EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the Food Chain
Unit E3 - Chemicals, Contaminants and Pesticides

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TEMPLATE TO BE USED FOR ASSESSMENT REPORTS REGARDING LEVEL 3 OF VOLUME 1

This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Background

This template is intended to align the current structure of Level 3 with the assessment that the Rapporteur Member State has to carry out against the approval criteria as set out in Regulation (EC) No 1107/2009. This template also identifies amongst other things data gaps, risk management measures, critical areas of concern and the overall proposal on approval for which a number of items corresponds to the issues dealt with in a "Conclusion on the peer review of the pesticide risk assessment of an active substance" as prepared by the European Food Safety Authority (EFSA).

Implementing schedule

This template should be used for assessment reports prepared for active substances covered by Commission Regulation (EU) No 1141/2010 *laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC* and for active substances for which an application for the approval has been submitted as from 1 June 2012.

VOLUME 1

LEVEL 3

-Active Substance-

SUMMARY AND CONSIDERATION WITH RESPECT TO THE APPROVAL CRITERIA OF REGULATION (EC) No 1107/2009

IDENTIFICATION OF DATA GAPS, PROPOSED CONDITIONS, RISK MANAGEMENT MEASURES, ISSUES THAT COULD NOT BE FINALISED AND CRITICAL AREAS OF CONCERN

PROPOSED DECISION

3 PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1 BACKGROUND TO THE PROPOSED DECISION

3.1.1 PROPOSAL ON ACCEPTABILITY AGAINST THE DECISION-MAKING CRITERIA – ARTICLE 4 AND ANNEX II OF REGULATION (EC) No 1107/2009

3.1.1.1 Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.			*Brief summary – name of active and assessed uses formulation considered. [Identify the representative uses/products that are considered to comply with Article 4 and those that are not]*
3.1.1.2 Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted			*[If no go to ii immediately below]*
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			*[If yes – specify here the rationale i.e. whether (a) or (b) applies and cross reference to section xx detailing the information still to be submitted* *If no – explain the further information to be submitted and its relevance to the decision on approval* *Explain if some of the information to be submitted relates only to specified products/uses/use scenarios]*
3.1.1.3 Restrictions on approval				
		Yes	No	

Proposal on acceptability against the decision making criteria

	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.			*[If yes –clearly specify the nature of the proposed restriction(s) i.e.* *(a) the minimum degree of purity of the active substance;* *(b) the nature and maximum content of certain impurities;* *(c) restrictions arising from the evaluation of the information referred to in Article 8 of 1107/2009 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;* *(d) type of preparation;* *(e) manner and conditions of application;* *(f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;* *(g) designation of categories of users, such as professional and non-professional;* *(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;* *(i) the need to impose risk mitigation measures and monitoring after use;* *(j) any other particular conditions that result from the evaluation of information made available in the context of Regulation 1107/2009.* *Explain if some of the information to be submitted relates only to specified products/uses/use scenarios]*

3.1.1.4 Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).			
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.			*[Insert brief overall summary of consideration of residues & consumer assessment here]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]*
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and			*[Explain if this applies to all or some of the representative uses/use scenarios/products]*

	its impact on non-target species.			
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.			*Brief summary of efficacy Cross refer to level 2 as necessary [Explain if this applies to all or some of the representative usesuse scenarios/products]*
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.			*[Explain if this applies to all or some of the representative uses/use scenarios/products]*
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.			*[Insert brief overall summary on identify here. Cross refer to level 2 as necessary]*
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			Explain as necessary
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted			Explain as necessary
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active			*[Insert brief overall summary here. Cross refer to level 2 as*

	substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.			*necessary]*
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.			*[Insert brief overall summary here. Cross refer to level 2 as necessary]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]*
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.			
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.			*[Insert brief overall summary of ref value setting here. Cross refer to level 2 as necessary]* *[If an increased safety margin is considered (i.e the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects) provide a explanation & cross reference here.]*
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or**			*[Insert brief overall summary of gentox here. Cross refer to level 2 as necessary]* *[If yes - cross refer to classification section]*

	proposed for classification, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**			
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**			*[Insert brief overall summary of carcinogenicity here. Cross refer to level 2 as necessary]* *[If yes - cross refer to classification section and go to ii) immediately below.]*
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*[if no provide a brief explanation of conditions of use and cross refer to the section containing full details to support the contention of negligible exposure]*
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by			*[Insert brief overall summary of repro tox here. Cross refer to level 2 as necessary]* *[If yes - cross refer to classification section and go to ii) immediately below.]*

	the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**			
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*[if yes provide a brief explanation of conditions of use and cross refer to the section containing full details to support the contention of negligible exposure]*
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**			*[If yes cross refer to classification section and go to ii) and iii) immediately below.]*
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**			*[Insert brief overall summary of consideration of toxic effects on endocrine organs here. Cross refer to level 2 as necessary]* *[If yes - cross refer to classification section and go to iii) immediately below.]*
iii)	Linked to either i) or ii) immediately above.			*[if yes provide a brief explanation of conditions of use and cross refer to the section containing full details to support the*

	It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*contention of negligible exposure]*
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.			*[Insert brief overall summary of persistence here.Cross refer to level 2 as necessary]*
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.			*[Insert brief overall summary of consideration here. Cross refer to level 2 as necessary]*
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.			*[Insert brief overall summary of consideration here. Cross refer to level 2 as necessary]*
Ecotoxicology				
		Yes	No	

	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.			*[Insert overall summary of ecotox. here. This would be the longest of the summaries. Cross refer to level 2 as necessary]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]*
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.			*[Insert brief overall summary of consideration of endocrine effects here. Cross refer to level 2 as necessary]*
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.			*[Explain if this applies to all or some of the representative uses/use scenarios/products]*
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.			*[Insert brief overall summary of honey bee assessments here. Cross refer to level 2 as necessary]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]*

Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.			*[Insert brief overall summary of residue definition here. Cross refer to level 2]*
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.			*[Insert brief overall summary of consideration of groundwater here. Cross refer to level 2 as necessary]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]*

3.1.2 PROPOSAL – CANDIDATE FOR SUBSTITUTION

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution			*[If yes identify the criteria considered met by the substance i.e.* *its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,* *— it meets two of the criteria to be considered as a PBT substance* *— there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones),* *— it contains a significant proportion of non-active isomers,* *— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,* *— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,* *— if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to*

				have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.]

3.1.3 PROPOSAL – LOW RISK ACTIVE SUBSTANCE

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.			

3.1.4 LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1 Identity of the active substance or formulation				
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
3.1.4.3 Data on uses and efficacy				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				

3.1.4.5 Methods of analysis				
3.1.4.6 Toxicology and metabolism				
3.1.4.7 Residue data				
3.1.4.8 Environmental fate and behaviour				
3.1.4.9 Ecotoxicology				

3.1.5 ISSUES THAT COULD NOT BE FINALISED

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
	[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]

3.1.6 CRITICAL AREAS OF CONCERN

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
	[specify if concern relates to all or specific representative use/use scenario/product or to all uses/products]

3.1.7 OVERVIEW TABLE OF THE CONCERNS IDENTIFIED FOR EACH REPRESENTATIVE USE CONSIDERED

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		Use "A" (X^1)	Use "B" (X^1)
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8 AREA(S) WHERE EXPERT CONSULTATION IS CONSIDERED NECESSARY

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
	[specify the reasons why expert consultation is considered necessary]

3.1.9 CRITICAL ISSUES ON WHICH THE Co-RMS DID NOT AGREE WITH THE ASSESSMENT BY THE RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	**Opinion of Co-RMS**	**Opinion of RMS**

3.2 PROPOSED DECISION

It is proposed that:

active substance **can be approved under Regulation (EC) No 1107/2009**

It is considered that the following is specified in Part A of the Commission Implementing Regulation for the approval of the active substance:

[example] **Only uses as seed treatment may be authorised.**

It is considered that the following be specified in Part B of the Commission Implementing Regulation as areas requiring particular attention from Member States when evaluating applications for product authorisation(s):

[example] **the risk to aquatic organisms.**

It is considered that it should be specified that conditions of use shall include risk mitigation measures, where appropriate.

It is proposed that the Member States concerned shall request the submission of confirmatory information:
(a) where new data requirements are established during the evaluation process, or
(b) as a result of new scientific and technical knowledge, or
(c) to increase confidence in the decision.

3.3 RATIONAL FOR THE CONDITIONS AND RESTRCITIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1 PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISKS IDENTIFIED

Proposed condition/risk mitigation measure	**Relevance in relation to representative use(s)**
	[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]

APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

[List of Guidance documents used in the conduct of the evaluation and risk assessment.]

REFERENCE LIST

List [in the conventional format] any references specifically cited in Volume 1 (i.e references to underpinning documents such as PPR-Panel Opinions, EFSA conclusions, national documents etc.).