

## IBMA comments:

On the draft proposal for a regulation repealing Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products, and its Annexes

### General comments on the document & annexes

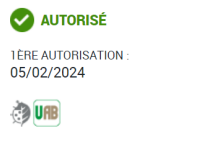
N°	Reference to the document Page/ Data point	Original Text in the DRAFT proposal	IBMA comment
1	Whole document	Entire document	<b>Comment: inclusion of a Biocontrol label</b> IBMA understands the EU Commission's goal is to use this regulation to orientate farmers to the more sustainable crop protection solutions, a goal which IBMA supports. IBMA believes that this Regulation revision is an opportunity to <b>include Biocontrol in the labels so farmers know whether or not they are using a biocontrol product</b> . This would be supporting the EU Agenda on sustainability by communicating to farmers that the product they are using is positively contributing to the EU agriculture transition. <b>The proposal as it stands would have the contrary effect by discouraging the use of biocontrol with the new proposed classification, as explained in the detailed comments.</b>
2	Whole document	Entire document	<b>Comment: inadequate introduction of new hazard criteria</b> It is IBMA's view that labels shall be used to communicate the results of the risk assessment and inform users of the best conditions for the use of the product as well as the restrictions of use resulting from the risk assessment conducted. The introduction of new hazard criteria during the review of the Label Implementing Regulation is inappropriate (e.g. new hazard pictogram for bees). The new hazard criteria being included here goes against the Regulation 1107/2009, the Uniform Principles and (the Microorganism) Data Requirements. The document should be cross-checked to ensure this revision of an Implementing Regulation for Labels is not establishing new criteria which are not aligned with the main Secondary Union law for PPPs (Regulation 1107/2009).
3	Whole document	Entire document	<b>Comment: timeline for implementation (digital labels)</b> IBMA supports label digitisation, one of the stated goals of this regulation and recognises the role of digital labelling in supporting farmer record keeping on plant protection products. IBMA believes that the 1st of January 2026 application date to be too soon to allow a smooth transition towards digital, machine-readable labels in all 27 EU MSs. IBMA would suggest a smooth transition under article 14 to ensure that Member States and the industry

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			<p>could prepare for the implementation of digital labels according to their specific needs. IBMA suggests that a more realistic application date should be proposed, 3 years from entry into force, or the 1st of January 2028, to allow business operators to set digital tools to allow for compliance with this Implementing Regulation. An effective digitization of label might not be possible for SMEs and for countries not participating in the pilot phase of implementation.</p> <p>Please also consider that some MS already have Digital Coding implemented on labels for product tracking and reporting. Would this be the same QR code or there will be multiple QR codes on the labels leading to different datasets?</p>
4	Page 2, Point 7	To ensure as much as possible a uniform communication to the user of plant protection products around the European Union, the format of the additional phrases notified by Member States have been harmonised in order to be included in this Regulation. At the same time, flexibility needs to be provided so that the phrases again could be adapted to the risk mitigation measures identified by the risk managers when authorising a plant protection product pursuant to Article 36(3) of Regulation (EC) No 1107/2009. Therefore, Annex V prescribed the format of such phrases while the specific content may be adapted.	<p><b>Comment:</b> IBMA welcomes the attempt to harmonise the communication of hazard and risk to growers across the Member States. This is a step forward towards alignment. IBMA agrees with the principle to have agreed sentences for the product labels. It is IBMA assumption that Member States agreed with the proposal and therefore national sentences (as required today) would no longer apply, at least at the start of the implementation. It would be important to get confirmation that all Member States are aligning their existing national sentences to prevent conflicting sentences on the products labels, coming from this EU Implementing Regulation and the existing National rules</p> <p><b>Suggestion:</b> We suggest that national legislation is revised to ensure consistent communication to the user. To that goal, we recommend the inclusion of a paragraph that states that MS additional sentences shall neither conflict nor overrule the sentences listed in this Implementing Regulation. We also recommend incorporating placeholders in sentences to indicate which parts of the standard phrases can be adapted.</p>
5	Page 2, Point 8	(8) The attribution criteria of some of the phrases of the Regulation 547/2011 were not always linked with the outcome of the risk assessment. This could challenge the harmonised way to attribute the relevant phrases to the label of plant protection products by risk managers in Member States. It is essential to have clear, transparent and harmonised attribution criteria for each of the phrases in order to facilitate the work of the risk managers in the Member States. Therefore, Standard phrases should be	<p><b>Comment:</b> This paragraph (8) is not in line with some of the proposals being made in the text. New criteria for classification are being introduced in this Implementing Regulation rather than revising the Label rules to better communicate the risks to the users of products assessed under the Uniform Principles. For example, the new sentence being proposed in Annex IV as a Hazard sentence, is not a result of a risk assessment. This is a misuse of an agreed precautionary sentence, applying the precautionary principle to microorganism active substances, being excessively extended by including a CLP-like statement to microorganisms without an assessment. The</p>

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		<p>assigned to the label to plant protection products for which the risk assessment according to the uniform principles show that restrictions of use or specific risk mitigation measures should be applied to protect human health and/or the environment. In addition, for certain groups of plant protection products such as fumigants, rodenticides or products for seeds treatment specific precautionary phrases and good practices recommendations should be systematically attributed, independently of the outcome of the risk assessment.</p>	<p>same applies to Annex III, which is not related to the risk assessment of the product and will likely result in misleading messages to the user using different products.</p> <p><b>Suggestion:</b> IBMA supports the statement, but new Hazard criteria should not be introduced in a revision of an Implementing Regulation for labels, therefore dismissing the risk assessment of the product under the Secondary Law provisions (Reg. 1107/2009). The purpose of the labels revision should be to communicate the results of the assessment of a safe and efficacious product that has been authorised under the conditions of use. It is a communication tool (Implementing Regulation) <b>of the results of a risk and efficacy assessment conducted</b> under Reg. 1107/2009 and the Uniform Principles, and applying the CLP Regulation for the final product classification. There seems to be a Legislative confusion between the scope of the CLP and Reg. 1107/2009: the PPP and its uses are regulated under Reg. 1107/2009, and the CLP rules are to be used for the classification of the product. But the product is regulated under Reg. 1107/2009 and not under CLP nor REACH, nor any other EU Chemical regulation. The criteria of CLP will apply but the PPP is regulated under the provision of Reg. 1107/2009, thus any changes on criteria (e.g. Bee cut-off value) does require a change in the PPP legislation.</p>

**Specific Technical comments on the DRAFT text:**

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6	Page 2, Point 11	In compliance with Commission Regulation (EU) No 283/20134 and the uniform principles set out in Commission Regulation (EU) No 546/20115, all micro-organisms are to be regarded as potential sensitisers until validated tests for assessing their sensitisation are available. Without prejudice to the standard phrases applicable according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, a specific precautionary sentence to warn against the potential sensitisation effects of micro-organisms should be included in this Regulation.	<p><b>Comment:</b> IBMA suggests rewording the sentence since this is not in line with the Data Requirements and the Uniform Principles (and the Explanatory Notes). According to the application of the “Precautionary Principle” set in the Maastricht Treaty, there is the need to inform the product user about the potential sensitisation until the negative can be proven by testing methods (if they are available). However, this precautionary sentence should not be discriminatory for microorganisms since there are no methods available to test the respiratory sensitisation for any plant protection product. Please note that the EFSA has stated in a study on Respiratory Sensitisers that “<i>it is not considered a general feature of bacteria to express sensitising properties</i>” (EFSA, 2010). Therefore, we request a fair treatment for microorganisms since science does not support a discriminatory application of the Precautionary Statement on Respiratory Sensitisation for microorganisms.</p>
7	Page 3, (15)	(15) The Farm to Fork Strategy adopted by the Commission in 2020, aims to reduce dependency on the use of chemical plant protection products, particularly those containing more hazardous active substances, as well as the risks associated with their use. To contribute to the Farm to Fork Strategy and facilitate the identification by the users of low-risk plant protection products under Article 47 of Regulation (EC) 1007/2009 as well as of plant protection products that contain a candidate for substitution under Article 24 of Regulation (EC) 1107/2009 or a low-risk active substance under Article 22 of Regulation (EC) 1007/2009, a coloured scheme should be included on the label of plant protection products.	<p><b>Comment:</b> IBMA understands the intention, but this would further hamper the use of biocontrol products and IBMA does not support the categorisation system being proposed in the diagram used in the Annex. <b>The majority of the biocontrol active substances (70% of all Biocontrol) is not low risk today</b>, due to an excessive use of the precautionary principle and the lack of objective criteria for granting “low risk” status to an active substance. Even if some active substances currently under the renewal processes could get low-risk status this will have no impact on product level since labels will be the ones authorised in 2025, i.e. likely that the active substances/product renewal will not be yet finalised. It will take several years until a certain number of biocontrol products could be low-risk, thus the relabelling of the products for 2026 (meaning the status of the product authorised in 2025) would give the wrong message to growers by assigning the categories C-orange to the majority of the microorganisms, place the majority of plant extracts/natural substances, and almost half of the pheromones in a dark orange category D, just above the candidates for substitution. This is extremely detrimental if the EU Commission and Member States truly want to increase the uptake of biocontrol products and promote its use by the growers.</p>

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			<p>The draft as it stands goes against the Farm to Fork goals and it will not promote biocontrol use, it would do the contrary. To facilitate achieving the Farm to Fork Strategy goal, a <b>Biocontrol category should be included</b> in the label so farmers can deliver on the EU goals by knowing when they are using a biocontrol product (which is already the case in France, under National provisions).</p> <p>To really promote the use of biocontrol, then this information should be included in the labels:</p> <ul style="list-style-type: none"> <li>- Low risk product</li> <li>- Biocontrol product</li> <li>- Product containing a Candidate for substitution</li> </ul> <p>A pictogram could be used for each of them with a Red for the CfS and a Green for the low-risk product and Biocontrol, for example.</p> <p>Please note that since the EU has no Biocontrol definition, some Member States did move ahead with it. Maybe this is the opportunity to consider such inclusion in the labels – there is no legal provision preventing it – and avoid yet another disconnection between MS in the single market.</p> <p>There are examples at Member State level of the implementation of a Biocontrol definition on the products labels to communicate to growers. France authorisation database (<a href="https://ephy.anses.fr/">https://ephy.anses.fr/</a>) for PPPs does include this information by using a pictogram to identify biocontrol products.</p> <div style="text-align: center;">  </div> <p>Please see the detailed comments for Annex VI (the colour diagram).</p>
8	Page 4, Art 1 (2)	(2) The information required by points (k) to (p) of Annex I may be indicated on a separate leaflet accompanying the package if there is not enough space available on the package.	<p><b>Comment:</b> Please note that the new version should list the required point from “m” to “r”, rather than from “k” to “p”.</p>

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9	Page 5, Article 4 (1)	<p>Without prejudice to Regulation (EC) No 1272/2008, the label of a plant protection product shall contain, where relevant, standard phrases for hazard communication as set out in Annex III.</p> <p>The label of a plant protection product containing micro-organisms as active substance shall include a standard phrase for hazard communication as set out in Annex IV.</p>	<p><b>Comment:</b> It should be differentiated the presence of hazard form the hypothetical potential of hazard, which until today, has not been substantiated with evidence but with the impossibility to prove the negative in science. It should be clearly communicated to the users as such to avoid confusion between the Hazard of Sensitisation and the Potential of Sensitisation.</p> <p>The separation of skin and respiratory is not appropriate because the potential for Respiratory Sensitisation could apply to every product, as there is no analytical method to disprove potential respiratory sensitisation for any of the PPPs and Basic Substances used in the EU today. Therefore, this sentence cannot be applied to microorganisms exclusively as this is discriminatory. Sensitisation is a chemical phenomenon, not a microbiological intrinsic property of microorganisms. We would therefore propose to revise the use of this sentence.</p> <p><b>Proposal for rewording:</b> The label of a plant protection product containing micro-organisms as active substance shall include a standard phrase <b>to communicate the potential sensitisation for hazard communication</b> as set out in Annex IV, <b>in accordance with Regulation (EU) No 546/2011, as amended by Commission Regulation (EU) 2022/1441 of 31 August 2022: “Micro-organisms may have the potential to provoke sensitising reactions”</b></p>
10	Page 6, article 7	The label of a plant protection product shall contain a coloured scheme that is directly visible to the user, as set out in Annex VI.	<p><b>Comment:</b> Please refer to the details on the Annex VI comment. Also, Art.66 (2) of Reg 1107/2009 on advertising low-risk should be checked: 2. The advertisement shall not include information in text or graphic form which could be misleading as regards possible risks to human or animal health or to the environment, such as the terms ‘low risk’, ‘non- toxic’ or ‘harmless.’</p>
11	Page 7, Article 14	<p>Transitional measures</p> <ol style="list-style-type: none"> <li>Plant protection products authorised or for which a parallel trade permit has been granted at the date of application of this Regulation shall comply</li> </ol>	<p><b>Proposal for rewording:</b></p> <ol style="list-style-type: none"> <li>Plant protection products already <b>authorised/renewed</b> or for which a parallel trade permit has been granted at the date of application of this Regulation shall comply only with the requirements of Regulation (EU) 547/2011.</li> </ol>

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		<p>only with the requirements of Regulation (EU) 547/2011.</p> <p>2. In case of applications for authorisation, as referred to in Article 28 of Regulation (EC) 1107/2009 submitted before the date of application of this Regulation, applicants may choose whether to apply the labelling requirements as set out in this Regulation or in Regulation (EU) 547/2011.</p>	<p>2. In case of applications for authorisation and <b>renewal authorisations</b>, as referred to in Article 28 of Regulation (EC) 1107/2009 submitted before the date of application of this Regulation, applicants may choose whether to apply the labelling requirements as set out in this Regulation or in Regulation (EU) 547/2011.</p> <p><b>Comment:</b> The intention seems to be based on the authorisation/renewal date of the product and not on the product being on the market (which means the PPP is already in the sales channel in the country, i.e. the placing on the market). IBMA suggests to further clarify that this refers to the authorisation/renewal decision date and not the placing on the market of the physical PPP.</p> <p>Also consider the inclusion of a Fac-simile being provided during the transition period instead of triggering product recalls and relabelling existing products on the other two points 1) and 2) since the decision dates on authorisation/renewal of products by MSs are not visible to applicants. We suggest the introduction of a third point 3) indicating clearly that this regulation shall only apply for new product authorisations and renewals submitted after January 2026.</p>

**Comments on the ANNEXES:**

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12	Page 1, Annex I (g)	<p>for active substances that are micro-organisms:</p> <ul style="list-style-type: none"> <li>- the number of active units per volume or weight of plant protection product, for example, colony forming units or international units per volume or weight, or any other manner that is most relevant to the plant protection action;</li> <li>- and the weight of active units per volume or weight of plant protection products.</li> </ul>	<p><b>Proposal for rewording:</b> for active substances that are micro-organisms:</p> <ul style="list-style-type: none"> <li>– the number of active units per volume or weight of plant protection product, e.g., colony forming units or international units per volume or weight, or any other manner that is most relevant to the plant protection action;</li> <li>– and the weight of <b>the active substance-units</b> per volume or weight of plant protection products, <b>if applicable</b>.</li> </ul> <p><b>Comment:</b> The term “active units” is likely a copy-paste mistake from the phrase below, it should refer to the active substance. The discussion of the content of active substances in w/w or w/v for microorganisms has been debatable regarding its meaning. In some products it has no meaning at all and no value for the grower. <b>The only point of having a value here is for the reporting databases of sales volumes in some Members States for the calculation and reporting of active substances volumes.</b> This is already included in the authorisation of the product and should just be on the label in case there is a meaning to have w/w in the product for the grower. An easy example: a Bt would be expressed in IU or CFU/g: two products with the same potency (e.g. min 32,000 IU) could have 5 g/kg, 25 g/kg or 90 g/kg w/w depending on the production process; yet for the grower the relevant unit will be the potency and adding w/w info will be confusing:</p> <ul style="list-style-type: none"> <li>- Product A: 20,000 IU, a.s. 100g/kg (will be used at higher dosage, but higher active substance w/w)</li> <li>- Product B: 90,000 IU, a.s. 5 g/kg (will be used at lower dosage, but less active substance w/w)</li> </ul> <p>The expression of w/w or w/v in the label is not always useful and can confuse the grower, as in the example case presented. For the annual reporting of sales quantities, such information is available in the national registries and authorisations of the products.</p>
13	Page 2, Annex I, Point (i)	(i) Formulation batch number and date of manufacture	<b>Proposal:</b>



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			<p>(i) Formulation batch number and date of manufacture (alternatively this information can be printed directly on the product packaging)</p> <p><b>Comment:</b> This information (batch and date) is typically printed on the packaging since label changes in certain Member States require pre-approval by the Agencies and it would make the production process unworkable. The Batch number and the data of manufacturing should not be part of the label (Regulatory Document) but be visible in the packaging, printed after the production of the product. Note well that Labels are pre-printed in advance of manufacturing the product, and they need to be ordered months in advance (when manufacturing date and batch number are not known).The manufacturing date and batch should therefore be printed/engraved on the packaging of the product and not part of the Label since this information is only available after the label has been printed, i.e. once the product is actually produced at the manufacturing plants. It would be useful to have this provision here to accommodate the operating practices at the manufacturing plants and prevent inconsistencies with Member States procedures.</p>
14	Page 3, Annex I, Point (r)	<p>(r) For plant protection products that do not contain micro-organisms, the expiry date for normal conditions of storage. For plant protection products containing micro-organisms, the label shall include the following:</p> <ul style="list-style-type: none"> <li>- Use before (to complement depending on the efficacy/safety studies).</li> </ul> <p>The expiry date shall be complemented with recommended conditions of storage of the product (for example, humidity, storage temperature, exposure to light of the package), safe disposal of the product and the packaging if they differ from the requirements for the standard phrases of Annex II.</p>	<p><b>Comment 1:</b> For microorganisms the existing sentence in the existing Label Regulation should be kept since there was a valid reason for it: microorganisms might have different expiries dates based on different storage conditions and therefore the sentence remains appropriate. Having 3 expiry dates for 3 different storage conditions would lead to much confusion at grower level and during inspections/enforcements actions. It is advisable to keep the existing sentence to account for this specificity of some microorganism-based products, where the manufacturing date shall be included and where necessary the expiry date under normal conditions of storage.</p> <p><b>Comment 2:</b> The sentence on safety and efficacy being proposed for microorganisms is unfair since it should be applicable to all PPP products and therefore not necessary here. <b>All plant protection products conditions should be set by the efficacy data and the safety studies.</b></p> <p><b>Comment 3:</b></p>

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			<p>Member States have different waste managing rules and provisions for packaging recycling/disposing. To avoid confusion, it should be stated that the National rules remain in place to avoid misunderstanding on the application of this implementing regulation.</p> <p><b>Proposal for rewording:</b> The expiry date shall be complemented with recommended conditions of storage of the product (e.g., humidity, storage temperature, exposure to light of the package), safe disposal of the product and the packaging, <b>according to Member State provisions on waste</b>, if they differ from the requirements of the standard phrases of Annex II.</p>
15	Page 5, Annex III	<p>RShb: Hazardous to bees. The phrase and the pictogram shall be assigned to any plant protection product for which a standard contact or oral acute LD50 endpoint on adult honeybees, bumble-bees or solitary bees is equal or below 11 µg formulation /bee. In case there are more than one datapoint for the formulation available, the one showing the lowest LD50 shall be considered.</p>	<p><b>Comment:</b> IBMA does not support the introduction of a new cut-off criteria for Bees based on a formulation volume and acute lab data without considering the risk assessment and the product uses. Toxicity to bees should be based on the risk assessment: a concentrate formulation (triggering the pictogram) can be diluted into a drip and a more diluted formulation (no pictogram) can be sprayed foliar and cause damage to bee, even though the pictogram was not in the product. Communication of product risk to bees should be based on the Risk Assessment and not defaulting to a LD50 laboratory value from acute studies, thus setting a new hazard criterion outside of the Regulation 1107/2009. It should be checked if such new hazard criteria can be introduced in the revision of an Implementing Regulation for labelling, overruling the text of Regulation 1107/2009, its Data Requirements and the Uniform Principles (where Hazard Quotients are used, e.g. Reg.2022/1441 Part A 2.5.2.3). IBMA is of the opinion that a risk assessment should be performed, in accordance with the Uniform Principles, considering the product and the exposure. If a new Hazard criteria of 11 µg product/bee is to be introduced for PPPs, then Reg.1107/2009 should be amended to introduce this new criterion. A product could have this pictogram on the label and then having a conclusion on the authorisation that the product is safe to be used with bees. This is confusing to the growers. On the pictogram itself, IBMA has reservation that it could be wrongly interpreted by grower as an efficacious product against wasps. The pictogram is very similar to the ones used for home-use insecticides and could lead to misuse of the products against wasps. In addition, this pictogram is also very similar to those from the UN GHS and CLP,</p>

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			<p>therefore creating possible confusion among users due to the co-existence of different sets of hazard pictograms and rules.</p> <p><b>Suggestion:</b> A positive pictogram with a happy bee (☀️) could be a solution to communicate with growers that a product is not harmful to bees and compatible with pollinators. After the product Risk Assessment, if there is evidence that the product and its uses will not be detrimental to pollinators, a happy bee pictogram (☀️) could be added to the label. This would also encourage the development of IPM programs to show the compatibility of the PPP use with pollinators.</p> <p>There are already examples implemented using such approach:</p> <ul style="list-style-type: none"> <li>- ANSES (France) is using the “bee” compatibility to communicate to growers that a product use is compatibility with pollinators; <a href="https://ephy.anses.fr/produits-substances-usages/produits-biocontr%C3%B4l%C3%A9s">https://ephy.anses.fr/produits-substances-usages/produits-biocontr%C3%B4l%C3%A9s</a> (The term “Bee” was therefore intended to respond to an agronomic need to intervene on plants during the flowering or exudate production period, while limiting the impacts of the treatment on pollinating insects).</li> <li>- FAO <a href="#">Guidelines on Good Labelling Practice for Pesticides</a>: “Specific claims on the safety of a product to bees, beneficial insects, fish, etc., when used correctly, are permitted, provided scientific evidence is available to support the claim.”</li> </ul>
16	Page 7, Annex IV	<p>ANNEX IV STANDARD PHRASE FOR HAZARD COMMUNICATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS</p> <p>1. STANDARD PHRASE FOR HAZARD COMMUNICATION (RSMO) RSMo: Contains a micro-organism as active substance. It may have the potential to cause skin and/or respiratory sensitisation.</p>	<p><b>Proposal for rewording:</b> STANDARD PHRASE FOR <b>POTENTIAL</b> HAZARD COMMUNICATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS 1.STANDARD PHRASE FOR <b>POTENTIAL</b>HAZARD COMMUNICATION (RSMO) RSMo: Contains a micro-organism as active substance. It may have the potential to cause <b>skin and/or respiratory</b>-sensitisation.</p>

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		<p>The phrase shall always be assigned to all plant protection product containing micro-organisms as precautionary statement.</p>	<p>The phrase shall always be assigned to all plant protection products containing micro-organisms as precautionary statement, <b>unless there is evidence at the strain/species level that the statement should not apply according to the Uniform Principles.</b></p> <p><b>Comment:</b></p> <p><b>Please note that we emphasise that potential respiratory sensitisation should be assigned to all products and not exclusively to microorganisms. Since to date there is no method to disprove respiratory sensitisation, in the case of mentioning the separation, only skin sensitisation should be mentioned.</b></p> <p>The proposed sentence is not based on any criteria, but it is used as a default precautionary sentence applied to all products containing microorganisms used as plant protection products. Therefore, it should be mentioned as a <u>Precautionary Statement</u>. The sentence “Micro-organisms may have the potential to provoke sensitising reactions” has been agreed because there are no available methods to prove the negative. Citing the UP (Commission Regulation (EU) 2022/1441 of 31 August 2022):</p> <p><i>“All shall therefore specify, as a non-specific risk mitigation measure, that personal protective equipment (...) ”micro-organisms shall be regarded as <b>potential sensitisers until a test method is validated <u>and unless it is established by means of relevant information that there is no risk of sensitisation.</u></b>”</i></p> <p><u>Splitting between Skin and Respiratory:</u> Note that there is no separation between Skin and Respiratory sensitisation in the UP and the reason being that there are no methods to prove no respiratory sensitisation of chemicals (incl. low risk) and this would trigger a default statement across all products, not only for microorganisms.</p> <p><u>The Uniform Principles for Microorganisms should be followed:</u> This Implementing Regulation should include the UP provisions for the cases where information has been provided during the assessment of the active substances and the precautionary sentence is no longer needed in the PPP: “(…) <i>unless it is established by means of relevant information that there is no risk of sensitisation.</i>” This provision from the UP shall be included in this Implementing Regulation for the cases where an assessment was conducted and concluded that such sentence is not needed for the microorganism assessed (e.g. baculovirus).</p>

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17	Page 14, Annex VI		<p><b>Comment</b></p> <p>IBMA does not support the current graphic/scheme on PPP labels. The current scheme does not indicate whether the product is harmless or not, since this is already strictly regulated by the CLP with pictograms. Thus, it is unnecessary a colour scheme to identify the hazard and should not be confused with indicating the possibility of risk. Either the coloured scheme is based on hazard, either it is based on the risk.</p> <p>The EC should say explicitly what category they discourage or encourage since it is their intention with this coloured scheme apparently. <b>Currently, most biocontrol products in the market today will fall within category C (orange) and D (dark orange). Using such diagram will discourage the use of biocontrol products and generate confusion to growers.</b></p> <p>A colour coding does not add value as regards the purpose of a label – which is to describe the conditions of use and precautions to take – for an authorised product and should not discourage the use of biocontrol products.</p> <p>If the intention is to discourage the use of products containing CfS and encourage the use of (today very limited) low-risk products, then this could be done differently. <b>Moreover, in line the Commission intention to promote Biocontrol alternatives, such category can be included in this regulation.</b></p> <p><b>IBMA proposal is not to proceed with the ‘Coloured Scheme’, as it will generate enormous confusion to growers and be misinterpreted as the product classification, safety of use and its efficacy.</b></p> <p>The separation of low-risk active substance and low-risk product in the label could lead to confusion at growers’ level. Either the product is low-risk or it is not low-risk. Also, such criterium for separation would make sense if the low-risk criteria would have been applied as per the legislation, but this is not the case in current practice (e.g. microorganisms recently renewed). In addition, it would be very confusing for farmers to see pheromones which have a target-specific and non-toxic mode of action and are naturally occurring, classified in category D.</p> <p><b>CONSIDERATIONS</b></p>

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			<ul style="list-style-type: none"> <li>• If there is an intention to reduce the input of CfS and increase the use of biocontrol, then a biocontrol logo or category should be added to the labels. The current proposal for the 'Coloured scheme' will discourage the use of biocontrol solutions, mostly under C &amp; D categories (70% of the biocontrol active substances are not low risk today). Please see proposed scheme below.</li> <li>• There is a real concern within IBMA that the food chain could be using this scheme to set new secondary standards and to dictate which products should be used by the growers.</li> <li>• It would put biocontrol at the same level as any other active substances being used today, thus not promoting its use by growers.</li> <li>• In addition, this would further lead to differences within the single market for PPPs. For example, an active substance can be low risk and products can be low risk in one country but not on the neighbouring country, thus put the product in different categories A &amp; B.</li> <li>• If a coloured scheme has to be adopted, it shall be based on the classification of the product and not on the status of the active(s) ingredient contained in the product as this coloured scheme shall reflect the overall hazard of the product. This will be in line with FAO colour scheme currently in use.</li> <li>• Currently company labels have different colours depending on the product type. This is done in order to avoid mismatches of products and to manage well the plant protection product storage for farmers.</li> <li>• Additional label elements exist at MS level and they will conflict with this proposal: biocontrol product, Use for Organic Agriculture, etc.</li> <li>• Some thought should be given to the Home &amp; Garden consumer market and how such diagram would be interpreted by consumers and the recommendation by personal at the garden centres.</li> <li>• From a competition point of view this is again putting Biocontrol products in yet another disadvantage position to biostimulant product in the single market by adding a layer of warning that have no technical reasoning. Natural Extracts and Microorganisms are extensively used in biostimulant products.</li> </ul> <p><b>Alternative proposal:</b></p>

N°	Reference to the document Page/Annex	Original Text in the DRAFT Document	IBMA comment
			<p>As the ranking will be misleading, an alternative could be to have a biocontrol pictogram (blue) appearing on the label product at country level based on the SUR definition. A Cfs pictogram (red) and a low-risk pictogram (green) should be included on the product label depending on the outcome of the evaluation process.</p> <p>Yet, it should be checked if mentioning “containing low-risk active substance” and “low-risk product” can actually be used on labels, in accordance with the text of Art 66 (2) of Reg 1107/2009: <i>“Only in the case of low-risk plant protection products shall the term ‘authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009’ be allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product.”</i></p> <p>For biocontrol and CfS this is possible, they can be mentioned in the labels since Reg.1107/2009 is omissive, thus permissive.</p> <p><b>Colour gradient of the proposed colour scheme:</b> In line with the Commission mentioning in the current draft <i>“To facilitate the identification of plant protection products that contain such substances [low-risk]”</i>, IBMA proposes a modification of the colour gradient of the labelling scheme since colour schemes can have a great impact for users, who mainly will base their purchasing decision on the colour scheme over the meaning of the category. We would like to <b>encourage the use of low-risk PPPs from categories A and B by using green-shaded colours</b>, associated with a positive decision. An <b>intermediate yellow colour could be used for products containing microorganisms from C category</b> that have not been approved as low-risk.</p> <p><b>When there is a legal definition of biocontrol, we would recommend to include it in category C. Unless the products fits in category A or B.</b></p> <p>Please see the proposed colour scheme below:</p>

N°	Reference to the document Page/Annex	Original Text in the DRAFT Document	IBMA comment