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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Safety of the food chain
Chemicals, contaminants, pesticides

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Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

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1 Background

Plant protection products generally consist of at least one technical active substance and co-formulants. Safeners or synergists are present in some cases. Among other reasons, new scientific and technical knowledge, economic demands, unavailability of supply, improved performance or classification or concerns regarding certain critical co-formulants can make it necessary to change the chemical composition of products with regard to their co-formulants. The key objective of this guideline is to harmonise the approach to significant and non-significant changes of the chemical composition of plant protection products in the EU, and to provide information on a process and timeframe for such a procedure.

This guidance document has been developed to elaborate the possibilities and procedures according to Regulation (EC) No 1107/2009 (hereinafter called "the Regulation"). However, the guidance document can also be used for assessments that still have to be conducted according to Directive 91/414/EEC.

2. Implementation schedule

This document has been finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012. It will apply to applications submitted from 1 March 2013 onwards.

3 Legal basis

The possibility of amending an authorisation is given in Articles 33, 44 and 45 of the Regulation. Article 45 covers the amendments on request of the authorization holder. A change in the chemical composition of a plant protection product after authorisation can be regarded as such an amendment.

4 Definitions

formulation change

A formulation change is considered a change in the chemical composition of a formulation, but where the content of active substance and the formulation type remains unchanged.

non-significant change

A change according to chapter 6 for which it is foreseen that no (zonal) assessment is required. In this respect reference is made to Chapter 6 of the *Guidance Document on renewal, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009*, SANCO 13170.

significant change

Any change in the chemical composition and/or content of co-formulants according to chapter 7 for which a zonal assessment is necessary, independent of whether new studies or only statements have been submitted. In this case an application is necessary for an amendment according to Article 45 (and 33) of the Regulation.

5 Procedures

An authorisation issued by the competent authority is only valid for the formulation applied for and to which reference is made in the authorisation certificate. The competent authority must therefore be notified of all changes to the authorised formulation.

Depending on the extent of the intended changes, this is done either in a procedure of notification in the case of non-significant changes (see chapter 6), in a procedure of application for an amendment of an authorisation in case of significant changes (see chapter 7) or a new authorisation procedure is necessary.

The procedures described in chapter 6 and 7 for changing the chemical composition of plant protection products only applies to changing co-formulants. For changes which go beyond this, a new application for authorisation must be submitted according to Article 33. This is applicable to changes in the content of pure active substance, safener or synergist or generally the type of formulation.

When product dossiers are submitted in the framework of an application for renewal of authorisation after active substance approval or renewal of approval, formulation changes can be accepted with these submissions.

6 Non-significant changes

It must be taken into consideration that the principle of commensurability demands that the evaluation depth by the authority and the requirements to be met by the applicant are limited to those necessary to achieve the protection targets of the Regulation. Therefore, in certain cases the authorisation holder/applicant only has to notify the competent authority of the change.

If a change in a formulation only consists of exchanging co-formulants for the same amount of chemically equivalent co-formulants, a notification is sufficient.

The following examples may be acceptable:

- Co-formulants have the same composition and the same or less severe hazard classification,
- Alternate source of same co-formulant,
- Cation exchange for anionic surfactants/dispersants,
- Adding a marker substance for authentication (in case the marker is not of toxicological or ecotoxicological concern and the concentration in the formulation is below 0.1 %).

In these cases the chemical composition is not really changed, so no assessment is required and these amendments do not fall under the zonal system (see Chapter 6 of the *Guidance Document on renewal, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009*, SANCO/2010/13170).

There are two aspects for judging the equivalence of co-formulants:

- the CAS or EINECS/ELINCS number of the substances. However, different CAS numbers do not necessarily mean chemical non-equivalence.
- the classification and labelling of the co-formulants according to current safety data sheets.

For clear and consistent decisions lists of all co-formulants (commercial products) which were regarded as equivalent or non-equivalent should be maintained. These lists should be available to all competent authorities via Circa/authorisations database. Due to the fact that commercial secrets of different manufacturers may be concerned, these lists cannot be made publicly available.

If the competent authority regards the new co-formulants as non equivalent (i.e. if the change is regarded as significant) an application for an amendment is necessary (Chapter 7).

Another particular case of non-significant change of the formulation is the situation where the declared composition of a plant protection product needs to be changed as the result of a notification/application for use of a new source of technical active ingredient in the formulation. As a matter of fact, if a technical a.i. with a lower minimum purity is used in the formulation, the declared content of the technical a.i. in the formulation will be higher and this has also an impact on the declared content of another co-formulant (normally the solvent or carrier). Since an assessment of equivalence of different technical active substances is already foreseen by Art. 29 and Art. 38 of Reg. (EC) No 1107/2009, such a change – i.e. adaptation of the solvent/carrier level in the formulation to compensate for less pure (but equivalent) technical active ingredient – can also be regarded as a 'non-significant change' in the context of this GD and thus does not require any further assessment. A notification of the changed composition to the competent authority is sufficient.

7 Procedure of application for an amendment of an authorisation (significant change)

In principle, all changes where co-formulants are exchanged, added, omitted or whose content is changed are to be applied for in a procedure for an amendment of an authorisation and an assessment at zonal level will be necessary.

It is no general prerequisite, that the new co-formulant has the same function as the old co-formulant, belongs to the same chemical class or is already contained in authorised plant protection products.

Depending on the extent of the change new studies may be required.

It is not possible to give a general percentage, up to which a change in the content of a co-formulant has no influence on the properties of the formulation and new studies are not necessary. For example, a 5 % change in the content of a dispersant might significantly change dispersion properties of the formulation, while a 5 % change in the content of a colorant should not influence the properties at all.

Attempting significantly to change a formulation, by making a series of “minor” changes (i.e. each within 10 % of original content) that would not in themselves require supporting data, is not acceptable.

Reference should always be made back to the original formulation, which is the formulation that the most recent full assessment and approval based on harmonised principles has been conducted on.

For the following changes new studies are not necessary for the physical and chemical properties (but might be necessary for other aspects):

- a) changes in dye, pigment or colouring material (< 5 % in formulation, already in authorized ppp),
- b) addition of an anti-foaming agent at < 5 % of the formulation,
- c) changing ethylene glycol for propylene glycol

Other changes may be identified for which new studies are not necessary regarding physical and chemical properties.

When changing the anti-foaming agent the persistent foaming should be tested.

When changing the composition to include the use of a Water Soluble Bag, further studies are required for persistent foam, wet sieve test, suspensibility, solution stability and wetting, as appropriate.

Regarding the hazard assessment the principles of the CLP regulation¹, Annex I point 1.1.3 can be applied. According to point 1.1.3.6, the following variations in initial concentration are possible without a new evaluation of hazard²:

initial concentration range of the constituent (% w/w)	permitted (relative) variation
$\leq 2.5 \%$	$\pm 30 \%$
$2.5 < c \leq 10 \%$	$\pm 20 \%$
$10 < c \leq 25 \%$	$\pm 10 \%$
$25 < c \leq 100 \%$	$\pm 5 \%$

¹ 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

² In case test data are available; if the original formulation is classified on composition, an increase may trigger a different classification.

In addition to these acceptable variations in concentration of co-formulants according to the CLP regulation, the following variations are considered acceptable for components at very low concentrations (regarding the hazard assessment):

initial concentration range of the constituent (% w/w)	permitted (relative) variation
$\leq 1.0 \%$	$\pm 50 \%$
$\leq 0.5 \%$	$\pm 100 \%$

In cases of changes higher than (absolute) 10 % (w/w) of the original formulation new toxicological studies may be required in general. In the case of changes below (absolute) 10 % (w/w) it has to be decided case-by-case whether studies using the new formulation have to be submitted.

Regarding phytotoxicity and efficacy aspects in the case of exchanging co-formulants with substances similar in their function reference is made to (future) guidance on this issue by EPPO.

Similarity assessment regarding environmental risk:

Guidance on appropriate assessment procedures and/or criteria for the similarity assessment regarding environmental risk is not given in this guidance document and should be dealt with in separate way.

In all cases an application for amendment of the authorisation according to Article 45 (and 33) of the Regulation shall be submitted and an assessment at zonal level will be necessary.

In the authorisation certificate the new composition should be given a new identifier to clearly distinguish it from the old composition.

8 Application

Only the authorisation holder is allowed to apply for changing the chemical composition. The application should be sent to all concerned MS, where the change in the chemical composition is intended.

An application must include the following documents, apart from a form specific to each MS.

		Procedure of notification chapter 6	Procedure of amendment chapter 7
1	Reason for changing the formulation	X	X
2	Comparison of the old and new formulation	X	X
3	Characterisation of new co-formulants, according to Regulation (EU) 545/2011(Part A, 1.4.3 and 1.4.4 or Part B, 1.4 iii) and iv))	X	X
4	Safety data sheets for all co-formulants according to the latest scientific and technical knowledge according to Regulation (EC) 1907/2006	X	X
	Safety data sheet of the new formulation	X	X
5	Physical, chemical and technical characteristics according to the valid data requirements, including details on storage stability ³ .		X
6	Statement on the validity of the method of analysis for the active substance and the relevant impurities in the new formulation		X
7	Details on the impact on classification and labelling		X

³ When the results of the accelerated storage of the new formulation are acceptable and the shelf life has been examined for the old formulation, a two year storage test may not be necessary.

8	Statement/studies on the effects on efficacy and phytotoxicity		X
9	Statement/studies on the effects on toxicology		X
10	Statement/studies on the effects on ecotoxicology		X
11	List of countries, where the change - has been notified / applied for - is already approved	X	X
12	Addendum or assessment report or decision of other MS concerning the change applied for	X	X

9 Assessment

The application for an amendment of an authorisation (chapter 7) is evaluated and a positive decision is made by the competent authority if:

- no problems are expected due to the physical, chemical and technical characteristics,
- efficacy is not impaired in an unacceptable way,
- phytotoxicity is not increased so as to cause problems in comparison to the old formulation,
- there are no objections to the new formulation from a toxicological point of view,
- there are no objections to the new formulation from an ecotoxicological point of view, including the protection of honeybees and
- restrictions and directions for use do not change.

10 Procedures and timelines

In the procedure of notification (chapter 6) the applicant should receive an answer within 6 weeks from the competent authority, whether the notification is sufficient or an application for an amendment is necessary.

In the procedure of application for an amendment of an authorisation (chapter 7) the procedure and timelines according to Guidance doc SANCO/2010/13170 and SANCO/13169/2010 should be followed.

When the change is applied for simultaneously in different MS, the applicant can propose a MS who should do the evaluation. It is highly recommended that for plant protection products authorised under Regulation (EC) No 1107/2009 the zonal RMS should evaluate the application (in case it is also concerned).

In case the product was authorised via mutual recognition, the formulation change must be evaluated in the MS of origin.

The change in chemical composition must be authorised in every concerned MS individually.