ECPA comments on Com discussion paper on unacceptable co-formulants rev4 29-4-2016

Line No	Page	Section title	Comments (including proposed text changes)
		General comments	Given the general nature of co-formulants used in pesticides and for efficiency purposes, and as already proposed earlier by ECPA, co-formulants should be solely regulated by the REACH chemical regulation.
		General comments	Implementation rules for the inclusion in annex III should be streamlined and confined only to assessments of intrinsic co-formulant properties. Formulation and/or use specific risk-assessments of PPPs considering co-formulant and a.i. toxicity combination is out of scope of annex III listing
		General comments	Overall the hazard based triggers for the first tier criteria (essentially SVHC) are broadly what ECPA already proposed (3.1 “critical concern”), as this anyway reflects REACH authorisation targets for removal from the EU market. However, REACH authorisation effectively puts in place a justified phase-out period on the basis of a socio-economic and alternatives analysis. Such an approach would be a significant improvement to smooth out the impact of any unexpected large reformulation activities.
		General comments	The second tier criteria (3.2 & 3.3 “of concern”) stray into risk assessment of individual formulations, with an outcome of “banning” as a possible result for inappropriate selection of risk management measures or use rate.
		General comments	Several measures have been proposed where the impact has not been fully appreciated. A full impact assessment must be carried out if they are not removed. Furthermore, clear consequences caused by listing under 3.1 & 3.2 must be given e.g.: - Clear limit must be set up to which a listed co-formulant could be intentionally added to a PPP - Clear limits must be set if an annex III listed co-formulant is impurity itself in other co-formulants or a.i..proposal: limits set by 1272/2008 (CLP).
		General comments	MS/COM appear to have effectively proposed a co-formulant review program, in parallel to REACH, but are unlikely to be able to deal with the additional workload, if such assessments are to be carried out correctly.
		General comments	Given the expected potential impacts of the MS / COM proposal, reasonable timelines and transition periods should be defined
		General comments	Given the number and fundamental nature of the comments provided here, these comments should not be construed as a complete and definitive critique of the discussion paper.
		Administrative comments	Clear definitions and consistent use of e.g. “applicant”; “notifier”; “registrant”; … is needed
1	1	Header	Title of the document indicates rev.3, whereas the file name indicates rev. 4. Versioning consistency should be established by MS / COM before circulating any document for commenting.

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10	1	1. introduction	*"... some guidance may be needed...of critical co-formulants"* As already reported, harmonized risk assessment of co-formulants should be performed under the horizontal REACH regulation. Furthermore, the wording is too weak. It should say "guidance will be required, so that MSs can perform a harmonized risk assessment". Otherwise it will lead to loss of harmonization and proportionality across member states, with different standards of protection for human health or environment. This is against EU principles. Finally, MS / COM have defined later in the document Tier 1 co-formulants, namely co-formulants of "critical concern" for which a risk assessment is not required for their selection as unacceptable co-formulants. This statement is contradicting the MS / COM proposal. Wording should be adapted.
15	1	2 Legal basis	Proposed change:"…*on Uniform principles and Regulation (EC) 284/2013 on data requirements for plant protection products."*
32 > 35	1	2.1. regulation (EC) 1107/2009	Proposed correction: *"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 about to be banned.~~"* Article 29(1)c states a PPP shall not be authorised for placing on the market where a constituent co-formulant is listed in Annex III. Neither Article 27 nor Point 22 of the 1107/2009 recital states that Annex III should act proactively (i.e. as a review program for co-formulants), or act on previously authorised formulations.
50 > 52	2	2.2 Regulation (EU) 546/2011 on uniform principles for evaluation and authorisations	The provisions of Regulation (EU) 546/2011 require the risk assessment of substances of concern in individual plant protection products. These provisions were not foreseen to result in the "banning" of a co-formulant as a result of non-approval (e.g. they only consider the GAP for the formulation at hand).

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69 > 75	2	2.3 Regulation (EU) 284/2013 setting the data requirements for plant protection products	Proposed change: *"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 provided as part of REACH registrations for co- formulants, where this is considered relevant."* Section 1.4.3 of regulation (EU) 284/2013 sets out the information requirements to be provided for co-formulants. It should be noted that the primary identifiers are for substances, with mixture identifiers (e.g. tradename) as additional information. Section 1.11 of Regulation 284/2013 requires a clear link to REACH and CLP legislation. Proposed deletion: ~~*"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."* Regulation 284/2013 does not set out requirements for active substances, but rather the formulation. Finally, performing test(s) on substance co-formulants, which the plant protection industry doesn't own, could be critical and raise issues with REACH over data sharing, inquiry, testing proposal and Downstream User provisions.
80 > 86	3	2.4.Horizontal and other regulations on chemicals	Proposed change: "*It should be noted that Art. 15(1) of REACH considers active substances as already registered where listed in Annex I to 91/414/EEC (considered to be equivalent to Annex I to 1107/2009), or one of the working lists to 91/414/EEC. Because co-formulants were never listed in Annex I to 91/414/EEC, these cannot take advantage of Article 15(1).* ~~*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.*~~ *"Substances which are used in plant protection products are exempt from the provisions of REACH authorisation for this use (Annex XIV).* ~~*The use of restricted substances listed in Annex XIV of REACH as co-formulants falls only under the provision of Reg. EC 1107/2009."*~~ The reference to setting rules for co-formulants is not relevant, as this was not part of the legal requirement. Confusing reference to Restriction (Annex XVII) and Annex XIV.

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89 > 92	3	2.4.Horizontal and other regulations on chemicals	*"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"* Correct reference(s) to CLP regulation should be done since DSD and DPD regulations are now withdrawn. Furthermore, this statement is inconsistent with the criteria laid out in the section 3 of the documents. Here all CLP hazardous endpoints would be considered of concern for a subsequent selection as potential unacceptable co-formulants.
94 > 95	3	2.4.Horizontal and other regulations on chemicals	Proposed change: '*Maximum use should be made of available information, including valid use of QSAR using ECHA guidance (Chapter R6) and read-across following the ECHA Read-across assessment framework (link: http://echa.europa.eu/support/grouping-of-substances-and-read-across).*"
96 > 98	3	2.4.Horizontal and other regulations on chemicals	Proposed change: *"~~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~~"* This section is based on the miss-conception that the notifier of a co-formulants is the same company as the one seeking market access of a PPP under 1107/2009. This is rarely (almost never) the case. The request for raw data (understood here as full study reports) fails to recognise that the applicant under PPPR is in nearly all cases not the data holder, and lacks the legal mechanisms to achieve access to this data. It must be stressed that access to full study reports is not a requirement to perform a risk assessment. The REACH robust study summary concept is conceived to provide all the necessary information, and to call this into question undermines one of the fundamental aspects of REACH. While it has to be acknowledged that some robust study summaries submitted to date have not been the highest quality, the aim should be to improve these specific cases rather than lose these gains in efficiencies. Any supplementary data requirements to be set must recognise the role of the PPP applicant as a Downstream User under REACH, and their role and obligations under that legislation. A full impact assessment must be carried out, particularly if these data requirements trigger vertebrate testing.

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102 > 106	3	2.4 Horizontal and other regulations on chemicals	Proposed change: "~~*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.*~~" The guidance developed for the BPR has a fundamentally different aim, to provide a proportionate framework for carrying out a risk assessment under a legislative scheme requiring explicit risk assessment for each hazardous substance, for every approved formulation. The BPR does not make any links to the risk assessments required under the horizontal REACH legislation, and missed this opportunity for efficiency gain, necessitating the tiered approach in guidance. The requirements of PPPR Article 27 are not how to carry out a risk assessment for an individual formulation, but to identify co-formulants which should be banned from use across all PPP.

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109 > 114	3	3. Criteria for the identification of unacceptable co-formulants	Proposed change: *"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~~".* This whole section is not correct and not consistent with definitions and descriptions provided in Reg. 1007/2009 for co-formulant. Under Reg. 1107/2009, Article 2(3)(c) describes "co-formulant" as "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". Art. 3(2) defines SUBSTANCE and Art. 3(3) defines MXITURE. Reg. 1107/2009 does not mention "unique identifier", or "group of co-formulants", nor reference is made to commercial label of co-formulant. Furthermore, it is basically impossibile to identify mixtures by a unique identifier (and surely not by any trade name). Also, many mixtures would be protected as trade secret by the manufacturer, and the composition would not be made available to the agro-chemical companies. If COM desires to regulate such mixtures, it must provide for a specific scheme with their manufacturers, not with the PP companies which are only the downstream users of such mixtures. Moreover, processes in place in EU to manage chemicals are all based on substance (REACH, CLP and related processes such CLH, registration, authorization, restriction) and Annex III must be consistent with other EU regulatory processes for chemicals. Proposed change: *"However unacceptable co-formulants may also be identified as a group, e. g. chemicals bearing the same functional chemical structure, however any such grouping must be unambiguous, and follow ECHA guidance on grouping of chemicals, and the Read-across assessment framework."* Furthermore, this suggests that the chemical / toxicological properties are defined by a functional group alone and not as a consequence of the reactivity in combination with the pharmacokinetic properties of the chemical. E.g. low bioavailability would prevent toxic action. This needs more clarification on how this shall be done in practice. Proposed change: *"~~As co-formulants can be also technical grades or formulated chemicals (e.g. containing preservatives, biocides), it is decided to consider co-formulants as marketed and labelled accordingly~~"* Only chemical substances as defined under REACH should be listed in Annex III. The EC number, CAS number and / or IUPAC name should be used wherever available, recognising that by 2018 all substances manufactured/imported above 1t/year and registered should have an EC number (thus encompassing the vast majority of co-formulants).
116	4	3. Criteria for the identification of unacceptable co-formulants	Proposed change: " Regulation (EC) No 284/2013 does not stipulate suitable/specific testing methods in…"

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120 > 123	4	3. Criteria for the identification of unacceptable co-formulants	Proposed change: "*Proportionate data requirements under REACH are set by using the tonnage manufactured as a proxy for the potential for exposure to humans and the environment. ~~This is especially the case for~~ toxicity testing on PPP formulations usually addresses ~~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)acute~~ and some longer term studies are conducted ~~with the PPP according to current data requirements (Regulation (EU) 284/2013).~~*" This point addresses individual formulation risk assessment, which is not the intent for listing in Annex III, and the different approach to setting data generation under REACH.
126	4	3. Criteria for the identification of unacceptable co-formulants	Proposed change: *"competent authority on a case-by-case basis. Any data generation requested should be substance specific, and carried out using the mechanisms under REACH such that all the co-formulant/substance manufacturers are fully involved e.g. supply chain communication, inquiry, testing proposal, etc."*
128 > 133	4	3. Criteria for the identification of unacceptable co-formulants	*Proposed change: " 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 registrant self-classification (REACH dossier) are relevant. However, harmonised classification under CLP must be sort before any consideration for listing in Annex III, to ensure that MS arrive at the same conclusion as chemical regulators, all stakeholders are involved including manufacturers, and all available data is used.*" First, the stepwise risk assessment procedure is at odds with the Commission's statement that a co-formulant review program is not being set up. Secondly, this section appears to also refer to the CLP Inventory self-classification. Indeed self-classification of substances is available through the CLP inventory. However, this source of information is not stewarded by ECHA or COM, and such information cannot be used as a basis for "banning". A given substance might be linked to dozens of differing self-classifications depending on the suppliers, the impurities profile, and the data available at the moment of the CLP notification. Moreover, the classifications of concern in the Inventory may have been entered historically by suppliers who no longer supply into the EU market and/or due to impurities that not all suppliers have in their products. The CLP inventory must not be used as a trigger to ban co-formulant as the grounds for classification is not given or verified. This is critically important for CMR substances.
140 > 142	4	3.1. Co-formulants of critical concern	"*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.*" A full legal and scientific rational should be given for this. This sentence should be moved to the introduction.

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142 > 144	4	3.1. Co-formulants of critical concern	Proposed change: "*Under the critical concern, it is also proposed to include relevant chemicals for PPPs which uses are restricted or ~~banned~~ authorised according to Reg. (EC) 1907/2006, because the decisions made on classification under REACH~~were already based on a risk assessment~~.*" REACH restriction and authorization processes should be leveraged for the identification of unacceptable co-formulants. First, where relevant, the restrictions in REACH Annex XVII already apply directly to PPP and a redundant entry in Annex III should not be made e.g. nonylphenol ethoxylates. However Annex XVII includes restrictions which should not be in scope e.g. use of flammable substances in ornamental lamps etc. For substances already listed in Annex XVII which could be relevant, the classification for the substance will make it a potential candidate, thus making Annex XVII redundant. REACH annex XIV should be used for the identification of unacceptable co-formulants, since any risk assessment for Authorisation cannot have considered PPP applications, because these are exempt. Finally, this proposal clearly leads to double regulation and is deviating from the current European Commission effort on fitness check of chemical regulations.
145 > 146	4	3.1. Co-formulants of critical concern	Proposed change: *"candidates for inclusion in Annex III ~~without risk assessment. No exception is possible~~"* Article 27(1) a & b does not provide a basis for direct application of hazard based cut-offs, but requires an assessment of risk.
147	4	3.1. Co-formulants of critical concern	Proposed change: *"Mutagen cat. 1A or 1B, according to Annex VI Regulation 1272/2008.* *POP, or PBT, vPvB as determined by a relevant REACH process.* *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~~"* REACH processes must be used to arrive at agreed and harmonised classification based on all available data, involving all relevant stakeholders. Substances fulfilling those criteria and exceeding classification and labelling criteria only should be potentially candidate for inclusion in Annex III
153 > 154	4	3.1. Co-formulants of critical concern	Proposed change: "*Carcinogen cat. 1A or 1B with exception of genotoxic carcinogen cat. 1A or 1B, according to Annex VI Regulation 1272/2008.* *Toxic for reproduction cat. 1A or 1B, according to Annex VI Regulation 1272/2008."*
155	4	3.1. Co-formulants of critical concern	Proposed change: *"~~Endocrine disrupting properties~~"* Criteria for the identification of unacceptable co-formulants should be based on well-established and recognized scientific criteria and / or regulatory processes. Provided the ongoing developments on endocrine disrupting properties, and the lack of impact assessment in the current proposal, such criteria should not be included in the MS / COM proposal without any proper and comprehensive impact assessment as initially planned.

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157 > 158	5	3.1. Co-formulants of critical concern	Proposed deletion: *"~~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."~~* The REACH candidate list has been developed based on criteria overlapping with the tier 2 criteria presented in the Commission proposal (e.g: Respiratory sensitizers). In order to avoid confusion and inconsistencies, proposal is made to delete this criteria.
159 > 161	5	3.1. Co-formulants of critical concern	*Proposed change: « A risk assessment is not necessary in this case because intentional use of substances with these hazard classes would not be considered acceptable.~~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.~~ »* Uses in PPP are exempt from consideration under REACH authorisation.
162 > 164	5	3.1. Co-formulants of critical concern	*"~~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 must be set. For example, these impurities shall not be present at 0.1%, or a concentration triggering the classification of the technical co-formulant, whichever is the higher."* Appears to mix the concepts of exposure and intentional use. See REACH Article 3(24)

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168 > 182	5 > 6	3.2. Co-formulants of concern	Proposed change: *"... • 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;* • ~~*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.*~~*"* Section 3.2 and 3.3 are only acceptable for triggering risk assessment within the context of an individual formulation. They are not an acceptable basis for "banning" of co-formulants. Risk is a function of hazard vs exposure. Both human health and environmental exposure are multivariant functions, and as such conditions of safe use can be defined depending on the appropriate selection of operational conditions and risk management measures. Thus such consideration belongs in the case-by-case risk assessment of individual formulations. MS must not arrive at classification conclusions for these endpoints outside the REACH & CLP processes, without full stakeholder involvement (i.e. co-formulant manufacturer, chemical regulator). Furthermore, data at the formulation level could be taken into account for the deselection of such unacceptable co-formulants initially identified. Use of two out of three is clearly out of step with the PBT concept, and has no basis (or precedence) under chemical legislation. Data generation mechanisms under REACH may thus not be triggered to arrive at definitive conclusions. A full impact assessment of use of any such half-criteria on co-formulants must be carried out. Finally, unacceptable co-formulants should be regulated at the substance level to prevent any miss-understanding / miss-alignment regarding impurities and / or co-formulants mixtures, and to enable their harmonized and efficient regulation.

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188 > 201	6	3.3. Other potential unacceptable co-formulants	Propose deletion of paragraph General comment: This is too vaguely defined and if it so, it may open space for discretionary MSs agendas, which would lead to differences of protection of human health and environment in MSs. Furthermore, a full impact assessment must be carried out, considering the huge potential impact from widely used co-formulants and not a “light impact assessment check” as proposed by MS / COM. More specific comments: • Co-formulant vs active substance toxicity is not acceptable, as it depends on the toxicity profile of the active ingredient. Low toxicity active ingredients will catch ALL classified co-formulants. • Co-formulants enhancing active substance toxicity would require listing of the relevant active substances in Annex III along with the co-formulant substance. • Use of presence of an OEL is unacceptable. For example, OEL have been set for dust. The criteria is redundant, because if there is a concern then classification will anyway trigger. Furthermore, appropriate risk assessment is already carried out for the setting up an OEL. Hence, this is again double regulation. • For the definition of categories, see previous comments regarding rigorous justification of any categories using full ECHA guidance and read-across assessment framework. Without any further clarification, all co-formulants could be seen as candaditates for annex III inclusion.
211 > 212	6	4.Decision-making process on unacceptable co-formulants	*"...have not been registered according to REACH. "* To ensure consistency, this process should not start before June 2018, or before list of all registered substances is published by ECHA.
212 > 213	6	4.Decision-making process on unacceptable co-formulants	Proposed change: *“~~MSs should also pay particular attention when the preservatives have not been notified or not approved according to Reg. (EU) 528/2012.~~”* Regulation 528/2012 does not cover preservatives for PPP use. A preservative is regarded as co-formulant under 1107/2009.
216	7	4.Decision-making process on unacceptable co-formulants	*"chemical name"* IUPAC name is more appropriate that chemical name, in order to ensure a consistency across EU when discussing a chemical.
216	7	4.Decision-making process on unacceptable co-formulants	"*trade name"* Trade names (not monitored under chemical management processes) should not be considered as data and information will be available on the chemical/CAS Nr/EC Nr and not on a trade name.

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217	7	4.Decision-making process on unacceptable co-formulants	*"mixture"* It will be virtually impossible in many ways for the MSs to obtain all this information from multiple suppliers.
217 > 218	7	4.Decision-making process on unacceptable co-formulants	*"the respective information on impurities if relevant for the proposal"* Pesticide authorization holders can only rely on their suppliers safety datasheets for the disclosure of such information.
221	7	4.Decision-making process on unacceptable co-formulants	*"self-classification"* As previously stated, reference appears to be to the CLP Inventory. Self-classification from the CLP inventory must not be used. Self-classification in REACH registrant dossiers should only be used for the purposes flagging for involvement of all stakeholders through harmonised classification process (CLH). Only after CLH has been formally set should this classification be used to meet criteria for Annex III.
224	7	*4.Decision-making process on unacceptable co-formulants*	*"plant protection products of concern in the reporting Member State"* It is not specified if the MS must consider: - Only the one PPP being registered, or - All the PPP containing the co-formulant and registered in the given MS, or - Randomly selected PPP containing the co-formulant, - Existing PPP or new PPP. The section must clearly state what is expected from the MS in proposal thoroughness.
225	7	4.Decision-making process on unacceptable co-formulants	*"justification for inclusion in Annex III"* Details on all the GAPs must be included across all formulations containing the substance, across all member states, to demonstrate that the concern is consistent and not just an outlier which is better dealt with by simple non-approval of the individual formulation, or use of a lower use rate, etc.
227 > 228	7	4.Decision-making process on unacceptable co-formulants	*"consideration if the co-formulant belongs to a group or "category" of substances which should be included in Annex III"* See previous comments on rigorous justification of grouping and categories, in addition a simple mechanism for the removal of individual substances from such categories is required E.g. data available demonstrating that the co-formulant does not share the same properties as other members of the group should be sufficient to allow for an exclusion/removal.
230 > 232	7	4.Decision-making process on unacceptable co-formulants	"*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."* All stakeholders must be involved: all holders of authorisations involving use of the co-formulant must be included, including all manufacturers/importers of the co-formulants which are being sold to the applicants.

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236 > 243	7	4.2.1. for specified co-formulants of critical concern	*Proposed change: "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~~.* *For the remaining criteria, the use of the ~~officially populated REACH candidate list,~~ REACH annex XIV list, REACH annex XVII and POP list should be leveraged and lead to, when relevant, a regulatory proposal, from the Commission to list those co-formulants on Annex III under co-formulants of critical concern."* It should be noted ECHA has developed a transparent process to identify substance of concern, which enables the authorities to clearly identify which chemical shall follow REACH processes such Authorization, Evaluation or Restriction or CLH: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
248 > 259	7 > 8	4.2.2. for co-formulants of concern and other potential unacceptable co-formulants	Proposed change: *"A risk assessment scheme along with a co-formulant risk assessment guidance should also be built up, in order to provide harmonisation and consistency in the EU"* As highlighted earlier, harmonization, predictability, and consistency of risk assessment for co-formulants is critical to the industry. To this end, a co-formulant risk assessment guidance should be proposed along to the current MS / COM proposal on the identification of potential unacceptable co-formulants.
249 > 250	7 > 8	4.2.2. for co-formulants of concern and other potential unacceptable co-formulants	Proposed change: *"Outputs from REACH scenario or Biocide Guidance for Human Risk Assessment and environment could be used for first tier assessment"* ECPA has put significant effort into the development of publically available tools and guidance to efficiently as possible carry out REACH screening level risk assessments independent of individual formulations.

Line No	Page	Section title	Comments (including proposed text changes)
253 > 260	8	4.3. What to be assessed?	Proposed change: *"Co-formulant substances manufacturers shall comply with REACH and CLP requirements. This means that they should provide a classification ~~proposal~~ and data to ECHA for co-formulant substances 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. An ~~proposed~~ assessment of this dataset should be submitted to ECHA, as part of the registration process. 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 (CoRAP), updated every year by ECHA ~~the competent standing committee (CARACAL)~~.* Under the REACH regulation the burden of proof is given to the registrant. Indeed, the manufacturer or importer is legally responsible for the "proposed assessment" supplied in the REACH dossier. Furthermore, it should be noted that the REACH substance evaluation does not intent to evaluate all substances under REACH but rather intents to target and clarify any concern for a selected number of substances. This process could be simply leverage to clarify any concern for a co-formulant. Substances with wide dispersive use are already priorities by the ECHA for evaluation.
262 > 263	8	4.3. What to be assessed?	*"For certain specific niche co-formulants, the submitted dataset may not be sufficient for a comprehensive risk assessment."* Co-formulants are not substances engineered to be biologically active, and as such it is not proportionate to require equivalent levels of data, nor to assume that such data is inherently required.
264 > 267	8	4.3. What to be assessed?	*"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 minimum data under REACH are two acute Ecotox studies, and three for all co-formulants manufactured in significant quantities. This is compensated for by use of 1000x assessment factor. If safe use cannot be demonstrated, higher tier data can and <u>must</u> be generated under REACH, irrespective of the tonnage band, including for terrestrial ecotox. Thus, existing REACH dossier and substance evaluation processes could be leveraged.
268 > 269	8	4.3. What to be assessed?	*"The end-points set according to REACH (DNEL or aquatic PNEC) are not in line with those usually used to perform pesticide risk assessment"* The REACH DNELs and PNECs are typically more conservative than the values used under PPP. i.e. chronic exposure for 8h/day is assumed for workers, and a typical 1000x assessment factor is used for PNECs.
270 > 271	8	4.3. What to be assessed?	Proposed change: *"~~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~~"* Full study reports are not a prerequisite to producing a robust risk assessment. The requested information under Regulation 284/2013 for co-formulants (where relevant) in fact only refers to <u>robust study summaries</u>, and not full study reports

Line No	Page	Section title	Comments (including proposed text changes)
273 > 274	8	4.3. What to be assessed?	*" 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"* The discussion paper sets expectation that co-formulant would need a full REACH Annex X dossier (point 4.3 "upgrading to the highest volumes chemicals"), with the potential outcome to have to generate more data. The REACH requirement to demonstrate safe use has the flexibility to generate additional data should a risk assessment require this. Further then, on top of additional costs for the industry which might not prove to add value to the overall safe use of the substance in PPP (as a risk assessment is run on the whole PPP, containing the co-formulant), the agrochemical company will face issues to run such studies and collect data on substances/mixtures which are proprietary, as co-formulants are mostly purchased from third companies. Furthermore, REACH requires data are generated on substances and not on mixtures, and REACH Downstream User obligations on inquiry, testing proposals, chemical safety reports, and communication back up the supply chain would still apply. Please note that the legislation proposed by COM for fertilisers only suggests increasing data requirements to Annex VIII, in a case where significantly fewer substances can be expected than for co-formulants as a whole. Any suggestion to increase data requirements must involve a full impact assessment, including the number of animals to be used.
274	8	4.3. What to be assessed?	*"Raw data must be available to the risk assessors "* Co-formulants are mainly commodity chemicals coming from third companies, and Agrochemical companies are downstream users. Agrochemical companies do not have full access to the whole studies, and might not have the legal possibility to ask for the whole studies to their suppliers. Therefore the COM will have to set legal framework to enable the access to raw data. Furthermore, even registrants who are the applicant's supplier under REACH may not have this data, but only letters of access from a lead registrant who holds the original study. See also previous comments on lack of legal requirement under 284/2013 for full study reports, and ability to carry out risk assessments using robust study summaries. Given that the same information must be supplied to the ECHA but in robust study summary form, the implication is that the MS expects to find information in the full study report allowing it to arrive at a different conclusion than that based solely on the robust study summary, and hence divergence of regulatory decision making can be expected. Any suspected deficiencies in a robust study summary must be addressed there, must be addressed on a case-by-case basis, and does not require blanket requests for full study reports.
281	8	4.4. Who assesses?	*"The onus of providing the data should be on the applicants "* Co-formulants are mainly commodity chemicals coming from third companies, and Agrochemical companies are downstream users. Agrochemical companies do not have full access to the whole studies, and might not have the legal possibility to ask for the whole studies to their suppliers. Therefore the COM will have to set legal framework to enable the access to raw data.

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284 > 287	8	4.4. Who assesses?	Proposed change: *"~~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~~."* The priorities set for CoRAP evaluation are fully documented on the ECHA website, transparent, and fully relevant to plant protection products. http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan There is no better regulatory framewok for the evaluation of co-formulant substances. It is to be noted that evaluation is targeted such that the substances of greatest potential concern are addressed first and as such already prioritize the identification of potential unacceptable co-formulants along with other REACH processes.
288 > 290	9	4.4. Who assesses?	"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" MS / COM proposal to submit co-formulant assessments clearly duplicates the existing REACH registration process. Furthermore, as already highlighted above, COM would have to set a legal framework to enable the access to raw data, which is not actually required.
290 > 292	9	4.4. Who assesses?	*"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?"* "Cumulative" risk assessment takes place under REACH, and is the responsibility of the ECHA. PPPR has no legal basis for assessment beyond PPP applications.
293 > 294	9	4.4. Who assesses?	"*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."* As highlighted earlier, harmonization, predictability, and consistency of risk assessment for co-formulants is critical to the industry. To this end, a co-formulant risk assessment scheme along with a guidance should be proposed along to the current MS / COM proposal on the identification of potential unacceptable co-formulants. The guidance should clarify the roles and responsibilities of each stakeholders in this process (e.g: ECHA versus EFSA, MSs, COM…) That being said, an assessment under the pesticide regulation is clearly of duplication of any effort already initiated under REACH and should be avoided.
295> 296	9	4.4. Who assesses?	"*Member States should be allowed to set proportionate fees in order to recover the expenses for the assessment of candidates for annex III."* It is not acceptable to have the industry to pay dual fees for the same chemical: REACH registration fee (registration dossier will contain risk assessment for use in PPP) and Annex III risk assessment fee (for MS to run risk assessment on co-formulant in PPP).

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299 > 300	9	4.5. How to assess?	*" Taking into account the data reasonably available, a discussion should define whether end-point reference values could be set "* The wording must be specific enough to not be subject to interpretation. Words such "reasonably" are not acceptable in a regulation. This is too vaguely defined and if it so, it may open space for discretionary MSs agendas, which would lead to differences of protection of human health and environment in MSs.
304 > 306	9	4.5. How to assess?	" *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."* This section must be clarified.
307 > 308	9	4.5. How to assess?	*"Where no end-points could be derived from the available data, MSs and/or COM should be allowed to legally request further information/data."* Regulation 284/2013 already provides this basis, as does REACH. However, any such requests must be fully co-ordinated with the broader regulatory activities under REACH and CLP.
309 > 315	9	4.5. How to assess?	Proposed change: *"~~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"* The exact wording in Art. 29(6) of Reg. (EC) 1107/2009 is: "…interaction between active ingredients, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products". This does not necessarily imply a cumulative risk assessment and should be part of PPP-formulation evaluation only! Hence this comment must be placed in the respective appropriate pesticide guidance.
320 > 321	10	4.5. How to assess?	*"For dietary exposure, such an assessment is worth if a wider range of sources of exposure (outside of PPPs) is taken into account."* REACH assesses man exposed via the environment at a basic level, considering these additional sources.

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324 > 325	10	4.6. Outcomes	*"The outcomes of the evaluation will be a draft Co-formulant Assessment Report (CoFAR) from the evaluating MS (eMS)"* In the current proposal, it is planned to have CoFar's of all potentially relevant co-formulants for each PPP during the preparation of the dRR, this would increase the workload of the MS and the planned time until authorization tremendously. Before proceeding any proposal, MS / COM should clearly also assess any impacts on their side. With the current CoFAr proposal, MS will have to search for all PPP's containing such co-formulants and simultaneously inform all companies, on top of the manufacturer SIEF's under REACH - an administratively virtual impossible provision. The text seems erroneously be based on the assumption that co-formulants are PPP specific and property of the same registrant as the PPP in which they are contained.
326	10	4.6. Outcomes	Proposed change: *"It should be shared and commented by other MSs, ECHA, Commission and EFSA. Stakeholders, including all the potential REACh registrants (i.e: manufacturers and importers), should be able to comment on the CoFAR. Where necessary a peer review could be arranged."* As the authority responsible for chemical regulation, the ECHA should be primarily consulted.
328 > 330	10	4.6. Outcomes	*"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."* Other MS must contribute to the impact assessment for formulations authorised containing the substance.
339 > 340	10	4.7.Translation into a regulation	"*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"* Any legally binding timescales for withdrawing existing authorised formulations must take into account the potential scenario for a commodity co-formulant where very large number of formulations across multiple indications and companies are affected, and the ability to reformulate replacement products in parallel.
346 > 349	10	5. Interim measures and implementatio n steps	*"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."* Applying the art. 46 grace periods is indeed not sufficient. Significantly longer minimum transition periods should be defined. Based on the complexity of the cases and potential individual impacts, grace periods should be defined on a case by case basis considering the number of formulations impacted.

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350	10	5. Interim measures and implementation steps	*"This transition may be longer for the first population of annex III as a lot of PPPs may be impacted"* Shorter transition periods are not warranted for later additions to Annex III, based on an expectation of fewer substances. The ability to reformulate and replace is primarily a function of the number of formulations which contain the given co-formulant. i.e. a single widespread co-formulant can pose greater difficulty than several co-formulants used in only one formulation each. This could take as a minimum four years. Moreover, provisions under the post AIII procedure do not allow a change of formulation during the review period, nor the submission of new data. Hence, no such replacement of a co-formulant can be provided under 1107/2009 in the present form Additional factors affecting the time required involve the ability to find a co-formulant which works functionally, and any additional studies which may be required.
353 > 355	10	5. Interim measures and implementation steps	*"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 MS can also choose to simply not approve the formulation. Alternative courses of action should there be a genuine cause for concern for human health or the environment, would be to submit a REACH Annex XV dossier to trigger harmonised classification, propose a REACH Restriction, propose for CoRAP Evaluation.
356 > 358	10	5. Interim measures and implementation steps	*"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."* This will significantly hinder the pesticide authorization process, while other existing regulatory processes would not be used / leveraged for the identification of potential unacceptable co-formulants.