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Outcome of the consultation with Member States and EFSA on the basic substance application for beer for use in plant protection against slugs and snails

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for beer are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of beer as a basic substance for use in plant protection against slugs and snails. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Keywords: beer, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00210

Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Beer is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in March 2017, EFSA was asked to organise a consultation on the basic substance application for beer, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for beer, organised by EFSA, was conducted with Member States via a written procedure in November 2016 – January 2017. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for beer and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Beer is one of the oldest prepared alcoholic beverages of the world, obtained via fermentation process; it is available all over the world. Beer contains ethyl alcohol.

With regards to the impact on human and animal health, the only toxicological concern identified for beer relates to its alcohol content (between 3.5 and 8%). Considering that beer is of food grade quality and it is used in specific slug traps, dietary and non-dietary exposure risk assessment is not required.

Contamination of edible crops by spill should normally not occur, but if spilling would exceptionally happen, the consequences for consumer health are deemed trivial, provided that food-grade beer is used in the traps.

The proposed use method (liquid placed on a plate / dish as a bait, manually removed after use) potentially limits environmental exposure. However this is difficult to assess properly as no information was provided on the number of traps that would need to be placed per land surface area associated with the crops to be protected. No specific toxicological data was provided and no estimates of the exposure to non-target organisms were available. The available information on the agricultural use suggests that, in general, the exposure to non-target organisms is limited. However, some considerable exposure to some non-target organisms, like bees, non-target arthropods or endangered snails, cannot be excluded, as they are not prevented to visit the traps and may be attracted by beer.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Beer is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from ITAB for approval as a 'basic substance' for use in plant protection against slugs and snails.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for beer, which was conducted via a written procedure in November 2016–January 2017. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for beer and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of beer as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2016; 2017).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 8 March 2017, EFSA was asked to organise a consultation on the basic substance application for beer, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 8 June 2017.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for beer and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. ITAB, 2016. Basic substance application on beer submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2016. Documentation made available to EFSA by the European Commission.
2. ITAB, 2017. Basic substance application update on beer submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2017. Documentation made available to EFSA by the applicant.

References

EFSA (European Food Safety Authority), 2009: Conclusion on pesticide peer review regarding the risk assessment of the active substance ethanol. *EFSA Journal* 2009;7(4):215, 48 pp. doi: 10.2903/j.efsa.2009.215r

Abbreviations

a.s.	active substance
AL	Any other Liquid
GAP	good agricultural practice
MS	Member State
PB	Plate Bait
PEC	predicted environmental concentration
PRIMo	Pesticide Residue Intake Model
RMS	rappporteur Member State
TMDI	theoretical maximum daily intake

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for beer and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		PL: no comments			Noted.

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

2.3. Manufacturer of the substance/products

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.4 Type of Preparation	DE: It is questionable whether plate bait (PB) is the correct type of preparation.	It seems that as type of preparation AL "Other liquids to be applied undiluted" would be more appropriate.	Corrected in §2.4 and §3	Addressed: The type of preparation was updated accordingly to AL.
2(2)	2.4 Type of Preparation	DE: If the beer is placed in plates or cups as suggested by the applicant, hedgehogs can be attracted and injured.	A recommendation here and in the GAP table could be helpful to use a specific trap that withholds hedgehogs from drinking the beer.	Corrected in §2.5 and §3 Use should be restricted to specific slug traps.	Addressed: Points 2.5 and 3 have been updated.

2.5. Description of the recipe for the product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3. Uses of the substance and its product

PL: no comments

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		EFSA: See EFSA comment 7(1)	EFSA: See EFSA comment 7(1)	See 7(1)	See comment 7(1)

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(2)	Usefulness in the framework of plant protection	DE: Type of container in column "Formulation/Type" (plate) does not correspond to column "Application/Method" (cup).	Please adjust.	Corrected in §2.4 and §3	Addressed: Points 2.4 and 3 have been corrected.
3(3)	Usefulness in the framework of plant	DE: An open "cup" (or plate) as recommended in column	It could be added: cup or specific trap that prevents hedgehogs from	Corrected in §2.5 and §3 Use should be restricted to	Addressed: Points 2.5 and 3 have been

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	protection	"Application/Method kind" makes the beer accessible for hedgehogs.	drinking the content.	specific slug traps.	updated. Use should be restricted to specific slug traps.
3(4)	Ibid.	DE: The "plate bait" use is not described in the application. It is not possible to assess the risk for non-target organisms without a precise description of the intended bait traps.		Corrected in §2.5 and §3 Use should be restricted to specific slug traps AL "Other liquids to be applied undiluted".	Addressed: Points 2.5 and 3 have been updated. Use should be restricted to specific slug traps.
3(5)	2.4 Type of Preparation	DE: It is questionable whether plate bait (PB) is the correct type of preparation.	It seems that as type of preparation AL "Other liquids to be applied undiluted" would be more appropriate.	Corrected in §2.4 and §3 AL "Other liquids to be applied undiluted".	Addressed: The type of preparation was updated accordingly to AL. See also comment 2(1).
3(6)		EFSA: A more detailed description of the plate, its placing requirements, if any, would help in evaluating the possible risks to the environment and non-target organisms.		Corrected in §2.5 and §3 Use should be restricted to specific slug traps. Pictures of specific traps provided.	Addressed: Points 2.5 and 3 have been updated. Use should be restricted to specific slug traps.
3(7)		EFSA: A description of a proposed handling of the bait after its use would also be of interest.		Corrected in §2.5 and §3 Use should be restricted to specific slug traps.	Addressed: Points 2.5 and 3 have been updated. Use should be restricted to specific slug traps.
3(8)		EFSA: See EFSA comment 7(1)	EFSA: See EFSA comment 7(1)	See 7(1)	See comment 7(1)

4. Classification and labelling of the substance

Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)		PL: no comments			Noted.

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		PL: The applicant should place a brief summary of information on toxicokinetics and metabolism, arising from the cited references.		More references added.	Addressed.

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)		PL: The applicant should place a brief summary of		Detailed and expended.	Addressed.

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		information on acute toxicity, arising from the cited references.			

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)		PL: no comments			Noted.

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)		PL: The applicant should place a brief summary of information on genotoxicity of ethanol, consumed in alcoholic beverages and its main metabolite - acetaldehyde, arising from the cited references.		Expend as requested.	Addressed.

5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		PL: no comments			Noted.

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)		PL: The applicant should place a brief summary of information on reproductive toxicity of ethanol, consumed in alcoholic beverages, arising from the cited references.		Expend as requested.	Addressed.

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)		PL: The applicant should place a brief summary of information on neurotoxicity of ethanol, consumed in		Expend as requested.	Addressed.

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		alcoholic beverages, arising from the cited references.			

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)		PL: The applicant should place a brief summary of information on toxicity of ethanol metabolites, arising from the cited references.		Expended as requested.	Addressed.

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)		PL: no comments			Noted.

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)		PL: no comments			Noted.

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(11)		PL: no comments			Noted.

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)		PL: no comments			Noted.

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(13)		PL: no comments			Noted.

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(14)		EFSA: Provided that beer is foodstuff, and of food grade quality, its toxicological concern relates to its alcohol content (assumed to be between 3.5 and 8%).		Food grade required. No comment from applicant.	Considering that beer is foodstuff, of food grade quality and it is used in specific slug traps, non-dietary exposure risk assessment is not required.

6. Residues**Residues**

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		EFSA: Provided it can be ascertained that the placing of the bait will not lead to any contamination of edible crops, residues are not of relevance.		Specific traps described.	Addressed. The intended application of beer is as bait, in specific traps as illustrated. Contamination of edible crops by spill should normally not occur, but if spilling would exceptionally happen, the consequences for consumer health are deemed trivial provided food-grade beer is used in the traps.
6(2)		PL: no comments			Noted.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Fate and Behaviour in the environment	EFSA: The proposed use method (liquid placed on a plate / dish as a bait, manually removed after use) potentially limits environmental exposure. However this is difficult to assess properly without information on the number of bait dishes that would need to be placed per land surface area associated with the crops to be protected.	Applicant to provide information / advice to users on the number of bait dishes to be placed per land area within or adjacent to the cropped areas to be protected, in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding RR. Reference added and expended.	The application still does not provide information on the number of traps that would need to be placed per land surface area associated with the crops to be protected.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

8. Effects on non-target species

PL: no comments

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1.1. Birds	DE: It is agreed that alcohol is toxic to birds. Is it ensured that the intended application does not endanger birds?		Specific described traps should be compulsory in the potential approbation and corresponding registration report	Clarification was provided on the type of the used bait stations/traps. See 8(2).
8(2)	8.1 Effects on terrestrial vertebrates	EFSA: It is mentioned that alcohol is assumed to be toxic to birds although no quantitative description (i.e. data) is available in the basic substance application. The risk to birds and other terrestrial vertebrates depends also on the level of exposure, which is not described/estimated in the application. It may be assumed that the exposure of terrestrial vertebrates is low from the intended use, however exact description of the intended use is also not available. The type of dispenser/trap can be an important element in order to judge how likely is for	Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the extent of the exposure of wild vertebrate populations and the overall risk in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Estimate of the exposure or overall risk to wild vertebrate populations was not provided. Neither information as regards the number of traps per land surface area. Therefore, qualitative or semi-qualitative estimation of the risk was not possible. Further information and clarifications were provided on the types of used bait stations/traps. Considering this, generally a low exposure to wild vertebrate populations is assumed. Even if it is not excluded that some small vertebrate species can occasionally visit the traps or might be attracted, this should not concern a

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		non-target organisms to come into contact with the beer. See also comment in 3(3).			large proportion of local populations.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)	8.2 Effects on aquatic organisms	DE: It is agreed that alcohol is toxic to aquatic organisms. Is it ensured that the intended application does not endanger aquatic organisms?		Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(4).
8(4)	8.2 Effects on aquatic organisms	EFSA: It is mentioned that alcohol is assumed to be toxic to aquatic organisms (no data presented in section 8.2). It is noted that a peer reviewed data set for ethanol was evaluated by EFSA (EFSA, 2009). This data set indicates low acute toxicity to aquatic organisms. The risk largely depends on the level of	Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the level of exposure of aquatic organisms and the overall risk in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Estimate of the exposure or the overall risk to aquatic organisms was not provided. Neither information on the number of traps per land surface area. Therefore, it was not possible to derive qualitative or semi-qualitative estimation of the risk. However, further information and clarifications were provided on the types of used

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		exposure to beer, which is not described/estimated in this application. It may be assumed that the exposure to aquatic organisms is low from the intended use, however exact description of the intended use is not available.			bait stations/traps. Considering this, a negligible exposure to aquatic organisms is assumed.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)	8.3.1. Effects on bees	DE: It is agreed that alcohol is toxic to bees. Is it ensured that the intended application does not endanger bees?		Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(8).
8(6)	8.3.2. Effects on arthropods	DE: It is agreed that alcohol is toxic to arthropods. Especially ground-dwelling arthropods may be affected by however built traps.	Describe the assumed effects on arthropods caused by the intended use of beer as a basic substance.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(8).
8(7)		DE: No data are presented that exclude a threat for bees and other arthropods.	Data should be added.	Specific described traps should be compulsory in the potential approbation and	Clarification was provided on the type of the used bait stations/traps.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				corresponding registration report.	See 8(8).
8(8)	8.3. Effects on bees and other arthropods	EFSA: It is mentioned that alcohol is assumed to be toxic to bees and other arthropods (no data were presented). The risk largely depends on the level of exposure, which is not described/estimated in the application. It may be assumed that the exposure of arthropods is limited from the intended use. On the other hand, arthropods may visit/may be attracted to visit the dispensers. The type of dispenser/trap can be an important element in order to judge how likely this might occur. Exact description of the intended use is not available.	Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the level of exposure of bees and other arthropods and the overall risk in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Estimate of the exposure or the overall risk to bees and other arthropods was not provided. Neither information on the number of traps per land surface area. Therefore it was not possible to derive a qualitative or semi-qualitative estimation of the risk. Further information and clarifications were provided on the types of used bait stations/traps. It is considered that bees and non-target arthropods are not prevented to visit the bait stations and may consume some considerable amount of beer, especially if attracted by it (e.g. wasps are known as attracted by beer). Taking this into account, a considerable oral exposure (therefore high risk) to bees and non-target arthropods cannot be excluded. However, this might be limited to local populations where the bait stations are

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application used.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)	Ibid.	DE: It is agreed that alcohol is toxic to soil organisms. They especially may be affected by however built traps.	Describe the assumed effects on soil organisms caused by the intended use of beer as a basic substance.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(11).
8(10)		DE: Soil macroorganisms might be trapped as well. Also snails (with shell) that are not detrimental are attracted, although some are under protection by nature protection legislation, as <i>Helix</i> spp.	This should be discussed and data presented.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(11).

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)	8.4. Effects on earthworms and other soil macroorganisms	<p>EFSA: It is mentioned that alcohol is assumed to be toxic to earthworms and other soil macroorganisms (no data were presented). The risk largely depends on the level of exposure, which is not described/estimated in the application. It may be assumed that the exposure of soil macroorganisms, in general, is limited from the intended use. However, some species may be attracted to visit the dispensers. The type of dispenser/trap can be an important element to judge how likely this might occur. Exact description of the intended use is not available.</p>	<p>Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the level of exposure of earthworms and other soil macroorganisms and the overall risk in an updated application.</p>	<p>Specific described traps should be compulsory in the potential approbation and corresponding registration report.</p>	<p>Estimate of the exposure or the overall risk to soil macroorganisms was not provided. Neither information on the number of traps per land surface area. Therefore qualitative or semi-qualitative estimation of the risk was not possible. Further information and clarifications were provided on the types of the used bait stations/traps. On the basis of these, it was considered to be unlikely that a considerable part of populations of soil dwelling macro-organisms, like earthworms, will visit or fall in the bait stations.</p> <p>Anyhow this does not exclude that some individuals could be trapped.</p> <p>Also, non-target macro-organisms living on soil surface, including snail species under protection by nature protection legislation of some MSs, may visit the bait stations and consume some considerable beer,</p>

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					especially if attracted by it.

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(12)	Ibid.	DE: It is agreed that alcohol is toxic to soil microorganisms. They especially may be affected by however built traps.	Describe the assumed effects on soil microorganisms caused by the intended use of beer as a basic substance.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Clarification was provided on the type of the used bait stations/traps. See 8(13).
8(13)	8.5. Effects on soil microorganisms	EFSA: It is mentioned that alcohol is assumed to be toxic to soil microorganisms (no data were presented). The risk largely depends on the level of exposure, which is not described/estimated in the application (it may be assumed to be low). Exact description of the intended use is not available.	Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the level of exposure of soil microorganisms and the overall risk in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Estimate of the exposure or the overall risk to soil microorganisms was not provided. Neither information on the number of traps per land surface area. Therefore, it was not possible to deliver qualitative or semi-qualitative estimation of the risk. Further information and clarifications were provided on the types of used bait stations/traps. Based on that, it was considered to be unlikely that soil dwelling micro-organisms are considerably exposed to

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					the use of beer as pesticide.

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)	8.6. Effects on other non-target organisms (flora and fauna)	EFSA: It is mentioned that 'Action on flora is not supposed to occur due to position of the trap at the soil'. However exact description of the intended use (including the position or the type of the traps) is not available. As regards other non-target fauna, please consider comments 8(10) and 8(11).	Applicant to clarify the intended use as requested by comments 3(6), 3(7) and 7(1). Applicant to estimate the level of exposure of other non-target organisms (flora and fauna) and the overall risk in an updated application.	Specific described traps should be compulsory in the potential approbation and corresponding registration report.	Qualitative or semi-qualitative estimation of the risk to other non-target organisms (flora and fauna) was not provided. However, further information and clarifications were provided on the types of used bait stations/traps. Based on this information, it was considered to be unlikely that other non-target organisms (flora and fauna) are considerably exposed to the use of beer as pesticide.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)	8.7. Effects on biological methods of sewage treatment	EFSA: EFSA disagrees that the issue is not relevant. Unused bait when disposed may contaminate sewage systems. Nevertheless, this exposure may not be considerable.		It seems that as type of preparation AL "Other liquids to be applied undiluted" would be more appropriate. Thus bait is modified adequately. Beer as food stuff is a habitual substance in sewage systems in case of spilling.	Estimation of the risk to biological methods of sewage treatment was not provided. The use of beer as pesticide may contaminate sewage treatment plants. However, taking into account the available information on the use, it was considered that this exposure may not be significant.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		PL: no comments			Noted.

10. Other comments

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		PL: no comments			Noted.

Appendix B – Identity and biological properties

Common name (ISO)	Not applicable
Chemical name (IUPAC)	Not relevant
Chemical name (CA)	Not relevant
Common names	beer
CAS No	8029-31-0
CIPAC No and EEC No	None
FAO specification	None
Minimum purity	Not applicable
Relevant impurities	Not applicable
Molecular mass and structural formula	Not applicable
Mode of Use	specific slug traps
Preparation to be used	AL (Any other liquid)
Function of plant protection	Molluscicide

Appendix C – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
All edible and non-edible crops	All MS	n.a.	F	Pest slugs and snails	AL Other liquids to be applied undiluted	pure	Specific traps for slugs	At the beginning of infestation	1 to 5	-	-	-	-	-	none	

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor

(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..

(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f): All abbreviations used must be explained

(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)

(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k): Indicate the minimum and maximum number of application possible under practical conditions of use

(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 000 g/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m): PHI - minimum pre-harvest interval