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Safety of the food chain
Chemicals, contaminants, pesticides

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GUIDANCE DOCUMENT ON DATA PROTECTION

This document was elaborated by representatives of some of the Member States. It does not represent the official position of the Commission. It does not intend to produce legally binding effects.

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SECTION 1

PERIODS OF PROTECTION AND HOW TO APPLY THEM

Section 1 – periods of protection and how to apply them

Status and scope of this guidance

1. This document provides Member States (MS) 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 1107/09 unless otherwise stated.

2. This guideline is intended to help MS apply the rules in a consistent way, and for applicants to understand those rules. This document was elaborated by the representatives of some Member States. It does not intend to produce legally binding effects. Nor does it constitute an official position of the European Commission.

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 outlines the provisions for data protection for data submitted as part of an application for authorisation or amendment to 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 MS 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.
   - 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.

5. For some time (until the transitional measures are completed) MS 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 MS level and varying greatly between MS, 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 MS 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 MS, linked to the date of product authorisation (or renewal of authorisation).

6. It is critical that MS 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 and Regulation (EU) No 544/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**
7. 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) approval of the active substance.	Active substance data protection expires at the same time in all MS.
8. 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) approval of the active substance.	Active substance data protection expires at the same time in all MS, for data which are essential for Annex I inclusion/approval and which were not used for national authorisation before submission of the dossier (for the latter data, 'old national rules may apply).
9. Active substance **confirmatory data** submitted under Dir. 91/414/EEC for NAS or EAS (assessed post-approval).	Generally not protected. See SANCO 5634/2009 rev. 4.5. These data are not protected unless the approval is amended as a result of the evaluation of the confirmatory data (or *critical* end points change as a result). In that case data protection will be 5 years from the date of the amended approval.	These data are generally not protected
10. Active substance **confirmatory information** submitted for NAS or EAS (assessed post approval) for approvals issued under Reg. (EC) No 1107/2009.	The situation arises when confirmatory information is submitted after the granting of an authorisation. In the case confirmatory information is necessary for the authorisation, confirmatory information will be protected for 30 months from the date of amended authorisation or from the date of decision to maintain the authorisation in each MS.	Generally the submission of confirmatory information will not be necessary for the authorisation (Art 59 (1) (a)).

Active substance data – as defined in Annex II of Directive 91/414/EEC and Regulation (EU) No 544/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**
11. 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.	10 years from date of first authorisation of first product containing that active substance in each MS.	Data protection may expire at different times in each MS, depending on date of national authorisation. Studies *necessary* for the a.s. approval are defined by the Rapporteur Member State (RMS) (MS subsequently defines the list of studies that are protected nationally). Note same protection periods apply if a.s. is identified as a Candidate for Substitution.
12. 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 product containing that active substance in each MS.	Data protection may expire at different times in each MS, depending on date of national authorisation. Studies *necessary* for the a.s. approval are defined by the RMS (MS subsequently defines the list of studies that are protected nationally).
13. Active substance data submitted with an application under **Article 15** of the Regulation (**renewal**) and with the application for renewal of authorisation of the corresponding product. Applies also to data submitted with applications for authorisation for products containing **AIR2** substances (Regulation (EU) No 1141/2010). Applies also to low risk active substances.	30 months from date of first renewal of authorisation of product containing that active substance in each MS.	Data protection may expire at different times in each MS, 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 a.s. is identified as a Candidate for Substitution.

Active substance data – as defined in Annex II of Directive 91/414/EEC and Regulation (EU) No 544/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**
14. Active substance data submitted for a NAS considered under Article 80 1 (a) – **'pending' NAS under Dir 91/414 (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.	Active substance data protection expires at the same time in all MS.
15. Active substance data submitted for a NAS considered under derogation Article 30 – **provisional authorisation**.	10 years from date of provisional authorisation in each MS.	Note where the provisional authorisation derogation is used, the starting date for protection data will potentially be before the date of approval.
16. 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 MS. 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.
17. Active substance data submitted with PPP application, not necessary to support approval and authorisation of the *representative product/uses*, but necessary to support **other products/uses**.	10 years from date of authorisation of the 'other' product/uses	

Product data – as defined in Annex III of Directive 91/414/EEC and Regulation (EU) No 545/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**

Product data – as defined in Annex III of Directive 91/414/EEC and Regulation (EU) No 545/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**
18. Product data submitted with an application under Article 33 of the Regulation (**new product under Regulation**). For the active substance data provided to support that authorisation see points 7,8, 11 15 or 17.	10 years from date of first authorisation of that product in each MS.	Data protection may expire at different times in each MS, based on date of first authorisation in that MS.
19. Product data submitted with an application under Article 80 5 (a) of the Regulation (**new product submitted before 14/6/2011**). See Article 80 (2). For the active substance data provided to support that authorisation see points 7, 8 or 16.	10 years from date of first authorisation of that product in any MS (Article 13 4 (b) of Directive 91/414 continues to apply)[1].	In practice, product data protection was/is applied nationally, thus may expire at different times in each MS.
20. Product data submitted with an application under Article 42 of the Regulation (**mutual recognition**). For the active substance data provided to support that authorisation see points 7,8, 11, 15 or 17.	10 years from date of first authorisation of that product in each MS.	Protection must be applied to data supporting MR authorisations, noting however that submission of dossier is required for MR only where requested by the MS concerned. Even if data are not submitted, they are still effectively protected in the mutually recognising MS.
21. New product/use data submitted with an application for amendment (new crop) under Article 33 of the Regulation (**new crop amendment**).	10 years from date of first authorisation of that *product* in each MS (*not* the date of authorisation of new crop).	Note Article 59 1 (a) refers specifically to amendment to allow the use on *another* crop.
22. New product/use data submitted with an application for amendment (new GAP on existing crop) under Article 33 of the Regulation (**new GAP existing crop amendment**).	No protection for 'new GAP data', but original dossier data protection remains unchanged.	Note Article 59 1 (a) refers only to amendment to allow the use on another crop.

[1] See section on data protection at re-registration and for new products submitted before 14 June 2011.

Product data – as defined in Annex III of Directive 91/414/EEC and Regulation (EU) No 545/2011		
Scenario – type of data submitted and necessary to support….	**Period of protection**	**Comment**
23. New product/use data submitted with an application for new formulation of existing product under Article 33 of the Regulation (**new formulation**).	10 years from date of first authorisation of that product in each MS (but only for data submitted to support the new formulation).	A significant formulation change requiring the submission of data is effectively a new product submission. See SANCO 12638/2011 *GD on significant and non-significant changes of the chemical composition of authorised plant protection products*.
24. 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 12.	13 years from date of first authorisation of that product in each MS.	Data protection may expire at different times in each MS.
25. Product data submitted with an application for **renewal of authorisation** under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards. For the active substance data provided to support that authorisation see point 13.	30 months from date of first renewal of authorisation of that product in each MS.	Data protection may expire at different times in each MS (although because of renewal timescales these dates should be similar). Applies *only* to new data used to support the re-authorisation of the product.
26. Product data submitted with an application for **re-registration** considered under Article 80 5 b – products containing *only included* actives, pending NAS, AIR 1 actives and resubmissions.	Article 80 2 allows for national data protection measures applied under Directive 91/414 (and before) to continue for both active substance and product data. See paras 42 & 43 for further details	

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.	Protected in line with product data protection expiry in each MS (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 application must be submitted within 5 years of original product authorisation. Extension up to maximum of 13 years (15 low risk).
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 MS. 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.
29. Data submitted by official or scientific bodies, professional agricultural organisations or professional users **(but generated by authorisation holders)** to support minor use extension (under Article 51) e.g. residues data.	Protected in line with product data protection expiry in each MS. 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 – *even if data are generated by the authorisation holder*.

General considerations before applying protection to a study

30. The Regulation specifies that in order to attract protection, the following requirements apply to tests and studies:
    a) Studies must be performed to **Good Laboratory Practices/Good Experimental Practices (GLP/GEP)** standards;
    b) The studies must be **necessary** to support the regulatory decision;
    c) The applicant must **claim** protection for the studies;
    d) The studies must **not** have been **protected previously** (or be subsequently unprotected) in the MS where the authorisation is sought.

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

    a), c) and d) must be specified by the applicant in their approval and authorisation submissions. The applicant must also identify vertebrate studies.

31. One general principle of data protection which applies equally to Directive 91/414/EEC and the Regulation is that once a PPP study has been used and protected under PPP legislation in a MS, the study should not be protected further via a new submission in the same MS[2].

32. The question of whether a study has been used before (and attracted protection previously) is a complex issue which raises many practical difficulties for MS. Whilst the MS 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 MS whether studies have been protected previously in that MS 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 submitted to support other formulations/uses.

33. It may not be possible for MS to routinely check whether each submitted study has been protected previously, so they will be reliant on the information provided by the applicant. MS may however check some of this information for accuracy, and applicants are respectfully reminded that the provision of knowingly false information may result in no authorisation/revocation of authorisation.

34. According to Article 60, MS must prepare lists of protected studies for each product authorised. It would be good practice for the MS to confirm to the authorisation holder, which data have been protected, for how long and under which data protection regime/scenario.

35. The general requirements for data protection under Directive 91/414/EEC were essentially the same as above with the exception that non-GLP studies could be protected.

36. Modelling calculations e.g. PEC calculations or OPEX calculations are not conducted according to GLP or GEP standards. Therefore, can not be eligible to data protection.

Preparation of lists of studies

37. This is covered by Guidance Document on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009 (SANCO/12580/2012), summarised below.

    a) The **applicant** must provide a list of studies **submitted** for both approval and authorisation in each MS. They must identify vertebrate studies[3], confirm if to GLP/GEP and identify if protected previously, as well as claims for protection.
    b) Following the approval process, 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 MS, as it forms a sub-set of the overall data which will be protected at individual MS level upon authorisation. This list will refer to the issues

[2] 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).
[3] See paragraphs 54 to 58.

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) Following the zonal process, the **ZRMS** must identify and prepare a list of studies necessary to support the decision on authorisation. This list is to be made available to MS, as it forms a sub-set of the overall data which will be protected at individual MS 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 MS must prepare a list of studies necessary to support the authorisation in that MS. This may include 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 MS (e.g. uses not supported in that MS). It is these studies that will be eligible for protection.

Product or active data under Directive 91/414/EEC?

38. Data protection under Directive 91/414/EEC was and is applied at MS 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 MS concerned.

39. 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' 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.

40. Some Annex II data requirements are met using data generated using a specific product formulation data. Although the data were generated using a product, they should be protected as active data, since they were generated to meet an Annex II requirement. Note dermal absorption (product) and mesocosm studies were/are Annex III requirements.

41. Some residues and fate and behaviour Annex II and III data requirements 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 would be protected as *Annex II* data. Residues data to support a product/use authorisation would be protected as *Annex III data*.

Data protection at re-registration

42. Article 80 2 allows for national data protection measures applied under Directive 91/414 (and before) to continue for both active substance and product data.

43. 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 protection. 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. In many cases this means that data submitted to support re-registration are protected.

Special situations - data protection of Annex III data in DAR (Directive 91/414/EEC)

44. 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).

45. However, when the *same* data were/are submitted subsequently nationally to support the representative product authorisation in a MS (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 Draft Assessment Report (DAR) may subsequently attract protection in a MS when submitted to support a new product authorisation.

46. There is no harmonised approach on how to deal with these product data from the DAR (until they are used to support a national authorisation). Some MS consider them unprotected and will use them on behalf of a third party without access. Other MS consider them unavailable for use by a third party. Applicants should be aware of this difference in approach between MS 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 MS to determine the national data protection status of the studies.

Data protection at renewal

47. Article 59 states that 30 months protection shall be given to all data necessary for the renewal or review of an authorisation. This Article will apply for the first time to those active substances considered under AIR2 and products subsequently renewed under Article 43. To support the AIR2 renewal, 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 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 MS at the date of renewal of authorisation.

48. 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 will be protected (in each MS) as soon as the first renewal of authorisation is issued. Any accompanying product 'updating' package will be protected (in each MS) as soon as the first renewal of *that* product authorisation is issued in that MS.

49. The practical procedures for renewal of authorisations will continue to be developed and will result in greater transparency regarding data protection. These important issues will be taken forward as further guidance on renewal is developed.

SECTION 2

VERTEBRATE DATA SHARING

When do the vertebrate data sharing rules apply?

50. 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 conventional methods described in Annex II to Directive 1999/45/EC and Regulation 1272/2008 (to be applied by 2015) 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.

51. 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. MS 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 actives, resubmitted actives and pending actives), where the approval Regulation *specifically refers to Article 62*, MS 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.

52. For new applications made after 14th 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 17 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?

53. 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".

54. 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[4] and after 1 January 2013 within the scope of Directive 2010/63/EU on the protection of animals used for scientific purposes[5].

55. 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.

56. 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).

57. 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?

58. 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 the proposed product, and in order to identify the studies to which access may be gained, applicants must request from the member State(s) a list of test and study reports such as those prepared in accordance with Article 60.

59. 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.

60. 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 SANCO/10435/2004, lists of product data used to support authorisations were *not* routinely prepared in MS. 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, MS should make efforts to provide information on submitted/used vertebrate studies where requested.

What are the requirements of a prospective applicant?

61. The MS 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 he proposes to use before they can be considered as a

[4] OJ L 358, 18.12.1986, p. 1.
[5] OJ L 276, 20.10.2010, p. 33.

prospective applicant. However, it is not a requirement for the MS to assess those data (i.e. determine technical equivalence) before they are considered as prospective applicants.

62. Note that MS may not be able to identify a prospective applicant until an application is received in that MS, thus it is important that they alert the data owner at that stage to comply with their obligations under Article 61 2. A standard letter is provided at Annex.

63. It is important that all applicants clarify the position on data access in their application, since MS 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).

64. The prospective applicant should contact the data owner at the earliest opportunity to initiate negotiations, prior to making their application.

Who must be involved in the access negotiations?

65. 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'. *This is simply an obligation on 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).

66. Where necessary, and if available in the MS, 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 MS. It is also noted that some arbitration schemes may only apply to companies based in that MS.

67. 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.

68. It is important that the context of those negotiations are 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 MS do to determine whether 'every effort' has been made?

69. The MS does not need to determine whether 'every effort' has been taken by the two parties, since the actions in Article 62 4 second paragraph are based only upon *failure to reach agreement.*

Requirements for accepting an application

70. 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 MS that they have failed to reach agreement with the data owner regarding vertebrate studies, *when they submit their application*. This will

indicate to the MS that negotiations are underway, and that all elements of the data package have been addressed by the applicant (and that the application is acceptable).

Issuing an authorisation

71. 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, MS 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

72. Article 62 (2) states that MS shall not accept the duplication of tests and studies on vertebrate animals or those initiated where conventional (calculation) methods could have been used. If vertebrate studies are submitted, they must be justified fully (see Article 8 (1) (d)). Whilst MS will not generally accept duplicate studies, the applicant may justify their submission if:
    - The studies were generated prior to 14 June 2011, providing justification is submitted that demonstrates that the studies were generated in good faith and on the basis that no alternative approaches were available at the time (for example following previous failed attempts to negotiate access under the previous legislation).
    - The studies were generated to support other regulatory regimes (non-EU requirements).

73. 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 point 58-60), 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).

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) 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.