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**GUIDANCE DOCUMENT ON THE INTERPRETATION OF THE TRANSITIONAL MEASURES
FOR THE DATA REQUIREMENTS FOR CHEMICAL ACTIVE SUBSTANCES AND PLANT
PROTECTION PRODUCTS ACCORDING TO REGULATION (EU) No 283/2013 AND
REGULATION (EU) No 284/2013**

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Revision history

When	What
Rev. 3 of 12.12.2014	Reference is made to Regulation (EU) No 1136/2014. Some clarifications and editorial changes have been made.
Rev. 5.2 of 09.10.2015	Reference is made to Commission Regulation (EU) 2015/1475 Some further clarifications and editorial changes have been made.

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1. Introduction

The “old” data requirements are laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 for plant protection products and continued to apply till 31 December 2013. “New” data requirements have been adopted by the Commission (Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013) and although transitional measures as regards procedures concerning approval of active substances and authorisation of plant protection products have been considered, cases have been identified which need further clarification to guarantee a consistent approach in Member States.

This Guidance Document will deal with the interpretation of the transitional measures regarding the new data requirements for chemical active substances and plant protection products.

2. Legal background

The data requirements for active substances are laid down in 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 market¹.

For procedures concerning the renewal of approval of active substances whose approval expires on 1 January 2016 or later, this Regulation shall apply as of entry into force (23/04/2013).

As regards all other procedures, it shall apply from 1 January 2014.

However, in Regulation (EU) No 283/2013 as amended by Regulation (EU) No 1136/2014² the following transitional measures are included:

Article 3

Transitional measures as regards procedures concerning active substances

With respect to active substances, Regulation (EU) No 544/2011 shall continue to apply as regards the following:

- (a) procedures concerning the approval of an active substance or an amendment to the approval of such a substance pursuant to Article 13 of Regulation (EC) No 1107/2009 for which the dossiers provided for in Article 8(1) and (2) thereof have been submitted by 31 December 2013;
- (b) procedures concerning the renewal of approval of an active substance pursuant to Article 20 of Regulation (EC) No 1107/2009 for which the supplementary dossiers referred to in Article 9 of Commission Regulation (EU) No 1141/2010 have been submitted by 31 December 2013.

Article 4

Transitional measures as regards procedures concerning plant protection products

- 1. In case of applications for authorisations, as referred to in Article 28 of Regulation (EC) No 1107/2009, which concern plant protection products containing one or more active substances for which the dossiers have been submitted in compliance with

¹ OJ L 93, 3.04.2013, p. 1.

² OJ L 307, 28.10.2014, p. 26.

Article 3 or for which the approval has not been renewed in accordance with Article 14 of Regulation (EC) No 1107/2009 and in accordance with Commission Implementing Regulation (EU) No 844/2012, Regulation (EU) No 544/2011 shall continue to apply to the submission of data concerning this (these) active(s) substance(s).

2. By way of derogation from paragraph 1, from 1 January 2014 applicants may choose to apply the data requirements, as set out in the Annex to this Regulation. This choice shall be made in writing when submitting the application and shall be irrevocable³.

The data requirements for plant protection products are laid down in Commission Regulation (EU) No 284/2013 of 1 March 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 market⁴.

For procedures concerning the renewal of approval of active substances whose approval expires on 1 January 2016 or later, this Regulation shall apply as of entry into force (23/04/2013).

As regards all other procedures, it shall apply from 1 January 2014.

However, in Regulation (EU) No 284/2013 as amended by Regulation (EU) No 2015/1475⁵ the following transitional measures are included:

Article 3

Transitional measures as regards procedures concerning active substances

With respect to active substances, Regulation (EU) No 545/2011 shall continue to apply as regards the following:

- (a) procedures concerning the approval of an active substance or an amendment to the approval of such a substance pursuant to Article 13 of Regulation (EC) No 1107/2009 for which the dossiers provided for in Article 8(1) and (2) thereof have been submitted by 31 December 2013;
- (b) procedures concerning the renewal of approval of an active substance pursuant to Article 20 of Regulation (EC) No 1107/2009 for which the supplementary dossiers referred to in Article 9 of Commission Regulation (EU) No 1141/2010 have been submitted by 31 December 2013.

Article 4

Transitional measures as regards procedures concerning plant protection products

1. Regulation (EU) No 545/2011 shall continue to apply as regards procedures concerning the authorisation of a plant protection product, as referred to in Article 28 of Regulation (EC) No 1107/2009, provided that the respective application has been submitted by 31 December 2015 and that the plant protection product contains at

³ The RMS should clearly state in their assessment report which data requirements were chosen by the applicant and were the basis for their evaluation.

⁴ OJ L 93, 3.04.2013, p. 85

⁵ OJ L 225, 28.8.2015, p. 10

least one active substance for which the dossiers or supplementary dossiers have been submitted in compliance with Article 3.

Regulation (EU) No 545/2011 shall continue to apply as regards procedures concerning the renewal of authorisations of plant protection product pursuant to Article 43(2) of Regulation (EC) No 1107/2009, following the renewal of an active substance carried out pursuant to Regulation (EU) No 1141/2010.

2. By way of derogation from paragraph 1, from 1 January 2014 applicants may choose to apply the data requirements, as set out in the Annex to this Regulation. This choice shall be made in writing when submitting the application and shall be irrevocable³.

3. Transitional measures: Applications for approval, renewal of approval or amendment of approval of Active Substances

NB: Some data requirements are at the same time requirements for active substances and plant protection products (e.g. for the sections residues, analytical methods, ecotoxicology). These data should be treated as active substance data with regard to the transitional measures.

Applications for approval, renewal of approval or amendment of approval of active substances can be grouped as follows as regards the type of submission:

Type of Submission	Data Requirements
Applications for the renewal of approval of substances following the procedure of Regulation (EU) No 1141/2010 (AIR-2 substances)	In accordance with Regulation (EU) No 1141/2010 all dossiers for 'AIR-2 substances' were submitted in 2012. Therefore the old AS and old PPP data requirements applied.
Applications for the renewal of approval of substances under Article 14 of Regulation (EC) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (e.g. AIR-3 substances)	For all dossiers to be submitted in accordance with Regulation (EU) No 844/2012, new AS and new PPP data requirements apply (for the representative product), as is provided for in Art. 5(2) of Regulation (EU) No 283/2013 and Art. 5(2) of Regulation (EU) No 284/2013.
Applications for the approval of new active substances (New AS) under Regulation (EC) No 1107/2009 ⁶	<p>If the dossier was submitted <u>by 31 December 2013</u>, old AS and old PPP data requirements apply (for the representative product).</p> <p>If the dossier is submitted <u>after 31 December 2013</u>, new AS and new PPP data requirements apply (for the representative product).</p>
Applications for the amendment to AS approval conditions under Regulation (EC) No 1107/2009 (application according to Article 7)	<p>If the dossier was submitted <u>by 31 December 2013</u>, old AS and old PPP data requirements apply (for the representative product).</p> <p>If the dossier is submitted <u>after 31 December 2013</u>, new AS and new PPP (representative formulation for amendment of the active approval conditions) data requirements apply (for the representative product).</p>

The procedure when no agreed test methods or guidance documents are available is described in "*Guidance Document for applicant on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013, May 2013)*".

4. Transitional measures: Applications for authorisation, renewal of authorisation or amendment of authorisation of Plant Protection Products

NB: Some data requirements are at the same time requirements for active substances and plant protection products (e.g. for the sections residues, analytical methods, ecotoxicology). These data should be treated as active substance data with regard to the transitional measures.

Applications for authorisation, renewal, amendment (including extensions) of authorisation of Plant Protection Products can be grouped as follows as regards the type of submission:

⁶ A New Active Substance (NAS) under Regulation (EC) No 1107/2009 is considered an active substance for which the application was submitted according to Article 7 and completeness has been established after 14 June 2011.

'AIR-2 active substance'	
<p><u>General note:</u> Here the submission dates for renewal of approval pre-date the new requirements, thus the old active substance data requirements apply until the <i>next</i> renewal of approval.</p>	
Type of Submission	Data Requirements
<p>1</p> <p><u>Renewal of authorisation:</u></p> <p>Applications for renewal of the authorisation of products containing only 'AIR-2 active substances'.</p> <p>Such applications for renewal of the authorisation will be submitted in accordance with Article 43 of Regulation (EC) No 1107/2009.</p> <p>.</p>	<p>If the application is submitted <u>by 31 December 2015</u>, old AS and old PPP data requirements apply.⁷</p> <p><i>According to Directive 2010/77/EU renewal of AIR 2 active substances should take place by 31 December 2015.</i></p> <p>If the application is submitted <u>after 31 December 2015</u>, old AS data requirements and old PPP data requirements continue to apply (in accordance with Reg. (EU) No 284/2013 as amended by Reg. (EU) No 2015/1475).</p> <p>For confirmatory information concerning the AIR-2 active substances see chapter 6.</p>
<p>2</p> <p><u>New or amended authorisations:</u></p> <p>Applications:</p> <ul style="list-style-type: none"> • for the authorisation of a new product; • for an extension of an authorisation or a minor use; • for an amendment to an authorisation, <p>for a product containing only 'AIR-2 active substances'.</p>	<p>If the application is submitted <u>by 31 December 2015</u>, old AS and old PPP data requirements apply.⁶</p> <p>If the application is submitted <u>after 31 December 2015</u>, old AS data requirements and new PPP data requirements apply.</p> <p>Only the new data which is necessary for the extension or the amendment of the authorisation is concerned. It is not expected that the original dossier is updated according to the new AS and PPP data requirements.</p>

⁷ Until 31 December 2015 applicants can choose to already apply the new data requirements for applications for authorisations of PPPs. The choice to be made should be done in writing with the submission of the application and is irrevocable.

The RMS should clearly state in their assessment reports which data requirements were chosen by the applicant and were the basis for their evaluation.

'AIR-3 active substance'⁸/substance not yet renewed	
<u>General note:</u> Here the submission dates for renewal of approval post-date the new requirements, thus the new active substance data requirements apply.	
Type of Submission	Data Requirements
<p>3</p> <p><u>Renewal of authorisation:</u></p> <p>Applications for renewal of the authorisation of products containing only substances renewed under Article 14 of Regulation (EC) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (e.g. AIR-3 substances).</p> <p>Such applications for renewal of the authorisation will be submitted in accordance with Article 43 of Regulation (EC) No 1107/2009.</p>	<p>As no transitional measures apply, new AS and new PPP data requirements are applicable.</p>
<p>4</p> <p><u>New or amended authorisations:</u></p> <p>Applications:</p> <ul style="list-style-type: none"> • for the authorisation of a new product; • for an extension of an authorisation or a minor use • for an amendment to an authorisation, <p>for a product containing only 'AIR-3 active substances'⁹</p>	<p>If the application is submitted <u>after 31 December 2013</u> and before the date of renewal of the approval of the 'AIR-3 active substance', old AS data requirements and new PPP data requirements apply.⁶</p> <p>If the application is submitted after the renewal of the approval new AS and new PPP data requirements apply.</p> <p>Only the data which is submitted for the extension or the amendment of the authorisation is concerned. It is not expected that the original dossier is updated according to the new AS and PPP data requirements.</p>

⁸ Active substances referred to in Regulation (EU) No 686/2012.

⁹ This concerns also other substances not yet renewed under Article 14 of Regulation (EC) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (including active substances listed Annex I to Regulation (EC) No 737/2007).

'new active substance'	
<p><u>General note:</u> A New Active Substance (NAS) under Regulation (EC) No 1107/2009 is considered an active substance for which the application was submitted according to Article 7 and completeness has been established after 14 June 2011.</p>	
Type of Submission	Data Requirements
<p>5</p> <p>Applications:</p> <ul style="list-style-type: none"> • for the authorisation of a new product; • for an extension of an authorisation or a minor use • for an amendment to an authorisation <p>for a product containing only 'New AS' under Regulation (EC) No 1107/2009.</p>	<p>If the application is submitted <u>by 31 December 2015, and the new AS dossier was submitted by 31 December 2013</u>, old AS and old PPP data requirements apply.⁶</p> <p>If the application is submitted <u>before 31 December 2015, but the new AS dossier was submitted after 31 December 2013</u>, the new AS and new PPP data requirements apply.</p> <p>If the application is submitted <u>after 31 December 2015, and the new AS dossier was submitted before 1 January 2014 (but the AS is not yet approved)</u>, old AS and new PPP data requirements apply.</p> <p>Only the new data which is necessary for the extension or the amendment of the authorisation is concerned. It is not expected that the original dossier is updated according to the new AS and PPP data requirements.</p>

‘mixtures’		
	Type of Submission	Data Requirements
6	<p>Applications:</p> <ul style="list-style-type: none"> • for the authorisation of a new product; • for an extension of an authorisation or a minor use • for an amendment to an authorisation <p>for a product containing a mixture of two or more active substances.</p>	<p>In order to determine, which data requirements are applicable for individual active substances contained in a plant protection product, one should refer the scenarios detailed above in rows 2, 4, and 5 with respect to each active substance.</p> <p>From 1 January 2014, all product data in applications for products authorisations should be according to the new data requirements except for products containing an AIR-2 substance or for products containing a new active substance for which the dossier was submitted by 31 December 2013.</p> <p>From 31 December 2015, all product data in all applications for products authorisations should be according to the new data requirements.</p> <p>For products containing more than one active substance the transitional measures apply to the whole product if the plant protection product contains at least one active substance for which the transitional measures apply.</p>

The procedure as regards data requirements for product re-authorisation which cannot be complied with is described in “*Guidance Document on renewal, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009 (SANCO/2010/13170; rev. xx -2014)*”.

5. Transitional measures: Maximum residue levels (MRLs)

1. Application for a MRL pursuant to Article 6(1) of Regulation (EC) No 396/2005

When the application for the MRL is prepared in the context of an application for an authorisation of a PPP, the data requirements applicable for the MRL will be the same as the data requirements applicable to the respective active substance in the application for the authorisation for the PPP (see Chapter 4 above).

This applies also for applications done in the context of Article 6(2) and 6(3) of Regulation (EC) No 396/2005 insofar it concerns the setting or modification of a MRL for an approved active substance. In the case the substance is not approved old data requirements apply for applications submitted by 31 December 2013 and new data requirements apply to applications submitted as from 1 January 2014.

2. Application for an import tolerance pursuant to Article 6(4) of Regulation (EC) No 396/2005

In the case the substance was not approved or the approval was not renewed under Regulation (EC) No 1107/2009 old data requirements apply for applications for import tolerance submitted by 31 December 2013 and new data requirements apply to applications for import tolerance submitted as from 1 January 2014.

In the case the substance was approved or the approval was renewed under Regulation (EC) No 1107/2009 the data requirements applicable to the application for import tolerance will be the same as the data requirements applicable to the application for the approval or the renewal of the approval of the active substance whatever is the latest (see Chapter 3 above).

3. Review of existing MRLs under Article 12 of Regulation (EC) No 396/2005

When MRL data is submitted in the context of Article 12 of Regulation (EC) No 396/2005, the data requirements applicable for the submission of MRL data are the data requirements applicable to the application for the approval (or renewal of approval or amendment of approval) of the active substance (see Chapter 3 above).

NB: Data requirements concerning residues can be at the same time active substance data and plant protection product data. These data should be treated as active substance data with regard to the transitional measures.

6. **Transitional measures: Special Cases**

A number of data submissions are not explicitly covered by the transitional measures and will be dealt with in this chapter.

1. Mutual recognition

In the case it is requested by the Competent authority pursuant to Article 42(1)(c) of Regulation 1107/2009, the application for mutual recognition should contain the original complete or summary dossier, including the information submitted according to data requirements applicable at the time of submission of the application of the reference product to the reference MS.

2. Application for new products or a new uses of a product:

- The new data requirements are applicable after a certain date and that concerns all applications for a new product or a new use of a product irrespective if the risk is qualified by a MS within the risk envelope.
- For a new use only the data directly applicable to that new use would need to meet the conditions of the new requirements (see Chapter 4).
- If an application concerns a product for which reference is made to another product authorisation, and no technical assessment is necessary, then there is no need to supply data according to the new data requirements, irrespective as to whether the reference product/use was assessed to the old or new data requirements.
- If there is a significant formulation change (see GD on significant and non-significant changes; SANCO/12638/2011) than the necessary new data should be provided according to the new data requirements.

3. Confirmatory information

Where the approval of an active substance provides for the submission of further confirmatory information, the Regulation will also provide the time limit (usually 2 years after the date of approval).

The confirmatory information should be provided according to the same data requirements as the original submission for the active substance unless specified otherwise, for example when the request for confirmatory information relates to information to be provided according to 'new data requirements established during the evaluation process' (ref Annex II 2.2 (a) of Regulation (EC) No 1107/2009 where it is stated that certain information is still to be submitted where: "*the data requirements have been amended or refined after the submission of the dossier*").

For substances for which the old data requirements were applicable (such as AIR 2 substances and New AS for which the dossier was submitted by 31 December 2013), confirmatory information may be requested in line with the new data requirements. This would allow for a harmonised EU-peer review of the data related to the new data requirements. A request for the submission of these data as 'confirmatory information' will be specified in the approval decision including a time limit (usually 2 years after entry into force of the approval Regulation). Such a request should also be limited to specific issue for an active substance. A full update of the dossiers according to the relevant data requirements will be required at the time of renewal of the approval of the active substance.