TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for approval of *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract to be used in plant protection as a repellent to seed-eating mammals and birds

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 *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract. 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 *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract as a basic substance to be used in plant protection as a repellent to seed-eating mammals and birds. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: Capsicum annuum L. var. annuum longum group cayenne extract, basic substance, application, consultation, plant protection, pesticide, repellent

Requestor: European Commission

Question number: EFSA-Q-2020-00012

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Summary

Capsicum annuum L. var. *annuum,* longum group*,* cayenne extract 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 BIO NATURAL PROTECT 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 on 07 January 2020, EFSA was asked to organise a consultation on the basic substance application for *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract, 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 *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract, organised by EFSA, was conducted with Member States via a written procedure in September-November 2019. 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 *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Capsicum annuum L. is a dicotyledonous flowering plant commonly grown worldwide, with many common names. It is used as a fresh and cooked vegetable, a source of food ingredients for sauces and powders and as a colourant, which is used as well in cosmetics. Moreover, the species is used medicinally and medically, and provides the ingredient for a non-lethal deterrent or repellent to some human and animal behaviours. Chili peppers are also cultivated ornamentally especially for their brightly glossy fruits with a wide range of colours. *Capsicum annuum* L. extract is used as a colouring and flavouring product in food products.

Capsicum annuum L. var. *annuum,* longum group*,* cayenne extract is obtained by solvent extraction process of the strains of *Capsicum* fruits with hexane or super critical carbon dioxide, further treated with methanol, in order to separate the pungent component. Capsaicin is considered the main active component of the extract. The specification for the proposed *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne ext. is considered a data gap as well as the application details.

According to the self-classifications provided by companies to ECHA there is evidence that components of *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract may have to be classified as serious eye damage, harmful if swallowed and also as cause of skin irritation. No harmonised classification according to Regulation 1272/2008[1] is available on these components. There are also indications that components of *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract such as capsaicin may have genotoxic properties (SCF, 2002). It is noted that capsaicin is claimed to be one of the active components of the extract.

Residues are not expected in food following the seed treatment of *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract for crops production and therefore the contribution to the dietary exposure is expected to be insignificant. It is noted however that the components of the extract are not well defined.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Capsicum annuum L. var. *annuum,* longum group*,* cayenne extract is ill-defined in the application. The fate and behaviour properties as provided of some of the possible extract components, including capsaicin, in the environment (matrices soil and water) are uncertain.

Basic components and concentrations of *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract proposed in this application are not clear. Additional studies for toxicity to all nontarget species is proposed.

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1. Introduction

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

Regulation (EC) No 1107/2009[2] (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.

Capsicum annuum L. var. *annuum,* longum group*,* cayenne extract is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from BIO NATURAL PROTECT for approval as a 'basic substance' to be used in plant protection as a repellent to seed-eating mammals and birds.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract, which was conducted via a written procedure in September-November 2019. 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 *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract 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 *Capsicum annuum* L. var. *annuum,* longum group*,* cayenne extract 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 (BIO NATURAL PROTECT; 2019), (BIO NATURAL PROTECT; 2020).

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 07 January 2020, EFSA was asked to organise a consultation on the basic substance application for *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract, 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 07 April 2020.

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.

[2] 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 *Capsicum annuum* L. var. *annuum*, longum group, cayenne ext. 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 used compounds, the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B, C and D respectively. The GAP table that has been presented in the updated application is not clear and consistent. Changes, proposed by EFSA have been included in the second GAP table provided in Appendix D.

Documentation provided to EFSA

1. BIO NATURAL PROTECT, 2019. Basic substance application on *Capsicum annuum* L. var. *annuum*, longum group, cayenne ext. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2019. Documentation made available to EFSA by the European Commission.

2. BIO NATURAL PROTECT, 2020. Basic substance application update on *Capsicum annuum* L. var. *annuum*, longum group, cayenne ext. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. January 2020. Documentation made available to EFSA by the applicant.

References

SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on Capsaicin adopted on 26 February 2002. SCF/CS/FLAV/FLAVOUR/8 ADD1 Final, 12 pp.

Abbreviations

a.s.	Active Substance
ASTA	American Spice Trade Association
BSA	Basic Substance Application
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council.
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
DAR	Draft Assessment Report
EINECS	European Inventory of Existing Commercial Substances
FAO	Food and Agricultural Organization
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
LC_{50}	Lethal Concentration, median
LD_{50}	Lethal Dose, median; dosis letalis media
MRL	Maximum Residue Level
MS	Member State
NESTI	National Estimated Short-Term Intake
OECD	Organisation for Economic Cooperation and Development
OSR	oilseed rape
PBI	plant-back interval
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PRIMo	Pesticide Residue Intake Model
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
RMS	Rapporteur Member State
TMDI	Theoretical Maximum Daily Intake

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Capsicum annuum annuum*, longum group, cayenne, ext 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)	1	DK: If by 'orphan use' is indicated that the use as seed treatment as a repellent against mammals does almost not fall under Reg. 1107/2009, then DK disagree. Repellents are included in the Regulation, also repellents against mammals. It does not make a difference that the repellent is applied as seed treatment.	DK: Please delate this sentence: "At this point, we must mention that the Seed Treatment Usage targeted toward wild boars and mammals, claimed for this basic substance is actually almost an orphan use."	Since the application deposit, pepper dust, and thiram approval were non-renewed. Ziram used as such is candidate for substitution and only approved until April 2020. Only Denathonium benzoate and quartz sand are left with only uses on trees, not as seed treatment. Sentence rewritten in the updated BSA.	Addressed: The sentence was slightly modified in the updated application.

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

2.1. Predominant uses outside of plant protection

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)	2.1 Predominant use, p.6	EFSA: *Capsicum annuum annuum*, longum group, cayenne, ext is stated to be a food additive in the EU, however COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives contains only E 160c Paprika extract, capsanthin, capsorubin		*Capsicum annuum annuum*, longum group, cayenne, extract is not E160c (a colouring agent). CAS numbers are different. References are given in the BSA (Olatunji 2018&2019) on food uses of Capsicum annuum. **OECD consider Capsicum annuum as food (OECD, 2006).** ***Capsicum annuum*, ext is also considered as active substances for which a compliant notification was submitted as biocidal product.**	Addressed: *Capsicum annuum annuum*, longum group, cayenne, ext is not included as a food additive in the COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives.

2(2)	2.2.4 Methods of manufacture	NL: In the methods it is described that the pungent part is separated from the non-pungent part. It therefore seems that the basic substance is not actually capisum annuum annuum longum group cayenne, but extracted capsaicin which is also claimed as the active component. Capsaicin is banned in the EU as a food additive due to safety concerns, including genotoxicity. According to the notifications provided under REACH the substance is also toxic if swallowed, causes serious eye damage and causes skin irritation. Such a substance cannot be considered as a basic substance.		The food substance capsicum annuum annuum longum group cayenne, extract is not capsaicin pure since it contains only less than 0.025 % capsaicin. However, capsaicin is still the main active compound in the capsaisinoid mixture. CAS number of capsicum annuum annuum longum group cayenne, extract is also different from capsaicin.	Addressed**:** *Capsicum annuum annuum*, longum group, cayenne, ext contains less than 0.025 % capsaicin.

2(3)	2.2.4	NL: As extraction solvents, various options are mentioned that are no longer compatible with EU food regulations. The applicant must demonstrate that the described manufacturing process, including the fractionation of the oleoresin, is equivalent to the typical manufacturing process of a foodstuff. In other words, can the final product (pungent fraction of the oleoresin) be considered a foodstuff (as per (EC) No 178/2002)?		Solvents use for the separation of oleoresin from E160c food colouring is the same: hexane or super critical carbon dioxide following by methanol. No difference: solvents are later removed to meet food requirements. Note: hundreds of food products are not listed in (EC) No 178/2002, like sugars, mustard seed powder, table salt, … and still common food!	Addressed: Solvents are removed by distillation under reduce pressure to meet food requirements.

2.2. 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.

2.2.1. Common name of the substance and product and their synonyms/plant nomenclature

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(4)	2.2.1	DK: Please explicitly here write out common name. the "ext" part should be written in full as "extract".		Corrected	Addressed: The "ext." was not corrected to "extract" in the updated application.

2.2.2. Chemical name with CAS, EC and CIPAC numbers

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(5)	2.2.2 Chemical name	DE: Please delete CIPAC number. There is no number assigned for *Capsicum annuum* annuum, longum group, cayenne, ext.		Deleted	Addressed: The CIPAC number was deleted in the updated application.
2(6)	2.2.2 Chemical name	DE: Please correct the Typo: It should be capsaicin instead of capsaisin.		Corrected	Addressed: The typo was corrected in the updated application

2.2.2. Chemical name with CAS, EC and CIPAC numbers

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(7)	2.2.5 Specification, p. 10	EFSA: small note: also here capsaicin instead of capsaisin, capsaisinoid		Corrected	Addressed. Correction was done in the updated submission.

2.2.3. Molecular and structural formula, molecular mass

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.

2.2.4. Method or methods of manufacture of the substance and of the product

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.

2.2.4.1. Separation of the pungent part

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(8)	2.2.4.1 Separation of the pungent part, p.8	EFSA: clarification is needed on what exactly is considered as basic substance. Is the basic substance identical with the extracts defined by E 160c?	It seems from this description that the "pungent part" is separated from the colour component while E 160c denotes Paprika extract, capsanthin, capsorubin. The process using super critical carbon dioxide extraction seems to contain the whole extract, but this is also not clear, as the oleoresin portion is separated from the essential oils.	Initial mixture of capsicum raw material provides by separation both: E160 (non-pungent) **and** capsicum annuum annuum longum group cayenne, extract (pungent). In fact, both extracts are the "opposite" substances during the separation of components.	Addressed: *Capsicum annuum annuum*, longum group, cayenne, ext is obtained by solvent extraction of the strains of Capsicum fruits, which consists of the ground fruits pods, with or without seeds, of *Capsicum annuum* L., and contains the major spicy components like capsaicin.

2.2.4.2. Purification of the pungent part

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.

2.2.5. Description and specification of purity of the substance and product

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(9)	2.2.5 Description and specification of purity of the substance and product	DE: Please give reference where the specification in the table is derived from and state whether this is the specification of the basic substance.		References modified	Data gap: The specification table was deleted, the mentioned references do not contain any specification of the extract. A specification of the proposed basic substance should be provided including the capsaicin.
2(10)	2.2.5 Description and specification of purity of the substance and product	DE: In the table in 2.2.5 a maximum content of capsaicin of not more than 250 mg/kg is given. However, in 2.2.2 capsaicin is stated as main active component. Also in the production process is described that the pungent part of the extract is purified. Please clarify and state the content of capsaicin in the basic substance as manufactured.		The food substance capsicum annuum annuum longum group cayenne, extract is not capsaicin pure since it contains an average of 6 % capsaicin. However, capsaicin is still the main active compound in the capsaisinoid mixture. Other main capsaisinoids do not exhibit pungency properties as capsaicin. They should be	See data gap 2(9)

2.2.5. Description and specification of purity of the substance and product

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
				considered as "inert" in the mixture.	
2(11)	2.2.5	DK: The description given for the extract and the proposed concentration of the extract given in chapter 3.4 (GAP table) does say the same thing. Also, it is not clear that the composition/specification is for the cayenne extract of this application. According to 2.2.5. the composition of Cayenne extract is >7% carotenoids, 60-80 % capsaisinoids, and sunflower oil up to 100 %. How does this translate into a a.i. content of the "formulation" of 94 g/kg? What substance/component is the 94 g/kg of the cayenne extract? If it is capsaicin, then		capsicum annuum annuum longum group cayenne, extract is an oleoresin containing 6% capsaicin Data updated Components updated	See data gap 2(9)

2.2.5. Description and specification of purity of the substance and product

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
		how does this fit with the max 250 mg/kg in the table?		Capsaicin content updated	
2(12)	2.2.5 Specification	EFSA: a clear description of what is considered the basic substance is missing. Is this the E 160c or something else? If so, is there a min/max requirement of the content of any components considered as main components? (capsaicin, capsanthin and capsorubin…)	Is our assumption correct that the basic substance is the extract meeting the specification described on pages 10-11?	Capsicum annuum annuum longum group cayenne, extract is the basic substance and it contains only less than 0.025 % capsaicin. However, capsaicin is still the main active compound in the capsaisinoid mixture. Other main capsaisinoids do not exhibit pungency properties as capsaicin. They should be considered as "inert" in the mixture.	See data gap 2(9)
2(13)	2.2.5 Specification, p.10	EFSA: the methods for checking the specification are not part of the submission	It is not clear what are the ASTA EOA methods. They are not freely accessible.	ASTA is an international ISO 972 Method, all labs are using it. Other references are local development of this worldwide accepted method.	Addressed: It should be noted that Method ISO 972 is not available in the submission, neither freely available for the laboratories.

2.2.6. Identity of inactive isomers, impurities and additives

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.					

2.2.7. Methods of analysis

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(14)	2.2.7 Methods of analysis Analytical methods for determination of residues Klatyik et al., 2017	DE: The submitted text is not suitable as summary of the study. It is the first paragraph of the introduction of the article.	DE: Please add an abstract of the article summarising the results.	Corrected	Addressed: The summary concerning study Klátyik et al. was updated in the revised submission.
2(15)	2.2.7 Methods of analysis, p.11	EFSA: Gardner (2001) is a summary of results of spray analysis, without any description of the method used, except the principle.	Based on this report it is not clear what method and how can be used for the analysis of the substance. A more detailed description of the method is needed if it is considered relevant.	Reference removed, replaced by: French *Pharmacopoeia* 2008	Addressed: The reference was removed in the updated submission.

2.2.7. Methods of analysis

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(16)	2.2.7 Methods of analysis, p.12	EFSA: it is not clear what specifications can be found in Chattopadhyay (2016)		Removed	Addressed: The reference was removed in the updated submission.
2(17)	2.2.7 Methods of analysis, p.12	EFSA: Asselt (2018) is mentioned under the methods section, however the publication deals with available monitoring data and RASFF notifications. Concludes that the results demonstrated that the mycotoxins aflatoxins and ochratoxin A, the pesticides chlorpyrifos and triazophos, and the dye Sudan posed the highest human health risk for spices and herbs. These compounds should, therefore, have an increased monitoring frequency in these products.	It should be described how it is assured that the product used as basic substance is free of the mentioned compounds? Are there methods available for the determination of their content?	FAO and OECD standard requirements for Capsicum annuum extract pesticide residues, together with Pharmacopeia requirements ensure Capsicum annuum extract purity.	Addressed: The plants used for the production of the basic substance should meet the requirements of ISO 972: 1997 'Chillies and capsicums, whole or ground (powdered) — Specification and of the Pharmacopeia requirements

2.3. Names of substances/products as put on the market

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(18)	2.3 Names of products on the market	EFSA: our understanding is that this is just an example of extract on the market, but any other available can be used		Many identical extracts are produced over the world with ASTA ISO 972 specifications. No detail	Addressed.

2.4. 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
2(19)	2.4	DK: Please insert the information in a more useful way than with copy paste logos.		Corrected	Addressed.

2.5. Type of preparation of the substance/product

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.

2.6. Description of the preparation for the product to be used for plant protection purposes

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(20)	2.6.	DK: DK questions whether it would be allowable to use a concrete mixer for seed treatment with cayenne extract. Please see DK comments for chapter 4 regarding hazard classification and potential risk mitigation measure.		The use a concrete mixer for seed treatment with cayenne extract is not only possible but recommended, to dippers the substance in the better way.	Addressed: The recommended use is mixing with a concrete mixer.
2(21)	2.6 Description of the preparation regarding intended purpose	NL: Information is provided that suggests that the substance is to be marketed as plant protection product. According to Article 23d of (EC) No 1107/2009, a basic substance is an active substance that is not placed on the market for this purpose.		Capsicum oleoresin is available everywhere including from web retailers. Later use is managed by buyers (pharmacopeia, food addition, …)	Addressed: Any *Capsicum annuum annuum* extract, meeting the requirements, can be used.

3. Uses of the substance and its product

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

No comments.

3.2. Effects on harmful organisms or on plants (including mode of action)

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)		DE: More information on the effect on harmful organisms should be provided. What is the reason for the repelling effect?	DE: E.g. explain the role of TRPV1.	TRPV1 receptor in mammals is targeted by the substance. Reference added in §3 in the updated BSA (Gervais, 2008, Guzmán 2018)	Addressed: Gervais, 2008, Guzmán 2018 were added to the updated submission.
3(2)		DE: In insects the active substance can act as a biocide, leading to nervous system dysfunction, membrane damage or metabolic disruption (see Gervais et al. 2008). As insects are not excluded in the GAP as target organisms, the statement that	DE: Clarify target organisms in GAP (see also comment below) or remove statement.	Sentence modified.	Addressed: The application was updated.

3.2. Effects on harmful organisms or on plants (including mode of action)

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 active substance is not a biocide is incorrect.			
3(3)		DE: Although some studies are provided according to which *Capsicum*-based substances showed a repellent effect on different mammals, no data is provided for the efficiency of the intended use on seeds of *Triticum* spp., sweet corn and sunflower.	DE: It should be made clear that there is no experience that proofs efficiency with regard to the intended uses.	Chapter §3 updated	Addressed: Additional information was inserted in the revised application. It should noted that there is no experience that proofs efficiency with regard to the intended uses on seeds of *Triticum* spp., sweet corn and sunflower.

3.2.1. Effects on harmful 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

No comments.

3.2.2. Mode of action

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. Usefulness in the framework of plant protection

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.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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(4)	Application rate in the GAP table	BE: The application rate is only expressed in g a.i./ha. The GAP table should also include useful and practical information for the user of the basic substance. The GAP table will, in case of approval, be integrated in the	The application rate should also be expressed in g of active substance per weight unit of the seeds.	Sentence added in GAP Table: The use a concrete mixer for seed treatment with cayenne extract is not only possible but recommended, to dippers the substance in the better way. Calculation for seed provided.	Data gap: Applicant to update the application rate using the correct units for seed treatment applications.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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
		Commission's review report, and be the first source of information on the authorised use.			
3(5)		DE: The specification of target organisms is extremely vague and basically includes all organisms of the kingdom Animalia ("Feeding animals and mammals boar, ravens, deer").	DE: It is recommended to ascertain the target organisms more specifically.	Corrected	Addressed: The GAP table was updated.
3(6)		DE: There is no information about how the applicant ascertained the application rate of 14-15 g a.i./ha.	DE: Provide reasons for the proposed concentrations and application rates, considering the amount of seeds which are commonly used (e.g. up to 240 kg Triticum seeds / ha) and information that is provided in chapter 2.6 (Description of the preparation for the product to be used for plant protection purposes).	150 ml is the Qt for 30 Kg seeds Modified in the GAP Table	Data gap: Applicant to propose a GAP in line with the specification of the basic substance. The GAP is inconclusive, it is not possible to define the correct application rate because of the contradictory and insufficient information of the resubmission.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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
					On p. 17 under point 2.6 it is stated that 150 ml of extract (capsaicin content 0.0375 mg) is used for 30 kg of seeds. In case of cereal seeds for example with 70- 250 kg/ha this would result in 350 to 1250 ml extract /ha, or 0.0875 to 0.3125 mg capsaicin/ha. The values in the GAP seem to come from a content of cca. 6% of capsaicin content of the extract. Clarification is needed which value is true? See also data gap 2(9) See also comment 3(8)
3(7)		DE: No data were provided that show that the intended application of the substance (in the intended concentration) is not harmful for the crops that are to be protected.	DE: Please provide reasons that exclude the possibility of toxicity for crop plants.	No phytotoxicity observed	Addressed: No data were provided, just a statement that phytotoxicity was not observed.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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(8)	3.4 GAP table	DK: **Column (a)**: Please change the long list of wheat types to just "cereals" if this basic substance would be helpful for other cereals than just wheat. **Column (i)**: Please give the concentration of a.i. in [g/L] as the type (column d-f) is a liquid (and not e.g. a powder). **Column (j)**: Please insert "BBCH 00" instead of "n.a.". **Column (l):** Please justify the total rate of a.i./ha given (14-15 g a.i./ha). This depends on how many seeds are sown, and will therefore vary among different agricultural practices and crops. Therefore, it is not expected that the same value should be valid for both cereal, maize and sunflowers?!	DK: Please specify for each crops ty	Corrected, GAP Modified	See data gap 3(6)

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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(9)	3.4 summary of intended uses, table, 4th column	NL: In column 4 (F, G, or I), currently it is stated that it concerns a field application. The actual application of a seed treatment product is considered to occur at treatment of the seed, not while sowing it. Seed treatments are therefore considered an indoor use.(I) however it is also relevant to note the product will be sown in the field.		Corrected	Addressed: The GAP table was updated.
3(10)	3.4 summary of intended uses, table, 9th column	NL: Column 9 (growth stage and season) has not been completed.	Growth stage: The growth stage is "BBCH 0" for seed treatments Season: the months of sowing would be needed in this column, this can be looked up for the different crops. It would be helpful to split the gap into separate rows for the mayor crop groups that differ in sowing time or other important	Corrected, GAP Modified	Addressed: The GAP table was updated.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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
			characteristics; e.g winter cereals, spring cereals, maize and sunflower.		
3(11)	3.4 summary of intended uses, table, column 14	NL: It is not clear how the amount of a.i. per hectare in column 14 has been calculated. We have taken into account the conc. of a.i/kg from column 7 and the assumption in paragraph 5.3.1 that 150 ml of product is used to treat 30 kg of seed and typical sowing densities taken from the supplementary information of lucchesi et al (2016). In any case due to differences in sowing densities it would be expected that for example maize would have different values from cereals or sunflower. it may be necessary to split the GAP into rows for the different mayor crops; e.g winter cereals,	Please update the values in this column taking into account the differences in sowing rates and seed characteristics for the different claimed crops, Please also indicate the amount of product per tonne seeds in column 14 or in the remarks column of the table of uses for clarity.	Corrected, GAP Modified Lucchesi et al (2016) taken in consideration Request validated	See data gaps 3(4), 3(6)

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Belgium	Column 3 Proposal by Belgium 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
		spring cereals, maize and sunflower.			
3(12)	GAP table, p.17	EFSA: please update the GAP table with application rates relevant for seed treatment	It would be more understandable if the unit would be g (ml)/t of seeds or kg(L)/t of seed or /100 kg of seeds.	Corrected, GAP Modified	See data gap 3(4)
3(13)	GAP table, p.17	EFSA: in the GAP table the purity of the a.s. is said to be 94 g/kg. It is not clear to what this purity is referring to? If this is the extract, what are the remaining 90.6%? If this is oil, this contradicts 2.2.5 where oil content is 10-30% If the "formulation" used for seed treatment contains also oil, it should be clearly described how to prepare it.	If the basic substance is the extract, it should be clearly described what and how is used for seed treatment.	Corrected, GAP Modified Corrected	See data gap 2(9)

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)		BE: contrarily to the dossier submitter, ECHA considers the substance (CAS RN 84603-55) Flam. Liq. 3 H226 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 https://echa.europa.eu/substance-information/-/substanceinfo/100.075.663 The indication is *„Danger! According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye damage, is harmful if swallowed, is a flammable liquid and vapour and causes skin irritation."* Taking into account the C&L either way, but also some worrying	BE: If a justification exists for the deviation, it should appear in the files. H335 and H318 is added in addition by the dossier submitter. Generally, also (sub)chronic toxicity findings are worth a discussion as regards the toxicological profile of the *Capsicum* extract or its main constituent capsicain.	CAS RN 84603-55-4 ECHA data added	See 5(9).

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
		results in genotoxicity and carcinogenicity, BE doubts whether this 'substance of concern' qualifies for a basic substance application.			
4(2)		DE: According to the submitted information on the product there are CLP classifications of Capsicum annuum cayenne extract. Also, according to the self-classifications provided by companies to ECHA Capsicum annuum cayenne extract fulfils the criteria for classification for serious eye damage, harmful if swallowed and also cause of skin irritation. Due to the CLP classifications provided by the company and information of ECHA, Capsicum annuum cayenne extract cannot be considered to be a substance of no concern. Therefore, the conditions of Article 23 of		Typical concentrations are 6-6.6 % w/w Concentrations used in the oil dilution is only 9.3 g dose (150 ml)	See 5(9).

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**
		Regulation (EC) No 1107/2009 are not fulfilled.			
4(3)	4 CLP	DK: CLP classification should be given for ALL substances in the Cayenne extract. As it is, only oleoresin has been listed. Please include capsaicin and all other capsaisinoids. According to chapter 2.2.5 60-80 % of the extract is capsaisinoids. According to ECHA capsaicin is classified H318 and H315. If all components of the extract were to be included in the classification it is likely that the extract would also be classified with H318 (eye damage category 1) and H315 (skin irritation category 2). If so, then some risk precautionary sentences is needed, which for a basic substance may likely translate	DK: Please update this section with CLP classification for all components of the extract. Especially capsaicin.	Added, modified BSA Concentrations used in the oil dilution is only 9.3 g dose (150 ml) Most of the capsaisinoids are not pungent.	See 5(9).

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**
		into **risk mitigation** for the treated seeds, or the equipment used for seed treatment e.g. only to be used in closed and industrialised facilities. Due to the classifications H315 and H318, of the proposed basic substance in the form which is to be purchased and applied, DK questions whether cayenne extract fulfils the criteria for basic substances as a substance of no concern (Art 23 Reg (EC) 1107/2009). However this awaits what the final specification of the basic substance is in chapter 2.2.5. If, as is suspected, that capsaicin is approx. 94 g/kg (approx. 10%) of the basic substance, and it is also to be expected that more components will have hazard classifications, then cayenne		Mask and gloves are sufficient to avoid irritation.	

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
		extract will probably not fulfil Art 23.			
4(4)	4. classification and labelling	NL: Considering the proposed classification and labelling for capsaicin as toxic if swallowed, causes serious eye damage and causes skin irritation under REACH the substance does not meet the criteria for basis substances and should not be approved as such.		Typical concentrations are 6-6.6 % w/w for REACH evaluation Concentrations used in the oil dilution is only 9.3 g dose (150 ml)	See 5(9).

5. Impact on Human and Animal Health

5. Impact on Human and Animal Health					
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)	5	DK: Please delete the statement "This is evident when the substance is used for policing by police forces". The exposure from police and the exposure from the proposed pesticide use are not comparable.	DK: Delete the sentence: "This is evident when the substance is used for policing by police forces".	Sentence removed	See 5(9).
5(2)	Impact on human and animal health	NL: As already indicated by the applicant capsaicin has been banned in the EU due to genotoxicity concern. Considering the manufacturing process in which the pungent part is separated from the non-pungent part it seems the active substance is mainly capsaicin. Beside the genotoxicity concern capsaicin is also acutely toxic, damaging to eyes and causes skin irritation. The safety concerns		Oleoresin capsicum is still food (Tabasco, etc.) Pure capsaicin was removed.	See 5(9).

5. Impact on Human and Animal Health

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
		regarding capsaicin have not been sufficiently addressed in the application. As such we do not consider this substance can be approved as a basic substance.			

5.1. 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

No comments.

5.1.1. 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

No comments.

5.1.2. 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(3)		DE: According to the submitted information on the product there are CLP classifications of Capsicum annuum cayenne extract. Also, according to the self-classifications provided by companies to ECHA Capsicum annuum cayenne extract fulfils the criteria for classification for serious eye damage, harmful if swallowed and also cause of skin irritation. Due to the CLP classifications provided by the company and information of ECHA, Capsicum annuum cayenne extract cannot be considered to be a substance of no concern. Therefore, the conditions of Article 23 of Regulation (EC) No 1107/2009 are not fulfilled.		Oleoresin capsicum is still food (Tabasco, etc.) Pure capsaicin was removed. Typical concentrations are 6-6.6 % w/w for REACH evaluation Concentrations used in the oil dilution is only 9.3 g dose (150 ml)	See 5(9). See also data gap 2(9).

5.1.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		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.					

5.1.4. 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(4)	Chronic toxicity / carcinogenicity:	BE: feels that the summary does not reflect the findings in the "Final Report on the Safety Assessment of *Capsicum Annuum* […] " Int J Toxicol. Vol 26(3), pp.1-105, 2007. In the summary, dossier submitter (p.30/58) remarks that *"Some of the available studies, however regarded as limited, indicated a carcinogenic potential of capsaicin."*	BE: the whole assessment should be made more substantial, taking into account all studies in the publication. For instance, the data display a variable outcome of carcinogenicity, but overall, a concern of gastro-intestinal tumour induction exists. In a 1997study (Chitra *et al*) the authors concluded that the test article not only promotes carcinogenesis, but, in the presence of a carcinogen, accelerates the process.	Oleoresin Capsicum aka Capsicum annuum annuum is food additive (see Tabasco and similar products) different from pure capsaicin. Piment extract like Capsicum annuum annuum extract are still foodstuff all over the word.	See 5(9).

5.1.4. 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
		A BS status of the substance is therefore considered inappropriate.			

5.1.5. 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(5)	Genotoxicity	BE: as for the long-term effects, the outcome of the published studies shows a quite high variability, going from no effect to strongly mutagenic in bacterial assays and significant findings including chromosome breakage, polyploidy, aneuploidy, and inhibition of spindle formation.	BE: a better overview of genotoxicity findings, as well as the reason why the positive findings should be disregarded, is compulsory. In the current form, the data point to intrinsic genotoxic activity, where it remains unclear which component should be considered worrisome.	Most of the effects are described for pure capsaicin	See 5(9).

5.1.6. 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)	Developmental toxicity	BE: also for reprotoxicity, the description in the dossier is limited to the Muralidhara and Narasimhamurthy study of 1988 on capsaicin, while other findings were published, although it could be remarked that none are guideline-compliant. However, in some of them crown-rump length was low or growth rate was decreased in treated animals. In another (Shono and Hutson, 1994) signs of abnormal testicular descent were reported.	BE: a full evaluation of developmental and fertility finding is needed to allow an independent evaluation.	Muralidhara 1988 cited by Committee of Experts on Flavouring Substances 2005 Shono and Hutson, 1994 not retained by same EU Committee perhaps due to Flutamide pre-treatment. Do not mix everything to blame Capsicum extract: Flutamide is a pure non-steroidal antiandrogen. It works by blocking androgenic prostatic receptors used against cancer, with lot of other negative side effects. This paper does not relate single capsaicin effect!	See 5(9).

5.1.7. 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

No comments.

5.1.8. Toxicity of metabolites or impurities

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(7)	5.1.8 impurities	NL: It is claimed that the production of impurities are controlled since Capsicum extract is a foodstuff. However, considering the purification steps that are conducted as described in section 2.2.4 it seems the substance is not actually the same as what is sold as foodstuff and therefore this claim is not valid.		**Chapter §2 modified**	See 5(9).

5.1.9. 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

No comments.

5.2. Reference values: Acceptable Daily Intake, Acute reference Dose, Acceptable Operator Exposure Leve

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.

5.3. Exposure to the substance and impurities 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

No comments.

5.3.1. Exposure through the use for plant protection purposes

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.

5.3.2. Background exposure (exposure to the substance through other means)

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.

5.3.3. Comparison of exposure through use for plant protection and the background exposure

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.

5.4. 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(8)		DE: According to the submitted information on the product there are CLP classifications of Capsicum annuum cayenne extract. Also, according to the self-classifications provided by companies to ECHA Capsicum annuum cayenne extract fulfils the criteria for classification for serious eye damage, harmful if swallowed and also cause of skin irritation. Due to the CLP classifications provided by the company and information of ECHA, Capsicum annuum cayenne extract cannot be considered to be a substance of no concern. Therefore, the conditions of Article 23 of Regulation (EC) No 1107/2009 are not fulfilled.		The problem is that these data have still not prohibited peppers like Cap neither in the sale nor in the use of food additive and constituents of tabasco like spices over the world. How in this case to apply a schizophrenia in the criteria: applicable to basic substances and not applicable to sold food products?	See 5(9).
5(9)		EFSA: There is evidence that components of Capsicum annuum cayenne extract may have to be classified as serious		Capsicum annuum annuum extract even with theses cited adverse properties is still admitted as food additive.	According to the self-classifications provided by companies to ECHA there is evidence that components of

5.4. 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
		eye damage, skin irritation and harmful if swallowed. There are also indications that components of Capsicum annuum cayenne extract may have genotoxic properties. In fact, the Scientific Committee on Food concluded in its opinion of 26 February 2002 that N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide (capsaicin, FL No 16.014) is genotoxic. https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_flavourings-out120.pdf		Should these evaluations almost 20 years ago confirmed or infirmed after re investigation? How this substance, containing capsaicin, can continue 20 years after, to be on eating tables as spicy food additive?	Capsicum annuum cayenne extract may have to be classified as serious eye damage, harmful if swallowed and also cause of skin irritation. No harmonised classification according to Regulation 1272/2008 is available on these components. There are also indications that components of Capsicum annuum cayenne extract such as capsaicin may have genotoxic properties (SCF, 2002). It is noted that capsaicin is claimed to be one of the active components of the extract. Opinion of the Scientific Committee on Food on Capsaicin (2012). Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_foo

5.4. 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
		It is noted that capsaicin is claimed to be one of the active components of the extract.			d-improvement-agents_flavourings-out120.pdf See also 4(1,2,3,4), 5(1,2,3,4,5,6,7,8) and 9(1,2,3). See also data gap 2(9).

5.5. 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

No comments.

5.6. 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

No comments.

6. Residues

6.	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)	6. Residues	NL: Indeed, it could be expected that seed treatment with Capsicum annuum annuum, longum group, cayenne, ext would not lead to residues into the final product for consumption. However, is there any information available to substantiate this argument? It could be required to confirm such a statement with experimental evidence.		Oil contend in the Capsicum extract is readily biodegradable and also a basic substance (sunflower oil). Other possible residues are typically identical to Capsicum peppers that have fallen to the ground including capsaicin content.	It is unclear which are components that form proposed extract See data gap 2(9)
6(2))	6. Residues	NL: The distribution of possible residues of capsaicin in animals is described here. However, is it therefore expected that humans will be exposed (in contrast to what is written in the conclusion)?		Humans are already exposed through spicy food additive containing capsaicin. Are these residues of concern still consumed as foodstuff?	Although no residues are expected in food there are still toxicological issues to be clarified (see data gap 5 (9)) and also unclarities regarding the composition of the extract (see data gap 2(9).

6.	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(3)	6. Residues	EFSA: Although no significant residues are expected in food due the mode of application (seed treatment), toxicological concerns are identified in the toxicology section. Thus, the potential of residues and their impact on the safety of consumers need to be addressed.		As used for seed treatment, residues in crop production many months after are not expected.	Refer to 6(2).

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)	Ads/des	NL: the applicant has to included QSAR estimates of capsaicin of the Koc of the compound. Together with the DT50 GW exposure scenario's can be conducted.		DT50 = 5 days see reference BPDB As of 2016	Soil adsorption values of 'capsaicin' were not available.

7(2)	Section 7 as a whole	EFSA: Some information has been presented on the expected extract components capsaicin and oleoresin Capsicum. There is no explanation / justification why these components of all those that might be present in the extract have been selected. There is also no clear explanation / specification of what 'oleoresin Capsicum' is and how it is characterised. BPDB database seems to treat capsaicin and oleoresin Capsicum as synonyms of a single compound. Is this the case? However we note that the npic technical fact sheet (Gervais JA 2008) indicates that oleoresin Capsicum contains many volatile compounds and Sterner (2002, 2005) cite papers that indicate a ca. 5% content of capsinoids. So probably capsaicin and oleoresin Capsicum should not be treated as synonyms of a single compound?	Following any clarifications provided to Member State and EFSA comments that have been made in sections 2.2.2, 2.2.4.1and 2.2.4.2 fate and behaviour information on other components of the proposed extract would probably need to be collected and added to the application.	Applicant agrees Capsicum annuum annuum extract is a mixture. Capsaicin is only 6% of the capsicum annuum annuum extract. As active component of capsicum annuum annuum extract (oleoresin), capsaicin is not the basic substance described.	Relevant updates to the application have not been made. It remains unclear which components of the extract make up the basic substance to be assessed. The material 'oleoresin Capsicum' remains ill defined. All that is clear is that the basic substance is not just the compound capsaicin.

7(3)	Section 7.1	EFSA: The application has not discussed the reportedly known soil incubation transformation products of vanillylamine, vanillin, vanillyl alcohol and vanillic acid as discussed in the Gervais 2008 NPIC document.	Information on the properties and fate and behaviour in the environment of known transformation products of the main components of the extract seem necessary to improve the completeness of the application.	Most of the capsinoids are readily metabolised compounds (vanillylamine, vanillin, vanillyl alcohol and vanillic acid). Some of them are also food additive like vanillin or contained in vanilla extracts (vanillic acid). These are also found in soils following plant decomposition.	Updates to the application have not been made. The application contains no discussion of the properties and fate and behaviour in the environment of known transformation products of the main components of the extract including vanillylamine, vanillin, vanillyl alcohol and vanillic acid.
7(4))	Section 7.2	EFSA: A graph has been presented comparing soil half life ranges for a number of compounds including capsaicin, but there is no indication / citation of the source of the values. This graph has no value without a proper citation of the origin of the data behind the graphical presentation.	Please provide a relevant reference to the scientific publication(s) where the investigations that are the source of the information in the graph are reported.	DT50 = 5 days see reference BPDB As of 2016	The soil half life values presented in the application or of unknown / unclear origin. Their reliability is therefore uncertain.

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.

7.2.1. Exposure through the use for plant protection purposes

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.

7.2.2. Background exposure (exposure to the substance through other means)

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.

7.2.3. Comparison of exposure through use for plant protection and the background exposure

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

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)		DE: The applicant expects the toxicity for non-target organisms to be similar to the toxicity for targeted insects and mammals. This toxicity, however, was not quantified in the dossier.	DE: Please clarify.	Capsicum extract is only repellent, if toxicity is proved, please ask for removal from food usages! Strange to find toxicity claims in M.S. with no indication of withdrawal from food. Sometimes the compound is considered not put on the market while still food additive and sometimes its toxicity highlighted without its food use being questioned since 2005!	EFSA: Applicants response is not clear. Main components and their concentrations in *C. annuum* extract remain unclear too, see 2(12), 4(1), 4(2), 7(2).
8(2)	8.1 Effects on birds	DE: If birds do not detect capsaicin, ravens should be deleted as target organisms in the list of intended uses.		Capsicum annuum annuum extract is indeed deterrent for birds, some other active components (than capsaicin) may be effective, although not identified.	EFSA: birds can be exposed through eating treated seeds. Additional information is needed.
8(3)	8.1 Effects on birds	DE: The study by Barnett (1998) is not suitable to assess the risk of the intended uses on birds.		Ref removed	EFSA: Accepted, reference not suitable.

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(4)	8.1 Effects on mammals	DE: The submitted information are not suitable to assess the risk on mammals. The question whether capsaicin is repulsive enough to avoid prolonged contact should be cleared before authorisation.		As food additive Capsicum annuum annuum extract is repellent but not risky to animals. Repellence occurs at first feeding by mammals	EFSA: mammals could be exposed through eating treated seeds. Concentration of *C. annuum* extract as seed treatment and food additive are probably different and can not be compared. Further investigation is required.
8(5)	8.1	NL: Repellence to capsaicin and oleoresin in birds is - at the very minimum questionable - as the applicant pointed out himself. This leads to a clear requirement of a full bird and mammals assessment, particularly because the substance is known to cause acute toxicity and irritation in mammals and therefore it cannot be excluded for birds. Such findings cannot be negated and indicate that a thorough aquatic assessment is required and the approval		Barnett (1998) was cited in § 8, reference moved to §3. Non-Detection by birds via TRPV1 receptors is quite different from repellent effect of Capsicum annuum annuum extract. The spice effect sought in human food can also be an irritant effect in certain other cases. At human consumption concentration level, Capsicum	Data gap: In the light of everything previously mentioned (See 8 (1), (2), (4)) it is agreed that full bird and mammal assessment is required.

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
		as a basic substance is not appropriate.		annuum annuum extract is not toxic. Spicy effect is only repellent.	

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(6)		DE: A study by Madhumathy et al. (2007) indicates toxic effects in mosquito larva.	DE: Please add this information to the dossier.	Reference added Same paper said: "*The results of the present study illustrate the possibility of using C. annum for mosquito larval control, as it is less toxic to mammals, where it is quickly metabolised in the liver and excreted in urine within a few hours, even in case of over indulgence3.*	Data gap: Treated larva showed signs of neurotoxicity therefore a risk assessment for aquatic organisms should be performed.

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
				The development of an in-soil repellent for pocket gopher (Thomomys talpoides) with capsicum oleoresin suggests its eco-friendly nature"	
8(7)		DE: The submitted studies are not suitable to assess the risk of the intended uses on aquatic organisms.		More references added on non-toxic concentrations (Turgut 2004)	EFSA: The mentioned reference (Tugut 2004) does not explain toxicity to aquatic organisms and is not considered valid.
8(8)	8.2	NL: It is stated that no studies were found for toxicity to aquatic organisms. While there may be little and few information available, this is not correct, the applicant himself des list a few studies subsequently.		More references added on non-toxic concentrations (Turgut 2004)	EFSA: See 8(7)
8(9)	8.2	NL: The studies cited by the applicant indicate that the aquatic toxicity of capsaicin needs to be considered further in a thorough		Capsicum annuum extract is not pure capsaicin and only content 6 %.	Data gap: One of the references additionaly added by the applicant (Molina-Torres 1999)

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
		assessment. From the publications mentioned the acute toxicity could vary quite a bit between the different aquatic organism groups (Oliviera et al 2014 found L/EC50s between 1.252 µg/L for sea urchin larvae and 5.248 µg/L for a copepod for capsaicin. An aquatic toxicity around 1 µg/L cannot be considered a light aquatic toxicity. In a study not mentioned by the applicant for a synthetic derivate of capsaicin (nonivamide) a 4day EC50 of 5100 µg/L and an increase in reactive oxygen species (ROS) was found for the algae *Phaeodactylum tricornutum*. Such findings cannot be negated and indicate that a thorough aquatic assessment is required		More references added on non-toxic concentrations (Turgut 2004) capsaicin at 6 % is not toxin for aquatic organisms. No synthetic product, No nonivamide in Capsicum annuum annuum extract, Why	also mentiones toxicity of capsain to fish. It is agreed that thorough aquatic assessment is required.

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
		and the approval as a basic substance is not appropriate.		mentioning chemicals when refereing to food additive?	

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(10)	8.3 Effects on other arthropod species	DE: If capsaicin is considered to be toxic for arthropods, a risk assessment should be provided.		LD 50 for bees is >100 µg/bee and was therefore virtually non-toxic. (Flesar, 2001)	EFSA: Applicant did not provide risk assessment for bees.
8(11)	8.3	NL: The applicant himself mentions the controversial toxicity of capsaicin to bees and other non-target arthropods species. Furthermore, the repellence to bees is not addressed. The substance itself is used in products for insect repellence and even as an insecticide in		Capsicum extract is feed (EU, 2015), food (CBI, 2018; FAO, 2015; OECD 2006, JFCA 1973) LD 50 for bees is >100 µg/bee and was therefore virtually non-toxic. (Flesar, 2001)	Data gap: As exposure to the soil can occur, a risk assessment for soil NTA is required.

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
		many countries. The toxicity to bees and insects renders this substance unsuitable for approval as a basic substance. A bee and NTA assessment is required.			

8.4. Effects on earthworms and other soil macro-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(12)		DE: The provided reference (Gervais et al. 2008) is not sufficient to describe effects on earthworms and other soil macroorganisms.		More ref on repellence added	EFSA: Added reference Spurr 2003 talks about capsaicin very shortly mentioning repellence, but not explaining if there were toxic effects and therefore is not considered as reliable reference for toxicity effects.
8(13)	8.4 Effects on earthworms and	DE: The submitted information is not suitable to assess the risk		More ref on repellence added	EFSA: See 8(12)

8.4. Effects on earthworms and other soil macro-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
	other soil macro-organisms	of the intended uses on earthworms and other soil macroorganisms.			
8(14)	8.4	DK: Please provide a suitable risk assessment for earthworms (as the GAP is for seed treatment).		More ref on repellence added	EFSA: See 8(12)
8(15)	8.4	NL: The applicant did not address potential effects on earthworms and other soil macro-organisms appropriately. Insect toxicity has already been mentioned and might apply here as well, particularly as the organisms live in soil and the exposure is not clarified. This should be addressed.		Repellence is always put forward in reports concerning the use of cap extract, even when used against insects.	Data gap: Effects on earthworms and other soil macro-organisms should be addressed properly.

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(16)		DE: The provided information and reference (Gervais et al. 2008) is not sufficient to describe effects on soil microorganisms.	DE: Please indicate that effects on soil microorganisms are unknown or provide adequate studies.	More references added, Capsicum extract show antimicrobial activity.	EFSA: According to provided reference Molina-Torres 1999. capsaicin has antibactericidal effect depending on the form of *C. annuum* used (crude or extract). Further analysis with extract mentioned in this application is recommended.
8(17)		NL: The bibliography on the effects of soil microorganisms seems very short and somewhat incomplete as antimicrobial effects have been found for capsaicin as well.		More references added, Capsicum extract show antimicrobial activity.	EFSA: See 8(16).

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(18)	Effects on non-target plants	DE: If capsaicin exhibits phytotoxic effects, a risk assessment for non-target plants should be provided.		Phytotoxic effect of Capsicum extract	Addressed Risk assessments for non-target plants for seed treatment is not currently required.
8(19)	8.6	NL: The applicant cited one study in which effects of capsaicinoids on seedling growth of lettuce were found. The bibliography is incomplete, there is at least one more study assessing growth of roots, shoots and germination in several plants (H. Kato-Noguchi et al, 2003), but a short search suggest there are more relevant publications. Furthermore, these findings indicate that an appropriate assessment of vegetative vigour and seedling emergence of non-target		No growth trouble nor germination problem are observed using Capsicum extract as seed treatment for cereal, maize and sunflower. Lettuce is highly lettuces are very fragile plant material.	EFSA: The cited study does not provide enough information about effects of *Capsicum annuum* on flora and fauna and is found unreliable.

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
		plants is required. The approvals basic substance is thus not appropriate.			

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

No comments.

8.8. Overall conclusion on effect on non-target 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

No comments.

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)		BE: taking into account potential effects which were reported in the open scientific literature in the sections including (but not restricted to) acute toxicity, genotoxicity, developmental toxicity and carcinogenicity (including epidemiological data), BE emits doubt on the appropriateness to consider the substance a "basic substance"	BE: at least, a thorough revisal of the dossier is warranted before drawing any conclusion. In the current form, an independent evaluation is extremely difficult.	All kind of concerns are evocated here concerning Capsicum annuum extract as seed protection substance, but no concern as food additive around the world.	See 5(9).
9(2)	9	NL: Based on the submitted information neither an immediate or delayed harmful effect on animal health nor unacceptable effects on environment (various organism groups) can be excluded and thus the approval as basic		More references added n order to answer request. Still, food and feed status should give some idea about the substance.	See 5(9) regarding human health. Basic components and concentrations of *Capsicum annuum* L. var. *annuum,* longum group, cayenne extract proposed in this

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

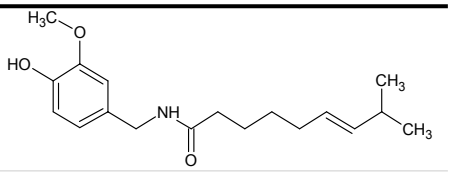
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		substance is not appropriate.			application are not clear. Additional studies for toxicity to all nontarget species is proposed.
9(3)	9	NL: The applicant claims that the substance is listed as a food and feedstuff in the EU, but the assessments were not provided and elsewhere the applicant states that the substance was 'deleted from the register of chemically defined flavouring substances used in or on foodstuffs in the EC due to observed genotoxic activity in-vitro and in-vivo (EC, 2004)'. This is contradicting information and thus the approval as basic substance is not appropriate.		Capsicum extract is feed (EU, 2015), food (CBI, 2018; FAO, 2015; OECD 2006, JFCA 1973), medicinal (French Pharmacopeia, 2008). Applicant don't understand why these FACTS are negated by readers and evaluators!	Specification of the proposed basic substance is a data gap (see 2(9)). See also 5(9).

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**

No comments.

Appendix B – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation[b]	Structural formula[c]
capsaicin	(6*E*)-*N*-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide Oc1ccc(cc1OC)CNC(=O)CCCC/C=C/C(C)C YKPUWZUDDOIDPM-SOFGYWHQSA-N	

(a): The name in bold is the name used in the technical report.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019)
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019)

Appendix C – Identity and biological properties

Common name	*Capsicum annuum* L. var. *annuum,* longum group, cayenne extract (main active component: capsaicin)
Chemical name (IUPAC)	not applicable
Chemical name (CA)	not applicable
Common names	Oleoresin Capsicum, cayenne pepper extract
CAS No	84603-55-4
EINECS No	283-256-8
FAO specification	none
Minimum purity	not applicable
Relevant impurities	none
Molecular mass and structural formula	not applicable (complex mixture)
Mode of Use	seed treatment
Preparation to be used	LS (solution for seed treatment)
Function of plant protection	repellent

Appendix D – List of uses

GAP table provided by applicant:

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth Stage & season (j)	No. of application min/ max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		
Crop seeds				Repulsive for seed				BBCH 00					Cereals 200		

Cereals seeds	All MS	Capsicum annuum annuum, longum group, cayenne, ext	I §	feeding birds crows ravens, *Corvus corax* and for seed feeding mammal animals wild boar, *Sus scrofa* Deer *Cervidae*	LS (Solution for seed treatment)	940 g/L oleoresin in oil	Seed treatment	Sowing Separated season for the mayor crop groups that differ in sowing time; e.g winter cereals, spring cereals, maize and sunflower	1	-	150 mL for 30 kg of seeds = 9.3 g dose (150 ml) of capsaicin	n.a.	to 450 seeds/m^2 (70 to 250 kg/ha) 300 ml/ha = 18.6 g/ha of capsaicin	n.a.	LS Solution has to be mix with seeds in concrete mixer *

Sweet Maize (*Sweet corn*) *Zea mays*													Maize 70 to 100 seeds/ha (25 to 35 kg/ha) 150 mL/ha = 9.3 g/ha of capsaicin		
Sunflower *Helianthus annuus*													Sunflower 65000 to 70000 seeds/ha (40 kg/ha) 200 mL/ha = 12.4 g/ha of capsaicin		

§ note the product will be sown in the field (F).

* The use a concrete mixer for seed treatment with cayenne extract is not only possible but recommended, to dippers the substance in the better way.

GAP table proposed by EFSA:

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth Stage & season (j)	No. of application min/ max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		
~~*Crop seeds*~~				~~Repulsive~~				BBCH 00					Cereals 200		

Cereals seeds	All MS	~~Capsicum annuum annuum, longum group, cayenne, ext~~ Capsicum extract, Oleoresin Capsicum	I §	repellent for seed feeding birds crows ravens, *Corvus corax* and for seed feeding mammals ~~animals~~ wild boar *Sus scrofa* deer *Cervidae*	LS ~~(Solution for seed treatment)~~	~~940 g/L oleoresin in oil~~ data gap	Seed treatment	Sowing Separated season for the mayor crop groups that differ in sowing time; e.g winter cereals, spring cereals, maize and sunflower	1	-	150 mL for 30 kg of seeds = 9.3 g dose (150 ml) of capsaicin	n.a.	to 450 seeds/m^2 (70 to 250 kg/ha) 300 ml/ha = 18.6 g/ha of capsaicin	n.a.	LS Solution has to be mix with seeds in concrete mixer *

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§ note the product will be sown in the field (F).

* The use a concrete mixer for seed treatment with cayenne extract is not only possible but recommended, to dippers the substance in the better way.

* For uses where the column „Remarks. As above or other conditions to take into account (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 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 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval