EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Pesticides and biocides

SANTE/2016/11449
(rev.1.5)
21 October 2021

GUIDANCE DOCUMENT ON DATA MATCHING

FOR APPLICATIONS FOR PLANT PROTECTION PRODUCT AUTHORISATIONS

ACCORDING TO ARTICLES 33 AND 43 OF REGULATION (EC) No 1107/2009

This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) Nº 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Revision history

When	What
Rev.1 of 30.06.2019	First version revised by UK, following comments from PAI 06.03.2019
Rev. 1.1 of 19.11.2020	Second version revised by NL, following comments from MS, ECCA and ECPA. Furthermore: - A general outline/ introduction was added, and a chapter on the data matching conclusion. - A chapter on timelines was added. - Headings to each point were added, for ease of finding the relevant text parts and several text parts were moved to another heading in the document, to bundle similar topics. - Further reference to article 61 and 62.4 of Reg. 1107/2009, in order to avoid duplicative testing. - Appendix 2 has been replaced by specific guidance for the aspects. Some examples from the previous appendix 2 were replaced to the text of the guidance document.
Rev. 1.2 of 28.11.2020	Some additions and changes were made after discussion in PAI: - A commenting round was added. - Furthermore specific points as discussed in PAI, November 2020 were amended.
Rev. 1.3 of 07.03.2021	Version following second commenting round by PAI after discussion in November 2020: - Numbering and chapter heading has been revised. The previous chapters 3 to 7 are taken together in one chapter 3, as they all concern 'Data matching of the relevant protected active substance data'. - Timelines clarified (3 months for first check, 3 weeks commenting round, 1 month for finalization). - Clarifications by additional text and amendments.
Rev. 1.4 of 12.04.2021	The joint GD on Pesticide Analytical Methods for Risk Assessment and post-approval Control and Monitoring Purposes SANTE/2020/12830, Rev.1 was implemented in the document.
Rev. 1.5 of 20.10.2021	After commenting in SCoPAFF some minor text clarifications have been added. Furthermore: - A table of contents was added - Some minor additions to appendix 1 (email template), in line with the agreements in the guidance document.

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1. Introduction

Regulation (EC) No 1107/2009[1] concerning the placing of plant protection products on the market (hereafter the Regulation) provides that application for a product authorisation shall be accompanied by a complete and a summary dossier for each point of the data requirements, for each active substance in the product. For renewal of the product authorisations, any new (active substance) information required as a result of amendments in data requirements or criteria shall be submitted.

In the light of equal market participation among producers, the Regulation leaves the opportunity for non-notifying companies to obtain access to the original dossiers supporting approval or renewal of active substances and the EU-agreed endpoints derived thereof, through a data matching process.

The structure of a data matching application is based on the data requirements for active substances, as set out in Regulation (EU) No 283/2013[2], with each separate Annex point requiring to be covered by the non-notifying company (or data matching applicant) according to the guidance detailed below. Furthermore, a list of test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval of an active substance prepared by the rapporteur Member State is to be made available to any interested party (Article 60, Regulation (EC) No 1107/2009).

To ensure a harmonized approach and to promote efficiency by work-sharing, the data matching check shall be performed by the active substance Rapporteur Member State (RMS).

2. General outline of the data matching process

For both data matching requests in connection to a new product authorisation (article 33) as to requests in connection with the renewal of a product (article 43), the RMS for the original approval or renewal of the active substance is carrying out the data matching check on behalf of the Member States (MS). Unless the submission is reliant solely on the active

[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] Commission Regulation (EU) No 283/2013 of 1 March 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)

substance data relied on for (renewal of) approval, or on a letter of access to these data; in such cases no check by the RMS will be needed, and the data matching request shall be handled at MS level.

Data matching applicants may demonstrate access to the active substance dossier in various ways, e.g. by providing letter(s) of access from the original notifier (main applicant or data owner), referring to non-protected existing data, or providing evidence that the protected studies are not relevant to their product/use.

The applicant requesting data matching should provide the required information, as further clarified in chapter 3 of this guidance document, and use the harmonised template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step (the data matching table, see point 2.2).

For both types of data matching requests (article 33 or 43) justifications specific to each data point in Regulation (EU) No. 283/2013 should be made. General/generic arguments should not be used and will not be accepted. All cases submitted need to be considered legitimate before data matching can be accepted.

All associated documents supporting the data matching dossier (data matching table, letters of access, statements, study reports and/or protocols/plans), including GAP tables of the relevant products in all MS concerned (CMS), must be submitted to the RMS, with a copy to the other Member States.

The RMS should check whether all data points in Regulation (EU) No. 283/2013 are matched and whether the studies submitted were conducted according to Good Laboratory Practices (GLP), used the same methodology as the data to be matched and that the endpoint was acceptable in respect to the reference study (see chapter 3 and aspect specific examples in Appendix 2).

Conclusions of the data matching assessment will be finalised after a commenting possibility has been given to the applicant and the MSs, and represent the opinion of the RMS that should be followed by the MSs. However each MS must check the protected status of relevant studies in their territory and, in case of limited data access, check whether restrictions should apply to the authorised uses (see chapter 5).

2.1 Timelines for the data matching process

The data matching process follows specific steps in time:

- The application for matching of the active substance dossier and supporting data (see chapters 2 and 3 of this guidance document) starts upon submission to the RMS, with a copy to the MSs. When connected to the renewal of a product (article 43) the submission should be on the date of application of the renewal regulation (DoA) at the latest, but preferably earlier.
- The data matching check by the active substance RMS should be performed as soon as possible (within 3 months after the application has been received).
- The applicant and the Member States will be given a single opportunity to comment on the draft version of the data matching table, within a commenting period of 3 weeks.
- For data matching in connection to article 43, only under specific circumstances (e.g. change of EU endpoints) it may be possible that some missing data matching studies could be justified as category 4 data (see 3.4). The conclusion to a request for category 4 delay will be communicated together with the (draft) data matching conclusion by the RMS.
- The RMS will prepare the final data matching conclusion within 1 month after the commenting round, and inform the applicant and the Member States.
- After the RMS has uploaded the data matching table with the final conclusion unto CIRCABC and (if applicable) the Letters of Access and/or the list with unprotected studies (see 3.3), the concerned MS will check the data matching request in relation to the product authorisation, (see chapters 4 and 5).

2.2 Use of the template

Applicants should use the data matching table 'Template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) No. 283/2013 and for the Data Matching Step' (SANTE/2016/11449).

Applicants should copy each data point of the active substance data requirements in Regulation (EU) No. 283/2013 and connected to this each study in the article 60(1) list in the table, and add their argumentation to the column titled "Reason for equivalence / justification for non-provision" including any updates made to the table. It is recommended to add a date ahead of each statement for the sake of clarity.

The use of this template is important particularly for RMS when they are dealing with multiple applicants as tables can be compared directly if provided in the same format.

There is a substantial amount of information in the tables and it is important that the information provided is as consistent as possible. Applicants should avoid inconsistencies in submissions e.g. include matching studies with the exact name of the metabolite, provide correct reference details, ensure that studies provided address the same data point to be matched.

3. Data matching of the relevant protected active substance data

Applicants must demonstrate access to, or match, the protected active substance data required for approval, amendment or renewal of approval of the active substance.

Applicants may do this by providing for each active substance in the product:

- Evidence of ownership (e.g. when data were transferred from the original notifier to a new owner)
- Letter(s) of access from the data owner, which should include a list of each individual study for which access is given. In order to avoid duplicative testing, the rules in Article 61 of Regulation (EC) No. 1107/2009 shall be followed by the applicant, especially *both the applicant and the notifier/owner of the original studies shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 59, in a fair, transparent and non-discriminatory way.* The Letters of Access will be considered by the RMS, but the final decision on the validity of these will be taken by the concerned MS.
- Only for vertebrate studies, if a letter of access is not yet available, it is possible to provide evidence that negotiations are ongoing or that all possible steps have been taken to gain access, in line with article 62.4 of Regulation (EC) No. 1107/2009. In the absence of letters of access, copies of correspondence between the relevant parties detailing requests for data access/status of negotiations could be provided as evidence. The acceptability of this evidence will, as far as possible, be considered by the RMS and where national rules are in place, by the concerned MSs. However, failure to reach agreement does not prevent MS from using the test and study reports involving

vertebrate animals for the purpose of the application for data matching (see also the Technical Guidelines on Data Protection[3]).

- Matching studies (except vertebrate studies*). The applicant may refer to unprotected existing data and/or provide alternative and equivalent studies (these could include even published studies, if justification could be provided by the applicant). However, if it concerns a GLP study, the matching study must be according to GLP as well.
- Evidence that the protected studies are not relevant to the product/use of the applicant e.g. by providing a case (see also appendix 2). In case data matching is waived for this reason, the specific study will be marked as such and data matching will be provisional. The conclusion of the RMS and possible restrictions with regard to the product uses will be stated clearly in the final column of the data matching table, and will be taken up as remark in the e-mail to the MSs (Appendix 1). Final assessment of "Evidence that the protected studies are not relevant to the product/use e.g. by providing a case" should be carried out by the (i)Zonal RMS/MSs during the process of product authorisation. For later product applications or extensions (Article 33) including these uses, data matching may have to be re-considered.
- Evidence that a reference study or an equivalent study is unprotected.

Annex points or issues that have been left unaddressed after approval or renewal and have as a result been marked as data gaps do not need to be covered during the matching process, but will be evaluated during the product authorisation (Guidance document on the evaluation of new active substance data post (renewal of) approval, SANCO/10328/2004, rev.9).

Active substance confirmatory data do not need to be checked during data matching, as these only attract data protection when necessary for the authorisation of PPP, which must be dealt with at MS level (see Technical Guidelines on Data Protection).

Also product data used for the active substance approval or renewal generally will not be checked in the data matching process, with the exception of residue data, for which the Annex II and Annex III data are the same. However, product data specific for the uses applied for, always need to be evaluated by the (i)Zonal RMS of the product application, to check whether they sufficiently support the authorisation or renewal of the PPP (please refer to appendix 2 for further explanation).

(*) See provisions in Article 62 of EU Regulation 1107/2009.

[3] OJ 2019/C 229/03

3.1 Data matching of studies required for the approval, amendment or renewal of active substance

Applicants are required to address each data point in the active substance data requirements, but not necessarily match each study that was relied upon and necessary for first approval, amendment or renewal (Article 60 of Regulation (EC) No 1107/2009). For each data point in the active substance data requirements, only the test and study reports necessary to address the data point need to be matched.

This is for example the case where multiple notifiers are involved during active substance renewal, where different solutions may be presented for the same technical challenge. Whatever the approach followed by the applicants it should be ensured that the dataset is sufficient to ensure the data point is addressed.

The RMS should check whether the studies submitted were conducted according to Good Laboratory Practices (GLP) or Good Experimental Practice (GEP), used similar protocol/methodology as the data to be matched and that the endpoint falls within the same range as the reference study. However, the situation can be more complex than that, and experience to date has seen a wide variety of data matching arguments being made by applicants. The RMS should carefully consider if the argument is scientifically acceptable (See also appendix 2).

In case Guidance has changed since the active substance (AS) dossier submission by the notifiers, data matching applicants may use newer Guidance or protocol/methodology for the matching study.

Modelling calculations and literature searches are not eligible for data protection; therefore, no alternative study is required.

3.2 Endpoints in the EFSA conclusion

Ideally EFSA should highlight or indicate with a footnote in the EFSA conclusion all endpoints which have been changed after the initial or previous approval of the active substance.

It is important that applicants make clear if the endpoint/outcome from their matching study falls within the same range as the EU agreed endpoint or shows the same outcome (e.g. genotoxicity for metabolites). Otherwise, an explanation is required. As outcomes from studies may differ and the RMS would need to evaluate the study to check the endpoint precisely, finally the quality of a study, i.e. whether it is well designed and well performed, will be most decisive. Some further explanation is given in appendix 2 (aspect specific guidance for data matching).

If the matching endpoint is significantly more critical than the EU agreed end-point this may constitute adverse data. Adverse data must be reported to the Commission by the applicant and is dealt with under a separate process in accordance with Article 56. If the matching endpoint of an acceptable, qualitatively well performed study is less critical this has no further effect; after data matching has been proven, the active substance endpoints from the EFSA conclusion will be used in the risk assessment for all products from all companies, to benefit a harmonized risk assessment.

3.3. Data protection

Given that data protection is a Member State issue the RMS can check the data protection status of studies in their country, but other Member States will need to check data protection to establish if the study can be accessed to support product authorisation in their Member State, before starting the product evaluation.

Therefore, in case applicants refer to unprotected studies, they need to submit a list with these studies, in which it is detailed when data protection for each study started and expired in each Member State, including the product registration number. Each Member State must verify the correctness of this list (Technical Guidelines on Data Protection).

3.4 Category 4 requests

According to the guidance document on the renewal of authorisations according to Article 43 of Regulation (EC) No. 1107/2009 (SANCO/2010/13170 rev.14), Category 4 (Cat. 4) extension can also be applied for during an active substance data matching request connected to the renewal of a product. This is intended exclusively for data requests that could not be anticipated before the EFSA conclusions for the active substance were available.

For data matching requests connected to new product applications (Article 33), no Cat. 4 claim is possible as regards active substance data.
The EU RMS will be responsible for considering Cat. 4 requests for active substance data, where the (i)ZRMS will be responsible for checking Cat. 4 requests for missing product data.

In the case of data matching in connection to Article 43 renewal, when claiming Cat. 4 delay for active substance data matching, applicants need to provide a justification which addresses the following:

a) Why the study could not have been anticipated prior to the publication of the EFSA conclusion.
b) Why there was insufficient time from publication of the EFSA conclusion to submission of the product renewal dossier to generate an equivalent study or, alternatively, negotiate access to the original study (evidence that negotiations have been started must be provided).
c) A declaration that the study is underway.
d) When the study will be available.
e) Signed study plans or contracts to prove commitment must be submitted.

The fact that new data requirements apply was known well in advance of the EFSA conclusion. A 'new data requirement' argument, therefore, is unlikely to be accepted as an adequate justification for a Cat. 4 delay.

In addition, arguments based on uncertainty of EU decisions and availability of 'official' conclusions as a reason for delay in generation/submission of studies are generally not acceptable. Without sound justification as to why this was necessary, applications claiming Category 4 delays for studies that were commissioned months after the publication of the Implementing Regulation, which should/could have been commissioned earlier, will not be accepted. In line with the guidance document on the renewal of authorisations according to Article 43 of Regulation (EC) No. 1107/2009 (SANCO/2010/13170 rev.14), studies should be commissioned/or access needs to be sought as soon as the EFSA conclusion is made available.

In case EFSA pointed towards data gaps or issues to be resolved in other publications that were published before the peer review, e.g. reasoned opinions or maximum residue levels (MRL) reviews, it is the responsibility of the applicant to initiate studies addressing these data gaps or issues from that time point.

The conclusion of the RMS whether or not a Category 4 delay can be granted shall be communicated to the applicant and MSs, together with the data matching conclusion. If no satisfying justification for the claim on Cat. 4 delay for (part of) the missing data is submitted by the applicant, the dossier is non-matching, and the conclusion of the data matching request will be negative.

In general, the submission date agreed with the RMS for the submission of active substance Category 4 data should not be extended. However, extension of the agreed submission date for Category 4 data may be re-considered and agreed with the RMS in exceptional circumstances, on the condition that satisfactory and sound justification can be provided why the deadline can no longer be met.

4. Completion of the data matching check by the RMS

On completion of the data matching check, the statement with the conclusion and the data matching table should be made available to the applicant and the rest of MSs.

The conclusion and data matching table, together with the Letters of Access and/or the list with unprotected studies (if applicable, see 3.3) should be uploaded at CIRCABC, location CIRCABC/non-confidential part/Post Annex 1- inclusion issues/Compliance check. The RMS should also notify the other Member States of the availability of the data matching table by e-mail, using the template in Appendix 1.

In addition, once Category 4 data have been received, the RMS should update the data matching table to confirm acceptability of the matching studies, upload the revised version to CIRCABC and inform the Member States.

5. Conclusion on the data matching request by the RMS and the CMSs

Once a data matching request in connection to the renewal of an existing product, or a Cat. 4 extension for data matching studies is agreed by the RMS and has been made available to

the MSs on CIRCABC, each CMS must verify in connection to the product authorisation in their MS:

- The validity of Letters of Access for the active substance data;
- the correctness of the data protection status in the list with unprotected active substance studies (see 3.3);
- and whether restrictions with regard to the product uses should be set due to limited active substance data access (see chapter 3 and Appendix 2).

In case this check by the CMS is positive, the authorisation will be allowed to continue until a decision is taken on renewal of the product, provided that acceptable Cat. 4 data is submitted to the RMS (with a copy to the MSs) by the agreed submission deadline.

The following situations result in a negative data matching conclusion, and the connected product authorisations will be immediately withdrawn, or amended (in case restricted use is supported by limited data access):

- the data matching conclusion by the RMS is negative;
- the data matching conclusion by the RMS is positive, but the above mentioned check by the CMS is negative;
- no submission of Cat. 4 data is made to the RMS and MSs by the agreed date;
- a submission of Cat. 4 data is made by the agreed date but is considered as non-matching by the RMS.

MSs could grant grace periods according to Article 46. The applicant would need to make an Article 33 application to re-instate their product once the data matching studies were available.

Before an Article 33 application can be submitted by an applicant intending to base its plant protection product on the approved active substance data, the RMS must have agreed on the corresponding data matching request. In the Article 33 submission the applicant shall refer to the data matching table on CIRCABC. Upon receipt of the Article 33 application each concerned MS must verify in connection to the product authorisation in their MS the validity of Letters of Access for the active substance data, the correctness of the list with unprotected active substance data (see 3.3) and whether the product uses applied for fall within the uses covered by the matching dossier (in case of limited active substance data access, see chapter 3 and Appendix 2).

Appendix 1

Email template - Reporting outcome of the data matching check by RMS to Member States

Subject: Data matching [commenting/conclusion] on [active substance]_[RMS]_ [date]

Dear MS contacts,

[MS], as RMS of the active substance [a.s.] would like to inform you that the draft data matching table has been uploaded to CIRCABC and is open for commenting:

Or:

[MS], as RMS of the active substance [a.s.] would like to inform you that the data matching table has been finalised and uploaded to CIRCABC:

Active substance:	
Product code(s))	
Product name(s)	
Applicant:	
Application reference code of member state (if available):	-
Application for (type of application):	Data matching – connected to art. 33 or art. 43* **to be indicated by the RMS*
RMS conclusion:	Data access / no data access / limited data access** *** where necessary add explanation under remarks*
Category 4 data	Y/N/not acceptable, Deadline: .. *[if y; short indication of Cat. 4 studies]* *[if not acceptable; this might result in conclusion 'no data access']*
Letters of Access	LoA received from: .. *[LoA's must be uploaded unto circabc by the RMS together with the data matching table]*
List of unprotected data in MS	Y/N *[the list of unprotected data in the MS must be uploaded unto circabc by the RMS together with the data matching table]*
Concerned member states:	MS with authorisation of the product (in case of art 43) / MS with PPP application (in case of art 33)
Direct link to the completed assessment uploaded to CIRCABC:	
Remarks:	e.g. for 'x' use(s) data is not matched
3 weeks deadline for comments:	
Please send comments in attached commenting table to:	

The data matching table has been uploaded to CIRCABC in the 'PLANT PROTECTION PRODUCTS AND THEIR RESIDUES' group in the active substance folder (Post Annex I - inclusion issues > Compliance check).

Please note that any comments submitted after the above deadline may not be accepted.

Please note:

- The RMS for the active substance did not consider whether or not data protection applies to all studies for which data protection has been claimed. It is the responsibility of MS to ensure that data protection standards as laid down in Regulation (EC) No 1107/2009 are respected.

- The RMS did not check whether valid Letters of Access for all MS were submitted. It is the responsibility of MS to ensure that appropriate Letters of Access, valid for the respective MS are available.

Appendix 2

Aspect specific examples for data matching

To inform the applicants and to ensure consistency of approaches by RMSs when carrying out data matching checks, some aspect specific examples for data matching can be found in this Appendix.

Identity

In principle, all studies related to the identity of the active substance are included in the confidential Annex of the Draft Assessment Report (DAR)/Renewal Assessment Report (RAR), unless they are listed in the public literature list of studies (Article 60 of Regulation (EC) No 1107/2009). Confidential data are considered inaccessible to third parties by default, as set out under Article 63 of Regulation (EC) No 1107/2009. The evaluation of the active substance manufacturing process for the relevant source(s) is performed in the context of a technical equivalence assessment, outlined in Article 38 of Regulation (EC) No 1107/2009, and further detailed in its corresponding guidance document (SANCO/10597/2003). Also matching studies submitted to cover non-confidential data relating to the Identity section shall be considered in the context of an equivalence application only. It should be emphasized that during the assessment of the data matching request in relation to a new/renewal of a product, the source(s) used by the applicant should be found equivalent to the current reference specification as established in the DAR/RAR. This check should be performed by the (i)Zonal RMS of the product, as agreed during an EU-Workshop in Brussels[4] between chemistry experts, however this is outside the scope of this guidance. In case the applicant nonetheless provides studies for data matching within the Identity section, no assessment is required and reference can be made to the equivalence application.

Physical and Chemical Properties

In agreement with the data requirements stated in Regulation (EU) No. 283/2013, the guidelines regarding recommended methodology used for determination of endpoints are stated in (i)

[4] Product chemistry of plant protection products – Harmonization of the assessment with regard to the zonal authorisation – 19-20 November 2019 in Brussels.

Regulation (EC) No 440/2008[5], (ii) Commission Communication 2013/C 95/01[6], (iii) CLP Regulation (EC) No 1272/2008[7], and (iv) its appending UN Recommendations on the Transport of Dangerous Goods manual, and (v) CIPAC -and (vi) OECD-protocols. Deviation from the stated methodology is not accepted, unless a fully substantiated statement is provided to show that the used method is equivalent to the required method for that particular endpoint. In case the alternative method was also considered acceptable in the RAR, a statement is not required. As general principle, arguments for non-addressal (i.e., waiving) of an Annex point should be fully substantiated.

For a number of Annex points, notably those related to phase transition temperature, solubility, and octanol/water partitioning, modelling software is readily available. As the performance of such software is generally too unpredictable for utilization in matching/compilation of Registration dossiers, data resulting from modelling are in principle not accepted, unless conventional experimental methods are evidently unsuitable for the specific purpose and/or the RAR-endpoint itself is based on modelling.

A matching study result is considered equivalent when it is within an acceptable range of its respective RAR-endpoint. For most cases, the decision whether a study is sufficiently matched will be taken based on expert judgement. Here, the acceptable range is highly dependent on the experimental difficulties inherent to the concerning compound and the particular Annex point. As such, a rule of thumb assigning a universal threshold value to the allowable deviation from reference values cannot be given. For example, a 20% deviation of the matching data point from the reference can be considered excellent for 'aqueous solubility', whereas it is likely unacceptable for 'melting point'. A guiding rule should therefore relate to the experimental context for the specific chemical of the assaying method / chemical substance. In practice, it is required that a study is well designed and well performed will be most decisive.

For the Henry's Law constant (2.2) no specific matching study have to be provided, as this is calculated from the vapour pressure and water solubility.

[5] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1)

[6] Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 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

[7] 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)

With regard to solubility in water (2.5) it must be noted that, if the active substance dissociates at a relevant pH (2 < pH < 12), data are required for all species that may exist within that range (please refer to Regulation (EU) No 283/2013).

According to Regulation (EU) No 283/2013, for all components included in the residue definition for risk assessment, the partition coefficient n-octanol/water (2.7) should be determined. This also applies for matching data. For self-heating, theoretical assessment is not allowed, due to the lack of predictability inherent to the property. For flammability on the other hand, theoretical assessment in compliance with CLP Regulation (EC) No 1272/2008 is allowed (2.9).

Analytical methods

4.1.1 Methods for the analysis of the active substance as manufactured

In principle, the analytical methods for the determination of the active substance, and the relevant and significant impurities in the technical material do not have to be matched, as in most cases the study reports are included in the confidential Annex. In case a study report is considered not confidential in the DAR/RAR and included in the non-confidential Annex, the study should be matched. However, in this case cross-reference can be made to the equivalence assessment (as included under section 1 (Identity)).

4.1.2 Methods for risk-assessment

In principle, pre-registration analytical methods that are part of studies used in other Sections (i.e., Fate and Behavior, Toxicology, Efficacy, Residues, Ecotoxicology and Physical and Chemical Properties) for risk assessment purposes do not have to be matched. The acceptability of the analytical methods used in support of the respective risk-assessment study is considered covered by the acceptability of the 'umbrella' study. In the data matching table, reference is made to the corresponding Annex points in the other Sections.

4.2 Methods for post-approval control and monitoring purposes

In principle, all post-registration analytical methods for plant and animal matrices, soil, water (drinking water, groundwater and surface water), air, and body fluids and tissues should be matched. Waiving is possible when no residue definition is in place, so that the requirement for related analytical methodology is cancelled. Argumentation that the GAP of the product does not contain certain plant matrices, or that the proposed use(s) would not lead to any residues above the MRL is not considered acceptable for waiving. Matching data are required, unless no analytical methodology has been presented in the RAR for the respective Annex point.

The followed procedure for validation of the post-registration analytical method should be in accordance with the relevant revision of the Guidance document on Pesticide Analytical Methods for Risk Assessment and post-approval Control and Monitoring Purposes SANTE/2020/12830 (superseding SANCO/825/00 rev. 8.1). Matching data submitted under 4.2 that are not explicitly SANTE/2020/12830 compliant are not accepted.

In this section, the analytical method submitted as matching data is considered equivalent when it is capable of determining all components included in the residue definition for monitoring, with a Limit of Quantification (LOQ) that is equal to or lower than the lowest MRL set for the respective

matrix group. However, to comply with the data requirements, multiple analytical methods for individual matrices can also be accepted (i.e. more than one analytical method to address the data point).

If the residue definition has changed in the course of the Renewal, the applicant may be eligible for Cat. 4 extension for the Annex points concerned. In this context, it will however be checked whether analytical methodology considered fit to cover the old residue definition would also be appropriate for the new one. In this case, no Cat. 4 extension can be applied for, as the applicant is supposed to have access to matching data that are compliant with the new residue definition. In this case, mostly the residue definition is less complicated (e.g. contain less components/metabolites) and therefore there is no need for developing new methodology. Therefore cat. 4 data should be fully substantiated by the applicant.

4.2 (b) Soil and Water (drinking water, groundwater and surface water)

In general, analytical methods intended for monitoring in soil and water, and thus the methods submitted as matching data, need to be capable of analysing the components in the residue definition for monitoring at an LOQ of 0.05 mg/kg for soil, and 0.1 µg/L for drinking and groundwater. For surface water, the LOQ depends on the outcome of the (eco)toxicological risk assessment in the DAR/RAR. Please refer to relevant revision of the Guidance document on Pesticide Analytical Methods for Risk Assessment and post-approval Control and Monitoring Purposes (SANTE/2020/12830) for guidance on these specific cases. For data matching purposes, an ILV in support of the primary method(s) for monitoring in drinking water is required.

4.2 (c) Air

Analytical methodology for monitoring in air, submitted for matching purposes, must be capable of analysing the components included in the residue definition for monitoring at the appropriate LOQ, as derived from relevant toxicological data. Please refer to relevant revision of the Guidance document on Pesticide Analytical Methods for Risk Assessment and post-approval Control and Monitoring Purposes SANTE/2020/12830 for specific guidance on determination of the LOQ.

4.2 (d) Body fluids and tissues

In general, analytical monitoring methods for body fluids and tissues, submitted as matching data, must be capable of analysing all components in the residue definition for monitoring, at an LOQ of

0.01 mg/L for body fluids and 0.01 mg/kg for body tissues. It is important to note that criteria stated in Regulations must always be considered prevalent to those formulated in Guidance. As such, methods for monitoring in body fluids and tissues are always required, regardless of the toxicological profile of the components included in the residue definition for monitoring.

Human toxicology

For toxicology studies on metabolites included in the residues definition, data matching should be proven. However, depending on the GAP, this should be considered on a case-by-case basis (see also section on Residues).

For toxicity studies on groundwater metabolites, matching is not always needed at active substance level. Data matching should be proven when needed for the groundwater non-relevance assessment at product level (this depends on the GAP). When not considered necessary, the data matching applicant should submit a waiver for the matching of these groundwater metabolite toxicity studies. The RMS must make sure that such waivers are clearly marked in the data matching table. In case non-notifiers want to extend their uses or use patterns in future, adequate studies addressing the relevant data points must be matched at that time point.

When a new study is provided by a data matching applicant and the endpoint of the study is more critical, e.g. when a new genotoxicity study shows a positive result in contrast to a negative result in the List of Endpoints (and the endpoint is not covered by an adequate *in vivo* study in the List of Endpoints) this information should be considered Article 56 information.

Residues

In principle, data matching applicants must match all data points addressed in the active substance dossier. With regard to residues, however, studies to address the data requirements are highly dependent on the intended uses. Besides, residue data can be seen as active substance data and product data alike. Therefore, necessary studies should be considered in the frame of the intended uses of the applicant. Consequently, data matching applicants may submit substantiated waivers for data points addressed and/or studies submitted in the active substance dossier in case these are not relevant in view of their intended uses.
The RMS must make sure that such waivers are clearly marked. In case data matching applicants want to extend their uses or use patterns in future, adequate studies addressing the relevant data points must be matched at that time point. For instance, if a data matching applicant does not

intend uses in crops fed to animals at the time point of data matching, substantiated waivers may be requested for all relevant data points (e.g. storage stability and metabolism in animal matrices, as well as feeding studies, if applicable). The RMS should accept these waivers. However, it should be clearly stated in the data matching table that these data points were not required to be matched at the time point of data matching. Another example concerns the supervised residue trials, which are only required for the intended uses of the data matching applicant: *"At the moment, the applicant does not support a use in [crop]. Therefore it is considered acceptable to waive this data requirement. MSs are advised to assess the availability of (or access to) residue data in [crop] if the applicant seeks authorisation for this crop in future"*.

Environmental fate

Data matching should in principle follow the decisions taken in the DAR/RAR. For example, where in the DAR/RAR it was concluded that exposure (e.g. aerobic mineralization), entry routes (drift relevant) or dissipation patterns (e.g. photolysis) are relevant, this decision should be followed by the data matching applicant, unless justified by a difference in the proposed use (see end of section).

All metabolites triggered for risk assessment according to the residue definition should be included in data matching, unless it is demonstrated that it is not relevant to the product/use. This involves matching of all data that is required for the metabolite according to Regulation (EU) No 283/2013 and that is included in the DAR/RAR. Proposed use of default values or QSAR estimates cannot be accepted, unless this was accepted by the RMS in the RAR and does not lead to an unacceptable risk.

Each data point (according to Regulation (EU) No 283/2013) should be matched in full and unconditionally (e.g. the correct number of soils, trials as laid down in Regulation (EU) No 283/2013 (hence not necessarily the amount presented in the List of End-Points (LoEP))). Non Good Laboratory Practice (GLP) data does not attract data protection and is as such accessible for the data matching applicant. However, where a combination of non GLP data and GLP data is necessary to demonstrate fulfillment of the data requirement, access to the GLP data is still necessary.

It is not excluded that trigger values (e.g. trigger for persistence; field dissipation study needed) are exceeded based on the matching data which was not the case for the data from the LoEP. These situations could be dealt with by the RMS, based on expert judgement. It should be noted that, in case an exceedance of the trigger did lead to an unacceptable risk, it should be considered adverse data and treated as such under Article 56.

In case a transformation or reaction product is identified that exceeds the trigger values in Regulation (EU) No 283/2013 (section 7.1.1, 7.2.1, 7.1.3, 7.2.1 and 7.2.2), and which has not been identified based on the information submitted by the original notifier, the metabolite concerned will not be present in the List of Endpoints. The data matching applicant should identify the metabolite and give an estimation of the effect on the risk profile of the active substance and the product. When the metabolite involved is considered as potential harmful or critical it shall be notified as article 56 data. Adverse data is dealt with under a separate process in accordance with Article 56.

Depending on the GAP table of the product, data access may be conditional. The applicant may limit the proposed uses based on application technique (e.g. granules instead of spraying), timing of application (e.g. anaerobic conditions (not) possible, late /early exposure scenarios), domain of application (e.g. limited to store houses, greenhouses). All these conditions may lead to a different exposure pattern compared to the product of the original notifier. In such case the dossier of the applicant must include:

a) For each data point that is not matched, a justification why this data point is not matched, based on application technique and/or GAP.

b) A proposal for the conditions / restrictions with regard to the product uses needed to justify data matching.

The RMS will describe the limitations for the product uses in the data matching table and the email to the MS (See Appendix 1).

Ecotoxicology

For each study in the DAR/RAR, it is normally indicated by the RMS whether or not the study was essential/needed according to the data requirements. All essential studies should be matched and submitted to the RMS. Product studies, such as field studies, mesocosm studies, or higher tier studies that were essential to the risk assessment of the product evaluated in the DAR/RAR do not need to be matched in the active substance data matching request to the RMS. As these studies are specific to the product and its uses they will be considered by the (i)Zonal RMS during product evaluation. In these cases data access should be arranged at product level.

Data matching must also be proven for ecotoxicology studies on metabolites included in the residues definition. It is noted that since the relevance of the metabolites may be dependent upon

the GAP, it should be considered on a case-by-case basis whether the metabolite studies from the DAR are also relevant for the GAP in question (see also section on Residues). The approach for assessing the metabolites should be based on a method that would also be acceptable for substance registration. Proposed use of default values or QSAR estimates cannot be accepted, unless this was accepted by the RMS in the RAR and does not lead to an unacceptable risk.