NATCOL
NATURAL FOOD COLOURS ASSOCIATION

Code of Practice for the Classification, Manufacturing, Use and Labelling of Colouring Foods (EU)

September 2021

Preface

The Natural Food Colour Association (NATCOL) represents the interests of companies and associations providing natural food colours and/or Colouring Foods for the food and drink industry but also feed, cosmetics and pharmaceutical industries.

Colouring Foods are food ingredients with colouring properties used for the primary purpose of imparting colour to food and beverage products. They should, in this respect, be distinguished from food colour additives.

The concept of Colouring Foods was already part of European Union legislation as far back as 1994 when it was referenced in the European Colour Directive (Directive 94/36/EC). The same principle of Colouring Food is referred to in the current EU food additives Regulation (EC) 1333/2008.

Building on its comprehensive experience, the Natural Food Colours Association (NATCOL) has developed the enclosed Code of Practice to provide support to manufacturers and users in understanding the EU provisions that govern Colouring Foods as well as their scope and application. It represents common and current industry practice concerning the classification, manufacture, use and labelling of Colouring Foods.

Colouring Foods have been successfully manufactured and safely used in the European Union market for more than 30 years, with their use steadily increasing over the last decade. They meet the increasing consumer preference for ingredients in food that consumers recognize and can relate to, as shown also by the fact that a significant part of the EU food & beverage markets has successfully converted to the use of Colouring Foods.

This Code of Practice is intended as a business to business support tool for food industry producers and users of Colouring Foods on the European market. The Code is not a substitute for legal advice and should be read in conjunction with the relevant legislation.

Disclaimer

This “Code of Practice” was developed by NATCOL members with the aim of providing support in understanding the EU provisions that govern Colouring Foods and their scope and application. It must be read in conjunction with the relevant legislation. This “Code of Practice” is not a substitute for legal advice, but represents common industrial practice concerning the classification, manufacture, use and labelling of Colouring Foods. The statements and interpretations provided in the “Code of Practice” are intended to reflect applicable European Union provisions. It cannot be excluded that interpretations by the national authorities in individual EU Member States may vary. The ultimate official interpretation of the legislation is the exclusive reserve of the judicial powers i.e. the national courts of the EU Member States and the Court of Justice of the European Union.

Table of content

1 Introduction

1.1 Objective

The intention of the Code of Practice (hereinafter referred to as 'the Code') is to describe current industry practice and to provide support for the classification, manufacturing, use and labelling of Colouring Foods to producers and users (i.e. food industry) of Colouring Foods on the European Union market (EU), thereby helping to ensure consistency, transparency and harmonisation of practices.

The Code must be read in conjunction with the appropriate legislation listed in the table found in Chapter 3 of this Code, particularly Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, especially Recital 5, Article 3 (2) (a) and Annex I (2) of this Regulation.

The Code is intended to serve as a Business to Business support tool.

The Code reflects the experience of NATCOL's members and prevailing principles relating to the classification, manufacturing, use and labelling of Colouring Foods. It is also inspired by the principles laid out in the European Commission Guidance Notes on the classification of food extracts with colouring properties of 2013[1].

1.2 Scope

The Code covers foods with colouring properties used for the primary purpose of imparting colour - so-called 'Colouring Foods'. It covers especially 'food extracts with colouring properties', which are not 'selectively extracted'. In accordance with applicable EU legislation, such extracts are considered as foods consumed as such or as a characteristic ingredient of food within the EU.

This Code is based on the relevant EU regulatory framework and describes the following:

- Principles of the manufacturing, classification and quality control of Colouring Foods
- Considerations for the use of Colouring Foods in food and drink applications
- Labelling of Colouring Foods both for Business to Business (B2B) supply and in finished products, with examples for the labelling on the ingredient list.

[1] The Guidance Notes on the classification of food extracts with colouring properties dated 29.11.2013 were endorsed by a large majority of EU Member States as a "working tool" for business operators and enforcement authorities of the EU Member States. They were removed in 2018 for legal review and have not been replaced.

2 Definitions

For the purposes of this Code, the following definitions shall apply:

a) '**Food**' as provided in Article 2 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ("General Food Law Regulation");

b) '**Novel food**´ as provided in Article 3 (2) (a) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001;

c) '**Food additive**' and '**colours**' as provided in Recital 5, Article 3 (2) (a) and Annex I (2) of Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives;

d) '**Ingredient**' is defined in Article 2 (2) (f) of Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers;

e) '**Extract**' in this document refers to preparations obtained from a food as defined in Regulation (EC) 178/2002 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 Code only relates to extracts in which the colouring constituents are intact (i.e. not chemically modified) and indigenous to the source material;

f) '**Colouring Foods**' are foods with colouring properties used for the primary purpose of imparting colour to food and beverage products. They are obtained from foods like fruits, vegetables, flowers, spices, algae and/or other edible source materials. "Colouring Foods" have not been obtained by way of 'selective extraction', which differentiates them from food additives (colours) (see Annex I (2) of Regulation (EC) 1333/2008, and the Scope as defined in Chapter 1, 3 and 4 of the present Code);

g) '**Selective**' and '**Non-selective**' extraction as provided in Regulation (EC) 1333/2008, Annex I (2) which defines food additive colours as: *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*. Whether an extraction is selective or not depends on the ratio of the pigments relative to the nutritive or aromatic constituents (see section 4.3.2. below on 'enrichment factor');

h) '**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;

i) ‘**Enrichment factor**´ expresses 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;

j) ‘**Threshold value**´ provides a commonly understood quantitative borderline between ´selective extraction´ and ´non-selective extraction´;

k) ‘**Primary extract**’ is a product used as the reference basis for the calculation of the enrichment factor, i.e. the water or oil soluble composition obtained from the source material by processing. All ingredients or additives added prior, during or after the processing do not contribute to the nutritive and aromatic constituents of the primary extract and therefore must be disregarded for the purpose of calculating the enrichment factor;

l) ‘**Nutritive constituents**’ defined as the energy value of the food, the amounts of fat, saturates, carbohydrate, sugars, protein and salt, mono-unsaturates, polyunsaturates, polyols, starch, fibre and any of the vitamins or minerals listed in point 1 of Part A of Annex XIII of Regulation 1169/2011, and present in significant amounts as defined in point 2 of Part A of Annex XIII of Regulation 1169/2011;

m) ‘**Aromatic constituents**’ defined as substances, irrespective of their chemical structure, imparting odour and/or taste to the food product;

n) ‘**Carry-over principle**’ defined by Article 18.1 of Regulation (EC) 1333/2008 on food additives.

3 Legal Framework: Classification of Colouring Foods – Key legislation

The European regulatory framework for food additives has recognised Colouring Foods for a long time.

European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs, which has been repealed, made a distinction between colours as food additives and Colouring Foods, where it defined food additive colours as substances in which the pigments were selectively extracted. The current Regulation (EC) 1333/2008 on food additives subsequently confirmed this distinction, where it defines food additive "colours" in Annex I (2) and provides further clarification on colours/additives in Recital 5. Recital 5 provides:

"Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation, such as the preservation of food. All food additives should be covered by this Regulation, and therefore in the light of scientific progress and technological development the list of functional classes should be updated. 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. Finally, food enzymes are covered by Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (4), which excludes the application of this Regulation." (emphasis added)

The definition of "colours" in Annex I (2) reads:
"'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;" (emphasis added)

As pointed out above, whether or not an extraction process for obtaining Colouring Foods is selective or not would depend on the ratio of the pigments relative to the nutritive or aromatic constituents in the obtained extract versus the corresponding ratio in the source material (enrichment factor). This principle is reflected in this Code. As a consequence, when Colouring Foods are added to final products for the primary purpose of colouring and have not been obtained through selective extraction, they are not food additives (colours) as provided in Regulation (EC) 1333/2008 but foods or food ingredients that impart colour, i.e. “Colouring Foods”.

This Code is intended to provide a working tool to support business operators, especially when considering if a substance is a Colouring Food.

The following non-exhaustive list of current key legislation (including subsequent amendments) and official publications is applicable to Colouring Foods:

Key European Legislation	
General food law	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Transparency Regulation	Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain
Food additives which can be used in Colouring Foods	Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Labelling	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
Enzyme used in the production	Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes
Extraction solvents	Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
Aluminium lakes	Not authorized
Impurities/contaminants	Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Novel food	Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods + Union list: Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods + Novel Food Catalogue
Pesticides on Feed and Food	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
Other legislation, links and documents relevant to Colouring Foods	
Organic production and labelling	Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products
Juices	Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption
Food and Feed Safety Rapid Alerts	RASFF
Joint Research Centre Report	Stefanka Bratinova (2015): Provision of scientific and technical support with respect to the classification of extracts/concentrates with colouring properties either as food colours (food additives falling under Regulation (EC) 1333/2008) or colouring foods. European Commission, EUR 27425 EN – Joint Research Centre – Institute for Reference Material and Measurement

4 Manufacturing principles (source materials, manufacturing, classification, quality control)

4.1 Source materials

Colouring Foods are manufactured from fruits, vegetables, flowers, spices, algae and/or other edible source materials.

The source materials used for the production of Colouring Foods are foods (either consumed as such or characteristic ingredients of foods), which have been consumed to a significant degree within the EU before 15th May 1997 or those source materials that are authorised as novel foods. Where there is any doubt whether the source material is recognized as food within the EU, the Novel Food Catalogue may be consulted. The Novel Food Catalogue is a non-exhaustive list of products of animal and plant origin and other substances subject to the EU Novel Food Regulation, based on information provided by the EU Member States (http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/?event=home).

All source materials used to produce 'Colouring Foods' need to meet the requirements of the Regulations as mentioned in Chapter 3.

Colouring Foods producers are responsible for providing information concerning source material(s) data to the enforcement authorities upon request, including:

- Clear definition of source material (both English and Botanical Name)
- Description of which parts of the source material are used for the production of the Colouring Food
- Documentation that the source material is a food or a characteristic ingredient of food (see above)
- Documented history of safe use of the source material within the EU before 1997 unless it has a novel food status in the EU.

Enrichment factor
With regard to data for source materials when calculating the enrichment factor, the industry, based on years of practice, has commonly relied upon the following principles:

- The native state of the actual starting material, e.g. fresh produce rather than the juice or juice concentrate, or the dehydrated state of the source material (e.g. dried spirulina powder) is used.
- Analytical data concerning the actual source material or reference values listed in Annex A of this Code (representing reference values of source materials that have historically and commonly been used by NATCOL members) or, where necessary, those values referred to in the JRC Report. Validated analytical methods must be used for the determination of pigment content of source materials, e.g. those defined in Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) 1333/2008 or in the Joint Food and Agriculture Organisation/World Health Organisation Expert Committee on Food Additives (JECFA) monographs.
- For the nutritive constituents of the actual source material (Ns) data refer typically to total solids (i.e. everything but water).
- Aromatic constituents may be based on a broad range of very different substances. In cases where it is not feasible to check the aromatic enrichment factor due to the specific character of the source material, such as fruit and vegetables, a practical solution may be to base the classification primarily on the nutritive enrichment factor.
- For the pigment content of the starting source material (Cs), either analytical data of the actual source material or appropriate reference values may be used for enrichment factor calculations.

Reference values for raw materials
For the calculation of the enrichment factor, reference values for the colouring principles and the nutritive and aromatic constituents of the source material are needed. In order to enable manufacturers and users of Colouring Foods to have easy access to data for source materials used by Colouring Foods producers, NATCOL has completed an updated list of the available “Reference Values (2021)” that are commonly relied upon by the industry. These are available in Annex A of this Code.

For source materials of Colouring Foods that are not included in Annex A of the Code, the JRC report can serve as a basis.

It is NATCOL’s intention to review and update the NATCOL Source Reference Values in Annex A of the Code regularly to reflect future developments resulting from innovation, e.g. new Colouring Foods source materials may be added, or an update on pigment levels or analytical methods may be provided, etc.

4.2 Manufacturing principles

In light of applicable legislative provisions and common practice, any production processes for Colouring Foods require that:

- The primary extract has not undergone selective enrichment of the pigment
- The colouring constituents are indigenous to the source material
- The essential characteristic properties of source materials should be maintained (colour properties, i.e. pigment(s) content, aromatic properties and nutritive value (see Chapter 4.3)
- The main chemical structure of the colouring constituents is not modified.

For the processing of Colouring Foods, any traditional or common food process may be applied. For the processing of Colouring Foods, manufacturers commonly rely on traditional or common food processes. Traditional food processes have a history of safe use. These may be dehydration, heating, chopping, pressing, filtration, etc.

It is the responsibility of each individual Colouring Foods manufacturer to provide to the enforcement authorities when requested:

- The relevant data on the source material (see Chapter 4.1 of this Code)
- Compositional and essential characteristic properties of the primary extract
- Information concerning the analytical method(s) used for testing and a description of sample preparation
- Information about the production process and any other information which might be relevant for the classification
- Details concerning the calculation of the enrichment factor (see Chapter 4.3 of this Code).

Ingredients or additives added during the processing of Colouring Foods must:

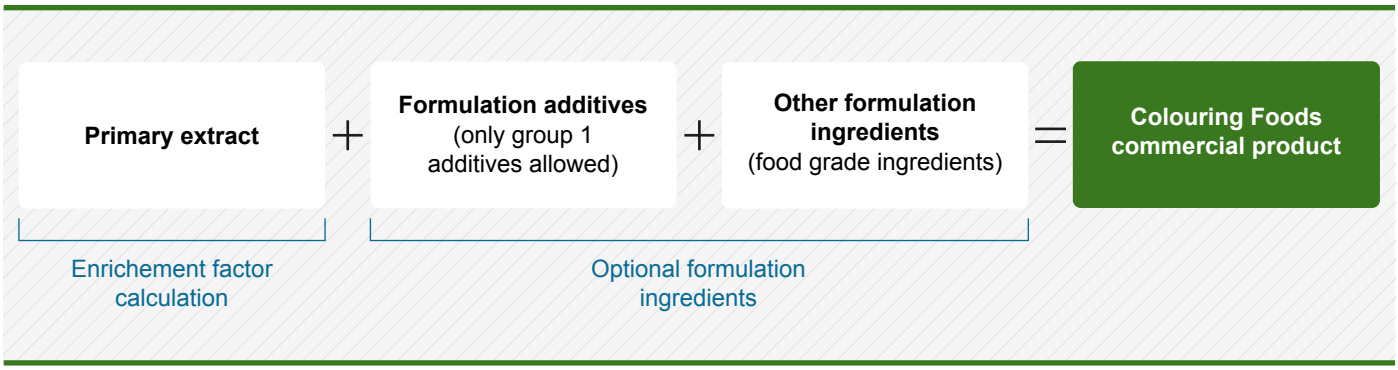
- Appear on the list of approved food additives provided in Annex II to Regulation (EC) 1333/2008
- Comply with the provisions of Directive (EC) 2009/32 on extraction solvents
- Comply with the provisions of Regulation (EC) 1332/2008 where enzymes are used in the processing of Colouring Foods and are permitted for use in the processing of the appropriate food category concerned
- Any other ingredients (including processing aids) must comply with the appropriate applicable Regulations
- Be labelled on the final food where required, in accordance with Regulation (EU) 1169/2011 on food information to consumers.

It is NATCOL's understanding that Colouring Foods typically belong to the Food Category 18 ("processed food") of Annex II Part D/E of Regulation (EC) 1333/2008. In these circumstances, therefore, only Group 1 additives could be used in the formulation of Colouring Foods.

In addition, as the current Register of authorised food enzymes is still not a positive list, manufacturers must verify with enzymes suppliers on a case-by-case basis, whether or not a specific enzyme has been notified to the European Commission.

The European Commission enzyme Register is available at:
https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_enzymes_register.pdf

Composition of commercial Colouring Foods products:



4.3 Criteria for non-selective extraction and enrichment factor calculation

Whether an extraction is selective or not depends, according to Regulation (EC) 1333/2008 on food additives Annex I (2), on the ratio of the pigments relative to the nutritive or aromatic constituents.

4.3.1 Non-selective extraction criteria

This classification criterion is necessary to identify when the colouring product is "a food normally consumed as such or normally used as a characteristic ingredient of food". In the absence of related definitions of the terms "a food normally consumed as such" or "normally used as a characteristic ingredient of food" determination of the category into which a Colouring Food should fall should be made case by case on the basis of available information. NATCOL understands that the following criteria have been and are commonly used by the industry:

Criterion 1: The primary extract retains essential characteristic properties
Does the primary extract (see definition in Chapter 2) retain the essential **characteristic properties** of the source material, such as pigment(s) content, aromatic properties and nutritive value?

- YES?
- NO?

Criterion 2: Non-selective extraction defined by enrichment factor
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 resulting in a selective extraction of the pigments? The information provided in Chapter 4.3.2 is intended to assist in the assessment of the primary extract.

- YES?
- NO?

If the answer to Criterion 1 is **"YES"** and to Criterion 2 is **"NO"** for every ratio tested then the extraction could be considered **non selective** and the corresponding product should be classified as a **Colouring Food**.

If the answer to Criterion 2 is **"YES"** then the extraction could be considered **selective** and the corresponding product should be classified as a **food additive (colour)**.

If the answer to Criterion 1 and Criterion 2 is **"NO"** then the primary extract should be assessed further **on a case by case basis**.

A more detailed analysis may be needed to verify whether the constituents of the primary extract are indigenous to the source material. If necessary an interpretation decision, as provided for in Article 19(c) of the Regulation (EC) 1333/2008 may be an appropriate route to classification of the extract.

4.3.2 Enrichment factor

In determining whether an extraction is selective or not, the ratio of the pigments relative to the nutritive or aromatic constituents in the colouring product is an essential parameter. The formula commonly used in industry to determine the enrichment factor is the ratio of the pigment content to the nutritive or aromatic constituents in the Colouring Food (primary extract) compared to the corresponding ratio of the pigment(s) content to the nutritive or aromatic constituents of the source material. Two enrichment factors are distinguished: one enrichment factor based on nutritive constituents and one based on aromatic constituents.

[2] 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 A.

Enrichment factor calculation:

$$Fn = \frac{\frac{Cp}{Np}}{\frac{Cs}{Ns}} \quad \text{OR} \quad Ff = \frac{\frac{Cp}{Ap}}{\frac{Cs}{As}}$$

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
Fn = the "enrichment factor" based on the nutritive constituents
Ff = the "enrichment factor" based on the aromatic constituents

A threshold value of 6 has historically and commonly been applied by the industry as a quantitative borderline between what constitutes “selective extraction” and what constitutes “non-selective extraction”. The threshold value is commonly set to be high enough to cover seasonal and geographical differences and differences in source material varieties. On the other hand it is set low enough that the primary extracts could be still considered to be foods or food ingredients (i.e. not selectively extracted).

Practical considerations for applying the enrichment factor
The definition of colours as food additives, provided in Regulation (EC) 1333/2008, indicates that once pigments are selectively extracted relative to the nutritive or aromatic constituents, the product under consideration should be classified as a food colour. Therefore, both the nutritive and the aromatic constituents have to be considered for the classification. Where there is a selective extraction at least for one of the two groups of the constituents the extract would be considered to be a food colour.

However, due to the fact that the aromatic constituents could be based on a broad range and a large number of very different substances, it would be extremely difficult to establish a general reference basis for aromatic constituents in practice. For that reason it has been industry practice to base the classification primarily on the nutritive enrichment factor in cases where it is not feasible to also check the aromatic enrichment factor. Total solids (i.e. everything but water) of the native raw material are used as the reference basis (Ns) for the nutritive enrichment factor calculations. Total solids of the primary extract are used as the nutritive content (Np) in the calculation.

Any added extraneous additives or ingredients have to be deducted from the results of the compositional analysis of the colouring product irrespective of the fact that they were added prior to, during, or after the extraction. Only the constituents originating from the source material are relevant for the calculation of the enrichment factor. Colouring Foods producers should provide sufficient information in this respect.

4.4 Quality Control

Colouring Foods must fulfil the safety requirements provided in Article 14.1 of the General Food Law Regulation (EC) 178/2002 before they are placed on the market in the EU. They must also comply with the key legislation described in Chapter 3 of this Code, including the legislative provisions listed in the table in Chapter 3. Therefore, as with other processed foods, it is necessary that the source materials used for the manufacturing of Colouring Foods comply with the limits as defined by the legislative provisions listed in the table in Chapter 3, for example Regulations (EC) 1881/2006 and 396/2005.

Further quality testing on Hazard Analysis and Critical Control Points (HACCP) principles in accordance with Regulation (EC) 852/2004 on the hygiene of foodstuffs and product related risk management analysis in accordance with the General Food Law Regulation (EC) 178/2002 must also be performed.

Each Colouring Foods producer remains responsible for ensuring compliance of the Colouring Foods products with the key governing legislation provided in the table in Chapter 3 of this Code, as well as for checking compliance with any nationally applicable rules at EU Member State level. This requires a special quality assurance policy governing Colouring Foods. A related documented data set must be made available to enforcement authorities on request.

5 Safety

It is the individual responsibility of Colouring Foods producers to ensure the safety of their food products.

Colouring Foods are classified as food with colouring properties (see Chapter 2, Definition (f) of this Code) and are not subject as such to pre-market safety evaluation by EFSA or any other EU food Authority. Colouring Foods are not food additives.

Colouring Foods are non-selectively extracted from food sources and manufactured in accordance with the description provided in Chapter 4 of this Code, retaining the essential characteristic properties of the source material.

The use of Colouring Foods is regarded as safe if the levels of exposure do 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 such a nature and in amounts as to be of toxicological concern.

In the food safety management program of each producer, it is important to include and document risk and compliance assessment for the entire production chain, from the source material (e.g. contaminants and pesticide residues etc.), manufacturing processes, and formulation ingredients to ensure a compliant safety profile throughout the shelf life of the product.

6 General Labelling of Colouring Foods

The manufacturer of Colouring Foods and of finished food products containing Colouring Foods must assess the scope and content of labelling on a case-by-case basis.

Business to Business (B2B)
The labelling of Colouring Foods when sold B2B is covered indirectly by Article 8(8) of the Food Information for Consumers Regulation (EU) 1169/2011. This Article requires business operators that supply food to other food business operators to "ensure that those other food business operators are provided with sufficient information to enable them, where appropriate, to meet their obligations".

This information does not need to be provided on the B2B product labels. It can be provided in other documentation such as product specifications. The table in Annex B describes the applicable requirements and how they apply to Colouring Foods.

Business to Consumer (B2C)
There are no specific instructions concerning B2C communications on the labelling of Colouring Foods in the Food Information for Consumers Regulation (EU) 1169/2011. The labelling must, however, be clear and understandable to the consumer and should not be misleading.

- Colouring Foods must not be designated in the same way as food colour additives, i.e. the additive function 'colour' followed by the specific additive name or E number only applies to food colour additives, not to Colouring Foods.
- Colouring Foods should be designated by their customary or descriptive names. Examples of possible labelling on the ingredient list of the final food within the EU are "Colouring Foods (carrot concentrate)" or simply "carrot concentrate".

With regard to the ingredient labelling in the ingredient list Colouring Foods are often compound ingredients themselves (as defined in Article 2.2.h of Regulation (EU) 1169/2011 on food information to consumers). The rules set for the listing of ingredients, in particular in Article 20 (omissions of constituents from the list of ingredients) and 21 (products causing allergies or intolerances labelling) of Regulation (EU) 1169/2011, must be applied accordingly.

7 Use of Colouring Foods in final products

Colouring Foods are classified as food ingredients and are not considered to be food additives (colour additives as discussed in Chapter 3 of this Code). Like any other food ingredients, they can be used in processed food products, such as confectionery, soft drinks, fruit preparations, ice creams, etc.

Before using Colouring Foods in a final product, it is important to be sure that all relevant European Union legislation and guidelines are respected to ensure their appropriate use and to avoid misleading consumers. This could be accomplished by co-operation between the Colouring Foods manufacturers and their customers.

Determining if individual Colouring Foods can be used in final food products is a case-by-case assessment. It depends on the categorisation, composition, labelling and constitution (overall impression) of the final food product. The final responsibility for using and labelling Colouring Foods in a food product is that of the food manufacturer.

Key considerations on the use of Colouring Foods are:

a) Colouring Foods must be safe
Both the General Food Law Regulation (EC) 178/2002 and Regulation (EU) 1169/2011 on the provision of food information to consumers are relevant to determining if individual Colouring Foods can be used in food products. Regulation (EC) 178/2002 “establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety”, as stated in Article 1.1. The objective is to ensure the safety of the product. Regulation (EU) 1169/2011 on the provision of food information to consumers aims to ensure the “provision of food information […] for final consumers to make informed choices and to make safe use of the food”, as stated in Article 3.1. The objective is to avoid any practice to mislead the consumer.

b) The use of Colouring Foods should not mislead consumers
In accordance with Regulation (EC) 1333/2008, the use of colour additives is prohibited in certain foods.[3] While Colouring Foods are not classified as colour additives, their use in foods in which colour additives are not permitted, however, could be perceived as misleading to the consumer. Regulation (EU) 1169/2011 on the provision of food information to consumers specifically seeks to ensure that consumers are not misled as to the true nature of the food or food ingredients they consume.

Food manufacturers should therefore, at all times, ensure that the use of Colouring Foods does not mislead consumers. Such assessment should be made on a case-by-case basis.

[3] The specific prohibitions can be found by reviewing the permitted food additives under the relevant food category listing in in Part E of Annex II to Regulation (EC) 1333/2008, as well as in Part A, Table 2 of Annex II: “Foods in which the presence of a food colour may not be permitted by virtue of the carry-over-principle set out in Article 18(1)(a) of Regulation (EC) 1333/2008”.

c) Carry-over additives

According to Regulation (EC) 1333/2008 a carry-over of food additives is not permitted in certain food categories (Chapter III, Article 18 and Annex II, Part A, Point 2.8. to Regulation (EC) 1333/2008). This prohibition must be considered for those Colouring Foods that are manufactured with Group I food additives.

d) Vertical Legislation

The relevance of vertical product standards such as product specific European Union or EU Member State national Regulations/Directives or Guidelines (e.g. Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption) should be checked for any evidence that might permit or restrict the use of Colouring Foods.

8 Annexes

Annex A: NATCOL Source Reference Values 2021

This Annex A lists reference data of commercially available source materials used for Colouring Foods production currently in the EU. It is not an exhaustive list.

The Annex is intended to complement the Code and the JRC Report (2015)[4] with recent industrial data. It may be used for enrichment factor (Fn) calculations and evaluations in case source material and source material data are not available for e.g. the industry or enforcement authorities.

As explained in this Code, Chapter 4, manufacturers of Colouring Foods shall assess if the characteristics of a given source material are retained in the primary extract and source materials are not selectively extracted. To perform such an evaluation, data on the specific starting source material from which the extract/concentrate is produced need to be provided. Either analytical data of the actual source material or the appropriate source material reference mean value can be used for such an assessment.

The reference values reflect the current status and will be regularly updated to reflect further developments resulting from innovation, e.g. new Colouring Foods source materials, update on pigment levels or analytical methods etc.

Standard analytical method for the determination of pigment content has been applied by NATCOL and is mentioned for each source material (see Table Annex A – 1). However, it is acknowledged that other test methods and sample preparations can be used as long as the same method for testing source material and primary extract is applied.

Data collection on source materials
The actual data collection started in March 2020 and ended in February 2021. Information on the nutritive constituents and pigment contents were received from 13 different industry data providers on a total of 15 different source materials for Colouring Foods. All data sets were directly submitted to a third party for review, calculation and compilation. Anonymity of data providers and confidentiality was ensured throughout the process.

[4] Stefanka Bratinova (2015): Provision of scientific and technical support with respect to the classification of extracts/ concentrates with colouring properties either as food colours (food additives falling under Regulation (EC) 1333/2008) or colouring foods. European Commission, EUR 27425 EN – Joint Research Centre – Institute for Reference Material and Measurement

The information provided for the data compilation meets the following conditions:

a) The source materials are accepted foods (i.e. fruits, vegetables, edible flowers and edible algae).

b) The source materials are clearly identified by their scientific and common English names.

c) The plant parts of the source materials used for Colouring Foods production are clearly described in detail.

d) Data are representative of the source materials used and reflect Colouring Foods production.

e) Information originates from source materials used since 2015 onwards to ensure contemporary relevance.

f) Data refer to the source materials as listed in (Table Annex A - 2).

g) Information reported as ranges is not considered in the data collection.

h) Pigment contents are determined using the assay methods described in Commission Regulation (EU) No 231/2012 laying down specifications for food additives or equivalent methods. For colouring principles not covered by this Regulation, other internationally recognized methods of analysis are applied.

By meeting these conditions, pooled data variation is minimised.

An overview of the source materials, plant parts, colouring principles and analytical methods reported by the data providers is presented in Table Annex A - 1: *“Overview on the source materials, plant parts and the analytical methods used by data providers for the determination of the colouring compounds.”*

Data processing
Data sets were received by the third party as Excel spreadsheets, Word documents or in form of analytical reports from external laboratories. All relevant information was transferred to a MS excel file and data were checked for transcription and transposition errors. Pigment and nutritive values expressed on fresh weight basis were converted into dry weight basis using the total solids value of the respective batch.

The structure of MS Excel spreadsheet containing the nutrient and pigment content data was based on the JRC report (2015). Each row contains the nutrient and pigment content values from a single batch. The worksheet columns are organised as follows:

Data provider	Name of the stakeholder who submitted the data (traceability of information)
Common name	English (vernacular) name of the source material
Scientific name	Latin name of the source material
Plant part	Part of the source material used for the production of Colouring Foods
Water	Moisture content (g/100 g) on fresh weight basis (except for hibiscus/roselle, red paprika, safflower, spinach, spirulina and turmeric which were analysed in their dried forms)
Total solids	Dry matter content (g/100 g) on fresh weight basis (except for hibiscus/roselle, red paprika, safflower, spinach, spirulina and turmeric which were analysed in dried forms)
Carbohydrates	Total carbohydrate content (g/100 g) on dry weight basis (including total dietary fibres) Total carbohydrates consist of total digestible and indigestible carbohydrates, including total dietary fibres. Also fractions actually not belonging to carbohydrates may be included (e.g. organic acids). The parameter was calculated by difference at batch level: Total carbohydrates = 100% - (water + protein + fat + mineral)
Available Carbohydrates	Available carbohydrate content (g/100 g) on dry weight basis (without total dietary fibres) Available carbohydrates are the total carbohydrates without total dietary fibre. The parameter was calculated by difference at batch level: Available carbohydrates = 100% - (water + protein + fat + mineral + fibres)
Fibres	Total dietary fibre content (g/100 g) on dry weight basis
Protein (Nx6.25)	Total protein content (g/100 g) on dry weight basis
Total lipids	Total fat content (g/100 g) on dry weight basis
Minerals (ash)	Total ash content (g/100 g) on dry weight basis
Pigment	Total pigment content (g/100 g) on dry weight basis

Statistics and deriving the NATCOL source reference values

The pooled data were checked for statistical anomalies (outliers). For each source material, minimum and maximum values, the arithmetic mean and standard deviation were calculated from the pooled data for the nutrient and pigment contents (not included in Annex A).

After careful review, NATCOL proposes to use the mean as reference values for the nutrient contents of the source materials. For the colouring compounds, an approach similar to the one from JRC (2015) was chosen and reference values were approximated by the mean plus one standard deviation. The basic compositional table with the suggested NATCOL reference values for 15 different source materials of Colouring Foods is shown in Table Annex A – 2: “Basic compositional table with NATCOL reference values 2021.”

Annex A - 1: Overview on the source materials, plant parts and the analytical methods used by data providers for the determination of the colouring compounds

Common name	Scientific name[1]	Plant part	Colouring principle	Analytical method
Carrot, black	Daucus carota (L.)	Taproot	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163)
Carrot, orange	Daucus carota (L.)	Taproot	Carotenoids	Spectrophotometry (expressed as beta-carotene)
Chokeberry	Aronia melanocarpa (Michx.) Elliott	Berry	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163)
Elderberry	Sambucus nigra (L.)	Berry	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163; or AOAC 2005)
Pumpkin	Cucurbita maxima (Duchesne)	Fruit	Carotenoids	Photometry (expressed as total carotenes)
Red beet	Beta vulgaris (L.)	Taproot	Betanin	Spectrophotometry
Red paprika	Capsicum annuum (L.)	Fruit	Carotenoids	Spectrophotometry (EU 231/2012, E 160c)
Red Radish	Raphanus sativus (L.)	Taproot	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163)
Hibiscus / Roselle	Hibiscus sabdariffa (L.)	Calyx	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163)
Safflower	Carthamus tinctorius (L.)	Petal	Safflominoids	Spectrophotometry (JECFA 2006) or HPLC
Spinach	Spinacia oleracea (L.)	Leaf	Chlorophylls	Spectrophotometry (Regulation (EU) 231/2012, E 140(i)
Spirulina	Arthrospira platensis (Gomont)	Algae	Phycocyanins	Spectrophotometry (Yoshikawa & Belay, 2008)
Sweet potato	Ipomoea batatas (L.) Lam.	Tuber	Anthocyanins	Spectrophotometry (Regulation (EU) 231/2012, E163)
Tomato	Lycopersicon esculentum (Mill.)	Fruit	Lycopene	Spectrophotometry (Regulation (EU) 231/2012, E 160d(ii))
Turmeric	Curcuma longa (L.)	Rhizome	Curcuminoids	Spectrophotometry (Regulation (EU) 231/2012, E 100; DAC 2003)

[1] Species name as currently accepted taxonomically (source: http://www.worldfloraonline.org, retrieved 26 February 2021)

Annex A - 2: Basic compositional table with NATCOL source reference values 2021

Common name	Plant part	Water	Total solids	Total carbohy-drates[1]	Available carbohy-drates	Fibres	Proteins	Total lipids	Minerals	Pigment	Colouring principle
		%	%	% DM	% DM	% DM	% DM	% DM	% DM	% DM	
Carrot, black	Taproot	87.5	**12.5**	83.3	53.6	30.0	8.0	0.85	7.0	**3.6**	Anthocyanins
Carrot, orange	Taproot	86.6	**13.4**	78.0	48.9	29.1	9.5	2.5	7.9	**0.38**	Carotenoids
Chokeberry	Berry	75.3	**24.7**	91.6	60.0	31.6	3.4	2.5	2.1	**2.6**	Anthocyanins
Elderberry	Berry	80.7	**19.3**	63.4	36.2	46.7	10.5	11.3	4.3	**4.5**	Anthocyanins
Pumpkin	Fruit	84.7	**15.3**	68.1	42.7	25.5	17.3	10.6	7.0	**0.13**	Carotenoids
Red beet	Taproot	84.8	**15.2**	81.5	59.9	21.5	11.5	0.30	6.9	**1.3**	Betanin
Red paprika	Fruit (dried)	9.1	**90.9**	65.8	NSD	NSD	15.8	10.0	8.4	**1.2**	Carotenoids
Red Radish	Taproot	91.3	**8.7**	73.4	41.7	31.1	15.7	1.2	9.7	**5.4**	Anthocyanins
Hibiscus / Roselle	Calyx (dried)	7.7	**92.3**	82.1	35.6	46.7	7.0	1.2	9.7	**2.5**	Anthocyanins
Safflower	Petal (dried)	5.7	**94.3**	70.5	32.0	38.8	16.6	6.5	7.2	**6.3**	Safflominoids
Spinach	Leaf (dried)	2.5	**97.5**	NSD	NSD	NSD	NSD	NSD	NSD	**1.1**	Chlorophylls
Spirulina	Algae (dried)	5.4	**94.6**	17.5	13.0	6.2	68.9	6.5	6.9	**11.7**	Phycocyanins
Sweet potato	Tuber	67.2	**32.8**	90.5	74.7	15.7	6.6	0.6	3.0	**5.3**	Anthocyanins
Tomato	Fruit	NSD	**NSD**	57.7	NSD	NSD	18.3	2.9	8.9	**0.38**	Lycopene
Turmeric	Rhizome (dried)	12.1	**87.9**	77.0	36.7	39.7	6.7	4.8	11.2	**9.7**	Curcuminoids

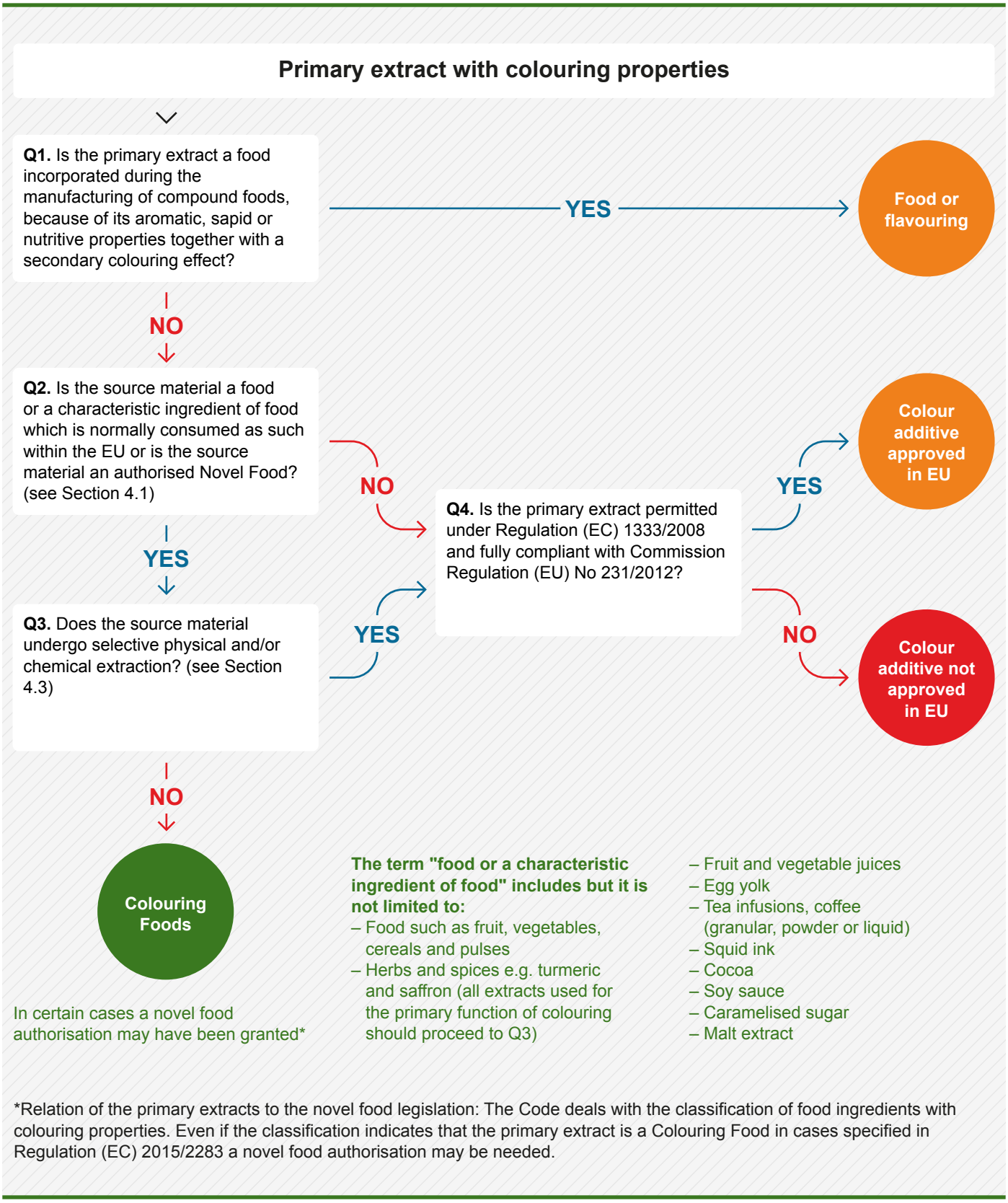
[1] Total carbohydrates including dietary fibres
NSD Not Sufficient batch Data available to establish reference value

Annex B: Business to Business Colouring Foods information

There are no specific requirements in the food legislation for B2B labelling for Colouring Foods but we recommend that manufacturers consider relying for information on Article 9(1) of the Food Information for Consumers Regulation (EU) 1169/2011 which requires the finished food label to contain the following information:

Information required – (label or additional documentation)	
Consumer label requirement (Article 9(1))	Recommended Colouring Foods Information
(a) the name of the food;	Yes
(b) the list of ingredients;	Yes
(c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;	Yes
(d) the quantity of certain ingredients or categories of ingredients;	If applicable according to Article 22 of Regulation (EU) 1169/2011, ingredients with special emphasis.
(f) the date of minimum durability or the 'use by' date;	Yes
(g) any special storage conditions and/or conditions of use;	If applicable
(h) the name or business name and address of the food business operator referred to in Article 8(1);	Yes
(i) the country of origin or place of provenance where provided for in Article 26;	If applicable according to Article 26 of Regulation (EU) 1169/2011.
(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;	If applicable
(k) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume;	Not normally applicable to Colouring Foods
(l) a nutrition declaration.	If applicable. Foods listed in Annex V of Regulation (EU) 1169/2011 are exempted from the nutrition declaration obligation in accordance with Article 16 of Regulation (EU) 1169/2011. If the Colouring Food is sold directly or would impact the nutritional declaration of the final food, then the information should be provided.
Additional Information applicable in the case of Colouring Foods	
	Statement/information confirming conformity with applicable food legislation

Annex C: Decision Tree - How to distinguish a Colouring Food and a Colour Additive



*Relation of the primary extracts to the novel food legislation: The Code deals with the classification of food ingredients with colouring properties. Even if the classification indicates that the primary extract is a Colouring Food in cases specified in Regulation (EC) 2015/2283 a novel food authorisation may be needed.

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