Colouring Foods – EU Regulatory Approach

Valerie Rayner
Colouring foods

- Difference between colours & colouring foods
- Legal difficulties – new guidance
- What does the guidance mean – calculations
- Further work
The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as color additives; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a color additive.
Colours are:
- 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.

And are not:
- 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;
## Legal definitions for colors

<table>
<thead>
<tr>
<th>EU</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>not consumed as foods as such and not normally used as characteristic ingredients of food;</td>
<td>any material which...is capable of imparting a color thereto;</td>
</tr>
<tr>
<td>Are selectively extracted</td>
<td>a food substance such as beet juice, deliberately used as a color ... is a <em>color additive</em></td>
</tr>
</tbody>
</table>
Selective Extraction

- Not defined in EU legislation
- Difficult to interpret
- Led to uncertainty in market

- Commission developed
- Guidance notes on the classification of food extracts with colouring properties
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

Primary extract with colouring properties

[Diagram of decision tree with steps and questions]

Q1. Is the primary extract a food incorporated during the manufacturing of compound foods, because of its aromatic, rapid or nutritive properties together with a secondary colouring effect?

[Pathway for Yes or No responses leading to further questions]

Q2. Is the source material a food or a characteristic ingredient of food which is normally consumed as such within the EU?

Q3. Does the source material undergo selective physical and/or chemical extraction? (Refer to selective extraction criteria section)

Q4. Is the primary extract permitted under Regulation (EC) No 1333/2008 and fully compliant with Commission Regulation (EU) No 251/2012?

[Pathways leading to yes or no outcomes]

COLOURING FOOD (in certain cases: a novel food authorisation may have been granted*)

COLOUR Approved in the EU

COLOUR Not approved in EU
Colouring Foods Decision Tree

Primary extract with colouring properties

Q1. Is the primary extract a food incorporated during the manufacturing of compound foods, because of its aromatic, sapid or nutritive properties together with a secondary colouring effect?

YES

NO

FOOD or FLAVOURING

See also section 3
Colouring Foods Decision Tree

Q2. Is the source material a food or a characteristic ingredient of food which is normally consumed as such within the EU?

See also section 4

YES

Q3. Does the source material undergo selective physical and/or chemical extraction? (Refer to selective extraction criteria section)
Selective Extraction Criteria

- Does the primary extract retain the essential characteristic properties of the source material i.e.
  - Colour properties (pigment content)
  - Aromatic properties and nutritive value

- 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 ...
Enrichment Factor

\[
F_n = \frac{\frac{C_p}{N_p}}{\frac{C_s}{N_s}} \\
F_f = \frac{\frac{C_p}{A_p}}{\frac{C_s}{A_s}}
\]

\(C_p\) = the "pigment(s) content" in the examined primary extract
\(C_s\) = the "pigment(s) content" in the source material
\(N_p\) = the "nutritive constituents content" in the examined primary extract
\(N_s\) = the "nutritive constituents content" in the source material
- $C_p$ = the "pigment(s) content" in the examined primary extract
- $C_s$ = the "pigment(s) content" in the source material
- $N_p$ = the "nutritive constituents content" in the examined primary extract
- $N_s$ = the "nutritive constituents content" in the source material
- $A_p$ = the "aromatic constituents content" in the examined primary extract
- $A_s$ = the "aromatic constituents content" in the source material

Compare the same pigment in the source and the extract
Enrichment Factor

- \( C_p \) = the "pigment(s) content" in the examined primary extract
- \( C_s \) = the "pigment(s) content" in the source material
- \( N_p \) = the "nutritive constituents content" in the examined primary extract
- \( N_s \) = the "nutritive constituents content" in the source material
- \( A_p \) = the "aromatic constituents content" in the examined primary extract
- \( A_s \) = the "aromatic constituents content" in the source material

Total solids content – 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.
Enrichment Factor

- $C_p =$ the "pigment(s) content" in the examined primary extract
- $C_s =$ the "pigment(s) content" in the source material
- $N_p =$ the "nutritive constituents content" in the examined primary extract
- $N_s =$ the "nutritive constituents content" in the source material
- $A_p =$ the "aromatic constituents content" in the examined primary extract
- $A_s =$ the "aromatic constituents content" in the source material

Difficult to establish in practice
Example – Orange carrot extract

<table>
<thead>
<tr>
<th></th>
<th>Carrot (dry weight basis)</th>
<th>Carrot Extract (dry weight basis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Solids</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Colour content</td>
<td>0.1</td>
<td>0.3</td>
</tr>
</tbody>
</table>

\[
Fn = \frac{\frac{C_p}{N_p}}{\frac{C_s}{N_s}} = \frac{0.3}{100} = \frac{0.1}{100} = 3
\]
Practical Application

- Threshold for selective extraction set at 6
- Both Fn and Ff must be below 6
- Aromatic constituents are difficult to analyse so Ff is difficult to calculate
- Typically Fn will be used for classification but Ff is equally important in law
- Reference values for raw materials will be established in an Annex
Brown colours

- Caramels are made from sugars
- Sugars do not contain the brown pigments
- How can an enrichment factor be calculated?
Brown colours

- Caramels are made from sugars
- Sugars do not contain the brown pigments
- How can a concentration factor be calculated?

- Caramelised sugars and malt extracts are considered as foods in their own right
Next Steps

- Completion Annex III
Information for Annex III

<table>
<thead>
<tr>
<th>Organisation:</th>
<th>Insert the name of the organisation</th>
<th>Date of submission:</th>
<th>Insert the date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person (Name + Email):</td>
<td>Insert the name and email of the contact person</td>
<td>Source material:</td>
<td>Insert the name of the source material + information from which parts of the source material is the extract obtained</td>
</tr>
</tbody>
</table>

| Colouring principle of the extract/concentrate and/or extraction/concentration method: | Insert the colouring constituents present in the extract/concentrate and information about the extractive/concentration method(s) |

| Data available on the source material as regards the content of: |
|------------------------|---------------------------------------------------------------|
| List | Data from literature available about the content | Analytical data available/method for analysis |

<table>
<thead>
<tr>
<th>Pigment(s)</th>
<th>pigment(s) present in the source material + proposal and justification as regards pigment(s) that should be used as a reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutritive constituents</td>
<td>Information on carbohydrates, fat, proteins, minerals and total solids</td>
</tr>
<tr>
<td>Aromatic constituents</td>
<td>Aromatic constituents present in the source material + proposal and justification as regards aromatic constituent(s) that should be used as a reference</td>
</tr>
<tr>
<td>Files and/or documents containing the requested information</td>
<td>Put the name of the file(s) or refer to the information provided for the road-test exercise</td>
</tr>
</tbody>
</table>

1 In the information provided it should be specified what pigment(s) should be included as a reference and what analytical method(s) should be used for its determination.

2 In the information provided it should be specified what substances should be used as a reference for aromatic constituents and what method(s) (analytical, sensory) should be used for their determination.
Information for Annex III

| Source material: | Insert the name of the source material + information from which parts of the source material is the extract obtained |
| Colouring principle of the extract/concentrate and/or extraction/concentration method: | Insert the colouring constituents present in the extract/concentrates and information about the extraction/concentration method(s) |

| Pigment(s)¹ | | | |
| Nutritive constituents | | | |
| Aromatic constituents² | | | |

Files enclosed containing the requested information

¹ In the information provided it should be specified what pigment(s) should be included as a reference and what analytical method(s) should be used for its determination.
² In the information provided it should be specified what substance(s) should be used as a reference for aromatic constituents and what method(s)/analytical approach(es) should be used for their determination.
### Information for Annex III

#### Information on the source material used for the production of extracts with colouring properties

<table>
<thead>
<tr>
<th>Organisation:</th>
<th>Date of submission:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person (name + email):</td>
<td></td>
</tr>
<tr>
<td>Source material:</td>
<td></td>
</tr>
<tr>
<td>Colouring principle of the extract/essence/extract and/or extraction/concentration method:</td>
<td></td>
</tr>
</tbody>
</table>

#### List

<table>
<thead>
<tr>
<th>Pigment(s)¹</th>
<th>Data from literature available about the content</th>
<th>Analytical data available/ method for analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>pigment(s) present in the source material + proposal and justification as regards pigment(s) that should be used as a reference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Nutritional constituents

- Protein
- Fat
- Carbohydrates
- Fibre
- Vitamins
- Minerals

---

¹ In the information provided it should be specified what pigment(s) should be included as a reference and what analytical method is to be used for its determination.

² In the information provided it should be specified what substances should be used as a reference for aromatic components and what method(s) (analytical procedures) should be used for their determination.
Information for Annex III

<table>
<thead>
<tr>
<th>Nutritive constituents</th>
<th>Information on carbohydrates, fat, proteins, minerals and total solids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aromatic constituents²</td>
<td>Aromatic constituents present in the source material + proposal and justification as regards aromatic constituent(s) that should be used as a reference</td>
</tr>
<tr>
<td>Files enclosed containing the requested information</td>
<td>Put the name of the file(s) or refer to the information provided for the road-test exercise</td>
</tr>
</tbody>
</table>

¹ In the information provided it should be specified what pigments should be included as a reference and what analytical method(s) should be used for its determination.
² In the information provided it should be specified what substances should be used as a reference for aromatic constituents and what method(s) (analytical procedure) should be used for their determination.
Completion Annex III
- Source material – parts used and material obtained
- Extraction/Process method
- Pigment(s) present in the source material + proposal and justification as regards pigment(s) that should be used as a reference
- Nutritive constituents
- Aromatic constituents – proposal & justification
Summary

- Colours are defined differently in US & EU
- EU guidance gives a flowchart and helps to determine whether a material has been selectively extracted
- Work is ongoing to determine reference values