



**Rotterdam Convention on the Prior
Informed Consent Procedure for
Certain Hazardous Chemicals and
Pesticides in International Trade**

Distr.: General

16 July 2018

English only

Chemical Review Committee

Fourteenth meeting

Rome, 11–14 September 2018

Item 4 (a) (i) of the provisional agenda*

**Technical work: consideration of draft
decision guidance documents: acetochlor**

**Comments and further information related to the draft decision
guidance document for acetochlor**

Note by the Secretariat

As referred to in the note by the Secretariat on the draft decision guidance document for acetochlor (UNEP/FAO/RC/CRC.14/3), the annex to the present note sets out a tabular summary of the comments and further information related to the draft decision guidance document for acetochlor. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.14/1.

Annex

Comments and further information related to the draft decision guidance document for acetochlor

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
CRC member Jeffery Goodman (Canada)	Throughout the draft DGD	Typos, formatting and minor editorial suggestions provided in marked-up version, for consideration	Accepted and amended.
	Page 7, Section 2, Paragraph 1, line 3	The term “prohibit” should be changed to “ban” to reflect the term used in the NFRA.	Accepted and amended.
	Page 10, Section 3.3	Based on the working paper for preparing internal proposals, add standard text such as “There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.”	Accepted and amended.
	Page 10, Section 4.1	The working paper indicates to add dates when this information was established.	Accepted and amended.
	Page 10, Section 4.2	The working paper indicates to only include internationally recognized exposure standards in this section. National standards should be added in Annex 2.	Accepted and amended.
	Page 11, Section 4.3	Based on the working paper, add standard text such as “Further specific guidance on appropriate symbols and label statements for acetochlor products may be available in the <i>FAO Guidelines on Good Labelling Practice for Pesticides</i> ”.	Accepted and amended.
	Page 15, Section 3.1	Information in this section does not present the risk evaluation. It identifies risk endpoints, but omits the exposure estimates related to those endpoints. Therefore the “risk evaluation” itself is omitted. i) EU supporting information indicated that the decision was based on: exceedance of ADI (when dietary + drinking water combined); and the lack of a method to quantify residues in plants. Need to state that ADI was exceeded in this section. ii) ARfD was not a basis of risk concerns and only the endpoint is identified here. Therefore consider removing, or add relevant exposure assessment showing that ARfD was not exceeded	i) Accepted, the following text is added: “No chronic or acute risks were identified when the consumer exposures to food commodities are calculated using the EFSA PRIMO Model and the MRL proposed for maize grains and oil seeds: the ADI and AFRD values were not exceeded. However, it must be highlighted that the potential consumer exposure exceeds the ADI value in many scenario, when the predicted concentrations of the ground water metabolites are considered. In addition, intakes for toddlers and infants resulting from the water consumption are at times above the threshold value of 20% ADI recommended by the WHO, when calculations are conducted using the

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
		iii) AOEL is not relevant to food so doesn't belong in this section, but rather in the occupational section. It was also not identified as a basis of risk concerns therefore consider removing, or add to occupational section with relevant exposure assessment results for AOEL assessment.	concentrations measured in a monitoring program conducted in Northern Italy.” ii) Accepted, text added: the ADI and ARfD values were not exceeded. iii) Accepted, the AOEL value was moved to section 3.4
	Page 16, Section 3.2	This is not the risk evaluation. An inhalation risk evaluation is not explicitly identified in the EU supporting info.	Rejected. Though the text presented in section 3.2 is a hazard statement, it is considered useful additional information and therefore cited in this section.
	Page 16, Section 3.3, paragraph 1	EU did identify surface water concerns with genotoxic metabolite (γ-norchloro acetochlor) and ground water contamination concerns by toxicologically relevant metabolites.	Accepted, text on concerns for human health due to water and groundwater contamination are added.
	Page 16, Section 3.3, paragraph 2	This is not a risk evaluation of acetochlor, but rather nonchemical specific information on water use in the area. CILSS supporting information did present qualitative and quantitative acetochlor risk evaluation information which should be included instead of (or in addition to) this information.	Accepted, the text is replaced by the following: “In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported. In the USA, due to concerns for groundwater contamination, acetochlor cannot be used on coarse soils (for ex. Sandy soil with less than 3% of organic matter) where the depth of groundwater in less than 30 feet. Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to ground water and/or surface water resources (US EPA, 2006). The supporting documentation from the CILSS countries indicates that no environmental management system respecting buffer strips between treated fields and streams as a precaution is not possible in the Sahel. Further, in the CILSS countries, soils are often very poor in organic matter. Modelling values are between 1.06% to 1.36% for soils within the perimeter (Direction culture/SN-SOSUCO,2008), and the mean OC in soils near the rivers is equal to 1.06% (Ouedraogo et al, 2012). Therefore

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
			<p>these soils are subject to erosion and leaching. The fragile ecology of CILSS countries, sometimes characterized by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching.</p> <p>The results of the modelling study by Ouedraogo et al (2012) conclude that acetochlor had very high potential to contaminate surface water under actual usage conditions in Burkina Faso.</p> <p>In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations up to 53.1 µg/L were measured (Soleri, 2013).</p> <p>Contamination of groundwater and surface water in the CILSS countries results in contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half the farmers (67.5 %) have a water point in their fields or nearby. Most water points are less than 100m from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water was drunk in 50% of cases, used for the preparation or the dilution of pesticides in 29.26% and for animal drinking in 26.96% (Toe, 2010). Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).</p> <p>The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”</p>
	Page 16, Section 3.3, paragraph 2, line 9	Risk evaluation from this document (Soleri, 2013) should be summarized in this section as it establishes exposure in CILSS region. Ouedraogo et al. 2012 should also be summarized as it establishes risk category estimates. Toe, 2010 also establishes that acetochlor is used in the region.	Accepted. See text in response to previous comment.
	Page 16, Section 3.4, paragraph 1	Suggest removing. This all belongs in section 3.1 “Food” and section 3.3 “Water” above.	Section 3.4 is on occupational exposure. It is presumed that this comment is on section 3.6 and is accepted for this section.
	Page 16, Section 3.4, paragraph 2	Suggest removing. This is all covered in section 3.3 “Water” above.	Section 3.4 is on occupational exposure. It is presumed that this

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
			comment is on section 3.6 and is accepted for this section.
	Page 17, Section 3.7, paragraph 1, line 6	Remove “a high risk for aquatic organisms and a high long term risk for herbivorous birds”. This is not “human exposure/ risk evaluation”. It should be captured in Section 5 “Environmental Exposure/ Risk Evaluation”.	Accepted. Text replaced by “The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”
	Page 17, Section 3.7, paragraph 3 (WHO/FAO)	This is not information provided in support of the NFRAs considered. Either context needs to be provided or it needs to be removed. Suggest removing as it is not addressing genotoxicity (as per meeting report reference to including JMPR 2015 in DGD). The way it is currently presented would suggest that is supporting information to either the EU or CILSS. It is not. The context of its possible inclusion in the DGD is addressed in the CRC13 report: “48. Ms. Van Leeuwen also addressed a number of comments by representatives of observers.....Regarding the genotoxicity, Ms. Van Leeuwen indicated that the task group could not take into account the information in a peer review of the pesticide risk assessment of the active substance acetochlor and in the European Food Safety Authority 2015 report because it had not been submitted by the notifying Parties, but that it could be integrated into the decision guidance document.”	Accepted and amended.
	Page 18, Section 4.1.1, paragraph 1	Should be consistent in sections 4.1 – 4.2.6 subheadings regarding whether the information is identified as coming from EU/CILSS supporting documentation or not identifying it as coming from either.	Accepted and amended.
	Page 19, Section 4.1.4	CILSS supporting information (Sahelian Pesticide Committee, Annex to the decision to ban Acetochlor) cites high potential for bioconcentration in aquatic organisms. Consider whether this is scientifically accurate information that should be added here. Also, additional bioconcentration information for other organisms should be summarized/added (see EU supporting information – EFSA, 2011).	Currently, the Footprint database (https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/12.htm , accessed 26 April 2018) does not mention the BCF value presented in the CILSS countries’ supporting documentation, therefore this value is not added. The CILSS countries supporting documentation also mentions the data from EFSA on bioaccumulation (low). Information on bioaccumulation in other organisms was added.
	Page 21, Section 5	Sections 5.1 – 5.6 subheadings should be consistent regarding whether information is identified as coming from EU/CILSS supporting documentation or not identifying it.	Accepted and amended.
	Page 21, Section 5.1	CILSS cites high long-term risk to herbivorous birds as a basis of their decision. That information should be outlined here.	Accepted and amended.
	Page 22, Section 5.2	Identify information as being provided by CILSS countries as per general comment above for sections 5.1-5.6 subheadings.	Accepted and amended.
	Page 22, Section 5.6,	Remove this text “A potential human exposure above the acceptable daily intake has been	Partially accepted. The text on human exposure is removed, however the text

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	paragraph 1, line 2	identified. In addition, there is a potential for human exposure to the surface water metabolite t-norchloroacetochlor, the genotoxicity of which cannot be excluded. There is a high risk of groundwater contamination for several metabolites,” as these are not part of the environmental exposure/risk evaluation. They are included in the human exposure /risk evaluation in a preceding section.	on groundwater contamination is also applicable to the environmental risks and therefore also mentioned in this section.
	Page 22, Section 5.6, paragraph 1, line 7	Remove this text “Finally, the information available was not sufficient to conclude on the risk assessment for the groundwater contamination for metabolites t-norchloroacetochlor and t-hydroxyacetochlor (Commission Implementing Regulation (EU) 1372/2011).” as these are not part of the environmental exposure/risk evaluation. They are included in the human exposure /risk evaluation in a preceding section.	Accepted and amended.
	Page 22, Section 5.6, paragraph 2, line 3	Remove this text “Risks of water resources contamination from several metabolites including t-norchloroacetochlor” as not relevant to environmental assessment.	Accepted and amended.
	Page 22, Section 5.6, paragraph 2, line 5	Remove this text “and to human beings” as not relevant to environmental assessment.	Accepted and amended.
	Page 22, Section 5.6, paragraph 2, line 8	Remove this text “Difficulties for the population to get adequate personal protection equipment” as not relevant to environmental assessment.	Accepted and amended.
	Page 22, Section 5.6, paragraph 2, line 13-15	Remove this text “the use of surface water as drinking water for man and animals; The use of groundwater as the only reservoir of drinking water” as not relevant to environmental assessment.	Accepted and amended.
	Page 28, last paragraph “Relevant guidelines and reference documents”	The below reference was not submitted by parties in support of NFRAs. It should be removed. JMPR, 2015: Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 15-24 September 2015: Acetochlor.	Partially agreed. The reference was moved to the subheading “other documents”
CRC member Juergen Helbig (Spain)	Page 5, List of abbreviations	New abbreviation on RAC	Accepted and amended.
	Page 8, Section 2.1, line 8	Editorial change/Clarification	Accepted and amended.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	Page 8, Section 2.2, lines 6-7, 17-21,	Editorial change/Clarification	Accepted and amended.
	Page 9, Section 2.2, lines 5, 20-24, 28, and 32, and Section 3.1, line 4	Editorial change/Clarification	Accepted and amended.
	Page 10, Section 3.3, Integrated production and pest management (IPPM)	Editorial change/Clarification	Accepted and amended.
	Page 10, Sections 4.1 and 4.2	Editorial change/Clarification	Accepted and amended.
	Page 11, Section 4.2	Removal of the references	Accepted and amended.
	Page 12, Annex I	Addition	Accepted and amended.
	Page 12, section 1, entry 1.6	Removal of the reference	Accepted and amended.
	Page 12, subsection 2.1.3	Clarification	Accepted and amended.
	Page 16, subsections 2.2.5, 2.2.7 and 3.1	Editorial/Reference	Accepted and amended.
	Page 17, section 3.3, lines 10-15	Editorial	Accepted and amended.
	Page 18, section 3.7	Reference	Accepted and amended.
	Page 24, Annex 2, section 1	Editorial	Accepted and amended.
	Page 28, Annex IV	Editorial, new reference	Accepted and amended.
USA	Various	Editorial changes	Accepted and amended.
	3.1 "The final	Why only operators? Exposure would also be reduced for people via food and water. I would suggest changing this to reduction of exposure	Accepted and amended.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	regulatory actions are expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of the exposure of operators and the environment."	to humans and the environment so it covers all routes	
	4.1 Hazard classification USA EPA	which route/study? Our current classifications for acetochlor acute toxicity are: oral, dermal and eye irritation - III, inhalation - IV, dermal irritation - II, and found to be a dermal sensitizer	Accepted and amended. Information included.
	Annex I Introductory text	there are some conclusions from JMPR that were not included in either notification	Information from the JMPR report is included, based on the following text from the handbook: "Annex 1 contains information submitted by the notifying countries based on the national assessments which were used to support the reported final regulatory action. The results of international reviews such as those of WHO/IPCS/JMPR/IARC should also be included in this section where available and considered relevant." The following text was added to the introduction: "Relevant information from WHO and FAO (JMPR, 2015) is included in the section 2.2.3 on genotoxicity (including mutagenicity) of this Annex. The JMPR report is from a more recent date (2015) than the information from the notifying countries and provides a different view on the genotoxicity of acetochlor."
	Annex I Introductory text	This is not all inclusive. Also citing information from other parts of the notifications (for example, EPA 2006 cumulative assessment for chloroacetanilide pesticides, JMPR, CSP 2014) and information from JMPR that is not in the notifications	Accepted. Text was deleted.
	Annex I 2.1.1. The Grouping of a Series of Chloroaceta	This is a citation within EPA 2006 cumulative assessment. I would suggest using the 2006 cumulative as a citation here instead since that was cited and included as part of the notification	Accepted and amended.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	nilide Pesticides Based on a Common Mechanism of Toxicity (USEPA 2001)	This is a citation from the 2009 EPA new use RA. Again, I would suggest using that as the citation since that RA was included as part of the notification	
	Annex I 2.3 Information from JMPR, 2015	I can't find this in the notifications. Was this the information provided at the CRC meeting by an observer?	Yes, this was the information provided by an observer during fCRC-13. The following text was added to the introduction: "Relevant information from WHO and FAO (JMPR, 2015) is included in the section 2.2.3 on genotoxicity (including mutagenicity) of this Annex. The JMPR report is from a more recent date (2015) than the information from the notifying countries and provides a different view on the genotoxicity of acetochlor."
	Annex I 2.2.5 and Annex I 2.2.7 Information from RAC, 2014	This doesn't appear to be in either notification	This information was added because the EUs classification of acetochlor was recently updated based on the RAC opinion. The following clarification was added: "(Additional information provided by CRC member from EU member state)"
	Annex I 3.3	I think this should say there is potential for contamination This sentence doesn't make sense. Contamination results in contamination? Reword to: There is potential for contamination of groundwater and surface water in the CILSS countries resulting in potential exposure to humans since these are used as sources of drinking water	Text replaced by: "In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported. In the USA, due to concerns for groundwater contamination, acetochlor cannot be used on coarse soils (for ex. Sandy soil with less than 3% of organic matter) where the depth of groundwater in less than 30 feet. Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to ground water and/or surface water resources (US EPA, 2006). The supporting documentation from the CILSS countries indicates that no environmental management system

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
			<p>respecting buffer strips between treated fields and streams as a precaution is not possible in the Sahel. Further, in the CILSS countries, soils are often very poor in organic matter. Modelling values are between 1.06% to 1.36% for soils within the perimeter (Direction culture/SN-SOSUCO,2008), and the mean OC in soils near the rivers is equal to 1.06% (Ouedraogo et al, 2012). Therefore these soils are subject to erosion and leaching. The fragile ecology of CILSS countries, sometimes characterized by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching.</p> <p>The results of the modelling study by Ouedraogo et al (2012) conclude that acetochlor had very high potential to contaminate surface water under actual usage conditions in Burkina Faso.</p> <p>In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations up to 53.1 µg/L were measured (Soleri, 2013).</p> <p>Contamination of groundwater and surface water in the CILSS countries results in contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half the farmers (67.5 %) have a water point in their fields or nearby. Most water points are less than 100m from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water was drunk in 50% of cases, used for the preparation or the dilution of pesticides in 29.26% and for animal drinking in 26.96% (Toe, 2010). Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).</p> <p>The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”</p>
CropLife International	Section 1, Trade names, Trade names listed	The only two trade names listed in the FRA of the CILSS CSP as having been approved by the CSP are ACEPRONET 400 EC and ACETO 900. None of the other trade names are listing in supporting documentation provided by the	Rejected. All trade names are mentioned in the notifications and thus in the DGD.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	by the Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo:	CILSS CSP. The list as it stands is misleading, implying that this list constitutes products officially approved by the CSP. Suggest that the list be shortened to only the two trade names of products approved by the CSP, or a statement be added to the italicized notes, as follows: This is an indicative list. It is not intended to be exhaustive. Not all trade names are for formulations necessarily approved by regional or national regulatory authorities.	
	Section 1, Formulation types, line 1.	“Capsule suspension (CS)” should be removed from this list as it should reflect only the formulation type(s) for products previously approved in the CILSS or EU markets.	Rejected. Both are part of the 2011 EFSA report on which the EU FRA is based, therefore both are mentioned in the DGD.
	Section 2.1, Para 1, CILSS countries, line 5.	Suggest the removal of the word “high”, the term is relative and there is nothing to compare “high” with. This should be replaced with the word “potential”.	Accepted. Text is removed.
	Section 2.2, Para 1, CILSS countries, line 4	The referral to the US EPA reports implies that final regulatory action has been taken in the USA, and is misleading since most of the EPA conclusions, including the acetochlor ADI and relative lack of toxicity of the acetochlor metabolites, seems to have been ignored. In fact, many acetochlor products are currently registered by EPA and used in major cropping systems including corn, sorghum, cotton, soybeans, and other important food crops. The US delegation highlighted this fact at CRC13.	Accepted.
	Section 2.2, Para 2, CILSS countries, line 5	Suggest the removal of the word “very”, the term is relative and there is nothing to compare “very” with.	Accepted.
	Section 2.2, Para 4, CILSS countries, Human Health, Bullet 3.	Typo, “stripes” should read “strips”.	Accepted.
	Section 2.2, Para 4, CILSS countries, Environment, Bullets 1-5.	Suggest the removal of the word “high”, the term is relative and there is nothing to compare “high” with.	Rejected. This text is cited literally from the supporting documentation.
	Section 2.2, Para 4, CILSS countries, Environment, Bullet 8.	Typo, “stripes” should read “strips”.	Accepted.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	Section 2.2, under European Union, Human Health, Bullet 1.	The metabolites listed as, "...f-oxanilic acid, tsulfinylacetic acid, f-sulfonic acid..." should be corrected to "...t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid...".	Accepted.
	Section 3.1 Regulatory measures to reduce exposure	These statements collectively are not valid for both the EU and the CILSS countries and should be separated and appropriately qualified. As no evidence is available on the actual amounts of acetochlor previous used in the CILSS, the conclusion that the final regulatory action in the CILSS would lead to a significant decrease in the quantity of the chemical used, and thus result in a significant reduction in exposure of operators and the environment, is based on unsupported assumptions. A separate paragraph for the CILSS countries is proposed, as follows: Acetochlor was registered in the CILSS for a relatively short time (~5 years) and no information is available on the actual amounts of the chemical used, nevertheless, the final regulatory action by the CILSS is assumed to lead to a decrease in the quantity of chemical used, resulting in a reduction in potential exposure of operators and the environment. Under this assumption, the reduction in exposure to the chemical would potentially lead to a reduction in risk of acetochlor to human health and the environment.	This section is separated between the CILSS countries and the EU. However both subsections contain the same information which was already accepted in the rationale to the CRC 13 decision on acetochlor.
	Annex 1, section 1. Physico-Chemical Properties, 1.6 Density	The first density listed should be corrected to "1.136 g/mL" from 136 g/mL.	Accepted.
	Annex 1, section 2 Toxicological properties, paragraph 2.2.3 Genotoxicity, last line Pg. 13	Typographical error, "In the JMPR report "form", should be corrected to "from".	Accepted.
	Annex 1, section 2.2.4, Long term toxicity and carcinogenicity	Under Long-term toxicity: Duration of mouse study cited was 78 weeks, not 2 years. Therefore, we suggest changing "Mouse (diet, 2-year)" to "Mouse (diet, 78-week)". In addition, for completeness and transparency, the conclusions of the JMPR regarding this study should also be cited here as it impacts the calculation of the ADI. Suggest adding the following line: Mouse (diet, 78-week): NOAEL = 1.1 mg/kg bw/day (JMPR, 2015; US EPA, 2009) Under Carcinogenicity In the interest of	Accepted. Only the information from the JMPR report is included, based on the following text from the handbook: "Annex 1 contains information submitted by the notifying countries based on the national assessments which were used to support the reported final regulatory action. The results of international reviews such as those of WHO/IPCS/JMPR/IARC

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
		completeness and transparency of the data, suggest the following statements be added: Rat: Adenomas in nasal epithelium Mouse: Marginal increase in histiocytic sarcomas Conclusion: Unlikely to pose a carcinogenic risk to humans from the diet. (JMPR, 2015) Rat: Nasal olfactory epithelial tumors and thyroid follicular tumors. Non-linear modes of action. Mouse: Weak evidence for benign lung tumors and histiocytic sarcomas. Conclusion: Suggestive evidence of carcinogenicity (US EPA, 2009)	should also be included in this section where available and considered relevant.”
	Annex 1, section 3, Human exposure/Risk evaluation, section 3.1 Food	The following paragraph from JMPR should be added to this section: The Meeting established an ADI of 0–0.01 mg/kg bw on the basis of a NOAEL of 1.10 mg/kg bw per day in the 78-week dietary study in mice, based on slight anaemia and an increased incidence of bronchiolar hyperplasia and interstitial fibrosis in the kidney in males observed at 11.0 mg/kg bw per day. A safety factor of 100 was applied. An ARfD of 1 mg/kg bw was established on the basis of a NOAEL of 100 mg/kg bw per day in a study of developmental toxicity in rabbits, based on decreased feed consumption, decreased body weight (GDs 6–8) and the death of two dams observed at 300 mg/kg bw per day. A safety factor of 100 was applied. (JMPR, 2015).	Accepted.
	Annex 1, section 3.3, Water, CILSS Countries	The following paragraph from JMPR should be added to this section: The Meeting established an ADI of 0–0.01 mg/kg bw on the basis of a NOAEL of 1.10 mg/kg bw per day in the 78-week dietary study in mice, based on slight anaemia and an increased incidence of bronchiolar hyperplasia and interstitial fibrosis in the kidney in males observed at 11.0 mg/kg bw per day. A safety factor of 100 was applied. An ARfD of 1 mg/kg bw was established on the basis of a NOAEL of 100 mg/kg bw per day in a study of developmental toxicity in rabbits, based on decreased feed consumption, decreased body weight (GDs 6–8) and the death of two dams observed at 300 mg/kg bw per day. A safety factor of 100 was applied. (JMPR, 2015).	Rejected. Duplication from the text under Annex I section 3.1.
	Annex 1, section 3.3, Water, CILSS Countries	This paragraph is highly misleading and should be deleted in its entirety. The general statements which assume the contamination of groundwater and surface water in the CILSS countries by pesticides, are simply supposition. No analytical water monitoring data is cited which shows contamination of water sources in the CILSS countries by acetochlor. No modeling results are presented or cited which show the realistic potential for runoff or leaching of acetochlor to water sources in the CILSS countries. It is well recognized, including by the	Text is replaced by the following: “In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported. In the USA, due to concerns for groundwater contamination, acetochlor cannot be used on coarse soils (for ex. Sandy soil with less than 3% of organic matter) where the depth of groundwater in less than 30 feet.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
		<p>author, that the results from Soleri (2013) are highly questionable. As these results were part of an internship project for which the data were not peer reviewed, along with acknowledgement by the author of difficulties in quantitation, the results are not reliable for drawing any conclusions. Thus, the conclusion of "...the presence of acetochlor in some water sources in Burkina Faso." is not substantiated. At a minimum, suggest the last sentence be deleted.</p>	<p>Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to ground water and/or surface water resources (US EPA, 2006).</p> <p>The supporting documentation from the CILSS countries indicates that no environmental management system respecting buffer strips between treated fields and streams as a precaution is not possible in the Sahel.</p> <p>Further, in the CILSS countries, soils are often very poor in organic matter. Modelling values are between 1.06% to 1.36% for soils within the perimeter (Direction culture/SN-SOSUCO,2008), and the mean OC in soils near the rivers is equal to 1.06% (Ouedraogo et al, 2012). Therefore these soils are subject to erosion and leaching. The fragile ecology of CILSS countries, sometimes characterized by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching.</p> <p>The results of the modelling study by Ouedraogo et al (2012) conclude that acetochlor had very high potential to contaminate surface water under actual usage conditions in Burkina Faso.</p> <p>In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations up to 53.1 µg/L were measured (Soleri, 2013).</p> <p>Contamination of groundwater and surface water in the CILSS countries results in contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half the farmers (67.5 %) have a water point in their fields or nearby. Most water points are less than 100m from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water was drunk in 50% of cases, used for the preparation</p>

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
			<p>or the dilution of pesticides in 29.26% and for animal drinking in 26.96% (Toe, 2010). Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).</p> <p>The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”</p>
	Annex 1, section 3.6, Public Exposure	<p>For clarity and completeness, suggest the following be added after the European Union section:</p> <p>It should be noted that potential consumer exposure (food plus water) exceeds the ADI value only if the ground water metabolites are considered of equal toxicity to parent acetochlor and compared to the acetochlor ADI established by the EU. Potential consumer exposure would not exceed the ADI if the JMPR (2015) or US EPA (2009) values for the acetochlor ADI were used. In addition, the metabolites are (much) less toxic than parent acetochlor (JMPR, 2015) and would not exceed the ADI if a metabolite-specific ADI was used.</p>	Text is deleted as the information is included in Annex I section 3.1-3.3.
	Annex 1, section 3.6, Public Exposure, CILSS Countries	The paragraph presents no empirical or modeling results for acetochlor in ground or surface water in the CILSS countries which could be used to draw any conclusion about “public exposure”, and as such, is not useful information and should be deleted.	Text is deleted as the information is included in Annex I section 3.1-3.3.
	Annex 1, section 3.7 Summary of risk evaluation, CILSS Countries. bullet 2	Suggest the removal of the word “high”, the term is relative and there is nothing to compare “high” with. This should be replaced with the word “potential”.	Text was replaced by the following: “The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”
	Annex 1	Section 3.7 para 1 and 2 are identical to Section 5.6 para 1 and 2; suggest there is only one “summary” section.	Text was adjusted to separate summary on human health and environmental risk evaluation.
	Annex 1, 4.1.1 Soil, CILSS countries, paragraph 1.	<p>Suggest that citation(s) should be added for stated data points.</p> <p>To be consistent with the CILSS CSP decision document, the third sentence in paragraph one should be changed to read, “Acetochlor degradation is 8 to 15% in loamy sand..., which shows that biodegradation is a major environmental fate process in soil.”.</p> <p>Further, information in the last two sentences states, “...DT50 = 2 to 3 months.”, which is inconsistent with existing data which shows a DT50 range of 3 to 45 days.</p> <p>Suggest also that this information be included in the previous paragraph, European Union.</p>	<p>This text is literally cited from the supporting documentation, reference to the supporting documentation is added.</p> <p>Information on DT50 values from the EFSA report is added.</p>
	Annex 1, 4.1.1 Soil, CILSS	This entire paragraph is misleading as it contains a series of unsupported conclusions; the paragraph should be deleted in its entirety	The paragraph reflects the contents of the supporting documentation provided by the CILSS countries.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	countries, paragraph 2.	unless data citations are included to support the statements. If the paragraph is retained or rewritten, the proper term in all instances related to soil, is “adsorption” or “adsorbs”	Editorial comment on adsorption was accepted.
	Annex 1, 4.1.2 Water, European Union, paragraph 2, line 2.	The units in this paragraph shown as “pg/L...” are incorrect and should be corrected to “µg/L”.	Accepted.
	Annex 1, 4.1.2 Water, CILSS countries, paragraph 1.	This entire paragraph should be deleted unless citations for the data points listed are included. The first sentence should be corrected to read, “Acetochlor is not expected to adsorb to suspended matter...”. In addition, the BCF of “250” listed in the fourth sentence is incorrect, and thus the conclusion that bioaccumulation in aquatic organisms is “high”, is also incorrect. This must be corrected or the statement should be deleted. The EFSA conclusion document lists a fish BCF of 20 (not 250) and concludes that this indicates “a low risk of bioconcentration in fish”. Suggest that the sentence be revised to read as follows: “An estimated BCF of 20 suggests that the bioaccumulation potential in aquatic organisms is low.” The statement: “...provided that the compound is not metabolized by the organism.”, should be deleted.	Accepted.
	Annex 1, 4.1.3 Air, European Union	The vapor pressure value in the first sentence should be corrected to 2.2×10^{-3} Pa at 20°C. The vapor pressure value of 2.2×10^{-5} Pa at 20°C, listed on p. 51 of the EFSA conclusion report is incorrect. Based on a data report submitted to the EU the vapor pressure listed there (report no.: MLL-31685) is 2.2×10^{-5} hPa at 20 C which equates to 2.2×10^{-3} Pa. The value at 20 C in the EFSA conclusion is therefore wrong. This then impacts the statement below.	Accepted.
	Annex 1, 4.1.3 Air, CILSS countries	Correction of the EFSA reported vapour pressure at 20 C to 2.2×10^{-3} Pa (per comment above) would then require the CILSS reported value to be corrected to 1.67×10^{-3} mmHg. Further, the conclusion by the CILSS, “A vapour pressure of acetochlor in the air of 1.67×10^{-7} mmHg at 20 °C suggests that acetochlor will exist in vapour and particle phases in the atmosphere.”, is incorrect and contradicts the EFSA conclusion in the previous section, that, “Vapour pressure of acetochlor (2.2×10^{-5} Pa at 20°C) indicates very slight volatility under the national scheme of the Netherlands. Therefore losses due to volatilisation might be expected to be minimal.”. The conclusion is also inconsistent with existing OECD (232/82) and US TFD (835.6100) guidance.	Accepted.

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
		Suggest the paragraph be changed to read as follows and appropriate citations added: “A vapour pressure of acetochlor in the air of $1,67 \times 10^{-5}$ mmHg at 20 °C suggests that acetochlor will not exist in vapour and particle phases in the atmosphere to any significant extent. In the vapour phase, acetochlor will degrade in the atmosphere by reaction with hydroxyl radicals; air half-life for that reaction is estimated 2.6 hours. In particle phase, acetochlor will be removed from the atmosphere by wet or dry deposition process. Acetochlor may be sensitive to direct photolysis by sunlight.”	
	Annex 1, 4.2, Effects on non-target organisms	4.2 is the start of the overall section, thus the paragraphs on Honey Bee, Earthworm, and Other Arthropod Species should be deleted from this section, as they are covered below in section 4.2.3 Honeybees and other arthropods , and 4.2.4 Earthworms .	Accepted.
	Annex 1, 4.2, Effects on non-target organisms, Honey Bee	Per the comment above, this paragraph is duplicated under 4.2.3 and should be removed from 4.2. Then in 4.2.3, the units for the acute LD50 values should be corrected as follows: Acetochlor, acute LD50 oral >100 a.s. µg/bee , contact > 200 µg/bee . Preparation WF-2061, MON 69447 and the metabolites, ...acute LD50 oral and contact all >86.7 µg/bee .	Accepted.
	Annex 1, 4.2.1 Terrestrial vertebrates, Terrestrial birds	The spaces between the digits of some of the end point values in this section should be removed. Bobwhite quail, acetochlor, acute LD50: 928 mg a.s./kg bw, and, Mallard duck, acetochlor, short-term LC50: 1057 mg a.s./kg bw/day	Accepted.
	Annex 1, 4.2.2, Aquatic species, Freshwater Species Aquatic invertebrates, <i>Daphnia magna</i>	The last line item should be corrected to remove “t-sulfinylacetic acid”, to read as follows: t-norchloroacetochlor, 48 h (static), EC50: 170 mg/l, NOEC = 100 mg/l	Accepted.
	Annex 1, 4.2.2, Aquatic species, Freshwater Species, Algae, <i>P. subcapitata</i>	In the first line, remove the spaces between the digits of the listed end point to read as follows: Acetochlor, 72 h, Biomass EbC50 : 0.00031 mg/l In the fourth line, remove extra “0” from the growth rate end point, to read as follows: 69447, 72 h (static), Biomass EbCsev 0.00071 mg/l, growth rate ErC50: 0.00155	Accepted.
PAN International	3.3 Alternatives page 10, last line	Please consider adding the following information: General: SAICM’s Fifth International Conference on Chemicals Management recommended that in replacing highly hazardous pesticides the focus should be on agroecologically-based practices.	The following text was added to the introduction: “There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
		<p>Information on such practices can be found at the following websites: FAO Agroecology hub: http://www.fao.org/agroecology/en/ IPAM (International Peoples Agroecology Multiversity): http://ipamglobal.org/ OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics): http://www.oisat.org/ Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology: http://panap.net/2015/11/replacing-chemicals-biology-phasing-highly-hazardous-pesticides-agroecology/</p>	<p>consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.”</p>
	<p>Annex 1 2.1.3 Absorption, distribution, excretion and metabolism in mammals, page 13, last line</p>	<p>Include the name of the main metabolite</p>	<p>Accepted and amended.</p>
	<p>Annex 1 3.3 Water, page 17 lines 7-8</p>	<p>The sentence “Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013)” does not follow from the fact that water is drunk. Perhaps reposition this sentence before “Water was drunk.”</p>	<p>Text was replaced by the following: “CILSS Countries In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported. In the USA, due to concerns for groundwater contamination, acetochlor cannot be used on coarse soils (for ex. Sandy soil with less than 3% of organic matter) where the depth of groundwater in less than 30 feet. Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to ground water and/or surface water resources (US EPA, 2006). The supporting documentation from the CILSS countries indicates that no environmental management system respecting buffer strips between treated fields and streams as a</p>

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
			<p>precaution is not possible in the Sahel. Further, in the CILSS countries, soils are often very poor in organic matter. Modelling values are between 1.06% to 1.36% for soils within the perimeter (Direction culture/SN-SOSUCO,2008), and the mean OC in soils near the rivers is equal to 1.06% (Ouedraogo et al, 2012). Therefore these soils are subject to erosion and leaching. The fragile ecology of CILSS countries, sometimes characterized by torrential rainfall on soils which are very often poor in organic matter and therefore subject to erosion and leaching.</p> <p>The results of the modelling study by Ouedraogo et al (2012) conclude that acetochlor had very high potential to contaminate surface water under actual usage conditions in Burkina Faso.</p> <p>In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations up to 53.1 µg/L were measured (Soleri, 2013).</p> <p>Contamination of groundwater and surface water in the CILSS countries results in contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half the farmers (67.5 %) have a water point in their fields or nearby. Most water points are less than 100m from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water was drunk in 50% of cases, used for the preparation or the dilution of pesticides in 29.26% and for animal drinking in 26.96% (Toe, 2010). Hence the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).</p> <p>The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted an unacceptable risk to human health because of drinking water contamination.”</p>
	4.1.2 Water CILS Countries, page 19, lines 5th and 4th	“An estimated BCF of 250 suggests that the bioaccumulation potential in aquatic organisms is high” – shift to section on bioconcentration	Text removed from this section. Currently, the Footprint database (https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/12.htm , accessed 26 April 2018) does not mention the BCF value presented in the CILSS countries’ supporting documentation, therefore

Source	Section, Page, Line	Comments and further information related to the draft DGD for acetochlor	Response
	from the bottom		this value is not added. The CILSS countries supporting documentation also mentions the data from EFSA on bioaccumulation (low).
	4.2.3, 4.2.4, pages 21, 22	delete, as repetitions	Accepted. Information deleted in section 4.2
