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Guidance notes on the classification of food extracts with colouring properties

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IMPORTANT DISCLAIMER

These Guidance notes on the classification of food extracts with colouring properties were elaborated by Commission services after consultation with the Member States' experts on food additives and the relevant stakeholders.

These Guidance notes were endorsed by a large majority of the representatives of Member States at the meeting of the Standing Committee on the Food Chain and Animal Health on 29 November 2013.

They should be read in conjunction with the appropriate legislation, especially Regulation (EC) No 1333/2008 on food additives which constitutes the legal basis for the placing on the market and use of the food additives in the EU.

These Guidance notes do not represent the official position of the Commission and they do not intend to produce legally binding effects.

Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

The Guidance notes have not been adopted on the basis of Article 19 (c) of Regulation (EC) No 1333/2008.

Guidance notes on the classification of food extracts with colouring properties

1. PURPOSE, DEFINITIONS AND SCOPE

The objective of this document is to give guidance for classifying food extracts as colours (food additives) or foods with colouring properties, which for the purposes of this document are called '*colouring foods*'. It describes the criteria that determine the difference between selective and non-selective extraction (especially the Enrichment factor) and proposes a decision tree (Annex I) and a checklist (Annex II) to facilitate the classification. Furthermore, Annex IV provides a practical example of a classification and Annex III, once established, will provide reference values for the source materials.

The term "*extract*" used in this document refers to preparations obtained from a food as defined in Regulation (EC) No 178/2002¹ obtained by physical and/or chemical extraction, *no matter whether they are labelled as extracts or concentrates* (i.e. it includes concentrates of extracts), used to colour foods - i.e. water soluble and oil soluble extracts. The guidance only relates to extracts in which the colouring constituents are intact (i.e. not chemically modified) and indigenous to the source material.

The term "*pigment*" in this document refers to both types of colouring principles, i.e. insoluble (usually associated with the term "pigment") as well as soluble (usually associated with the term "dye") colouring principles.

This document is based on the definitions and principles set out in Regulation (EC) No 1333/2008² of the European Parliament and of the Council on food additives, which applied from 10 January 2010. Its purpose is to provide a working tool for business operators and enforcement authorities of the Member States when considering if a substance is a colour or a colouring food. A good cooperation and information sharing between business operators and enforcement authorities is essential for the purpose of the extracts classification.

It is recommended that operators start following the principles developed in the present Guidance notes and start adapting their products accordingly from 1 January 2014. Moreover it is recommended that all food products placed on the market after 29 November 2015 be in line with the Guidance notes.

This document does not deal with labelling of colouring foods or labelling of foods containing colouring foods as an ingredient.

2. THE TERM "COLOUR" AND THE LEGISLATIVE FRAMEWORK

The term "colour" is referred to in Annex I to Regulation (EC) No 1333/2008 on food additives and provides elements for differentiating colours (food additives) from foods with colouring properties. It needs to be read in conjunction with the definition of food additive in Article 3 (2) (a) of Regulation (EC) No 1333/2008.

¹ OJ L 31, 1.2.2002, p. 1

² OJ L 354, 31.12.2008, p. 16

Annex I of Regulation (EC) No 1333/2008 on food additives describes colours as *"substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally **not consumed as foods as such and not normally used as characteristic ingredients of food**". Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a **selective** extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation"*.

Article 3 (2) (a) of the Regulation defines 'food additive' as *'any substance **not normally consumed as a food in itself and not normally used as a characteristic ingredient of food**, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods'*;

Furthermore, Article 3(2) (a) (ii) of the Regulation states which substances are not considered to be food additives:

- *'foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a **secondary** colouring effect;'*

In addition recital 5 of the Regulation explains further when substances should be considered food additives and when not:

"...However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste or for nutritional purposes, such as salt replacers, vitamins and minerals. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for colouring and food enzymes should also not fall within the scope of this Regulation. However, preparations obtained from foods and other natural source material that are intended to have a technological effect in the final food and which are obtained by selective extraction of constituents (e.g. pigments) relative to the nutritive or aromatic constituents, should be considered additives within the meaning of this Regulation....."

Article 19(c) of the Regulation (EC) No 1333/2008 states that the Commission may decide by means of implementing acts whether a given substance meets the definition of food additive in Article 3.

Extraction solvents used or intended for use in the production of foodstuffs or food ingredients should comply with the rules laid down in Directive 2009/32/EC³.

3. FOODS AND FOOD INGREDIENTS WITH COLOURING PROPERTIES

The starting point for the classification is the exception noted in Article 3 (2) (a) (ii) of Regulation (EC) No 1333/2008. It eliminates foods and flavourings with a secondary colouring effect from the food additive definition and so they are outside the scope of

³ OJ L 141, 6.6.2009, p. 3

Regulation (EC) No 1333/2008. For this reason Article 3(2) (a) (ii) is considered as a first step of the decision tree (see question Q1).

According to the definition of 'food additive' in Article 3 (2) (a) and the term "colours" in Annex I of Regulation (EC) No 1333/2008, foods normally consumed as such or normally used as characteristic ingredients of food should not be considered as food additives. Foods normally consumed as such in the EU e.g. fruit juices (for example, cherry juice added to yoghurt), tomato concentrates, or coffee often has colouring properties. Such foods would be regarded as ingredients and would have to be labelled as such, even when added principally for colouring purposes.

On the other hand, products which are extracted from those foods by other processes than drying or concentration to be used in food for their colouring properties, should not automatically be regarded as colouring food (unless they are normally consumed as such – e.g. red palm oil) and should be examined and classified in accordance with sections 4 and 5 (see **questions Q2 and Q3** of the decision tree).

Provided that these foods or food ingredients retain their essential characteristics, foods with colouring properties should not be regarded as food colours whether used in the raw state or in a processed form, e.g. by concentration, drying, cooking or milling. For example spinach used in the manufacture of noodles as such or dried or in the form of concentrated juice, without a selective extraction of pigments, would be considered as a food ingredient and not as a food colour. On the other hand if pigments are 'selectively extracted' from the spinach and added to noodles in order to add colour, then these are regarded to be food additives (i.e. food colours - chlorophylls and chlorophyllins (E140)).

4. CLASSIFICATION OF FOOD EXTRACTS

When a product is obtained from a food for the primary function of colouring, the key to determining whether or not the product is a colour is whether it has been obtained by way of 'selective extraction'. This leaves some room for preparations obtained from foods using a process of physical and/or chemical extraction which may be interpreted as not being selectively extracted (pigment(s)/nutritive constituents; pigment(s)/aromatic constituents). If it concerns a food normally consumed as such or normally used as a characteristic ingredient of food, these preparations are food ingredients and can be called '**colouring food**' for the purpose of this document.

Extraction can range from simple extraction, to degrees of selective extraction up to isolation of the pure pigments. To decide upon the classification of the product it is essential to identify when the product is no longer "*a food normally consumed as such or normally used as a characteristic ingredient of food*", but a colour which needs approval.

The criteria taken into account for classification are described in the following section.

5. CRITERIA TO BE CONSIDERED IN DECIDING IF AN EXTRACTION IS SELECTIVE OR NOT AND THUS IF THE EXTRACT IS A FOOD ADDITIVE (COLOUR) OR A COLOURING FOOD

Whether an extraction is selective or not depends, according to Regulation (EC) No 1333/2008, on the ratio of the pigments relative to the nutritive or aromatic⁴ constituents. Once the pigments are selectively extracted relative to the nutritive or aromatic constituents the extract is a colour within the meaning of Regulation (EC) No 1333/2008. No other guidance (numerically expressed) is provided by the legislation.

The legislation does not directly address a common situation when the source material contains more than one pigment. Based on the legislation, the ratio between pigment(s) relative to the nutritive or aromatic constituents seems to be the decisive factor for the classification of the extraction no matter whether all pigments present in the source material are present also in the extract. Indeed, only the pigment(s) present in the extract should be compared with the same pigment(s) in the source material in order to properly reflect the ratio between the pigment(s) and the nutritive or the aromatic constituents when calculating the Enrichment factor (see section 6).

C1: Does the primary extract⁵ retain the essential **characteristic properties** of the source material i.e.:

- colour properties – i.e. pigment(s) content
- aromatic properties and nutritive value

<YES/NO>

C2: Is the ratio of the content of the pigment(s) to that of the nutritive or aromatic constituents in the primary extract significantly different from that present in the source material as a result of physical and/or chemical extraction leading to a selective extraction of the pigments (using e.g. processing techniques as deodorisation or crystallisation etc.)?

<YES/NO>

- 1) If the answer to C1 is “**YES**” and to C2 is “**NO**” for every ratio tested⁶ then the extraction could be considered **non selective** and the corresponding product should be classified as a **colouring food**.
- 2) If the answer to C2 is “**YES**” then the extraction could be considered **selective** and the corresponding product should be classified as a **food colour**.
- 3) If the answer to C1 and C2 is “**NO**” then the primary extract should be assessed further **on a case by case basis**. More detailed analysis might be needed to verify whether the

⁴ "Aromatic" does not refer to a chemical structure but to substances imparting odour and/or taste.

⁵ Primary extract should be interpreted as a product used as the reference basis for the calculation of the enrichment factor. All ingredients or additives added prior, during or after the extraction do not form the primary extract and must be disregarded for the purpose of calculating the Enrichment factor.

⁶ More pigments may be present in the source material. The threshold value shall not be exceeded for any pigment or combination of pigments used for the calculation of the enrichment factor. Further guidance as regards which pigment(s) are recommended to be analysed for a specific source material will be provided in Annex III.

constituents of the primary extract are indigenous to the source material. If necessary a decision could be taken in accordance with Article 19(c) of the Regulation (EC) No 1333/2008 to classify the extract.

6. ENRICHMENT FACTOR

Enrichment factor formula

In order to assess the primary extract and to reply to the question C2 the relationship between the ratio of the pigment(s) content to the nutritive or aromatic constituents in the colouring product (primary extract) compared to the corresponding ratio of the pigment(s) content to the nutritive or aromatic constituents of the source material has to be considered. This ratio can be expressed as an *Enrichment factor* (see the formula below).

$$F_n = \frac{\frac{C_p}{N_p}}{\frac{C_s}{N_s}} \quad \text{or} \quad F_f = \frac{\frac{C_p}{A_p}}{\frac{C_s}{A_s}}$$

Where: Cp = the "pigment(s) content" in the examined primary extract

Cs = the "pigment(s) content" in the source material

Np = the "nutritive constituents content" in the examined primary extract

Ns = the "nutritive constituents content" in the source material

Ap = the "aromatic constituents content" in the examined primary extract

As = the "aromatic constituents content" in the source material

F_n = the "enrichment factor" based on the nutritive constituents

F_f = the "enrichment factor" based on the aromatic constituents

The application of the formula has to be practical and feasible for the enforcement authorities. At the same time it should verify whether the primary extract's composition is not significantly different from the source material and therefore that it could be still considered to be a food or a characteristic ingredient of food. The pigment(s) present in the examined primary extract should be taken into account to compare it with the same pigment(s) present in the source material. Further guidance will be provided in Annex III to this document.

Practical application of the Enrichment factor

As mentioned before the definition of colour indicates that once the pigments are selectively extracted relative to the nutritive OR aromatic constituents the extract under consideration should be classified as a food colour. Therefore, both the nutritive and the aromatic constituents should be considered for the classification (see the box on the next page).

Preparations obtained by extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours (i.e. food additives)

Pigments selectively extracted relative to the nutritive constituents► food colour

Pigments selectively extracted relative to the aromatic constituents► food colour

According to the legislation both groups of constituents should be checked to conclude whether the pigments are selectively extracted or not. Once there is a selective extraction at least for one of the two groups of the constituents the extract is a food colour.

However, due to the fact that the aromatic constituents could be based on a broad range of very different substances (e.g. volatile flavouring molecules, non-volatile constituents with different tastes, glycosidically bound flavouring molecules, carbohydrates, acids, proteins, phenolic constituents and intrinsic water) it would be extremely difficult to establish a general reference basis for aromatic constituents in practice.

For that reason it is recommended as a practical solution to base the classification primarily on the nutritive enrichment factor in cases in which it is not feasible to check also the aromatic enrichment factor due to the specific character of the source material. This suggested pragmatic approach could apply in many cases. However, this approach should not undermine the equal importance of the aromatic constituents for the classification and the content of the aromatic constituents should be checked if it is needed to verify whether the aromatic substances have not been removed from the extract given that such extract would also be regarded as a food additive. In case of difficulties in classification a decision could be taken in accordance with Article 19(c) of the Regulation (EC) No 1333/2008.

As regards the nutritive constituents it is recommended to use total solids (i.e. everything but water) as the reference basis for the enrichment factor calculations provided the conditions described below are met. The data on the composition of the source material (i.e. Annex III) should be related to the parts of the source material from which the extract is obtained (e.g. orange juice, orange peel or orange pulp) and expressed on a dry weight basis.

Any added extraneous components have to be deducted from the results of the compositional analysis of the colouring product irrespective of the phase in which they were added. Only the constituents originating from the source material are relevant for the calculation of the enrichment factor. Colouring foods producers/users should provide sufficient information in this respect.

In addition, for the purpose of control in case that the analysis of only total solids would not be considered sufficient, which might be relevant due to the simplicity of the total solids concept, it could be analytically verified that the identity of the solids in the primary extract corresponds to those present in the source material and that the original solids indigenous (naturally present) to the source material from which the colouring food is derived were not replaced by the same or other constituents (e.g. invert sugar, maltodextrin, glucose syrup, starch, organic acids etc.). Enforcement authorities might consider also on spot controls and controls of the information on the manufacturing process provided by producers.

The producer and the user of the colouring foods has the responsibility to prove that a primary extract is a colouring food and not a colour (food additive). This includes the responsibility for providing the enforcement authorities with the relevant data on the source material (until

the Annex III of this Guidance notes has been established), compositional and essential characteristic properties of the extract, calculation of the Enrichment factor (Fn, Ff), the information about the production process and any other information which might be relevant for the classification.

Threshold value

The threshold value provides a quantitative borderline between "selective extraction" and "non-selective extraction". The threshold value should be high enough to cover seasonal and geographical differences and differences in source material varieties. On the other hand it should be low enough that the primary extracts could be still considered to be foods or food ingredients (i.e. not selectively extracted) and should assure that such products do not overlap with food colour specifications. Based on these considerations the following threshold value is proposed:

The threshold value for a selective extraction > 6

Reference values for the source materials

The source material reference values might have significant impact on the enrichment factor calculations. For practical reasons (source material might not be available to enforcement officers, especially for imported products) it is recommended to use reference values based on the literature relevant to the edible part from which the colouring food is extracted. The table with the generally applicable reference values should be established as Annex III to this guidance.

In order to facilitate innovation a colouring food producer might demonstrate to the enforcement authorities by means of the analytical values from an independent accredited laboratory that the Enrichment factor threshold value is not exceeded until the new source material has been added to Annex III. The analytical data might be accompanied by other supporting information indicating why the extract can still be considered a food/food ingredient and not a food colour.

7. CONSEQUENCES FOLLOWING THE CLASSIFICATION OF A FOOD EXTRACT

If the extract is a colour (food additive) it should be authorised and used in accordance with the food additives legislation and meet the purity criteria set out in Regulation (EU) No 231/2012⁷.

Colouring foods and colours (food additives) should be used in accordance with the rules of the general food law – i.e. Regulation (EC) No 178/2002⁸ and any other relevant Community (e.g. Directive 2000/13/EC) or national rules applicable to them. The use of colouring foods or colours should not mislead the consumer.

Moreover, if an extract from a plant or animal source is used as a colouring food then the plant or animal source is a food and should comply with the food legislation, e.g. the pesticide residue legislation.

⁷ OJ L 83, 22.3.2012, p. 1

⁸ OJ L 31, 1.2.2002, p.1

Any preservative or antioxidant or other additive added to a colouring food should comply with the food additives legislation. For colouring foods, no authorisations of Annex III of Regulation (EC) No 1333/2008 apply, while for preparations of food colours, authorisations for uses of additives are given in Annex III. Since colouring foods are not additives, exemptions for labelling of additives as outlined in Directive 2000/13/EC (see Article 6 (4)) do not apply to them. Any enzyme used in the production of a colouring food has to comply with Regulation (EC) No 1332/2008, while for food colours, the use of enzymes is dealt with case by case in the additive specifications in Regulation (EU) No 231/2012. Any use of extraction solvents during the production of colouring foods should comply with Directive 2009/32/EC (e.g. sulphur dioxide extraction is not authorised; new authorisations could be requested, if needed), whereas for food colours, the use of extraction solvents is dealt with case by case in the additive specifications in Regulation (EU) No 231/2012. For some food colours, it is authorised to change the physical properties by making an aluminium lake, while it is not authorised for colouring foods. For contaminants in colouring foods, Regulation (EC) No 1881/2006 applies, while for impurities in food colours, Regulation (EU) No 231/2012 applies.

The key legislation can be summarised as follows:

| Legislation applicable | Colours | Colouring foods |
|------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------|
| General food law | Regulation (EC) No 178/2002 | Regulation (EC) No 178/2002 |
| Food additives which can be used in colours/colouring food | Annex III to Regulation (EC) No 1333/2008 | Annex II to Regulation (EC) No 1333/2008 |
| Labelling | Directive 2000/13/EC Regulation (EC) No 1333/2008 | Directive 2000/13/EC |
| Enzyme used in the production | Regulation (EU) No 231/2012 | Regulation (EC) No 1332/2008 |
| Extraction solvents | Regulation (EU) No 231/2012 | Directive 2009/32/EC |
| Aluminium lakes | Authorised for some colours - Annex II to Regulation (EC) No 1333/2008 | Not authorised |
| Impurities/contaminants | Regulation (EU) No 231/2012 | Regulation (EC) No 1881/2006 |
| Novel food | NA | Regulation (EC) No 258/97 |

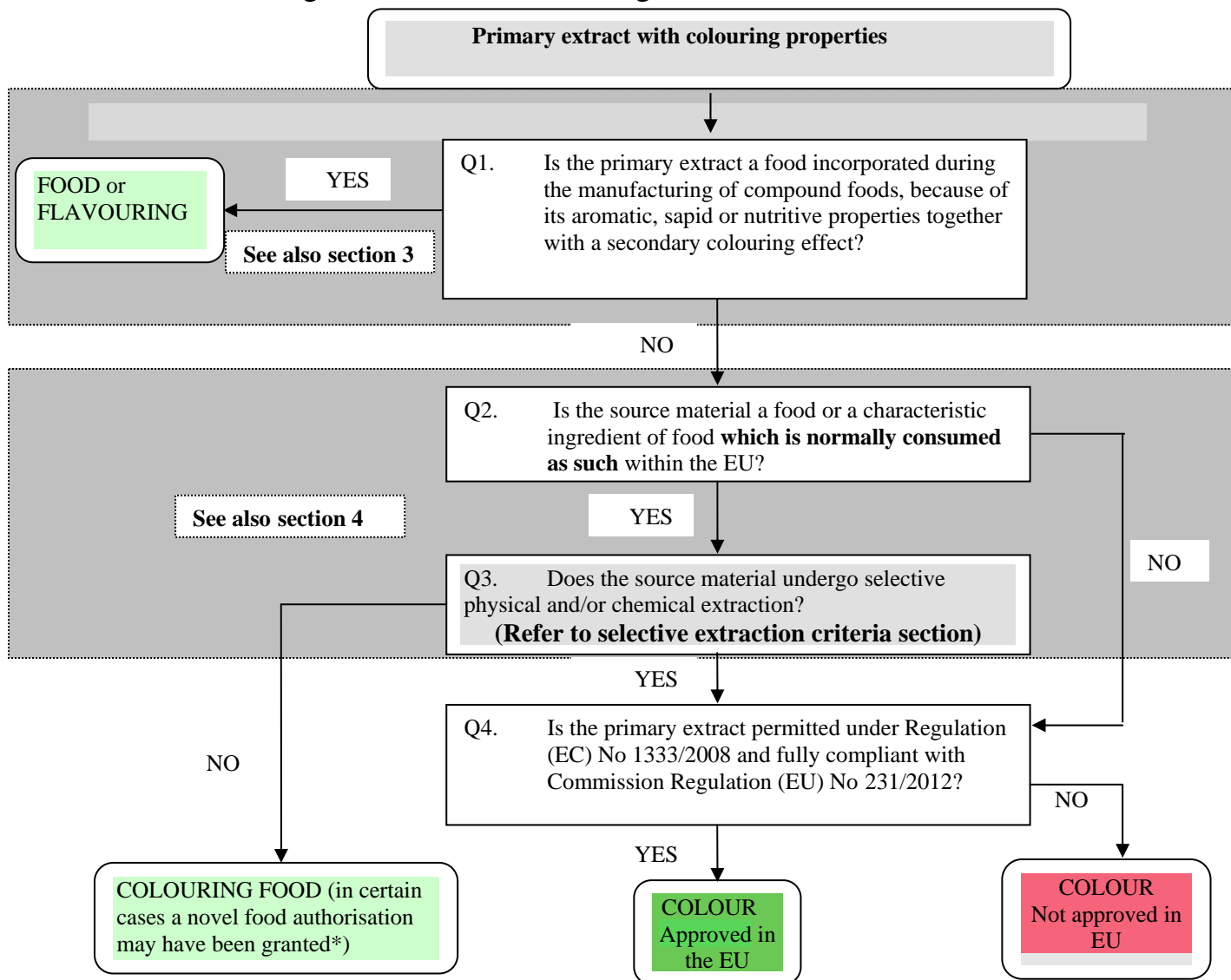
As for food safety aspects, generally, the use of colouring foods could be regarded as safe if the levels of exposure would not exceed those resulting from normal use of the colouring foods source materials in the human diet. Furthermore, the extraction process should not lead to the concentration of contaminants such as naturally occurring toxicants, or to the generation of reaction products or residues of a nature and in amounts as to be of toxicological concern.

The Guidance notes might be updated based on the practical experience with their implementation and reflecting the development in the colouring food area.

8. ANNEX I – DECISION TREE

DECISION TREE

(to be used together with the Guidance notes and the checklist in Annex II)
How to Distinguish between a Colouring Food and an Additive Food Colour



The term "food or a characteristic ingredient of food" includes but it is not limited to:

- Food such as fruit, vegetables, cereals and pulses;
- Fruit and vegetable juices
- Tea infusions, coffee (granular, powder or liquid);cocoa
- Caramelised sugar;
- Palm oil;
- Herbs and spices (e.g.turmeric and saffron) (all extracts used for the primary function of colouring should proceed to Q3);
- Egg yolk;
- Squid ink;
- Soy sauce;
- Malt extract.

This also includes a product, which is a food or a characteristic ingredient of food normally consumed as such within the EU, which has been subject to traditional food processing/ preparation processes such as:

- Dehydration to produce a more concentrated form
- Dehydration to the extent it is dried or in powder form
- Cooking or roasting
- Chopping or milling
- Pressing etc.

Relation of the primary extracts to the novel food legislation

The Guidance notes deal with the classification of extracts obtained from foods. Even if the classification indicates that the extract is a colouring food in cases specified in Regulation (EC) No 258/97 a novel food authorisation is needed.

ANNEX II - CHECKLIST

Checklist for the classification of extracts on the basis of the decision tree

| | Replies to the questions and criteria of column 1 | Description of the product and justification for the reply in column 2 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|------------------------------------------------------------------------|
| Name of the product | | |
| Composition and Essential characteristic properties of the source material | | |
| Constituents | | |
| <p>Q1: Is the extract a food incorporated during the manufacturing of compound foods, because of its aromatic, sapid or nutritive properties together with a secondary colouring effect?</p> <p>If "yes", go to classification</p> <p>If "no", go to Q2</p> | <YES/NO> | |
| <p>Q2: Is the source material a food or a characteristic ingredient of food which is normally consumed as such within the EU?</p> <p>If "yes", go to Q3</p> <p>If "no", go to Q4</p> | <YES/NO> | |
| <p>Q3: Does the source material undergo selective extraction? (see criteria below)</p> <p>If "yes", go to Q4</p> <p>If "no", go to classification</p> | <YES/NO> | |
| <p>C1: Does the primary extract retain the essential characteristic properties of the source material i.e.:</p> <ul style="list-style-type: none"> - colour properties – i.e. pigment(s) content - aromatic properties and nutritive value | <YES/NO> | |
| <p>C2: Is the ratio of the content of the pigment(s) to that of the nutritive or aromatic constituents in the primary extract significantly different from that present in the source material as a result of physical processes and/or chemical extraction? i.e. is F_n or $F_f > 6$?</p> | <YES/NO> | |
| <p>If C1 "YES" and C2 "NO" (for every ratio tested) ⇒ Q3 is "NO"</p> <p>If C2 "YES" ⇒ Q3 is "YES"</p> <p>Note: If the answer to C1 and C2 is "NO" then the extract should be assessed further on a case by case basis. More detailed analysis might be needed to verify whether the constituents of the extract are indigenous to the source material. If necessary a decision could be taken in accordance with Article 19(c) of the Regulation (EC) No 1333/2008 to classify the extract.</p> | | |
| Q4: Is the extract permitted under Regulation (EC) No 1333/2008 and fully compliant with Commission Regulation (EU) No 231/2012 | <YES/NO> | |
| Classification | | |

9. ANNEX III – REFERENCE VALUES FOR THE SOURCE MATERIALS

Annex III has to be established

The reference values for the source materials are to be determined in cooperation with the Joint Research Centre. Cooperation and an input from the stakeholders are expected.

What is requested: information about the composition of the source material (data sources, varieties), what parts of the source material are used for the extraction, colouring principle(s), analytical methods for pigment(s) determination, etc.

Until Annex III has been established producers and users are responsible for providing the necessary evidence to demonstrate to an enforcement authority that a product should be considered as a colouring food (appropriate reference values or analytical data from the relevant source material).

10. ANNEX IV – EXAMPLE OF A CLASSIFICATION

To better illustrate the classification process the example is provided below. Two carrot root extracts are to be classified.

Table 1: Classification process

| Question | Reply | Carrot root extract A - remarks | Reply | Carrot root extract B - remarks |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-----------------------------------------------------------------------|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of the product | | Carrot root extract | | Carrot root extract |
| Composition and Essential characteristic properties of the source material | | See Annex III to the guidance | | See Annex III to the guidance |
| Constituents | | For the content of the basic constituents see the table 2 below | | For the content of the basic constituents see the table 2 below |
| Q1 Is the extract a food incorporated during the manufacturing of compound foods, because of its aromatic, sapid or nutritive properties together with a secondary colouring effect? | No | No. The extract is used to impart a colour. | No | No. The extract is used to impart a colour. |
| Q2 Is the source material a food or a characteristic ingredient of food which is normally consumed as such within the EU? | Yes | | Yes | |
| Q3 Does the source material undergo selective extraction? | No | | Yes | |
| C1 Does the primary extract retain the essential characteristic properties of the source material i.e.: - colour properties – i.e. pigment(s) content - aromatic properties and nutritive value | Yes | The extract retains the characteristic properties of carrot. | No | The extract does not retain the characteristic properties of carrot. |
| C2 Is the ratio of the content of the pigment(s) to that of the nutritive or aromatic constituents in the primary extract significantly different from that present in the source material (as | No | Fn = 3 Ff = 1.3 Both values indicate a non-selective extraction | Yes | Fn = 40...Fn largely exceeds the threshold value – it indicates a selective extraction – pigments have been selective extracted relative to nutritive constituents Ff = 1.2...Ff is within the threshold value |

| | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------|-----|----------------|----|---------------------------------------------------------------------------------------------|
| a result of physical processes and/or chemical extraction)? | | | | |
| Q4 Is the extract permitted under Regulation (EC) No 1333/2008 and fully compliant with Commission Regulation (EU) No 231/2012 | N/A | N/A | No | The extract is not complying with the specifications listed in Regulation (EU) No 231/2012. |
| CLASSIFICATION | | Colouring food | | Food colour not complying with the specifications |

Table 2: Basic compositional data

| | Carrot root – reference values⁹ % on a dry weight basis | Extract A % on a dry weight basis | Extract B % on a dry weight basis |
|-----------------------|-------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------|
| Carbohydrates | 76 | 80 | 0 |
| Fibre | 11 | 3 | 0 |
| Protein | 11 | 12 | 4 |
| Total lipids | 2 | 5 | 96 |
| Pigments | 0.1 | 0.3 | 4 |
| Aromatic constituents | 0.03 | 0.07 | 1 |

Note: for simplification it was assumed that the nutritive constituents that are mentioned in the table would form 100% of the total solids.

⁹ Reference values used for the example are only indicative and do not prejudice the reference values which will be established in Annex III.

Calculation of the enrichment factor – to reply to the question Q3/C2

Extract A

$$F_n = \frac{\frac{C_p}{N_p}}{\frac{C_s}{N_s}} = \frac{\frac{0.3}{100}}{\frac{0.1}{100}} = \mathbf{3}$$

$$F_f = \frac{\frac{C_p}{A_p}}{\frac{C_s}{A_s}} = \frac{\frac{0.3}{0.07}}{\frac{0.1}{0.03}} = \mathbf{1.3}$$

Both the nutritive and the aromatic enrichment factor indicate that extract A is a colouring food.

Overall, it can be concluded that the extraction is non-selective.

Extract B

$$\begin{aligned} \text{Fn} &= \frac{\frac{\text{Cp}}{\text{Np}}}{\frac{\text{Cs}}{\text{Ns}}} = \frac{\frac{4}{100}}{\frac{0.1}{100}} = \mathbf{40} \\ \text{Ff} &= \frac{\frac{\text{Cp}}{\text{Ap}}}{\frac{\text{Cs}}{\text{As}}} = \frac{\frac{4}{1}}{\frac{0.1}{0.03}} = \mathbf{1.2} \end{aligned}$$

The nutritive enrichment factor substantially exceeds the threshold value of 6. Even if the aromatic enrichment factor is very low, *extract B cannot be considered a colouring food since the pigments were selectively extracted relative to the nutritive constituents.*

It is also clear that the extract B does not comply with the specifications for E 160a (ii) Plant carotenes (E 160a (ii) (content of carotenes not less than 5%), therefore, it would be classified as a food colour not complying with the specifications.