Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on

Eligibility of certain food and feed active substances for inclusion into Annex I to the BPR

ECHA/BPC/186/2017

Adopted:

14 December 2017

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR

In accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR.

This document presents the opinion adopted by the BPC, having regard to the conclusions of the rapporteur.

Process for the adoption of opinions

A request by Commission was received by ECHA on 8 February 2017. ECHA was appointed the rapporteur at BPC-19. The rapporteur presented the draft opinion to the BPC at its meeting of 11-14 December 2017. Following the adoption of the opinion at the BPC meeting of 14 December the opinion was amended.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion was reached on 14 December 2017.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at:

https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-other-requests-under-the-biocidal-products-regulation.

Further details of the opinion and background

1. Request for the opinion and background

Article 28(1) of Regulation (EU) No 528/2012 (the BPR) empowers the Commission to adopt delegated acts in order to include active substances into Annex I to the BPR after receiving the opinion of ECHA, provided that there is evidence that they do not give rise to concern according to the conditions set out in Article 28(2).

Article 15(b) of Regulation (EU) No 1062/2014 provided companies with an opportunity to support those active substances that benefitted from the food and feed derogation provided for by Article 6 of Regulation (EC) No 1451/2007. A declaration of interest to notify according Article 16(1)(b) of the same regulation had to be submitted to ECHA by 30 October 2015. ECHA finalised the review of these declarations last year and concluded on their acceptability or refusal.

During its assessment of the declarations of interest to notify, ECHA was able to identify active substances that might be suitable candidates for inclusion into Annex I to the BPR, as they would not give rise to concern in accordance with Article 28(2) of the BPR.

At the 66th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 it was agreed that the Commission will request a formal opinion to ECHA in order to be able to proceed with the inclusion into Annex I to the BPR.

Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, ECHA was therefore requested to formulate an opinion addressing the following questions:

(1) Does the active substance give rise to concern in accordance with Article 28(2) of the BPR, and is it eligible for inclusion into Annex I?

(2) If the substance is eligible for inclusion into Annex I, is the active substance of natural origin?

(3) If the substance is eligible for inclusion into Annex I, is the active substance authorised as a food additive according to Regulation (EC) No 1333/2008?

Elements that will be provided by ECHA to answer questions (2) and (3) will be useful to decide in which category the active substance may be included in Annex I as such type of substances could be suitable candidates to be listed in category 1, 4 or 7.

2. Overview of substances

Article 16(1)(b) required companies to submit a declaration of interest to notify a substance which was eligible for inclusion in the Review Programme for a substance which benefitted from the derogation for food and feed provided for by Article 6 of Regulation (EC) No 1451/2007. Declarations of interest according to Article 16(1)(b) could be submitted to ECHA until 30 October 2015.

Based on the declarations received ECHA (in accordance with Article 16(4) of Regulation (EU) No 1062/2014) published the list of substances eligible for inclusion in the Review Programme for product-type 19 at: https://echa.europa.eu/documents/10162/17158508/list_substances_deadline_en.pdf/7fcf0bf2-8339-4f55-9e98-91c86ad177cd. For these substances, a notification in accordance with Article 17 of Regulation (EU) No 1062/2014 had to be made to ECHA within six months of the publication, being 24 February 2017.

Table 1 includes the substances subject of this opinion as for these substances a compliant notification has been submitted to ECHA by the deadline of 24 February 2017.

Table 1. Active substances for which a compliant notification was submitted.

Active substance	EC/List* number	CAS number
Capsicum oleoresin[1]	NA	8023-77-6
Capsicum annuum, ext[1]	283-403-6	84625-29-6
Reaction mass of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnonanamide[1]	NA	NA
Cheese	NA	NA
Concentrated apple juice	NA	NA
D-fructose	200-333-3	57-48-7
Garlic, ext	232-371-1	8008-99-9
Honey	NA	8028-66-8
Malt, ext	232-310-9	8002-48-0
Orange, sweet, ext.	232-433-8	8028-48-6
Powdered egg	NA	NA
Saccharomyces cerevisiae	n/a	68876-77-7
Vinegar (food grade containing a maximum of 10% acetic acid)	NA	8028-52-2

3. Approach followed

3.1. Data sources used

Regulation 88/2014 in its Annex section A establishes the data requirements for inclusion of active substances in Annex I to Regulation (EU) no 528/2012. Paragraph 1(b) clearly states that the applications shall contain conclusive evidence to demonstrate that there is a robust consensus of expert opinion that the substance does not give rise to concern in accordance with Article 28(2) of the BPR.

[1] Notified as Capsaicin (EC: 206-969-8; CAS 404-86-4)

In order to demonstrate this robust consensus of expert opinion, the Regulation provides a list of data sources that shall be used. That includes among others, all relevant published literature references regarding the substance in question, all relevant information on the substance generated by the applicant and conclusions from other regulatory authorities or frameworks.

For the purpose of these opinions, ECHA has followed the same approach to ensure robust consensus of expert judgment and to demonstrate methodological consistency. Accordingly, to define if the notified active substances give rise to concern in accordance with Article 28(2), ECHA has used all the information available in the declarations of interest to notify, information submitted in the notifications, the Classification and Labelling Inventory and other bibliographic information easily accessible to ECHA (please refer to the list of references). Also the conclusions from other regulatory authorities or frameworks, European and international, have been used.

Information concerning EU frameworks was extracted from:

- Regulation (EC) No 178/2002 - Food Law
- Regulation (EC) No 1331/2008 - EU authorisation for food additives, food enzymes and food flavourings.
- Regulation (EC) No 1332/2008 - Food enzymes
- Regulation (EC) No 1333/2008 - Food additives
- Regulation (EC) No 1334/2008 - Flavourings and certain food ingredients with flavouring properties
- Directive 2012/12/EU – Fruit Juice Directive
- Regulation (EC) No 1107/2009 – Plant Protection Regulation

The information regarding the non-EU frameworks was mainly taken from international databases and governmental web inventories (e.g. United States Environmental Protection Agency-US (EPA) and National pesticide information center (npic))

3.2. Evaluation of the information

1. With regard to the question, does the active substance give rise to concern in accordance with Article 28(2) of the BPR, and is it eligible for inclusion into Annex I?

Article 28 of the BPR defines the specific criteria concerning the properties that active substances shall not have to be listed in Annex I. According to Article 28(1) and (2), active substances can be included in Annex I if there is evidence that they do not give rise to concern.

According to Article 28(2) a substance is considered to give rise to concern where:

(a) it meets the criteria for classification according to Regulation (EC) No 1272/2008 as:

- Explosive/highly flammable
- Organic peroxide
- Acute toxicity category 1, 2 or 3
- Corrosive category 1A, 1B or C
- Respiratory sensitizer
- Skin sensitiser
- Germ cell mutagen of cat 1 or 2
- Carcinogen of cat 1 or 2
- Human reproductive toxicant of category 1 or 2 with effects on or via lactation

- Specific target organ toxicant by single or repeated exposure
- Toxic to aquatic life of acute category 1

(b) it fulfils any of the substitution criteria set out in Article 10(1); or

(c) it has neurotoxic or immunotoxic properties.

An active substance also gives rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

Each of the substance subject of this opinion was screened against the above mentioned criteria. The approach followed consisted of a tiered approach:

a) In the first step, the classification and labelling inventory was checked for each of the active substances. The information extracted from the inventory was in most cases sufficient to establish whether the substance may give rise to concern according to Article 28(2). However, as not all the substances were included in the inventory other sources of information were considered and additional checks were necessary.
b) In a second step European and international database and the conclusions from other regulatory authorities or frameworks were screened for additional evidence to support the decision.
c) In a third step the scientific literature available to ECHA was checked to rule out the remaining uncertainties which could not be dealt with the sources used in step 1 and 2 alone.

In this context, Regulation (EC) No 1107/2009 was of particular relevance. The Plant Protection Regulation introduces in Recital 18 the concept of 'basic substances' which are further defined in Article 23. The specific provisions used to ensure that these basic substances can be used throughout the European Union and do not have immediate or deferred harmful or unacceptable effects on the environment and on animal or human health, are similar to the provisions in Article 28 of the BPR. In addition, Article 23 states that "*an active substance which fulfils the criteria of a 'foodstuff' as define in Article 2*[2] *of Regulation (EC) No 178/2002 shall be considered as a basic substance*".

The basic substances approved by the Commission are listed in a separate list in Regulation (EC) No 540/2011 and included in the Pesticides Database on active substances.

The overlap between the US and EU legislation concerning pesticides was also considered to reinforce the result of the assessment. None of the active substances notified was included in the active ingredients eligible for minimum risk pesticides products[3] from the US-EPA.

The summaries with the relevant information to define if these substances give rise to concern in accordance with Article 28(2) are included in an Appendix to this opinion.

[2] The definition of "foodstuff" given in Article 2 of Regulation (EC) No 178/2002: 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

[3] EPA has determined that certain "minimum risk pesticides" pose little to no risk to human health or the environment and are therefore, exempted from the requirement that they be registered under the Federal Insecticide, Fungicide, and Rodenticide Act. This exemption provision is located in 40 CFR 152.25(f).

2. With regard to the question, if the substance is eligible for inclusion into Annex I, is the active substance of natural origin?

The substances proposed by ECHA of inclusion into Annex I are of plant or animal origin.

3. With regard to the question, if the substance is eligible for inclusion into Annex I, is the active substance authorised as food additives according to Regulation (EC) No 1333/2008?

None of the notified substances are authorised as food additive according to Regulation (EC) No 1333/2008.

4. Overall conclusions

It is concluded that the active substances cheese, concentrated apple juice, D-fructose, honey, powdered egg, *Saccahoromyces cervisiae* (yeast), and vinegar do not give rise to concern according to Article 28 and therefore are eligible for inclusion in Annex I of Regulation (EU) No 528/2012 with the following substance identifiers:

Common name:	Cheese
Chemical name:	Cheese
EC No:	NA
CAS No:	NA

Common name:	Concentrated apple juice[4]
Chemical name:	Concentrated apple juice
EC No:	NA
CAS No:	NA

Common name:	D-Fructose
Chemical name:	D-Fructose
EC No:	200-333-3
CAS No:	57-48-7

Common name:	Honey
Chemical name:	Honey
EC No:	NA
CAS No:	8028-66-8

[4] Directive 2012/12/EU, Annex I, 1(b) *'Where the product is intended for direct consumption, the removal shall be at least 50 % of the water content".*

Common name:	Powdered egg
Chemical name:	Powdered egg
EC No:	NA
CAS No:	NA

Common name:	Yeast
Chemical name:	*Saccharomyces cerevisiae*
EC No:	NA
CAS No:	68876-77-7

Common name:	Vinegar[5]
Chemical name:	NA
EC No:	NA
CAS No:	8028-52-2

Specific concerns based on the information extracted from the Classification and Labelling Inventory were identified for six of the notified active substances:

- Capsicum oleoresin[6];
- Capsicum annuum, ext.[6];
- Reaction mass[6] of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8- methylnonanamide;
- Garlic, ext;
- Malt, ext;
- Orange, sweet, ext.

ECHA cannot confirm that these substances do not give rise to concern as required in Article 28. Accordingly, the above mentioned substances are not proposed for inclusion in Annex I of Regulation (EU) No 528/2012.

[5] Food grade containing a maximum of 10% acetic acid; EN 13188
[6] Application submitted for capsaicin.

Reference list

EU. 2012. Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 SANCO/10363/2012 (rev.9 of 21 March 2014).

Plants. European Commission. https://ec.europa.eu/food/plant/pesticides/approval_active_substances/application_report_en

Marchand, P.A. 2015. Basic substances: an opportunity for approval of low-concern substances under EU pesticide regulation. Pest Management Science 71(9):1197-1200.

Marchand, P.A. 2015. Basic substances under EC 1107/2009 phytochemical regulation: experience with non-biocide and food products as biorationals. Journal of plant protection research, Vol. 56 (3), 312-318.

EU. 2010. Guidance on the implantation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law. Conclusions of the Standing Committee on the food chain and animal health. (vs. 26 January 2010).

Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners. OJ L 253 of 20.9.2008 p. 1

Regulation (EC) No 110/2008 of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89. OJ L 39, 13.2.2008, p. 16-54.

Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, p. 18-63.

Sari Lehto, Maria Buchweitz, Alexandra Klimm, Raphaela Straßburger, Cato Bechtold & Franz Ulberth (2017) Comparison of food colour regulations in the EU and the US: a review of current provisions, Food Additives & Contaminants: Part A, 34:3, 335-355, DOI: 10.1080/19440049.2016.1274431

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Appendix

Factsheets for active substances for which a compliant notification was received

Cheese

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Cheese
CAS No	NA
EC No	NA
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not occurring in the CL inventory
with regard to toxicological data	Not occurring in the CL inventory
with regard to fate and behaviour data	Not occurring in the CL inventory
with regard to ecotoxicological data	Not occurring in the CL inventory

Other Regulations

Regulation (EC) No 178/2002 - Food Law	Cheese fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. Catalogue of feed materials COM Regulation (EU) No 2017/1017: 8.5.1. Cheese and cheese products
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Cheese does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

No specific concerns were identified regarding the inclusion of cheese in Annex I:

- Cheese does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.
- Cheese does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Cheese does not fulfil the criteria according to Article 28(2) of the BPR (see table below)

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Cheese does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Cheese does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Cheese does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Cheese does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Cheese does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Cheese does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Cheese does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Cheese does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Cheese does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Cheese is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Cheese is not considered to have neurotoxic or immunotoxic properties

Concentrated apple juice

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Concentrated apple juice
CAS No	NA
EC No	NA
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not occurring in the CL inventory
with regard to toxicological data	Not occurring in the CL inventory
with regard to fate and behaviour data	Not occurring in the CL inventory
with regard to ecotoxicological data	Not occurring in the CL inventory

Other regulations

Regulation (EC) No 178/2002 - Food Law	Concentrated apple juice fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and Directive 2012/12/EU
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Concentrated apple juice does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

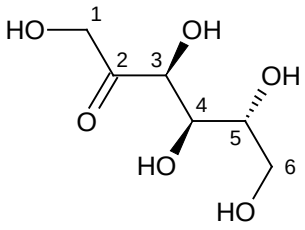
No specific concerns were identified regarding the inclusion of concentrated apple juice in Annex I:

- Concentrated apple juice does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Concentrated apple juice does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Concentrated apple juice does not fulfil the criteria according to Article 28(2) of the BPR (see table below):

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Concentrated apple juice does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Concentrated apple juice does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Concentrated apple juice does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Concentrated apple juice does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Concentrated apple juice does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Concentrated apple juice does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Concentrated apple juice does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Concentrated apple juice does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Concentrated apple juice does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Concentrated apple juice is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Concentrated apple juice is not considered to have neurotoxic or immunotoxic properties

D-fructose

Identity

Chemical name (IUPAC)	1,3,4,5,6-Pentahydroxy-hexan-2-one
Chemical name (CA)	D-Fructose
CAS No	57-48-7
EC No	200-333-3
Other substance No	NA
Molecular formula	C6H12O6
Molecular mass	180.16 g/mol
Structural formula	

Classification and proposed labelling

with regard to physical/chemical data	Not classified
with regard to toxicological data	Not classified
with regard to fate and behaviour data	Not classified
with regard to ecotoxicological data	Not classified

Regulatory status

Regulation (EC) No 178/2002 - Food Law	Fructose fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 Catalogue of feed materials COM Regulation (EU) No 2017/1017: 13.2.3. Fructose
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Approved as a 'basic substance' Reg. (EU) 2015/1392, Reg. (EU) No 540/2011
Regulation (EC) No 1333/2008 – Food additives	Fructose does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

No specific concerns were identified regarding the inclusion of fructose in Annex I:

- Fructose does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Fructose does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Fructose does not fulfil the criteria according to Article 28(2) of the BPR:

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Fructose does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Fructose does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Fructose does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Fructose does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Fructose does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Fructose does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Fructose does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Fructose does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Fructose does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Fructose is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Fructose is not considered to have neurotoxic or immunotoxic properties

References

- EU. 2015. Commission Implementing Regulation (EU) No 1392/2015 of 13 August 2015 approving the basic substance fructose, OJ L 215, 14.8.2015, p. 34-37

- EU. 2014. Commission Implementing Regulation (EU) No 916/2014 of 22 August 2014 approving the basic substance sucrose, OJ L 251, of 23.8.2014, p. 16

- Derridj, S. 2013. Du sucre pour protéger les plantes. Alter Agri 118: 29-31

Honey

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Honey
CAS No	8028-66-8
EC No	NA
Other substance No	List no: 617-041-0
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not classified
with regard to toxicological data	Not classified
with regard to fate and behaviour data	Not classified
with regard to ecotoxicological data	Not classified

Regulatory status

Regulation (EC) No 178/2002 - Food Law	Honey fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 Catalogue of feed materials COM Regulation (EU) No 2017/1017: 9.3.1. Apiculture by-products Honey, beeswax, royal jelly, propolis, pollen, processed or unprocessed
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Honey does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008

Specific concerns

No specific concerns were identified regarding the inclusion of honey in Annex I:

- Honey does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Honey does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Honey does not fulfil the criteria according to Article 28(2) of the BPR (see table below)

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Honey does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Honey does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Honey does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Honey does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Honey does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Honey does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Honey does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Honey does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Honey does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Honey is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Honey is not considered to have neurotoxic or immunotoxic properties

References

- Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ L 10, 12.1.2002, p. 47)

- EU. 2014. Council Directive 2014/63/EC of 15 May 2014 amending Council Directive 2001/110/EC relating to honey, OJ L 164, of 3.6.2014, p. 1-5

Powdered egg

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Powdered egg (whole egg whites and yolks)
CAS No	NA
EC No	NA
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not occurring in the CL inventory
with regard to toxicological data	Not occurring in the CL inventory
with regard to fate and behaviour data	Not occurring in the CL inventory
with regard to ecotoxicological data	Not occurring in the CL inventory

Regulatory status

Regulation (EC) No 178/2002 - Food Law	Powdered egg fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. Catalogue of feed materials COM Regulation (EU) No 2017/107: 9.15.3. Egg products dried
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Powdered egg does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

No specific concerns were identified regarding the inclusion of powdered_egg in Annex I:

- Powdered egg does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Powdered egg does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Powdered egg does not fulfil the criteria according to Article 28(2) of the BPR (see table below).

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Powdered egg does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Powdered egg does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Powdered egg does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Powdered egg does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Powdered egg not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Powdered egg does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Powdered egg does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Powdered egg does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Powdered egg does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Powdered egg is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Powdered egg is not considered to have neurotoxic or immunotoxic properties

Saccharomyces cerevisiae (yeast).

Identity

Chemical name (IUPAC)	*Saccharomyces cerevisiae*
Chemical name (CA)	*Saccharomyces cerevisiae* (yeast)
CAS No	68876-77-7
EC No	NA
Other substance No	List no: 614-750-7
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	No classification proposed
with regard to toxicological data	No classification proposed
with regard to fate and behaviour data	No classification proposed
with regard to ecotoxicological data	No classification proposed

Other Regulations

Regulation (EC) No 178/2002 - Food Law	*Saccharomyces cerevisiae* fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 Catalogue of feed materials COM Regulation (EU) No 2017/1017: 12.1.5.Yeasts and parts thereof [brewers' yeast] [yeast product]
Regulation (EC) No 1107/2009 – Plant Protection Regulation	*Saccharomyces cerevisiae* strain LAS02 is approved as a low-risk active substance. Reg. (EU) 2016/952, Reg. (EU) No 540/2011
Regulation (EC) No 1333/2008 – Food additives	*Saccharomyces cerevisiae* (yeast) does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008

Specific concerns

No specific concerns were identified regarding the inclusion of *Saccharomyces cerevisiae* in Annex I:

- *Saccharomyces cerevisiae* does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- *Saccharomyces cerevisiae* does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- *Saccharomyces cerevisiae* does not fulfil the criteria according to Article 28(2) of the BPR (see table below)

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	*Saccharomyces cerevisiae* does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	*Saccharomyces cerevisiae* does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	*Saccharomyces cerevisiae* does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	*Saccharomyces cerevisiae* does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	*Saccharomyces cerevisiae* does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	*Saccharomyces cerevisiae* does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	*Saccharomyces cerevisiae* does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	*Saccharomyces cerevisiae* does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	*Saccharomyces cerevisiae* does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	*Saccharomyces cerevisiae* is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	*Saccharomyces cerevisiae* is not considered to have neurotoxic or immunotoxic properties

References

- EU. 2016. Commission Implementing Regulation (EU) 2016/952 of 15 June 2016 approving the low-risk active substance *Saccharomyces cerevisiae* strain LAS02 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 159, 16.6.2016, p. 10–13.

- EU. 2016. Commission Regulation (EU) 2016/1726 of 27 September 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards carvone, diammonium phosphate, *Saccharomyces cerevisiae* strain LAS02 and whey, OJ L 261, 28.9.2016, p. 3–4.

Vinegar

Identity

Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Vinegar
CAS No	8028-52-2
EC No	NA
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not occurring in the CL inventory
with regard to toxicological data	Not occurring in the CL inventory
with regard to fate and behaviour data	Not occurring in the CL inventory
with regard to ecotoxicological data	Not occurring in the CL inventory

Regulatory status

Regulation (EC) No 178/2002 - Food Law	Vinegar fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Approved as a 'basic substance' Reg. (EU) 2015/1108 Reg. (EU) No 540/2011
Regulation (EC) No 1333/2008 – Food additives	Vinegar does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008

Specific concerns

No specific concerns were identified regarding the inclusion of vinegar in Annex I:

- Vinegar does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.
- Vinegar does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Vinegar does not fulfil the criteria according to Article 28(2) of the BPR (see table below).

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Vinegar does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Vinegar does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Vinegar does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Vinegar does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Vinegar does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Vinegar does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Vinegar does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Vinegar does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Vinegar does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Vinegar is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Vinegar is not considered to have neurotoxic or immunotoxic properties

References

- EU. 2015 Commission Implementing Regulation (EU) No 1392/2015 of 8 July 2015 approving the basic substance vinegar OJ L 181, of 9.7.2015, p. 75-77.

- EFSA (2013) Conclusion on the peer review of the pesticide risk assessment of the active substance acetic acid; EFSA Journal 2013; 11(1): 3060 [57 pp.]. doi: 10.2903/j.efsa.2013.3060

Capsicum oleoresin

Identity

Chemical name (IUPAC)	Capsicum oleoresin
Chemical name (CA)	Capsicum oleoresin
CAS No	8023-77-6
EC No	NA
Other substance No	List no: 617-016-4
Molecular formula	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Flam. Liq. 3
with regard to toxicological data	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3
with regard to fate and behaviour data	Not occurring in the CL inventory
with regard to ecotoxicological data	Not occurring in the CL inventory

Other Regulations

Regulation (EC) No 178/2002 - Food Law	Capsicum oleoresin fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Capsicum oleoresin does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008

Specific concerns

Specific concerns were identified regarding the inclusion of capsicum oleoresin in Annex I:

- Capsicum oleoresin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.
- Capsicum oleoresin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Capsicum oleoresin meets some the criteria according to Article 28(2) of the BPR (see table below).
- Capsaicin, one of the main constituents of capsicum oleoresin, is listed in Annex III to Regulation (EC) No 1334/2008 as a substances which shall not be added as such to food. Therefore, ECHA is of the opinion that a risk assessment of capsicum oleoresin shall be carried out.

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Classification for flammability required. Capsicum oleoresin **fulfils** criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Classification for acute toxicity required Capsicum oleoresin does not fulfil the criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Capsicum oleoresin does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Capsicum oleoresin does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Capsicum oleoresin does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Capsicum oleoresin does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Classification for specific target organ toxicant required Capsicum oleoresin meets the criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Capsicum oleoresin does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Capsicum oleoresin does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Capsicum oleoresin is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Capsicum oleoresin is not considered to have neurotoxic or immunotoxic properties

References

- EU. 2002. Opinion of the Scientific Committee on Food on Capsaicin. (vs. 28 February 2002).
- Surh, YJ and Lee, S.S. (1995). Capsaicin, a double-edged sword: Toxicity, metabolism, and chemopreventive potential. Life Sciences, 56 (22), 1845-1855.
- Capsaicin General Fact Sheet. National Pesticide Information Center (npic). http://npic.orst.edu/factsheets/capgen.html#whatis. (October 2017)
- Fact Sheet for Capsaicin – EPA. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-070701_1-Jun-92.pdf
- Reilly CA, Crouch DJ, Yost GS. Quantitative analysis of capsaicinoids in fresh peppers, oleoresin capsicum and pepper spray products. J Forensic Sci 2001; 46(3):502–509

Capsicum annum, ext.

Identity

Chemical name (IUPAC)	Capsicum annum, ext.
Chemical name (CA)	Capsicum annum, ext.
CAS No	84625-29-6
EC No	283-403-6
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Flam. Liq. 3
with regard to toxicological data	Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2
with regard to fate and behaviour data	No classification proposed
with regard to ecotoxicological data	No classification proposed

Other Regulations

Regulation (EC) No 178/2002 - Food Law	Capsicum annum, ext. fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Capsicum annum, ext. does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

Specific concerns were identified regarding the inclusion of capsicum oleoresin in Annex I:

- Capsicum annum, ext. does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Capsicum annum, ext. not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Capsicum annum, ext. meets some the criteria according to Article 28(2) of the BPR (see table below)
- Capsaicin, one of the main constituents of capsicum annum ext., is listed in Annex III of Regulation (EC) No 1334/2008 as a substances which shall not be added as such to food. Therefore, ECHA is of the opinion that a risk assessment of capsicum annum, ext. shall be carried out.

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Classification for flammability required Capsicum annum, ext. **fulfils** criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Classification required for acute toxicity Capsicum annum, ext. does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Capsicum annum, ext. does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Capsicum annum, ext. does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	No classification required. Capsicum annum, ext. does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Capsicum annum, ext. does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Capsicum annum, ext. does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Capsicum annum, ext. does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Capsicum annum, ext. does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Capsicum annum, ext. is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Capsicum annum, ext. is not considered to have neurotoxic or immunotoxic properties

References

- EU. 2002. Opinion of the Scientific Committee on Food on Capsaicin. (vs. 28 February 2002).

- Surh, YJ and Lee, S.S. (1995). Capsaicin, a double-edged sword: Toxicity, metabolism, and chemopreventive potential. Life Sciences, 56 (22), 1845-1855.

- Capsaicin General Fact Sheet. National Pesticide Information Center (npic). http://npic.orst.edu/factsheets/capgen.html#whatis. (October 2017)

- Fact Sheet for Capsaicin – EPA. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-070701_1-Jun-92.pdf

- Reilly CA, Crouch DJ, Yost GS. Quantitative analysis of capsaicinoids in fresh peppers, oleoresin capsicum and pepper spray products. J Forensic Sci 2001; 46(3):502–509

Reaction mass of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnonanamide

Identity

Chemical name (IUPAC)	Reaction mass of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8- methylnonanamide[7]
Chemical name (CA)	Reaction mass of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8- methylnonanamide
CAS No	NA
EC No	NA
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Not occurring in the CL inventory-read across from capsaicin (CAS no 404-86-4): No classification proposed
with regard to toxicological data	Not occurring in the CL inventory read across from capsaicin (CAS no 404-86-4): Acute Tox.3 Skin Irrit.2 Eye Irrit. 2 Resp. Sens. 1 STOT SE 1
with regard to fate and behaviour data	Not occurring in the CL inventory read across from capsaicin (CAS no 404-86-4)
with regard to ecotoxicological data	Not occurring in the CL inventory read across from capsaicin (CAS no 404-86-4)

Other Regulations

Regulation (EC) No 178/2002 – Food Law	'The reaction mass', fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered

[7] In the text mentioned as 'the reaction mass'

Regulation (EC) No 1333/2008 – Food additives	The ‘reaction mass’ does not fulfil the criteria of a ‘food additive’ as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

Specific concerns were identified regarding the inclusion of reaction mass of (6E)-N-(4-hydroxy-3-methoxy- 2-methylphenyl)-8-methylnon-6-enamide and N- (4-hydroxy-3-methoxy-2-methylphenyl)-8- methylnonanamide in Annex I:

- The ‘reaction mass’ does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- The ‘reaction mass’ does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- The ‘reaction mass’ meets some the criteria according to Article 28(2) of the BPR (see table below) (read across from capsaicin):
    - Acute toxicity
    - Skin sensitiser
    - Respiratory sensitiser
    - Specific target organ toxicant by single or repeated exposure
- Capsaicin, one of the main constituents of the ‘reaction mass’, is listed in Annex III to Regulation (EC) No 1334/2008 as a substances which shall not be added as such to food. Therefore, ECHA is of the opinion that a risk assessment of the ‘reaction mass’ shall be carried out.

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Based on a read across to capsaicin, the 'reaction mass' does not fulfil criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Based on a read across to capsaicin, the 'reaction mass' **fulfils** the criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Based on a read across to capsaicin, the 'reaction mass' does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Based on a read across to capsaicin, the 'reaction mass' **fulfils** criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Based on a read across to capsaicin, the 'reaction mass' **fulfils** criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Based on a read across to capsaicin, the 'reaction mass' does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Based on a read across to capsaicin, the 'reaction mass' **fulfils** criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Based on a read across to capsaicin, the 'reaction mass' does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Based on a read across to capsaicin, the 'reaction mass' does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Based on a read across to capsaicin, the 'reaction mass' is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Based on a read across to capsaicin, the 'reaction mass' is not considered to have neurotoxic or immunotoxic properties.

References

- EU. 2002. Opinion of the Scientific Committee on Food on Capsaicin. (vs. 28 February 2002).
- Surh, YJ and Lee, S.S. (1995). Capsaicin, a double-edged sword: Toxicity, metabolism, and chemopreventive potential. Life Sciences, 56 (22), 1845-1855.
- Capsaicin General Fact Sheet. National Pesticide Information Center (npic). http://npic.orst.edu/factsheets/capgen.html#whatis. (October 2017)
- Fact Sheet for Capsaicin – EPA. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-070701_1-Jun-92.pdf
- Reilly CA, Crouch DJ, Yost GS. Quantitative analysis of capsaicinoids in fresh peppers, oleoresin capsicum and pepper spray products. J Forensic Sci 2001; 46(3):502–509

Garlic, ext.

Chemical name (IUPAC)	Food grade garlic juice concentrate
Chemical name (CA)	Garlic extract
CAS No	8008-99-9
EC No	232-371-1
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Flam. Liq. 3
with regard to toxicological data	Acute Tox. 3 Skin Irrit. 2 Skin Sens. 1 Eye Irrit.2
with regard to fate and behaviour data	No classification proposed
with regard to ecotoxicological data	Aquatic chronic 3

Regulatory status

Regulation (EC) No 178/2002 - Food Law	Garlic, ext. fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Garlic, ext. is approved as a plant protection product. Reg (EU) 2008/127, Reg. (EU) No 540/2011
Regulation (EC) No 1333/2008 – Food additives	Garlic, ext. does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008

Specific concerns

Specific concerns were identified regarding the inclusion of Garlic, ext. in Annex I:

- Garlic, ext. does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.
- Garlic, ext. does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Garlic, ext. is considered to meet some of the criteria according to Article 28(2) of the BPR:
    - o Explosive/highly flammable
    - o Acute toxicity category 1, 2 or 3
    - o Skin sensitiser

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Classification for flammability required. Garlic, ext. **fulfils** criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Classification for acute toxicity required. Garlic, ext. **fulfils** the criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Garlic, ext. does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Garlic, ext. does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Classification for skin sensitiser required. Garlic, ext. **fulfils** criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Garlic, ext. does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Garlic, ext. does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Garlic, ext. does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Garlic, ext. does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Garlic, ext. is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Garlic, ext. is not considered to have neurotoxic or immunotoxic properties

References:

- EU. 2015. Review report for the active substance garlic extract finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of garlic extract in Annex I of Directive 91/414/EEC (vs. 14 July 2015).

Malt, ext.

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Malt extract
CAS No	8002-48-0
EC No	232-310-9
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Flam. Liq. 2
with regard to toxicological data	Skin Irrit. 2 Eye Dam.1 STOT SE 3
with regard to fate and behaviour data	No classification proposed
with regard to ecotoxicological data	Aquatic Chronic 3

Other regulations

Regulation (EC) No 178/2002 - Food Law	Malt, ext fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. Catalogue of feed materials COM Regulation (EU) No 2017/1017: 1.1.18. Malt
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Malt, ext. does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

Specific concerns were identified regarding the inclusion of Malt, ext. in Annex I:

- Malt, ext. does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Malt, ext. does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Malt, ext. meets some of the criteria according to Article 28(2) of the BPR:
    - o Explosive/highly flammable
    - o Specific target organ toxicant by single or repeated exposure

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Classification for flammability required Malt, ext. **fulfils** criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Malt, ext. does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Malt, ext. **fulfils** the criteria (a) of Article 28(2)
Respiratory sensitisation properties	Malt, ext. does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	No classification required. Malt, ext. does not fulfil criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Malt, ext. does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Malt, ext. does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Malt, ext. does not fulfil criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Malt, ext. does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Malt, ext. is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Malt, ext. is not considered to have neurotoxic or immunotoxic properties

Orange, sweet, ext.

Identity

Chemical name (IUPAC)	NA
Chemical name (CA)	Orange, sweet, extract
CAS No	8028-46-6
EC No	232-433-8
Other substance No	NA
Molecular formula	NA
Molecular mass	NA
Structural formula	NA

Classification and proposed labelling

with regard to physical/chemical data	Flam. Liq 2
with regard to toxicological data	Asp.Tox 1. Skin Irrit. 2 Skin Sens.1
with regard to fate and behaviour data	No classification proposed
with regard to ecotoxicological data	Aquatic Acute 1 Aquatic Chronic 1

Other Regulations

Regulation (EC) No 178/2002 - Food Law	Orange, sweet, ext. fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.
Regulation (EC) No 1107/2009 – Plant Protection Regulation	Not covered
Regulation (EC) No 1333/2008 – Food additives	Orange, sweet, ext. does not fulfil the criteria of a 'food additive' as defined in Article 3(2) of Regulation (EC) No 1333/2008.

Specific concerns

No specific concerns were identified regarding the inclusion of orange, sweet, ext. in Annex I:

- Orange, sweet, ext. does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012
- Orange, sweet, ext. does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution
- Orange, sweet, ext. meets some of the criteria according to Article 28(2) of the BPR:
    - Explosive/highly flammable
    - Skin sensitiser
    - Toxic to aquatic life of acute category 1

Property	Conclusions
Physical hazards: - Explosive/highly flammable - Organic peroxide	Classification for flammability requested Orange, sweet, ext. **fulfils** the criterion (a), of Article 28(2)
Acute toxicity category 1, 2 or 3	Orange, sweet, ext. does not fulfil criteria (a) of Article 28(2)
Corrosive category 1A, 1B or C	Orange, sweet, ext. does not fulfil criteria (a) of Article 28(2)
Respiratory sensitisation properties	Orange, sweet, ext. does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2)
Skin sensitiser	Classification for skin sensitiser required. Orange, sweet, ext. **fulfils** the criteria (a) of Article 28(2)
CMR properties: - Carcinogenicity (C) - Mutagenicity (M) - Toxic for reproduction (R)	Orange, sweet, ext. does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)
Specific target organ toxicant by single or repeated exposure	Orange, sweet, ext. does not fulfil criteria (a) of Article 28(2)
Toxic to aquatic life of acute category 1	Orange, sweet, ext. **fulfils** criteria (a) of Article 28(2)
PBT and vPvB properties: - Persistent (P) - Very Persistent (vP) - Bioccumulative (B) - Very Bioaccumulative (vB) - Toxic (T)	Orange, sweet, ext. does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
Endocrine disrupting properties	Orange, sweet, ext. is not considered to have endocrine disrupting properties
Neurotoxic or immunotoxic properties	Orange, sweet, ext. is not considered to have neurotoxic or immunotoxic properties