

APPROVED: 6 October 2016

# **Outcome of the consultation with Member States and EFSA on the basic substance application for paprika extract, capsanthin, capsorubin E 160 c (admissibility accepted when named *Capsicum* spp. spice) for use in plant protection as repellent to various invertebrates, 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* spp. spice are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of *Capsicum* spp. spice as a basic substance for use in plant protection as repellent to various invertebrates, mammals and birds. The applicant subsequently clarified that the material that was the basis for the application was paprika extract, capsanthin, capsorubin E 160 c. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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**Keywords:** *Capsicum* spp. spice, paprika extract, capsanthin, capsorubin E 160 c, basic substance, application, consultation, plant protection, pesticide

**Requestor:** European Commission

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## Summary

*Capsicum* spp. spice 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 Groupe PEYRAUD NATURE for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in July 2016, EFSA was asked to organise a consultation on the basic substance application for *Capsicum* spp. spice, 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* spp. spice, organised by EFSA, was conducted with Member States via a written procedure in April-June 2016. 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* spp. spice and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

The initial application was unclear in relation to which kind of *Capsicum* spp. spice derivative was being proposed as basic substance to be used in plant protection (powder, oil extract) and in relation to which uses were proposed (seed treatment only, foliar spray...). The applicant provided a response that stated that the substance for which agricultural uses as plant protection product are proposed is *Capsicum annuum* and/or *Capsicum frutescens* spice corresponding to E 160 c (paprika extract, capsanthin, capsorubin) in Regulation (EU) No 231/2012 which is a food colourant.

According to recent EFSA ANS Panel Scientific Opinion (EFSA ANS Panel, 2015) E 160 c is a paprika extract food additive used as colourant with high content in carotenoids capsanthin and capsorubin but with low content on the capsaicin. The use of capsaicin (the chili pungent compound) as food flavouring is banned in the European Union because of genotoxicity concerns. Therefore, as an additional specification of the proposed substance, the content of capsaicin must be < 0.025 % (< 250 mg capsaicin / kg of *Capsicum annuum* and/or *Capsicum frutescens* spice) in order to be considered equivalent to the E 160 c evaluated by EFSA as a food colourant.

Analytical methods for active components specified (in particular capsanthin, capsorubin) and the relevant capsaicin need to be provided. The recipe for the product to be used is still unclear and incomplete. A clear and unambiguous recipe needs to be provided in order to ensure consistency with E 160 c.

The applicant claimed that *Capsicum annuum* and/or *Capsicum frutescens* spice corresponding to E 160 c (paprika extract, capsanthin, capsorubin) in Regulation (EU) No 231/2012 may act as repellent of various invertebrates, mammals and birds. However, the claim is not documented sufficiently by scientifically sound studies (e.g. not supported by peer reviewed scientific publications). In addition the referred material is used as colourant and contains very low levels of the pungent substance capsaicin that is referred in some parts of the application as the main active component responsible of the repellent effect of *Capsicum* spp. spice. If pungency is supposed to explain the repellent effect, the material notified (E 160 c) is probably ineffective. From the information available in the application presented it may be concluded that insufficient experience on efficacy with regard to the intended uses exist. The repellent effect on birds seems to be even less substantiated than the claims on invertebrates and mammals. No data has been provided to exclude potential phytotoxic effects. There

is no information to justify the seed treatment rate for the different proposed crops.. It remains unclear whether foliar spray uses are actually intended.

Regarding the impact on human and animal health several *Capsicum* spp. preparations that differ in their toxicological profile.

If the applicant is pursuing the approval of *Capsicum* spp. preparations containing capsaicinoids (pungent alkaloids), the use of capsaicin (claimed to be one of the active components of the extract) as food flavouring is banned in EU because its genotoxic concerns (COMMISSION DECISION 2004/357/EC). There is also evidence that components of *Capsicum* spp. may have to be classified as having the potential to cause serious eye damage, skin irritation and to be harmful if swallowed. No harmonised classification according to Regulation 1272/2008 is available on these components.

If the applicant is pursuing the approval of *Capsicum* spp. preparations (paprika extract) containing capsanthin and capsorubin (food colourant E 160 c with the specifications laid down in Reg. (EU) No 231/2012) the EFSA ANS Panel published a Scientific Opinion on the re-evaluation of paprika extract (E160 c) as a food additive (EFSA ANS Panel, 2015). The ANS Panel concluded that paprika extract (E 160 c) containing less than 0.025% capsaicin do not raise a genotoxic concern and it is not carcinogenic. The ANS Panel established an ADI of 24 mg/kg bw per day for paprika extract (E 160 c). Exposures to paprika extract (E 160 c) for the refined exposure assessment scenarios as food additive were below the ADI established by the ANS Panel. However, non-dietary exposure estimates have not been provided for the use as a plant protection product, so the non-dietary risk assessment cannot be concluded.

If the applicant is pursuing the approval of *Capsicum* spp. preparations containing capsaicinoids (pungent alkaloids) that were assessed as flavouring by the Scientific Committee on Food (SCF, 2002) – as can be deduced from the chapter on consumer intake estimations – the applicant failed to demonstrate the levels of consumer exposure to capsaicinoids expected from the representative uses. It is unclear how this capsaicinoid exposure would relate to the maximum estimated intake of capsaicin from food of 0.025 mg/kg bw (1.5 mg/day assuming 60 kg bw) and contribute to the overall dietary exposure to this compounds. It is noted that the SCF concluded in 2002 that it was not possible to establish a safe exposure level for capsaicinoids in food and therefore not confirmed the TMDI for capsaicinoids of 0.2 mg/kg bw used by the applicant.

If the applicant is pursuing the approval of *Capsicum* spp. preparations (paprika extract) containing capsanthin and capsorubin (food colourant E 160 c with the specifications laid down in Reg. (EU) No 231/2012), the dietary exposure to these components has been previously assessed by the EFSA ANS Panel. Considering food consumption via the regular diet and the reported uses of E 160 c in food, the ANS Panel concluded that the mean intake coming from natural diet is negligible compared to the food additive intake, however the refined exposure assessment scenarios were below the ADI. Without any information or estimates regarding expected levels in crops related to the representative uses as a pesticide it is difficult to put any possible additional consumer exposure to E 160 c into context of the assessment and conclusion by the ANS Panel. It is noted that seed treatment uses and uses on crops before the plant part for human consumption has been formed are expected to insignificantly contribute the existing dietary exposure to E 160 c while this cannot be concluded per se for uses where consumable plant parts are already present at treatment (e.g. brassica vegetables).

Information provided in the application does not support the proposed  $DT_{50}$  soil = 5 days and  $K_{oc}$  = 1100 mL/g for capsaicin (initially claimed to be the active component in the environment section of the application but subsequently stated to be only present at the low levels specified in E 160 c). There is no data in relation of the fate and behaviour of *Capsicum* spp. spice and/or its components (capsanthin, capsorubin, capsaicin) in water. No exposure assessment has been presented for the components of *Capsicum* spp. spice in the different environmental compartments.

The available data were not sufficient to perform a risk assessment for non-target organisms. Since the exposure to non-target organisms cannot be excluded for the proposed uses, further data are considered necessary.

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## 1. Introduction

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

Regulation (EC) No 1107/2009<sup>1</sup> (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* spp. spice is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Groupe PEYRAUD NATURE for approval as a 'basic substance' for use in plant protection as repellent to various invertebrates, mammals and birds.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Capsicum* spp. spice, which was conducted via a written procedure in April-June 2016. 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* spp. spice 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* spp. spice 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 (Groupe PEYRAUD NATURE; 2015, 2016).

### 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 13 July 2016, EFSA was asked to organise a consultation on the basic substance application for *Capsicum* spp. spice, 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 13 October 2016.

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.

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<sup>1</sup> 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* spp. spice and the conclusions drawn by EFSA are presented in the format of a reporting table.

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

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

### Documentation provided to EFSA

1. Groupe PEYRAUD NATURE, 2015. Basic substance application on *Capsicum* spp. spice submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2015. Documentation made available to EFSA by the European Commission.
2. Groupe PEYRAUD NATURE, 2016. Basic substance application update on *Capsicum* spp. spice submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2016. Documentation made available to EFSA by the applicant.

### References

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of paprika extract (E 160 c) as a food additive. EFSA Journal 2015;13(12):4320, 51 pp. doi:10.2903/j.efsa.2015.4320

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
ADI	acceptable daily intake
CLP	Classification, Labelling and Packaging
ECHA	European Chemicals Agency
EMA	European Medicines Agency
GAP	good agricultural practice
Koc	Organic-carbon sorption constant
LC <sub>50</sub>	lethal concentration, median
LD <sub>50</sub>	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
NESTI	national estimated short-term intake
NOAEL	no observed adverse effect level
OSR	oilseed rape
PAN	Pesticides Action Network
PBI	plant-back interval
PEC	predicted environmental concentration
PEC <sub>gw</sub>	predicted environmental concentration in groundwater
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
QSAR	quantitative structure–activity relationship
RMS	rappporteur Member State
TMDI	theoretical maximum daily intake
US EPA	United States Environmental Protection Agency



## Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Capsicum* spp. spice and the conclusions drawn by EFSA on the specific points raised

### 1. Purpose of the application

UK: no comments

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)		NL: No comments.			Noted
1(2)		ES: No comments			Noted
1(3)		EFSA: According the manufacturing process described in section 2, the name of <i>Capsicum</i> spp. spice may refer to more than one technical substance with different specifications. Elsewhere, specifications for the powder spice are given. The actual substance/s that is intended to be used needs to be clarified and specification/s need to be given.		Applicant agree with " <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice" or " <i>Capsicum</i> spp spice" corresponding to E 160 c in Regulation (EU) No 231/2012 <sup>2</sup>	Applicant clarified that the substance for which agricultural uses as plant protection product are proposed is <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice corresponding to E 160 c (paprika extract, capsanthin, capsorubin) in Regulation (EU) No 231/2012.  According to recent EFSA Opinion (EFSA ANS Panel, 2015). E 160 c is a food additive paprika extract used as colourant with high content in carotenoids capsanthin and capsorubin but with low

<sup>2</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council . OJ L 83, 22.3.2012, p. 1–295.

<b>General</b>					
<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
					<p>content of capsaicin (the flavouring compound giving pungency and also the one forbidden as flavouring due to genotoxicity toxicological concerns). Therefore, as an additional specification of the substance proposed, the content of capsaicin must be &lt; 0.025 % (&lt; 250 mg capsaicin / kg of <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice) in order to be considered equivalent to the E 160 c evaluated by EFSA as a food colourant.</p> <p>The use of capsaicin as food flavouring is banned in EU because its genotoxicity (COMMISSION DECISION 2004/357/EC)<sup>3</sup>.</p>

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

UK: no comments

<sup>3</sup> Commission Decision 2004/357/EC of 7 April 2004 amending Decision 1999/217/EC as regards the register of flavouring substances. OJ L 113, 20.4.2004, p. 28–36.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.4 Method of manufacture.	EFSA: The method described is not specific for a single oleoresin of pepper. Different technical material basic substances, with different specifications, will be produced depending on the raw material mixtures used and the extraction solvents used. The different possible resulting specifications need to be detailed. Depending on the variability of the composition the listing of more than one basic substance may be appropriate.		Definitions are all linked to names. Many names exist. Clarification is provided by Regulation (EU) No 231/2012 Added Specifications included.	Addressed  See 1(3)
2(2)	2.1.5	EFSA: For the specifications the ISO 206 ISO 7540 Ground Paprika is referred. However, the manufacturing method is for oleoresin extracts. The identity of the actual active substance that is intended to be use needs to be clarified.		Regulation (EU) No 231/2012 Added ISO 7540 removed	Addressed  See 1(3)
2(3)	2.1.5	NL: The specifications should be summarized.		Regulation (EU) No 231/2012 Added ISO 7540 removed	Addressed  See 1(3)
2(4)	2.1.7.	NL: All methods of analysis should be briefly summarized.		Regulation (EU) No 231/2012 Added	Regulation (EU) No 231/2012 contains the specifications but

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				ISO 7540 removed	not the methods of analysis. Analytical methods for active components specified (in particular capsanthin, capsorubin) and the potentially toxicological relevant capsaicin need to be provided.
2(5)	2.1.5	DE: A specification for capsicum spp. spice is missing and should be provided. ISO 7540 is only for ground paprika and not for oleoresin. However, no specification is included in the submitted document of ISO 7540.		<i>Capsicum</i> spp. spice meet the requirement of E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN in Regulation (EU) No 231/2012 (paprika oleoresin) ISO 7540 removed	See 1(3)
2(6)	2.1.6	DE: The content of capsicum spp. spice and the additive in the product should be provided.		Natural oil (sunflower) Is the only tolerated additive authorized.	See 1(3)
2(7)		EFSA: It should be clarified if a valid method for the oleoresin has been provided. The two iso methods refer to the powder paprika or the whole paprika fruit not to the oleoresin.		<i>Capsicum</i> spp. spice meet the requirement of E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN in Regulation (EU) No 231/2012 (paprika oleoresin)	See 1(3) and 2(4)
2(8)	Conclusion §2	DE: In Regulation (EU) No 231/2012 the specification for the food additive E 160 c Paprika extract (synonym: Paprika oleoresin) is laid		<i>Capsicum</i> spp. spice meet the requirement of E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN in Regulation (EU) No 231/2012	See 1(3)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		down. It should be addressed whether <i>Capsicum</i> spp. spice complies with these requirements. If it is not compliant it cannot be considered as a food product according to Regulation (EC) No 178/2002 <sup>4</sup> .		Compliant to Regulation (EC) No 178/2002. Intrinsic basic substance.	
2(9)	General comment	ES: A title of the application with a more restrictive description as " <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice" would be more suitable.		Applicant agree with " <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice" or " <i>Capsicum</i> spp spice"	See 1(3)

## 2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(10)	2.2	NL: more than one trade name should be specified		Trade name added	Addressed
2(11)		ES: No comments			Noted

<sup>4</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

### 2.3. Manufacturer of the substance/products

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(12)	2.3	NL: more than one manufacturer should be specified		More manufacturer added	Addressed
2(13)		ES: No comments			Noted

### 2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(14)		NL: No comments.			Noted
2(15)		ES: Point 2.4 specifies that the type of preparation is solution for seed treatment but point 2.5 talks about seed treatment and water spray. Furthermore, in point 3.4 (summary of intended uses), two application methods are considered; seed treatment and seeding 1 to 2 leaves. Please, clarify it.		EW Emulsion, oleoresin oil in water added. Updated in 3.4	See 1(3)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(16)	2.5	NL: The recipe for the product to be used is unclear and seems to be incomplete. Please include a clear and unambiguous recipe.		EW Emulsion, oleoresin oil in water added. Updated in 3.4	The recipe for the product to be used is still unclear and incomplete. A clear and unambiguous recipe needs to be provided.
2(17)		ES: No comments			Noted
2(18)		EFSA: Agrees with NL comment.			See 2(16)

## 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
3(1)		NL: No comments.			Noted
3(2)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in the uses described.	In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exists.	More references added. CA PdL 2015	Applicant claims that <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice corresponding to E 160 c (paprika extract, capsanthin, capsorubin) in Regulation (EU) No 231/2012 may act as repellent to various invertebrates and mammals. However, the claim is not enough scientifically documented (eg. not supported

### 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
					by peer reviewed scientific publications). In addition the referred material is used as colourant and contains very low levels of the pungent substance capsaicin. If pungency is supposed to contribute to the repellent effect, this material (E 160 c) is probably ineffective. From the information available in the presented dossier it may be concluded that no sufficient experience on efficacy with regard to the intended uses exists.
3(3)		DE: The extrapolation from invertebrates to vertebrates is very speculative.	Provide information about target organisms.	More references added	See 3(2)
3(4)		ES: No comments			Noted
3(5)	3.1 Field of use	EFSA: It is claimed that the substance works as repellent for birds, but the report on capsaicin (general fact sheet USA National pesticide Information centre) specifically indicates that birds cannot taste capsaicin and are therefore not repelled by it.	The efficacy as repellent to birds needs to be further substantiated with appropriate scientific information.	Capsaicin is described as component, may not be active ingredient of the mixture. This food additive has astringent taste responsible to repellent effect.	The repellent effect to birds seems to be even less substantiated than the claims on invertebrates and mammals. According EFSA opinion on E 160 c capsaicin levels are low and the use of the additive is for colourant (not flavouring properties). No component is identified in E 160 c to have



### 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
					any particular astringent taste.

### 3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(6)		NL: No comments.			Noted
3(7)		ES: No comments			Noted
3(8)		EFSA: repellent action against birds needs to be further justified.	See also comments in Section 8 on the susceptibility of birds to detect <i>Capsicum</i> spp. spice components.	This food additive has astringent taste responsible to repellent effect. Birds like crows.	See 3(5)

### 3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(9)		NL: No comments.			Noted
3(10)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Please provide reasons for your opinion that no phytotoxicity must be expected.	Germination, seedling and growth are not affected by the substance.	No data has been provided to exclude potential phytotoxic effects.
3(11)		ES: The application rate per treatment and total rate		Corrected	Addressed

### 3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		should be revised (24 to 36 g/ha)			
3(12)		ES: Is there specific studies or information regarding the efficacy in the use of the substance in maize, brassicas, sunflower, wheat... by spray?		Efficacy is regarding repellence vs birds not depending on seed type, species or variety.	See 3(2) and 3(5)
3(13)		EFSA: There is no information to justify the proposed treatment rate for the different seeds of crops proposed.	Further information on the efficacy as repellent at the rates proposed for the different crop seeds would need to be provided.	Efficacy is regarding repellence vs birds not depending on seed type, species or variety.	There is no information to justify the proposed seed treatment rate for the different proposed crops.  See also 3(2) and 3(5).

#### 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)		NL: No comments.			Noted
4(2)	Section 4, page 17	UK: Self-classifications of serious eye damage, harmful if swallowed and causes skin irritation have not been sufficiently addressed in document.		Applicant agree	Noted

#### 5. Impact on Human and Animal Health

##### 5.1. Toxicokinetics and metabolism in humans

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

##### 5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)		DE: According to the submitted information on the product		Although <i>Capsicum</i> spices are suspected to be carcinogenic	Data gap There is evidence that

## 5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>and the main components there are data gaps with regard to submission of toxicological studies, safety data sheets and data on identity. According to the classifications provided by companies to ECHA in CLP notifications <i>Capsicum</i> spp. spice fulfils the criteria for classification for serious eye damage, skin irritation and for harmful if swallowed. Furthermore there are indications on genotoxicity, carcinogenicity and neurotoxicity. Therefore, <i>Capsicum</i> spp. spice cannot be considered to be a substance of no concern. The conditions of Article 23 of Regulation (EC) No 1107/2009 are not fulfilled.</p>		<p>and neurotoxic at high rate, they are still food additives. Purpose of this application is seed treatments or early seedlings spray, not crop production treatment.</p>	<p>components of <i>Capsicum</i> spp. spice may have to be classified as serious eye damage, skin irritation and harmful if swallowed. No harmonised classification according to Regulation 1272/2008<sup>5</sup> is available.</p> <p>There are also indications that components of <i>Capsicum</i> spp may have genotoxic, carcinogenic and neurotoxic properties. In fact, the use of capsaicin (claimed to be one of the active components of the extract) as food flavouring is banned in EU because its genotoxic concerns (COMMISSION DECISION of 7 April 2004 amending Decision 1999/217/EC as regards the register of flavouring substances).</p> <p>The toxicological profile of the substance needs to be clarified</p>

<sup>5</sup> 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

<b>5.2. Acute toxicity</b>					
<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
					<p>in line with the type of extract proposed.</p> <p>Should the type of extract be in line with the specification of food colourant paprika extract (E 160 c; with low content of capsaicin) the recommendations published in the EFSA ANS Panel Scientific Opinion on the re-evaluation of paprika extract (E 160c) as a food additive (EFSA ANS Panel, 2015) should also apply to the proposed basic substance. See also 1(3)</p>

<b>5.3. Short-term toxicity</b>					
<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
5(3)		No comments			Noted

#### 5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	Section 5.4, page 20	UK: capsaicin and chilli extract can act as tumour promoters (see comment 9(1))		Applicant agrees but substance is still used as food additive in sauce, chilli...	See 1(3) and data gap in 5(2)
5(5)		<p>DE: The submitted information in the basic substance application contains indications of genotoxicity of capsaicin. For example capsaicin was shown to be mutagenic in at least one <i>S. typh.</i> strain (review in Surh and Lee, 1995)*. After i.p. application capsaicin produced micronuclei in polychromatic erythrocytes in the mouse bone marrow assay (Nagabhushan and Bhide, 1986)* and induced sister chromatid exchanges and micronucleated normochromatic erythrocytes in mouse bone marrow (Diaz Battiga Arceo et al., 1995)*. Therefore, there are indications for a genotoxic potential and it is unlikely that the conditions of Article 23 of Regulation (EC) No 1107/2009 are fulfilled.</p> <p>*= cited in basic substance</p>		Applicant does not contradict DE M.S. to that respect but the substance is food additive. Regarding issue of this application, how a non-approved substance (basic or not) under pesticide regulation EC 1107/2009 can still be a food additive!	See 1(3) and data gap in 5(2)

<b>5.4. Genotoxicity</b>					
<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
		application, capsicum spice, August 2015.			
5(6)		<p>EFSA: According the manufacturing process described in section 2, the name of <i>Capsicum</i> spp. spice may refer to more than one technical substance with different specifications. Elsewhere, specifications for the powder spice are given. The actual substance/s that is intended to be used needs to be clarified and specification/s need to be given.</p> <p>Based on the available data it is not possible to conclude properly on the genotoxic potential of <i>Capsicum</i> spp. spice. The genotoxic potential of <i>Capsicum</i> spp. spice cannot be excluded.</p>	<p>EFSA: At least an in vitro genotoxicity test battery or genotoxicity data on the actual substance/s to be used in line with the specification should be available to demonstrate the lack of genotoxic potential.</p>	See above	See 1(3) and data gap in 5(2)

### 5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)		<p>ES: Further support is needed in these aspects:</p> <ul style="list-style-type: none"> <li>-“Capsaicin has been 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”</li> <li>-“A number of studies have shown that capsaicin and chilli extract can act as tumour promoters”</li> </ul>		<p>Pure Capsaicin has been 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 but oleoresin capsicum is still used as food additive.</p>	<p>See 5(2) and 1(3)</p>
5(8)		<p>ES: In conclusions, it is said that “Data about carcinogenicity in animals and humans are limited and contradictory”. Further information/research is needed regarding this fact.</p>		<p>Data were provided, not hidden. Food additive status of the oleoresin is clear, like alcohol containing beverages.</p>	<p>See data gap in 5(2).</p>
5(9)		<p>DE: The submitted information in the basic substance application contains indications of carcinogenicity of capsaicinoids and of chilli pepper. After oral long term application of a mixture of capsaicinoids to mice the incidence of caecum adenomas was significantly increased in females (Toth and Gannett, 1992)*.</p>		<p>Applicant agrees but substance is still consumed all over the world. Should food additive status remove for this substance? Like alcohol containing beverages, who's taking care of this restriction?</p>	<p>See data gap in 5(2).</p>



### 5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>In rats after oral application of a diet containing 10 % chilli pepper and ardein for 7 months a higher incidence of neoplastic changes in the liver was observed (Hoch-Ligeti, 1951)*.</p> <p>Furthermore, SCF (2002)* considered the available toxicological data as inadequate to establish a safe exposure level for capsaicinoids in food. It was stated that high consumption of chillies was reported to be associated with cancer of the upper digestive tract in humans. A number of studies have shown that capsaicin and chilli extract can act as tumour promoter (Surh and Lee, 1995)*.</p> <p>Therefore, there are indications for a carcinogenic potential and it is unlikely that the conditions of Article 23 of Regulation (EC) No 1107/2009 are fulfilled.</p> <p>*= cited in basic substance application, <i>Capsicum</i> spp.</p>			

### 5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)		spice, August 2015 EFSA: Should the genotoxic potential of the actual substance/s to be used in line with the technical specification be excluded a risk for carcinogenicity might be considered for <i>Capsicum</i> spice.	EFSA: to determine a relevant NOAEL for long-term toxicity and carcinogenicity studies and perform a risk assessment considering exposure.	The NOAEL for capsaicin appeared to be 0.1 mg/kg/day for dog. The NOAEL appeared to be 128 mg/kg for rat. EMA 2009 Ref Added	See data gap in 5(2).

### 5.6. Reproductive toxicity

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

### 5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)		DE: The submitted information in the basic substance application contains		Same as above, Authority may ask to remove oleoresin <i>Capsicum</i> E 160 c from food	See 5(2), 1(3) and 9(2)

### 5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>indications of neurotoxicity of capsaicin. Effects on sensory nervous system, neuromotor dysfunction and neuroinhibition have been described (Olajos and Salem, 2001*; Busker and van Helden, 1998*).</p> <p>Therefore, there are indications for a neurotoxic potential and it is unlikely that the conditions of Article 23 of Regulation (EC) No 1107/2009 are fulfilled.</p> <p>*= cited in basic substance application, <i>Capsicum</i> spp. spice, August 2015.</p>		additive list.	

### 5.8. Toxicity studies on metabolites

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

**5.9. Medical Data: adverse effects reported in humans**

No.	Column 1 Reference to Applica tion Templa te	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(14)		EFSA: Capsaicin is used topical analgesic (Groninger H, Schisler RE. Topical Capsaicin for Neuropathic Pain #255. Journal of Palliative Medicine. 2012;15(8):946-947. doi:10.1089/jpm.2012.9571.)	EFSA: The use of capsaicin as a topical analgesic, their side effects and label prescription as a topical analgesic should be further addressed.	Major described side effects are localized and include erythema and uncomfortable burning, stinging, or itching. Ref added.	Addressed.

**5.10. Additional Information related to therapeutic properties or health claims**

No.	Column 1 Reference to Applica tion Templa te	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(15)		No comments			Noted

### 5.11. Additional information related to use as food

No.	Column 1 Reference to Applica tion Templa te	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(16)		No comments			Noted

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(17)		ES: Point 5.12: the value of mg kg bw should be corrected		Corrected Ref added	Addressed.
5(18)	Section 5.12, page 24	UK: Some of the available studies, however regarded as limited, indicated a carcinogenic potential of capsaicin (see comment 9(1))		More values added. Applicant agrees toxic potential of capsicum oleoresin but indicate food additive status.	See data gap in 5(2).
5(19)		EFSA: the genotoxic potential of the actual substance/s should be first clearly excluded in order to set reference values.		Given values are documented.	See data gap in 5(2).

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(20)		NL: More information could be provided on expected exposure levels due to the use as a basic substance compared to the background daily intake levels stated in paragraph 5.12.		Treated seeds are directly transferred to sewing machines without contact. Background daily intake is 1.5 mg capsaicinoids/day (25-200 mg in some region) compared to 36 g/ha (3.6 mg/m <sup>2</sup> ) oleoresin.	Data gap Non-dietary exposure estimates are missing. For dietary exposure see Section 6.

## 6. Residues

UK: no comments

### 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)	Paragraph 6, conclusion	NL: More argumentation could be provided in this paragraph (like it is being done in the concluding paragraph 9) about expected residues levels (if any) compared to levels in food. Furthermore, it could be added that residues are not relevant, since <i>Capsicum</i> spp. spice is also used in food. In		Residues are comparable to food additive uses. Metabolic degradation are known in humans and soil	Data gap: The claim that residues are comparable to food additive uses needs to be demonstrated by further information.

<b>Residues</b>					
<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
		addition, it should be mentioned that no MRLs are required.			
6(2)		ES: No comments			Noted
6(3)		EFSA: Having regard to the mode of application (seed/shoot treatment), residues of <i>Capsicum spp. spice</i> are not expected to be present in significant amount at harvest. However if toxicological concerns are identified in the section on toxicology, the potential of residues and their impact on the consumer safety would need to be addressed.		Toxicological concerns are identified. Substance is food additive	See data gap in 5(2).

## 7. Fate and Behaviour in the environment

UK: no comments

### 7.1 Fate and Behaviour in the environment

<b>No.</b>	<b>Column 1 Reference to Application Template</b>	<b>Column 2 Comments from Member States / EFSA</b>	<b>Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment</b>	<b>Column 4 Follow up response from applicant</b>	<b>Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application</b>
7(1)	7.1	EFSA: Just referring to the description of PAN is a little bit		More Ref added	An additional reference on the dissipation of <i>Capsicum</i>

### 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
		<p>unsatisfactory. Can you elaborate a bit more on the general aspects of the pesticide's characteristics regarding fate &amp; behaviour (e.g. key endpoints, metabolism, natural occurrence ed)?</p>			<p>oleoresin in soil has been provided. The investigation does not follow any agreed guidance. Nevertheless the results of this study do not support the proposed DT50 soil = 5 days (28 d or longer, if conditions are dry, are indicated by the authors of the only reference provided: Sterner R.T., Ames A.D., Kimball B.A. 2002 Persistence of <i>Capsicum</i> oleoresin in soil. <i>International Biodeterioration &amp; Biodegradation</i> 49, pp 145-149).</p> <p>There is no data to support the proposed capsaicin Koc - Organic-carbon sorption constant.</p> <p>There is no data in relation to the fate and behaviour of <i>Capsicum</i> spp. spice and/or its active components (capsanthin, capsorubin, capsaicin) in water.</p>
7(2)		ES: No comments			Noted
7(3)	7.1	EFSA: The main references given	Adequate literature search should be	Soil degradation (days)	See 7(1)



### 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
		<p>are the National Pesticide Information Center (npic) fact sheet report on Capsaicin and the PAN (Pesticides Action Network) report on <i>Capsicum</i> oleoresin. Both are secondary sources with no clear links to references of primary studies. The npic fact sheet refers only to one of the components on the <i>Capsicum</i> spp. spice. The origin (experimental QSAR etc) of the few end points reported are not provided in these reports. Original primary literature would need to be provided to confirm these end points. All relevant components in <i>Capsicum</i> spp. spice would need to be considered. The npic reports mentions adverse effect of Capsaicin on bees. However, nothing seems to be reported about toxicological effects on other organisms that may be also exposed; as earthworms and fish. If toxicity to those organisms cannot be completely precluded from</p>	<p>performed to identify studies that may help to establish worst case environmental end points (Koc, DT50 's) in order to perform a risk assessment of non-target species that may be exposed. In case no adequate data is found in scientific peer reviewed literature <i>ad hoc</i> studies on persistence in soil and water media would need to be performed.</p>	<p>(aerobic) DT<sub>50</sub> (typical): 5 Koc - Organic-carbon sorption constant: 1100 More Ref added</p>	

### 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
		data presented in the ecotoxicology chapter more robust fate and behaviour end points for soil and water would be needed to perform a proper environmental exposure assessment (DT50 soil, DT50 water or water/sediment, Koc etc).			

### 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
7(4)	7.2.1	EFSA: Are there Koc values known from literature and/or studies?		Koc - Organic-carbon sorption constant: 1100 Ref added	See 7(1)
7(5)	7.2.1	Typo in abstract: ta=to		Corrected	Addressed
7(6)		ES: No comments			Noted
7(7)	7.2.1 7.2.2	EFSA: It does not seem possible to derive reliable soil and surface water end points from the scientific papers provided.	A proper and exhaustive scientific literature search would need to be performed.	More ref added	See 7(1)
7(8)	7.2.1 7.2.2	EFSA: PEC <sub>soil</sub> and PEC <sub>GW</sub> , PEC <sub>SW</sub> would need to be estimated	At least risk assessment for soil organisms and to aquatic life is required (see Section 8).	More ref added	PEC <sub>soil</sub> and PEC <sub>GW</sub> , PEC <sub>SW</sub> for <i>Capsicum</i> spp. spice and/or its components

## 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
			Therefore appropriate exposure assessment to soil and surface water needs to be provided. However, currently no adequate and /or robust end points are available that allow such calculations to be performed.		(capsanthin,capsorubin, capsaicin) need to be estimated.

## 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)	8.1.1	NL: What does it mean that 'Birds do not detect capsaicin'? Will it still work as a repellent then?		The capsaicin content in chili peppers is variable and ranges from 0.1 to 1%. It is described in the application as one possible active substance (efficient on mammals) not the unique also it is the most known component.	As reported in 3(2), the repellent effect of <i>Capsicum</i> spice cannot be demonstrated through the available information. See also 1(3)
8(2)	8.1.1. Birds	DE: If birds do not detect capsaicin, how is it supposed to work as a repellent against birds?	Please clarify the discrepancy.	See above	The repellent effect cannot be ruled out from the available information. See also 1(3), 3(2), 3(5), 8(1)
8(3)	8.1.1. Birds	DE: If <i>Capsicum</i> spp. spice works	Please clarify the discrepancy.	See above	Please refer to 8(5).

### 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 repellent against birds, how are they supposed to ingest the seeds, so that gut retention times of the seeds can be influenced?			See also 3(2), 3(5)
8(4)	8.1.1. Birds	DE: If gut retention times of the seeds are influenced, the intended uses may have unacceptable effects on the birds' digestion.		See above More reference provided Barnett 1998	Please refer to 8(5). See also 3(2), 3(5)
8(5)	8.1.1. Birds	DE: No toxicity information for birds is presented in the application. It is not possible to predict how the gut retention times of seeds are influenced by seeds treated with <i>Capsicum</i> spp. spice. Whether this possible effect may influence the plant reproduction is pure speculation and irrelevant.		More reference provided Barnett 1998 US EPA 1986 Capsicum (Pc Code 070701) Avian Repellent	The additional paper provided (Barnett 1998) does not address the concerns raised in relation to the potential toxicity of <i>Capsicum</i> spp. spice and to the effects on the gut retention time. Indeed, the submitted paper investigates the potential rodent repellence of oleoresin <i>Capsicum</i> without addressing it in a sufficient manner (e.g. oleoresin capsicum not tested alone but with clay or thiram). The US EPA 1986 evaluation of a product containing capsicum (0.5%) states that <i>'it is not possible to address the risk to endangered species posed by the use of this pesticide until basic toxicity properties data</i>

### 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
					<p><i>are submitted'</i>. Between the basic toxicity data required studies on upland game birds (bobwhite quail) and a species of waterfowl (mallard duck) are listed.</p> <p>From the above and considering that the repellent effect is not demonstrated, the risk to birds and mammals is considered as not sufficiently addressed i.e. if the repellent effect is not demonstrated exposure to terrestrial vertebrates cannot be excluded.</p>
8(6)	8.1.2. Mammals	DE: In the application it is stated that capsicum <i>Capsicum</i> spp. spice should be enough repulsive to avoid prolonged contact. If it is not enough repulsive, harmful effects on terrestrial vertebrates can occur. <i>Capsicum</i> spp. spice should only be used when an unacceptable risk for terrestrial vertebrates can be excluded.		<i>Capsicum</i> oleoresin is not a biocide due to its food additive status, this substances is intended for repellent uses, not as biocide to kill crop bioagressors.	As reported above the repellent effect of <i>Capsicum</i> spp. spice is not fully demonstrated. See also 3(2)
8(7)		ES: No comments			Noted

### 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(8)	8.1.1. Birds	EFSA: As commented NL and DE, it is stated that capsaicin is used as repellent for animals and birds and also that birds do not detect capsaicin (Gervais et al., 2008). Therefore, it is not clear how capsaicin could be used as repellent for birds.	An explanation should be given.	Capsaisin is not the substance in this application, is only one minor component of the mixture. Garvais et al were working on capsaisin. Basic Substance Application is for <i>Capsicum</i> oleoresin, not for pure Capsaisin. Ref added US EPA 1986 Capsicum (Pc Code 070701) Avian Repellent	See 8(5)
8(9)	8.1.1. Birds	EFSA: it is stated that capsaicinoids may influence gut retention time. Then, it seems that birds can be exposed to capsaicin by ingestion.	Toxicity data for birds should be provided in order to show whether the intended uses have or not effects on birds.	Ref added US EPA 1986 Capsicum (Pc Code 070701) Avian Repellent	See 8(5)
8(10)	8.1.2. Mammals	EFSA: The statement "modes of toxicity for non-target organisms are expected to be similar to those of targeted insects and mammals" should be supported by a clear justification.	More information should be provided in order to demonstrate whether harmful effects on mammals occur or not for the representative uses of <i>Capsicum</i> spp. spice.	More ref added Madhumathy 2007	The effects on mammals are not specifically addressed by Madhumathy 2007 which deals with larvicidal effects of <i>Capsicum annuum</i> . See also 1(3), 3(2) and 3(5)

## 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(11)		NL: No comments			Noted
8(12)	Section 8, page 29	UK: No information provided evaluating the toxicity of capsaicin to fish and aquatic life		BPDB: Bio-Pesticides DataBase provides no data for fish.	See 8(15)
8(13)	8.2 Effects on aquatic organisms	DE: In its Re-registration Eligibility Decision, the U.S. EPA waived the ecological effects studies that are typically required because it was determined that restrictive labelling would adequately protect aquatic species. A correspondingly restrictive labelling should be provided for the intended uses.		Applicant agrees but Substance is used in contact with fish. More ref added BUYUKCAPAR 2012 Madhumathy 2007	Noted
8(14)		ES: No comments			Noted
8(15)	8.2 Effects on aquatic organisms	EFSA: only one reference was reported (Gervais et al., 2008), and furthermore it did not give enough information in order to reach a conclusion regarding the risk to aquatic organisms from the representative uses of <i>Capsicum spp. spice</i> .	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk for aquatic organisms.	Substance is used in contact with fish. More ref added BUYUKCAPAR 2012 Madhumathy 2007	The available information is not considered to be sufficient to address the risk to aquatic organisms from the representative uses of <i>Capsicum spp. spice</i> . The provided additional references do not give enough information to reach a conclusion regarding the risk to aquatic organisms. See also 7(8).

### 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(16)	8.3.1	NL: It is stated that 'Capsaicin is toxic to bees and other beneficial insects'. This statement could use some further clarification in order to clarify the possible risk.		BPDB: Bio-Pesticides DataBase Unknown mode acute 48 hour LD50 ( $\mu\text{g bee-1}$ ) > 0.1 toxic Seed and seedlings treatment give maximum prevention for bees.	See 8(23)
8(17)	Section 8, page 29	UK: Capsaicin is considered toxic to honeybees and other beneficial insects		Applicant agrees See above	See 8(23)
8(18)	8.3 Effects on bees and other arthropods species	DE: Capsaicin is considered toxic to honeybees and other beneficial insects. A use in flowering plants is not planned, but insects present at the corresponding BBCH stages of the intended uses may be influenced by the use of <i>Capsicum</i> spice.		Applicant agrees See above	See 8(23)
8(19)		DE: The presented data (Gervais, J. A., Luukinen, B., Buhl, K., Stone, D. 2008) indicate that the active substance Capsaicin is potentially toxic to honeybees. However, these data are not appropriate to assess the risk to bees from <i>Capsicum</i> annum / <i>Capsicum</i> frutescens when used as	Please indicate in dossier.	Applicant agrees See above	See 8(23)



### 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
		repellent for seed treatment.			
8(20)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Please indicate in dossier.	Except bees are actively pollinating <i>Capsicum</i> plants, no references were found.	See 8(23)
8(21)		ES: Further information/research is needed regarding this statement: "Capsaicin is considered toxic to honeybees and other beneficial insects"		BPDB: Bio-Pesticides DataBase Unknown mode acute 48 hour LD50 ( $\mu\text{g bee-1}$ ) > 0.1 toxic Seed and seedlings treatment give maximum prevention for bees.	See 8(23)
8(22)	8.3.1 Effects on bees	EFSA: As commented by NL, UK, DE and ES, only one reference was reported (Gervais et al., 2008), which did not give enough information in order to reach the conclusion that capsaicin is toxic to bees.	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk of capsaicin on bees.	BPDB: Bio-Pesticides DataBase Unknown mode acute 48 hour LD50 ( $\mu\text{g bee-1}$ ) > 0.1 toxic Seed and seedlings treatment give maximum prevention for bees.	See 8(23)
8(23)	8.3.2 Effects on other arthropods	EFSA: information provided regarding the effects on non-target arthropods is considered insufficient to be able to perform a risk assessment for non-target arthropods for the representative uses of <i>Capsicum spp. spice</i> .	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk for non-target arthropods.		The information provided regards the toxicity to bees for capsaicin only (i.e. Bio-Pesticides DataBase) and is as such considered as not sufficient to be able to address the risk for non-target arthropods including bees for the representative uses of <i>Capsicum spp. spice</i> .

### 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
					See also 1(3)

### 8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(24)		NL: No comments			Noted
8(25)	8.4 Effects on earthworms and other soil macro-organisms	DE: Modes of toxicity for non-target organisms are expected to be similar to those of targeted insects and mammals. This means that earthworms and other soil macro-organisms may be influenced by the intended uses.	Perform a risk assessment for earthworms and other soil macro-organisms for the intended uses.	<i>Capsicum</i> spp. are known to exhibit repellent activity against B tabacci and mosquitoes. Ref added Madhumathy 2007 Castillo-Sánchez 2012	See 8(28)
8(26)		DE: Robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm <i>Eisenia fetida</i> ) were not submitted.	Please indicate in the dossier.	Repellence is described	See 8(28)
8(27)		ES: No comments			Noted
8(28)	8.4 Effects on earthworms and other soil macro-	EFSA: considering the representative uses of <i>Capsicum</i> spice (seed	Toxicity data and exposure estimates or scientific justifications should be provided in order to	No more reference found either with capsaicin or <i>Capsicum</i> oleoresin.	The representative uses of <i>Capsicum</i> spp. spice are as seed treatment and foliar

#### 8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	organisms	treatment and foliar spray on wheat, maize, sunflower, etc...) capsaicin may have effects on earthworms and other soil macro-organisms. Even in this case only the reference Gervais et al. (2008) was reported and was not enough to assess the risk capsaicin to earthworms and other soil macro-organisms.	assess the risk for earthworms and other soil macro-organisms for the intended uses.		spray. Therefore, exposure for earthworms and other soil macro-organisms cannot be excluded. The information provided is considered as not sufficient to be able to perform a risk assessment regarding the effects earthworms and other soil macro-organisms. See also 1(3)

#### 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(29)		NL: No comments			Noted
8(30)		ES: No comments			Noted
8(31)	8.5 Effects on soil micro-organisms	EFSA: considering the representative uses of <i>Capsicum</i> spp. spice (seed treatment and foliar spray on wheat, maize, sunflower, etc...) capsaicin may have effects on soil micro-organisms. Even in this case	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk for soil micro-organisms for the intended uses.		The representative uses of <i>Capsicum</i> spp. spice are as seed treatment and foliar spray. Therefore, exposure for soil microorganisms cannot be excluded. The information provided, is therefore considered as not sufficient to

### 8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		only the reference Gervais et al. (2008) was reported and was not enough to assess the risk capsaicin to soil micro-organisms.			address the risk to soil microorganism.

### 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(32)		NL: No comments			Noted
8(33)		ES: No comments			Noted
8(34)	8.6 Effects on other non-target organisms (flora and fauna)	EFSA: only the reference Gervais et al. (2008) was reported and was not enough to investigate the effects of capsaicin to other non-target organisms.	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk for other non-target organisms for the intended uses.	Repellence is described	The information provided is considered as not sufficient to be able to address the risk for other non-target organisms (e.g. flora).

### 8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(35)		NL: No comments			Noted

### 8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(36)		ES: "Oleoresin <i>Capsicum</i> is soluble in water and can be found in sewage". This should be considered in the assessment.		As all food products, oleoresin <i>Capsicum</i> may end up in sewage.	See 8(37)
8(37)	8.7 Effects on biological methods of sewage treatment	EFSA: As commented by ES, it is stated that "oleoresin <i>Capsicum</i> can be found in sewage". Therefore the risk for sewage treatment organisms should be assessed.	Assess the risk for sewage treatment organisms.	See above.	The information provided is considered as not sufficient to address the effects on biological methods of sewage treatment.

## 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)		NL: No comments.			Noted
9(2)		UK: The UK does not believe this substance fits the definition of substance of no concern – specifically Article 23 (a) Regulation 1107/2009 is not met. Examples include - section 5, page 17 - available toxicological data as inadequate to establish a safe exposure level for capsaicinoids in food and Capsaicin has been 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		<i>Capsicum</i> spp. spice meet the requirement of E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN in Regulation (EU) No 231/2012 (paprika oleoresin).	EFSA considers that fulfilment of basic substance criteria in Regulation 1107/2009 is a risk management issue and does not express an opinion on it.  According current EFSA opinion on E 160 c levels of capsaicin must be < 0.025 % (< 250 mg capsaicin / kg). Doubts remain on the efficacy of this food colourant as repellent since elsewhere in the dossier capsaicin is presented as one of the active components responsible of the repellent effect and the colourant has low content of this component. It is not clear if this was actually the <i>Capsicum</i> extract intended to be used for plant protection. It is noted that the use of capsaicin as food flavouring is banned in EU because its genotoxicity (COMMISSION

**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
					DECISION 2004/357/EC).  With respect to toxicological issues see Section 5.
9(3)		<p>DE: It is not agreed to approve <i>Capsicum</i> spp. spice as basic substance. According to Article 23 of Regulation (EC) No 1107/2009 a basic substance is an active substance which is not a substance of concern. However, the submitted information in the basic substance application contains indications of genotoxicity, carcinogenicity and neurotoxicity of <i>Capsicum</i> spp. spice and its main components. Furthermore, according to the submitted information on identity of the product and of the main components and according to the classification provided by companies to ECHA in CLP notifications <i>Capsicum</i> spp. spice fulfils the criteria for classification for serious eye</p>		<p>If <i>Capsicum</i> oleoresin is of concern, EU has to remove food additive status; otherwise, intrinsic basic substance status is validated. If concerns are validated through this application EU has to conclude about the removal of the food additive status in case of non-approval as basic substance.</p>	See 9(2)

**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
		<p>damage, skin irritation and for harmful if swallowed. Therefore, the conditions of Article 23 of Regulation (EC) No 1107/2009 are not fulfilled.</p> <p>It is proposed that the application for authorisations of plant protection products containing <i>Capsicum</i> spp. spice should be based on the guidance document on botanical active substances (SANCO/11470/2012)<sup>6</sup>.</p>			
9(4)	General comment	<p>ES: The fulfilment of the criterion "(a) is not a substance of concern" is questionable, because one of the main components of the current basic substance proposal, i.e. capsaicin, has been deleted from the register of chemically-defined flavouring substances used in or on foodstuff in the EC due to observed genotoxic activity <i>in vitro</i> and <i>in vivo</i> (2004/357/EC).</p>	ES: No more comments	<p><i>Capsicum</i> extract are still food additives and flowering as specified in Reg. 231/2012 (E 160 c).</p> <p><i>Capsicum</i> spp. spice is identical to sold food!</p> <p>Dilemma has to be solved at EU level especially if concerns conduct to non-approval under Plant Protection Product Reg and food status maintained.</p>	See 9(2)
9(5)		EFSA: The substance referred as		Repellence to birds is	See Sections 1, 2, 3, 5, 6, 7

<sup>6</sup> Guidance document on Botanical active substances used in plant protection products (SANCO/11470/2012 – rev.8), 20 March 2014, 28 pp.



**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
		<p><i>Capsicum</i> spp. spice is not well defined (lack of specifications) and the efficacy as repellent to all organisms listed when used according the proposed GAP (especially efficacy as repellent to birds) needs to be further justified. Human health cannot be completed because of lack of adequate end points and indications of genotoxic, carcinogenic and neurotoxic effects of some of the components of <i>Capsicum</i> spp. spice.</p> <p>Environmental risk assessment cannot be completed due to the lack of adequate end points for fate and behaviour into the environment and ecotoxicology. Risk assessment for birds, bees, beneficial arthropods and soil and aquatic organisms needs to be performed.</p>		<p>validated by further publications.</p> <p>Misunderstanding may have come from confusion between capsaicin and oleoresin <i>Capsicum</i> due to lack of specifications.</p> <p>Substance is better described as specified in Reg. 231/2012 (E 160 c).</p> <p>Human health concern is clearly specified in the basic substance application although <i>Capsicum</i> oleoresin is still an allowed food additive.</p>	<p>and 8.</p>

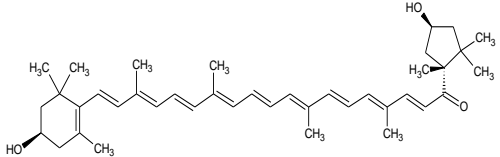
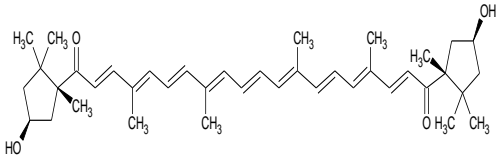
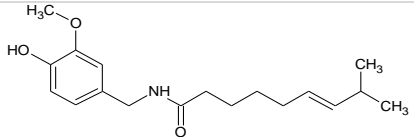
## 10. Other comments

UK: no comments

### Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		NL: No comments.			Noted
10(2)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorization of basic substances is that no product approval takes place after the final decision on the as.	Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	Efficacy is proven. More references added.	See Section 3.
10(3)		ES: No comments			Noted

## Appendix B – Used compound codes

Code/trivial name(a)	Chemical name/SMILES notation**	Structural formula**
<b>capsanthin</b>	(3R,3'S,5'R)-3,3'-dihydroxy- $\beta$ , $\beta$ -caroten-6'-one  <chem>CC2(C)C[C@H](O)CC(C)=C2/C=CC(\C)=C\C=C\C(\C)=C\C=C=C\C=C/C(\C)=C\C=C/C(\C)=C\C=C(O)[C@]1(C)C[C@@H](O)CC1(C)C</chem>	
<b>capsorubin</b>	(3S,3'S,5R,5'R)-3,3'-dihydroxy- $\beta$ , $\beta$ -carotene-6,6'-dione  <chem>O=C(/C=CC(\C)=C\C=C\C(\C)=C\C=C=C(/C)\C=C\C=C/C(\C)=C\C=C(O)[C@]1(C)C[C@@H](O)CC1(C)C)[C@]2(C)C[C@@H](O)CC2(C)C</chem>	
<b>capsaicin</b>	(6E)-N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide  <chem>Oc1ccc(cc1OC)CNC(=O)CCCC/C=C/C(C)C</chem>	

(a): The compound name in bold is the name used in the report.

## Appendix C – Identity and biological properties

<b>Common name (ISO)</b>	There is no ISO common name for this substance
<b>Chemical name (IUPAC)</b>	Not relevant, the substance is a complex mixture
<b>Chemical name (CA)</b>	Not relevant, the substance is a complex mixture
<b>Common names</b>	Paprika Oleoresin
<b>CAS No</b>	8023-77-6 ( <i>Capsicum</i> oleoresin)
<b>CIPAC No and EEC No</b>	283-256-8 (EINECS/ELINCS)
<b>FAO specification</b>	Not available
<b>Minimum purity</b>	Not relevant Purity is depending on the origin
<b>Relevant impurities</b>	< 0.025 % (< 250 mg capsaicin / kg of <i>Capsicum annuum</i> and/or <i>Capsicum frutescens</i> spice)
<b>Molecular mass and structural formula</b>	Not relevant, the substance is a complex mixture
<b>Mode of Use</b>	Seed treatment and spray applications
<b>Preparation to be used</b>	LS (solution for seed treatment) EW (emulsion, oil in water)
<b>Function of plant protection</b>	Animal repellent

## Appendix D – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*, **)	
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)			g a.i./ha min max (g/ha) (l)
<i>Crop seeds</i> Wheat seeds <i>Triticum vulgare</i> <i>Triticum aestivum</i> Durum wheat <i>Triticum durum</i> Spelt <i>Triticum spelta</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds boar, ravens	LS (Solution for seed treatment)	94.0	Seed treatment	n.a. sowing	1	-	n.a.	n.a.	14-15	14-15	n.a.	
Sweet Maize (Sweet corn) <i>Zea mays</i>																
Sunflower <i>Helianthus annuus</i>																
Sweet Maize (Sweet corn) <i>Zea mays</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds boar, ravens	EW Emulsion, oil in water	94.0	spray	Seedling 1 to 2 leaves  see corresp. BBCH	1	-	30	100 (80 to 120)	24 to 36	24 to 36	n.a.	
Canola <i>Brassica napus</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds	EW Emulsion, oil in water	94.0	spray	Seedling 1 to 2 leaves	1	-	30	100 (80 to 120)	24 to 36	24 to 36	n.a.	

				boar, ravens				see corresp. BBCH								
Cabbage <i>Brassica oleraceae</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds boar, ravens	EW Emulsion , oil in water	94.0	spray	Seedling 1 to 2 leaves  see corresp. BBCH	1	-	30	100 (80 to 120)	24 to 36	24 to 36	n.a.	
Sunflower <i>Helianthus annuus</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds boar, ravens	EW Emulsion , oil in water	94.0	spray	Seedling 1 to 2 leaves  see corresp. BBCH	1	-	30	100 (80 to 120)	24 to 36	24 to 36	n.a.	
Wheat <i>Triticum vulgare Triticum aestivum</i> Durum wheat <i>Triticum durum</i> Spelt <i>Triticum spelta</i>	France All M.S.	PNF19	F	Repulsive for Feeding animals and birds boar, ravens	EW Emulsion , oil in water	94.0	spray	Seedling 1 to 2 leaves  see corresp. BBCH	1	-	30	100 (80 to 120)	24 to 36	24 to 36	n.a.	

\* 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 active substance (according to ISO)

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

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

(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 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