Discussion paper[1] on Co-formulants (rev. 3)

Implementation rules for the inclusion of unacceptable co-formulants in Annex III of the Regulation (EC) No 1107/2009

1. Introduction

This document is intended to establish a procedure for the inclusion of unacceptable co-formulants in Annex III of Regulation (EC) No 1107/2009 according to the provisions stipulated in Article 27 of the Regulation. The purpose is to achieve a harmonised approach among the EU Member States (MSs) on the identification of unacceptable co-formulants in plant protection products (PPPs).
At a later stage, some guidance may be needed for MSs to perform a harmonised risk assessment of critical co-formulants in PPPs.

2. Legal basis

The legal basis for these implementation rules is Regulation (EC) No 1107/2009 and implementing regulations, such as Regulation 546/2011 on Uniform principles.

2.1. Regulation (EC) 1107/2009

According to Art. 2(3)c, "substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, are referred to as 'co-formulants'". These chemicals may be of concern, as provided in art. 3(4), where they have an inherent capacity to cause an adverse effect on humans, animals or the environment and are present or are produced in a plant protection product in sufficient concentration to present risks of such an effect.
According to Article 27 a co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

> *"(a) its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or*
> *(b) its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment."*

Such co-formulants should be listed up in Annex III. Commission can lay down implementing detailed rules according to Art. 27(5). According to the general spirit of Reg. (EC) 1107/2009, the procedure to identify and ban unacceptable co-formulants should be pro-active and should allow MSs not to grant new authorisations or renew existing ones for products containing co-formulants

[1] *This document is conceived as a working document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.*

about to be banned.

According to Article 29(6) and the regulations on data requirements, *"interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products."*

In Art 81(2) of Regulation (EC) No 1107/2009 it is noted that:

> *"By way of derogation from Article 27 and without prejudice to Community law, Member States may apply national provisions for co-formulants not included in Annex III until 14 June 2016;*
> *Where, after 14 June 2016, a Member State has serious grounds for considering that a co-formulant not included in Annex III is likely to constitute a serious risk to human or animal health or the environment, it may temporarily prohibit or restrict the application of a co-formulant in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision. Article 71 shall apply."*

2.2. Regulation (EU) 546/2011 on uniform principles for evaluation and authorisations

Regulation (EU) No 546/2011 lays down the uniform principles for evaluation and authorisation of plant protection products. The following is stated at paragraphs 2.4.1.1, 2.4.1.4 and 2.4.2.5:

> *"Member States shall evaluate operator exposure to the active substance and/or to toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions) using by preference realistic data on exposure and, if such data are not available, a suitable, validated calculation model.[…]*
> *Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use. […]*
> *Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using a suitable calculation model. This evaluation shall take account, where relevant, of other sources of information such as other authorised uses of plant protection products containing the same active substance or which give rise to the same residues."*

2.3. Regulation (EU) 284/2013 setting the data requirements for plant protection products

Regulation (EU) 284/2013 sets the requirement for the formulated PPPs. Some of the requirements are focused on co-formulants. Their description (nature, content and function) should be included in the dossiers. Section 7.4 on toxicological data refers specifically to the available toxicological data for co- formulants.

On a more general point of view, the regulation requests notifiers to perform tests, modelling and provide data for the active substance(s) and the toxicologically relevant compounds. The latter could encompass candidate co-formulants for Annex III. Such pieces of information should be taken into account for the assessment for unacceptable co-formulants.

2.4. Horizontal and other regulations on chemicals

As all the known co-formulants are chemicals, they also fall under the provisions of Regulation (EC) 1272/2008 (CLP Regulation) and Regulation (EC) 1907/2006 (REACH Regulation).

It should be noted that Art. 15 of REACH excludes active substances and some co-formulants exclusively used in PPPs from registration. However, this provision should be read as restricting this possibility to active substances only as Reg. 1107/2009 (and formerly Dir. 91/414/EEC) does not set rules for co-formulants yet.

The use of restricted substances listed in Annex XIV of REACH as co-formulants falls only under the provision of Reg. EC 1107/2009. Therefore chemicals already listed up in Annex XIV of REACH and which could be used as co-formulants in PPPs need to be also taken on board into Annex III, when necessary.

When it comes to CLP, it should be also noted that co-formulants of concern "include, but are not limited to, [co-formulants] meeting the criteria to be classified as hazardous in accordance with [the CLP Regulation], and present in the plant protection product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC".

While deciding to list unacceptable co-formulants, Commission and MSs should take advantage of the existing provisions for chemicals in order to avoid duplication of studies and work. Maximum use should be made of available information, including QSAR and read-across. Use of vertebrates to generate additional data should be avoided wherever possible. However the raw data should be made available for the assessment of the risk of a co-formulant. This is not provided in the REACH Regulation as only a summary of these studies and an assessment of them is required.

Where protection goals and risk assessments differ between horizontal regulations on chemicals and those addressing plant protection products, specific supplementary data requirements should be set.

Where possible, information on a co-formulant also used in a biocide product could be useful. Under the biocide regulation, ECHA recently revised the guidelines for the risk assessment of biocide products and addressed the question of co-formulants. The co-formulant scheme under Reg. 1107/2009 should benefit from the science and guidance laid down for the assessment of biocidal products. However it should be noted that biocide provisions are slightly different, in a way they do not set a list of unacceptable co-formulants.

3. Criteria for the identification of unacceptable co-formulants

A co-formulant in terms of Article 27 of the Regulation (EC) No 1107/2009 is regarded as a substance or mixture which is defined by a unique identifier. However unacceptable co-formulants may also be identified as a group, e. g. chemicals bearing the same functional chemical structure.

As co-formulants can be also technical grades[2] or formulated chemicals (e.g. containing

[2] According to REACH, a single CAS number reference covers all the products containing at least 80% of the same

preservatives, biocides), it is decided to consider co-formulants as marketed and labelled accordingly.

Regulation (EC) No 1107/2009 does not stipulate suitable/specific testing methods in order to ascertain whether a co-formulant has unacceptable effects). Generally, the evaluation of the toxicity and eco-toxicity of co-formulants is not performed as thoroughly as in the case of active substances in the context of the authorisation of plant protection products, as most of the co-formulants are not biologically active chemicals. This is especially the case for toxicity testing where only acute toxicity studies, irritation and sensitisation studies are required with the PPP, while for the ecotoxicity testing a much wider range of studies (sub-chronic, chronic) are conducted with the PPP according to current data requirements (Regulation (EU) 284/2013). However, if there are scientific indications that harmful effects on human or animal health or unacceptable effects on the environment are caused by a certain co-formulant; either additional data or the change of the formulation should/may be requested by the competent authority on a case-by-case basis.

It is proposed to set up a step-wise risk assessment procedure with a first trigger based on the hazard classification, to identify unacceptable co-formulants. For the purpose of identification of candidates for Annex III, both harmonised and self-classification are relevant. The draft general scheme laid down below is presented in Appendix I. The identification can also be triggered by results of the assessment within the authorisation procedure for plant protection products or by other scientific sources of information. The principles laid down below should also apply for identification of unacceptable co-formulants at national level, according to art. 81(2).
The risk assessment performed may also help MSs for the authorisation of the corresponding plant protection product.

3.1. Co-formulants of critical concern

Reg. (EU) 1107/2009 provides that actives substances with certain hazard classifications (e.g. CMR 1A or 1B, EDs) should not be approved for use in PPPs, subject to certain exceptions. It is proposed to extrapolate the protection goal set for the biologically active substances as a trigger for non-biologically active co-formulants of a PPP. Under the critical concern, it is also proposed to include relevant chemicals for PPPs which uses are restricted or banned according to Reg. (EC) 1907/2006, because the decisions made under REACH were already based on a risk assessment.
Co-formulants of critical concern which fulfil the following (hazard) criteria should be regarded as candidates for inclusion in Annex III without risk assessment. No exception is possible.

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chemical.

- Mutagen cat. 1A or 1B,
- POP[3], PBT[4], vPvB[5].

Co-formulants of critical concern which fulfil the following (hazard) criteria should be regarded as candidates for the inclusion in Annex III, with possible derogation in case of impurities.

- Criteria as mentioned for active substances in Annex II of Regulation (EC) No 1107/2009
  - Carcinogen cat. 1A or 1B with exception of genotoxic carcinogen cat. 1A or 1B,
  - Toxic for reproduction cat. 1A or 1B,
  - Endocrine disrupting properties[6],
- Substances included in Annex XVII of REACH (in case the restriction is relevant for PPP).
- Substances on the list published according to art. 59(10) of REACH (candidate list) or which fulfil the criteria for inclusion in the candidate list.

A risk assessment is not necessary in this case where any significant presence is described, exposure would not be considered as acceptable. For restrictions coming from REACH, the risk assessment was already performed and led to the inclusion of the chemical on Annex XIV.

"Any significant exposure" means that no voluntary use of such a critically classified chemical would be allowed. When it comes to impurities in a co-formulant technical grade, a tolerance could be set. For example, these impurities shall not be present at a concentration triggering the classification of the technical co-formulant.

3.2. Co-formulants of concern

The following hazard criteria can be used to further identify candidate co-formulants for annex III. They would require a dedicated risk assessment before their listing up on this Annex:

- Co-formulants classified as carcinogens cat. 2, mutagens cat. 2 or toxic for reproduction cat.2 if their concentrations would lead to classification and labelling of the PPP;
- Co-formulants classified for specific target organ toxicity after single or repeated exposure (STOT-SE or RE) category 1 and 2, especially if they show other critical effects or immunotoxicity or neurotoxicity if their concentrations would lead to classification and labelling of the PPP;
- Co-formulants classified for two of the three criteria for PBT;
- Co-formulants classified for skin or respiratory sensitizer category 1 if their concentrations would lead to classification and labelling of the PPP;

[3] According to Reg. (EC) 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
[4] According to the criteria set in REACH, as only REACH data are available
[5] According to the criteria set in REACH, as only REACH data are available
[6] To be implemented once the final criteria on ED according to Annex II have been set.

- Co-formulants that may contain impurities/additives/constituents of toxicological relevance (i.e., those that fulfil the properties mentioned above) over established limits (as set out in e.g. Regulation (EC) No 1272/2008) and/or their concentrations lead to classification and labelling of the PPP.

3.3. Other potential unacceptable co-formulants

Other co-formulants may also be considered as candidates for Annex III, even if they may not be classified according to the CLP. The following categories are examples where an assessment of such co-formulants would be required in order to decide whether they should be listed on Annex III.

- Co-formulants which are more toxic for human health than the active substance(s) in the product. For such co-formulants, the toxicity of the product might not be driven by the active substance itself as commonly assumed but by the co-formulant. The same procedure could also apply to ecotoxicology. The appropriate assessment of such a product should be based on the co-formulant data.
- Co-formulants that enhance the toxicity of the active substance in the product. For such cases, critical information/data shall relate to the interaction between the active substance and the co-formulant, not only to the co-formulant itself. In such situations, an appropriate evaluation of the risks posed by the active substance in the presence of the co-formulant rather than an evaluation of the risks posed by the co-formulant itself should be undertaken.
- Co-formulants for which there are indicative occupational exposure limit values according to Dir 2000/39/EEC.
- Consideration if the co-formulant belongs to a group or “category” of substances which should be included in Annex III.

As a number of chemical substances may fall under the criteria set above, COM will perform a light impact check, taking into account the EU-available information about co-formulants in authorised plant protection products.

4. Decision-making process on unacceptable co-formulants

4.1. Notification of potential unacceptable co-formulants

A Member State (MS) coming to the conclusion that a certain co-formulant (hereafter the reporting MS, rMS) should be considered for inclusion in Annex III prepares a <u>confidential</u> report on the co-formulant with the following information. MSs should take particular attention to chemicals which have not been registered according to REACH. MSs should also pay particular attention when the preservatives have not been notified or not approved according to Reg. (EU) 528/2012.

- identity of the co-formulant
  (chemical name, CAS number(s), EC number(s), trade name(s), an appropriate description of the composition in the case of mixtures; the respective information on impurities if relevant for the proposal)
- decisions under REACH regulation concerning the co-formulant or the substance(s) in the co-formulant (e.g. SVHC, candidates for restriction or authorisation)
- overview of the different classifications: EU harmonised ones and self-classification proposals, according to CLP.
- function of the co-formulant
- plant protection products of concern in the reporting Member State
- justification for inclusion in Annex III
- data relied upon for identification
- consideration if the co-formulant belongs to a group or "category" of substances which should be included in Annex III.

The reports will be submitted to the COM, EFSA, the other MSs and the applicant(s) and/or authorisation holder(s) (hereafter applicant). A commenting period may be needed before moving on.

4.2. Evaluation reports

4.2.1. for specified co-formulants of critical concern

Confirmation of the current harmonised classification and/or notified self-classification should lead to a regulatory proposal from the Commission to list the co-formulants on Annex III under co-formulants of critical concern. It is considered that any exposure would lead to a unacceptable risk for co-formulants identified as mutagen cat. 1A or 1B and genotoxic carcinogens cat. 1A.
For co-formulants identified under other criteria of section 3.1, it should be checked whether the classification is driven by impurities. If not, confirmation of the classifications as described above should lead to a proposal for inclusion on Annex III.
A way to deal with diverging self-classifications should be established also.

4.2.2. for co-formulants of concern and other potential unacceptable co-formulants

For chemicals identified under section 3.2 or 3.3, a risk assessment has to be carried out. Different possibilities may exist regarding the data available, the data set to be assessed and the authorities to perform such an evaluation. A risk assessment scheme should also be built up, in order to provide

harmonisation and consistency in the EU. REACH scenario or Biocide Guidance for Human Risk Assessment could be used for first tier assessment. Refinement of the scenario will be needed.

4.3. What to be assessed?

Co-formulant manufacturers shall comply with REACH and CLP requirements. This means that they should provide a classification proposal and data to ECHA for co-formulants which are put on the European market by more than 1 ton/year. The higher the marketed volume, the more comprehensive the data set to be submitted. A proposed assessment of these dataset should also be provided to ECHA, as a registration report. According to the REACH step-wise implementation, all the registration reports should be submitted by 2018. These registration reports will be evaluated by voluntary MSs according to a multi-annual rolling plan, updated every year by the competent standing committee (CARACAL). However REACH data will not be sufficient to perform a full risk assessment for co-formulants used in formulated PPPs:

- For certain specific niche co-formulants, the submitted dataset may not be sufficient for a comprehensive risk assessment.
- REACH data requirements mainly focus on non-dietary exposure and acute hazard, especially for the low volume chemicals. Very few requirements address the risk to environment. A first tier dietary assessment may be possible, without taking into account the fate of the co-formulant on the crop.
- The end-points set according to REACH (DNEL or aquatic PNEC) are not in line with those usually used to perform pesticide risk assessment.
- Manufacturers and importers should provide consolidated data to ECHA, but not the raw data, on the contrary to what the notifiers are requested to according to Reg. 1107/2009.

The REACH requirements may be reinforced, either by upgrading the data requested to the highest volume chemicals or by adding specific requests under Reg. 1107/2009. Raw data must be available to the risk assessors. The detail rules foreseen in art. 27(5) could set a legal ground for such requests, through information contained in the product dossiers, according to the data requirements.
For unacceptable co-formulants of critical concern, it is agreed that no risk assessment is required. Only (self-) classification should be checked.

4.4. Who assesses?

The onus of providing the data should be on the applicants. The data should be normally evaluated according to the regulatory framework to which they were provided. This means that at the first stage, classification data and REACH registration reports should be assessed by REACH and/or

CLP authorities, co-ordinated by ECHA. However, with regards to the tremendous number of registration dossiers submitted, the capacities of MSs and the priority set in the rolling plan for chemicals not relevant to pesticides, it may take a very long time before the assessments provided in Reg. (EC) 1907/2006 will be available.

Pesticide authorities, and specifically MSs having notified unacceptable co-formulants under sections 3.2 to 3.3, need to request to notifiers and assess relevant data and evaluate draft Co-formulant assessment reports submitted by applicants. The scope of such evaluations should be defined: should it be restricted to the use as co-formulants or go beyond the PPP use when a scheme for cumulative risk assessment will be available?

The work may be also shared between pesticide and chemical authorities, e.g. REACH authorities may set EU end-points and PPP assessors may use them for the exposure evaluation.

Member States should be allowed to set proportionate fees in order to recover the expenses for the assessment of candidates for annex III.

4.5. How to assess?

Taking into account the data reasonably available, a discussion should define whether end-point reference values could be set. In case the end-points would be the same as those requested for active substance assessments, there is no need to develop a specific procedure for co-formulants. However, considering the possibility to rely on data submitted under REACH, the end-points differ, quantitatively and qualitatively.

Where the end-points relate to different concepts, the risk assessment may be performed in an alternative (qualitative) way. As a first tier, REACH exposure scenario could be used as worst-case surrogate.

Where no end-points could be derived from the available data, MSs and/or COM should be allowed to legally request further information/data.

For co-formulants (and active substances) sharing the same qualitative and quantitative toxicity profile, the potential exists that they act additively with other co-formulants and/or with the active substance(s) and that a combined risk assessment would be required. However, as there is little experience of applying such methodology at present, it has been proposed that for the time being a combined risk assessment should only be applied to multiple (2 or more) active substances within a product, and not to potential unacceptable co-formulants. When sufficient experience has been gained, the combined risk assessment methodology should be extended to include co-formulants.

Art. 29(6) calls for a cumulative risk assessment for formulated products but up-to-now very few data are available and technical issues regarding the models to use have to be solved beforehand. A first tier assessment may however be performed, taking into account safety factors to cover the

uncertainties. For non-dietary exposure, additivity, dissimilarity and synergism could be assessed according to this principle. For dietary exposure, such an assessment is worth if a wider range of sources of exposure (outside of PPPs) is taken into account.

4.6. Outcomes

The outcomes of the evaluation will be a draft Co-formulant Assessment Report (CoFAR) from the evaluating MS (eMS). It should be shared and commented by other MSs, Commission and EFSA. Stakeholders, including all the manufacturers, should be able to comment on the CoFAR. Where necessary a peer review could be arranged.

The CoFAR should clearly state whether a risk was identified. If a risk is identified, the conclusions should determine whether this risk exists for all or specific formulations and/or uses. If not, the unacceptable situations should be described.

4.7. Translation into a regulation

Commission should prepare a draft implementation regulation according to art. 27 and art. 79(4). Annex 3 will be divided into two sections, depending on the criteria which lead to add a co-formulant. The first section will list co-formulants which cannot be used in any circumstances, whereas the second one will contain a table where non acceptable situations are identified for co-formulants.

Regulations amending Annex III should specify timescales for withdrawing extant authorisations of products which contain the listed co-formulants, depending on the reason for their listing. The check whether an authorised PPP contains unacceptable co-formulants should be performed during the renewal of the authorisation at last.

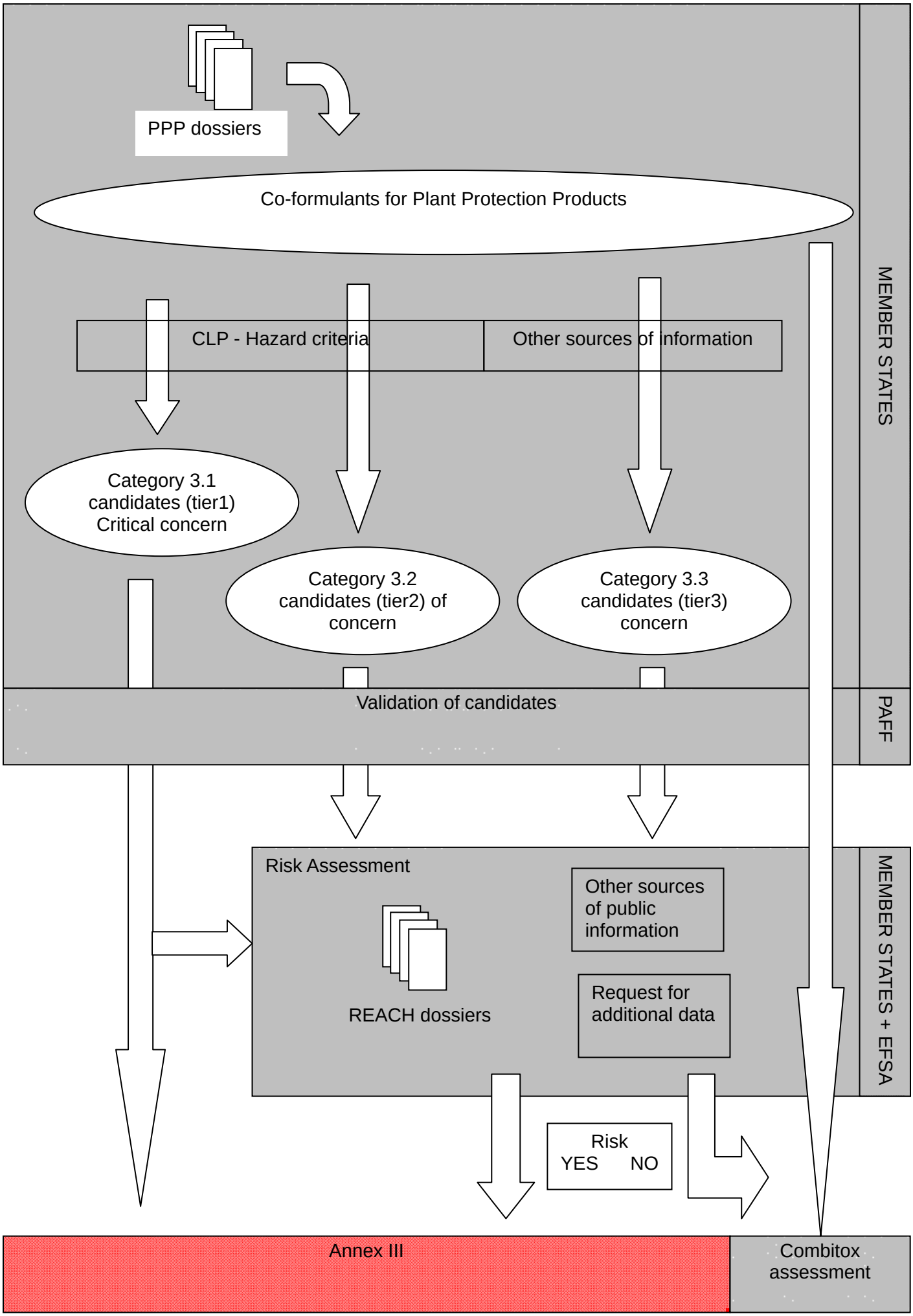
5. Interim measures and implementation steps

Interim measures may be implemented in order to allow concerned authorisation holders to submit updated dossiers where the unacceptable co-formulant would be substituted. Such a transitional period is not applicable to co-formulants of critical concern. It should be noted that the grace period as provided in art. 46 may not be long enough to allow applicants to submit a new formulation and get the decision by the end of the zonal assessment.

This transition may be longer for the first population of annex III as a lot of PPPs may be impacted.

The current provisions of art. 81 allow MSs to apply national laws for co-formulants not included in Annex III'. From the 14 June 2016, MSs may temporarily prohibit or restrict the application of an

unacceptable co-formulant on their territory. It shall immediately inform the other MSs and the Commission thereof and give reasons for its decision. The report mentioned in section 4.1 contains all the information required for such a notification. This procedure may be used when a MS identifies an unacceptable co-formulant during the assessment of a new product, in order to ban this co-formulant before the product is authorised and not later.


PPP dossiers
Co-formulants for Plant Protection Products
MEMBER STATES
CLP - Hazard criteria
Other sources of information
Category 3.1 candidates (tier1) Critical concern
Category 3.2 candidates (tier2) of concern
Category 3.3 candidates (tier3) concern
Validation of candidates
PAFF
Risk Assessment
Other sources of public information
REACH dossiers
Request for additional data
MEMBER STATES + EFSA
Risk
YES NO
Annex III
Combitox assessment