the applicant claims protection and *accurately* confirms via their submission to that Member State whether studies have been protected previously in that Member State or at an EU level (or whether that protection has expired) as required in Article 59(3) of the Regulation. This consideration particularly applies to active substance data, representative product data and data used previously to support other formulations/uses.
31. It may not be possible for Member States to routinely check whether each submitted study has been protected previously, so they may be reliant on the information provided by the applicant. Member States may however check some of this information for accuracy, and applicants are respectfully reminded that the provision of knowingly false data protection claims may result in no authorisation/revocation of authorisation.
32. According to Article 60, Member States must prepare lists of protected studies for each product authorised. It would be good practice for the Member States to confirm to the authorisation holder, which data have been protected, for how long and under which data protection regime/scenario.
33. Modelling calculations e.g. PEC (⁵) calculations or OPEX (⁶) calculations are neither tests nor studies and are not conducted according to GLP/GEP standards. Therefore, they cannot be eligible for data protection.

(⁴) The notable exception to this rule is that under the Regulation, data protection periods can be extended by three months for every minor extension of use added by the authorisation holder (when submitted within 5 years of product authorisation).

(⁵) Predicted Environmental Concentrations.

(⁶) Exposure of operators, workers, bystanders and residents.

Preparation of lists of studies

34. This is covered by Guidance Document ⁽⁷⁾ on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009, summarised below:

- a) The applicant must provide a list of studies submitted for both approval and authorisation in each Member State. They must identify vertebrate studies ⁽⁸⁾, confirm whether they are performed according to GLP/GEP and whether they claim for protection and identify whether protected previously.
- b) At the latest at the time of the approval decision, the RMS must identify and prepare a list of studies necessary for approval, amendment or renewal of approval. This list is to be made available to COM and Member States. This list will refer to the issues highlighted by the applicant in a) above, in addition to confirmation that each study was necessary. It will include data on the representative product.
- c) At the latest when issuing the final registration report, the ZRMS must identify and prepare a list of studies necessary to support its decision. This list is to be made available to Member States, as it forms a sub-set of the overall data which will be considered for protection at individual Member State level upon authorisation. This list will refer to the issues highlighted by the applicant in a) above, in addition to confirmation that each study was necessary.
- d) Following authorisation, the individual Member State must prepare a list of studies necessary to support the authorisation in that Member State. This includes all the studies listed in b) and c) above; noting however that some studies may be excluded if they are not relevant to the authorisation in that Member State (e.g. uses not supported in that Member State). These necessary studies fulfilling Art. 59 (1) (a) will be eligible for protection, unless they no longer benefit from data protection or they do not meet the criterion of Article 59(1)(b).

Product or active data under Directive 91/414/EEC

35. Data protection under Directive 91/414/EEC was and is applied at Member State level, however Annex II data to be protected was/is determined centrally (and triggered by date of inclusion/approval), while the list of Annex III data protection was determined by the Member State concerned.
36. As data protection under Directive 91/414/EEC was applied differently to active and product data, it is necessary to make a clear distinction between the two types of data. Essentially the data were divided into 'active substance' and 'product' data by virtue of the Annex point they address in the data requirements. If the data were submitted to meet an Annex II requirement, then they are considered as 'active' data. If data were submitted to address an Annex III requirement, then they are considered as 'product' data.
37. Some Annex II data requirements are met using data generated using a specific product formulation. Although the data were generated using a product, they should be protected as active substance data, since they were generated to meet an Annex II requirement. Note dermal absorption (product) and mesocosm studies were/are Annex III requirements.
38. Some Annex II and III data requirements in the area of residues and environmental fate and behaviour were (are) the same. In this situation, the context of the submission would determine the protection status. Residues data to support the representative product/use for Annex I inclusion, where submitted as an Annex II data point, would be protected as *Annex II* data. Residues data to support a product/use authorisation would be protected as *Annex III* data.

⁽⁷⁾ Guidance Document on Preparing Lists of Test and Study Reports according to Article 60 of Regulation (EC) No 1107/2009 (SANCO/12580/2012– rev. 3.1, from May 2013 or later, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en).

⁽⁸⁾ See paragraphs 54 to 58 hereunder.

39. Article 80(2) allows for national data protection measures under Directive 91/414/EC (and before) to continue to be applied for active substance for a period of 5 (from the re-approval of EAS) or 10 (from the first approval of NAS) years.
40. Essentially, if the active or product was/is assessed in accordance with Directive 91/414/EEC (including those situations covered under Article 80(1)), then the data protection applied to those data must follow '91/414 national rules'. At re-registration, Directive 91/414/EEC specified that new or additional Annex III data necessary for re-registration does not attract any additional protection (*i.e. past the expiry date for protection given under previous national rules*). However, where, at re-registration, a new 'form' of the product is used to replace the original, the new data necessary to support what becomes a first authorisation for that 'form' of the product, attracts protection for 10 years in accordance with Article 13(4)(b) of Directive 91/414/EEC. In many cases this means that data submitted to support re-registration are protected. In all such cases the only data to attract protection should be bridging data considered essential to establish the relevance of data on earlier products together with essential new data on the product that cannot be bridged from other data on other products.

Special situations — data protection of Annex III data in Draft Assessment Report (DAR) (Directive 91/414/EEC)

41. Applications for inclusion under Directive 91/414/EEC required the submission and assessment of a 'representative product' data package alongside the active substance. Under Directive 91/414/EEC rules, these data should not specifically attract protection under Article 13(4) of Directive 91/414/EEC, since these data were not being used to support an *authorisation* (it is noted that these data may have attracted protection nationally in accordance with Article 13(4)(c) of Directive 91/414/EEC).
42. However, when the *same* data were/are submitted subsequently nationally to support the representative product authorisation in a Member State (either as a new product or at re-registration), they would attract protection under Article 13(4)(b) of Directive 91/414/EEC. It is thus possible that studies which did not attract protection in the DAR may subsequently attract protection in a Member State when submitted to support a new product authorisation. Applicants should be aware of this difference in approach between Member States when citing product data from the DAR. Where such product data has been cited with an application for authorisation, it should be made clear that the studies were assessed in the DAR, to allow each Member State to determine the national data protection status of the studies.

Data protection at renewal of authorisation

43. Article 59 states that 30 months protection shall be given to all data necessary for the renewal or review of an authorisation. To support the renewal of approval of the active substance, various new active substance data will be submitted (to 'upgrade' the data package to modern requirements), and it may also be necessary to submit product data during the active substance renewal and the Article 43 process (again to 'upgrade' the data package to modern standards). If these data were necessary to support the renewal of authorisation then they would be eligible for the 30 month protection, applied in each Member State at the date of renewal of authorisation.
44. To support products at renewal, *all* authorisation holders must make a submission to address the 'updating' issues (active and product), within 3 months of the date of renewal of approval for the active substance. The active substance 'updating' data package may be protected (in each Member State) as soon as the first renewal of authorisation is issued if the data is deemed necessary for the re-authorisation of the product. Any accompanying product 'updating' package may be protected (in each Member State) as soon as the first renewal of *that* product authorisation is issued in that Member State.
45. For PPPs containing more than one active substance where an assessment of the application for renewal of the authorisation will be carried out after the renewal of the approval of each active substance, each of these renewals of authorisation may trigger data protection. In case the renewal of the authorisation will take place only after the renewal of the second active substance, then the data protection will cover all the data submitted at different time points but will only start from the date of the renewal of the authorisation.

SECTION 2

VERTEBRATE DATA SHARING

When do the vertebrate data sharing rules apply?

46. Article 62 of the Regulation introduced new vertebrate data sharing provisions, in order to reduce the number of tests carried out on vertebrate animals. Member States must not accept duplication of tests and studies on vertebrate animals or those initiated where alternative methods described in the Commission Communications adopted according to point 6 of the Introduction of the Annex to the Implementing Regulation (EU) No 283/2013⁽⁹⁾, to point 6 of the Introduction of the Annex to the Implementing Regulation (EU) No 284/2013⁽¹⁰⁾ and to Regulation (EC) No 1272/2008⁽¹¹⁾ could reasonably have been used. Article 62 also allows member States to use vertebrate studies for the purpose of the application of a prospective applicant who has not been able to reach agreement on sharing the data with the data owners.
47. The rules outlined under Article 62 of the Regulation are not covered under the transitional measures (Article 80(2) of Regulation (EC) No 1107/2009 refers *only* to Articles 13(1)-(4) as continuing to apply). Article 13(7) of Directive 91/414/EEC (relating to vertebrate data sharing) was not carried forward under the transitional measures, thus Article 62 of the Regulation applies from 14 June 2011. Member States should thus apply the vertebrate data arrangements of the Regulation to all submissions made after 14 June 2011, including those for:
- new product (zonal) applications;
 - amendment applications;
 - ‘Step 1’ re-registration – including those approved from end 2010 onwards and under the transitional arrangements (AIR1 active substances, resubmitted active substances and pending active substances), where the approval Regulation *specifically refers to Article 62*, Member States must apply the vertebrate data sharing provisions prescribed in the Regulation;
 - ‘Step 2’ re-registration submissions, irrespective as to whether the approval Regulation specifically refers to Article 62.
48. For new applications made after 14 June 2011, Article 62 applies and the applicant may request access to data which were submitted with applications prior to 14 June 2011. Article 62 does not apply to any submissions made before 14 June 2011, including those for re-registrations. However prior to this, Article 13(7) of Directive 91/414/EEC encouraged data sharing, particularly with regard to vertebrate studies.

What type of vertebrate studies are included under the special provisions?

49. Regulation (EC) No 1107/2009 provides for specific rules concerning in particular the duplication and sharing of ‘tests and studies involving vertebrate animals’ (ref. Article 62(2), (3) and (4)). The question arises which studies are considered ‘tests and studies involving vertebrate animals’ in the meaning of Regulation (EC) No 1107/2009. For example in the case of monitoring of birds and mammals in the fields, it is not very clear whether these constitute ‘tests and studies involving vertebrate animals’.
50. The terms ‘tests and studies involving vertebrate animals’ should be interpreted as experiments within the scope of Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes⁽¹²⁾ and after 1 January 2013 within the scope of Directive 2010/63/EU on the protection of animals used for scientific purposes⁽¹³⁾.

⁽⁹⁾ Implementing Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013 p. 1).

⁽¹⁰⁾ Implementing Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

⁽¹¹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽¹²⁾ Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 358, 18.12.1986, p. 1).

⁽¹³⁾ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

51. Directive 86/609/EEC covers animals used in 'experiments' defined as 'any use of an animal for experimental or other scientific purposes which may cause it pain, suffering, distress or lasting harm'. Drawing from Articles 1(5)(f) and 3(1) of Directive 2010/63/EU, if the study involves a procedure which will cause the animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by an introduction of a needle, this study is covered by Directive 2010/63/EU.
52. In conclusion for monitoring studies, only the studies involving procedure(s) causing a certain level of distress, suffering or lasting harm will be covered. (NB: It is important to note that this includes also non-invasive interventions such as restrain and/or restrictions to housing/care if the minimum threshold of pain, suffering distress or lasting harm is reached). In practice, monitoring studies conducted as a condition of authorisation granted previously are unlikely to be covered.
53. Finally for studies approved and performed after 1 January 2013, it should be clear which studies are concerned because the performance of the studies falling within the scope of Directive 2010/63/EU will require a case-by-case project evaluation and authorisation prior to the work being allowed to start.

How does a potential applicant determine if vertebrate studies are available?

54. Article 61 of the Regulation introduces general rules on the avoidance of duplicate testing. It requires prospective applicants for authorisation to consult details of products authorised in the relevant member State(s). Where authorised products contain the same active substance, safener or synergist as their prospective product, applicants must request from the Member State(s) a list of test and study reports such as those prepared in accordance with Article 60 in order to identify the studies to which access may be gained according to Article 61.
55. It is noted that these lists may be publically available (on websites, etc.) thus it may not always be necessary for the prospective applicant to request these lists.
56. Under the Regulation, RMS/ZRMS are required to produce these lists of studies (see Section 2 above), however this was not a legal requirement under Directive 91/414/EEC. Whilst lists of Annex II data were routinely prepared in accordance with the Guidance document⁽¹⁴⁾ in place under the Directive, lists of product data used to support authorisations were not routinely prepared in Member States. Thus information relating to (particularly product) data used to support authorisations prior to the Regulation may be difficult to provide/obtain. However to ensure duplicative vertebrate testing is not undertaken, Member States should make efforts to provide information on submitted/used vertebrate studies where requested.

What are the requirements of a prospective applicant?

57. The Member State determines whether an applicant is a prospective applicant. Whilst a prospective applicant may ask for the data list, they *must* provide all data regarding the identity and impurities of the active substance they propose to use before they can be considered as a prospective applicant. However, it is not a requirement for the Member State to assess those data (i.e. determine technical equivalence) before the applicant is considered as prospective applicants.
58. Note that a Member State may not be able to identify a prospective applicant until an application is received in that Member State, thus it is important that the Member State alerts the data owner at that stage to comply with their obligations under Article 61 2. A standard letter is provided at Annex.
59. It is important that all applicants clarify the position on data access in their application, since Member States should not accept an application without data, or a letter of access, or evidence that studies are no longer protected, or (in the case of vertebrate studies) confirmation that negotiations on access have failed (to date).
60. The prospective applicant should contact the data owner at the earliest opportunity to initiate negotiations, prior to making their application.

⁽¹⁴⁾ Guidance document on preparation of lists of studies relied upon with a view to Annex I-inclusion of existing active substances (SANCO/10435/2004 15 April 2005 rev 7, superseded by the current technical guidelines).

Who must be involved in the access negotiations?

61. Article 62(3) requires the prospective applicant and data owners to make 'every effort' to ensure that they share vertebrate tests and studies, and specifies that the costs must be determined in a 'fair, transparent and non-discriminatory way'. *There is an obligation for the two parties concerned.* Note there may be multiple potential applicants negotiating together, similarly the data owner may be made up from multiple data owners (task force).
62. Where necessary, and if available in the Member State, the parties may wish to consider participating in arbitration as an alternative dispute resolution procedure to resolve the terms of sharing vertebrate studies. Since arbitration schemes are applied nationally, decisions arising from such consideration may only apply in that Member State. It is also noted that some arbitration schemes may only apply to companies based in that Member State.
63. Litigation may also be used to determine costs, although this should be a last resort, noting such proceedings may attract additional legal costs for both parties.
64. It is important that the context of those negotiations is clear to both parties; for example, prospective applicants should inform the data owner whether they are seeking authorisation of a new product in all or specific member States. Access negotiations conducted historically (e.g. for 'Step 1' re-registration purposes) may not be considered relevant to those for new product submissions.

What does the Member State do to determine whether 'every effort' has been made?

65. The Member State does not need to determine whether 'every effort' has been taken by the two parties, since *failure to reach agreement* does not prevent Member States from taking the actions provided in second paragraph of Article 62(4).

Requirements for accepting an application

66. It is a requirement that applications must contain a complete dossier for all vertebrate and non-vertebrate studies (or access to the same, or make reference to unprotected data). The potential applicant must inform the Member State that they have failed to reach agreement with the data owner regarding vertebrate studies, *when they submit their application*. This will indicate to the Member State that negotiations are underway, and that all elements of the data package have been addressed by the applicant (and that the application is acceptable). In the event that the parties fail to reach agreement, the determination of whether 'every effort' has been made will become relevant in the assessment during possible arbitration or litigation.

Issuing an authorisation

67. The time between accepting the application and issuing the authorisation should be sufficient for access negotiations to continue to a mutually satisfactory conclusion (letters of access to be issued). However in the event that access negotiations are prolonged, Member States may issue the authorisation without the provision of a letter of access to vertebrate studies. Letters of access to non-vertebrate studies (or equivalent studies) must be provided if appropriate.

Acceptance of duplicate vertebrate studies

68. Article 62(2) states that Member States shall not accept the duplication of tests and studies on vertebrate animals or those vertebrate studies carried out when other methods (calculation) could have been used instead. If vertebrate studies are submitted, this must be fully justified (see Article 8(1)(d)).
69. Vertebrate studies should never be accepted, unless fully justified (see Article 8(1)(d), if any of the following conditions apply:
 - a) where suitable alternative methods could reasonably have been used;
 - b) there is a comparable formulation for which vertebrate studies already exist;
 - c) they show more favourable classification as those derived by calculation method or in vitro alternatives.

Vertebrate studies conducted for regulatory regimes outside the EU should also never be accepted where any of the above conditions apply.

70. Exceptions to the rules in paragraph 69 are:
- a) Vertebrate studies which were conducted or initiated prior to 14 June 2011; or
 - b) Cases where it can be proficiently demonstrated that calculation method or in vitro-studies could not be reliably applied; or
 - c) Vertebrate studies should always be taken into account if they show a more adverse outcome.
71. Applicants should always demonstrate that they have undertaken any attempts to find out if there are comparable formulations for which vertebrate data already exist.
72. In case of zonal applications, where possible the ZRMS should advise during the pre-submission phase whether the applicant, prior to initiating tests and studies on vertebrate animals, has either gained sufficient information from the Member State(s) on existing vertebrate test and study reports (see paragraphs 58-60 above), or has provided a justification on why no existing vertebrate test or study reports are expected (e.g. in case of a new active substance).
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*Appendix***Standard letter to vertebrate data owner**

Notification of application for new product — vertebrate data access requested *(for new product)*

or

Notification of requests for continued authorisation for *[insert product or active]* - **vertebrate data access requested**
(for re-registration)

[competent authority] wish to notify you of an application for new product/request for re-registration of existing products. The applicant name and address is provided below:

[Insert applicant name and address].

They confirmed that negotiations are underway to access your protected vertebrate studies. They have provided all data regarding the identity and impurities of the active substance.

Whilst we will ensure an appropriate data package has been provided to allow an assessment to Uniform Principles, you are respectfully reminded that, in accordance with Article 62 4 of Regulation (EC) No 1107/2009, failure to reach an agreement on access to those vertebrate studies in question will not prevent us from using those studies on their behalf.

Regulation (EC) No 1107/2009 requires applicants and authorisation holders to 'make every effort to ensure that they share tests and studies involving vertebrate animals' and we urge you to enter into/continue negotiations at the earliest opportunity.
