EU “borderline” food additives: Their legal basis and classification for the Specialty Food Ingredients Industry

MASTER THESIS

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I. Introduction

The EU legislation classifies food substances to bring them a determined and needed treatment among them (such as undergoing an authorization procedure to assess their risk for establishing restrictions) in order to ensure a high level of protection of human health and consumer protection, being this the case of the Regulation (EC) No 1333/2008 concerning the substances called "food additives".

For reaching such purpose, the authority should establish within the regulation not only the measures applying to those substances, in this case, conditions of use including food categories and levels in which the substance is allowed, or the way of declaring them within food labelling, but also an efficient definition capable to cover and distinguish the substances willing to be placed under the regulation’s scope (for applying all the proposed measures on them) from the other substances also co-existing within the food substances’ universe.

From a broad perspective, this classification involves -in principle- the establishment of “intangible cuts” created by regulators’ minds for their application into a universe of elements being present over the nature (such as substances, life-beings, extensions of land, etc.) by differencing them according to their features. Nonetheless, sometimes these features are assumed as "discrete" like black and white situations, but in reality they may present a “continuous” nature leading to the existence of grey-hues, some of them being more blackish or whitish than others. Within this reality, classification should be flexible enough to execute an effective differentiation, being able to distinguish the elements even if they present these blackish or whitish hues, at least up to a reasonable and practical extend.

This universe of “continuous” elements is also the case of food additives, which classification is relevant for the food industry and among them, especially for the specialty food ingredients sector because of containing the producers of these substances. In the current thesis research, the substances presenting “blackish and whitish hues” on food additive’s characteristics will be studied from a legal perspective in order to find the rules that they follow, and in this way to depict the paths for their application by the specialty food ingredients industry.

1.1. Problem Statement

There exist food additives that are difficult to classify as such because they appear to be on the “border” between food additives and other food substances like enzymes, flavourings, or even with food ingredients: For example, foodstuffs with colouring properties that are not classified as food additives, enzymes approved as food additives, etc. Therefore, the nature of these substances concerning being or not food additive seems to be debatable.

1.2. Research Objectives

Explaining the existence of these EU borderline food additives from the legal perspective, assessing the relevance of their classification for the specialty food ingredients industry, identifying all these “borderline spots” on the EU legislation and mapping all the conditions in which those substances occur.

1.3. Research Questions

In the current research, there exist the following main questions to be answered:

- What is the legal basis (legal evidences) for the existence of borderline food additives?
- What is the relevance of classifying EU borderline food additives within the specialty food ingredients industry?
- What are the conditions and principles for classifying these EU borderline food additives?
- How can those principles be translated into a tool for classifying the EU borderline food additives?
- Which are the resulting limitations, challenges and opportunities from the proposed classification of EU borderline food additives?
1.4. Demarcation of the Study

Addressing the legal basis and classification of EU borderline food additives applying to the specialty food ingredient sector according to the European Union Legal framework of foodstuffs.

1.5. Methodology of the Research

The current research possesses the following sources of acquiring information:

*Academic literature research*
The function of food additives on foodstuffs and discussions on food substance’s classifications

*Literature from the Specialty food ingredients sector*
Market trends, classification guidance documents, analyses of regulatory impact, and the role of specialty food ingredients on food industry

*Sources of Law and policy documents*
From Codex Alimentarius Commission: Guidelines, meeting reports from the Codex Committee on Food Additives (CCFA)
From EU Commission: Presentations, information from official website, classification guidance documents, technical reports, meeting reports from the Standing Committee on Plants, Animals, Food and Feed (SCFAFF)
From EFSA: Guidance documents on dossier elaboration of food substances, requests of scientific risk assessment on food substances by the EU Commission
From EU legislation: Historical and current decisions, directives and regulations on food substances

*Empirical research*
Expert opinions from regulatory affairs professionals in the field of specialty food ingredients
II. Theoretical Framework

2.1. Food additives within the Specialty food ingredients industry

The specialty food ingredient industry is the companies’ sector—within EU or from third countries—on food additives, food enzymes, flavourings, nutrients and similar products (being these different from the “staple ingredients such flour, rice, sugar, etc) placed between the primary producers and the food manufacturers as explained by the Federation of European Specialty Food Ingredients Industries (Figure 1), which is a non-profit association addressing the collective interests of this industry on scientific, technical and regulatory issues related to food products in Europe (EU Specialty Food Ingredients, 2014a and 2017a).

![Figure 1. Position of specialty food ingredients in the food chain. (EU Specialty Food Ingredients, 2014a)](image)

This food ingredient industry represent a global market of €40 billion (sales value), in which 40% belongs to the EU market (Brookes, 2016). This industry plays an important role on the following current food market trends in EU (EU Specialty Food Ingredients, 2014a-d) by innovating on ingredients capable to fulfil with them:

*Food waste and sustainability:* Specialty food ingredients help on making the food processing more efficient, thus limiting the quantity of raw materials required for production and resulting in energy saving, thus reduction of Greenhouse gas, for example: Food enzymes increasing juice extraction from fruits, cultures helping to capture more protein during cheese manufacturing, or enzymes used in the brewery process induces large energy saving.

*Contribution to healthier diets and healthy ageing:* Specialty food ingredients can be designed for bringing not only a healthier alternative on food formulation like the introduction of low calories sweeteners, fat replacers or the development of vitamins and minerals, but also looking beyond for addressing specific health conditions by keeping normal content on blood cholesterol (i.e. phytosterols), helping on keeping normal vision (i.e. tocotrienols), allergies conditions (by processing aids removing allergens, prebiotics/probiotics for coeliacs, developing alternative protein sources), etc.

*Convenience and safety of foods:* Specialty food ingredients delay product’s deterioration (i.e. preservatives, antioxidants) and maintain its nutritional profile (i.e. the use of antioxidants, and the addition of nutrients).

Particularly concerning to food additives, Leatherhead on its document from 2014 called "White Paper: Food Additives – A Growing Global Market" (Leatherhead Food Research, 2014) identified trends that can be grouped as follows:

*Moving to "Natural":* Consumers are turning away from artificial and/or synthetic food additives in ever-greater numbers, in favour of more natural equivalents. In the case of Europe, up to 80% of consumers prefer their foods to be free from artificial additives. Flavourings and colours are the categories most involved in this trend. The purpose of this trend is to achieve the "Clean labels", which involves the consumer's desire for labels to contain nothing that may be interpreted as artificial or chemical (Saltmarsh, 2014).
Health and Wealthness: Similarly to the specialty food ingredients, food additives are also seeking to produce food and drinks with lower levels of sugar, salt and saturated fat by allowing the manufacturers to compensate the loss of taste while reformulation.

From the mentioned trends, it is reasonable to expect the related companies producing these ingredients to invest on Research and Development (R&D). In case of the Federation of European Specialty Food Ingredients Industries, their companies dedicate 3-8% of their turnover to research and development, reaching a total among those companies an average of €2 billions in R&D per year (EU Specialty Food Ingredients, 2014a).

2.2. The EU regulation on food additives and its history

The Regulation (EC) No 1333/2008 is the current regulation concerning how food additives are governed within the EU. This piece of legislation describes the following aspects from the food additives:

- The regulation's purposes (Art. 1)
- Regulation's scope (Art. 2)
- Definitions, including "food additive" (Art. 3)
- The establishment of a positive list (Art. 4, 10)
- Conditions for allowing a food additive to be used in food products (Art. 4 – 20)
- Food additive's labelling (Art. 21 – 25)
- Regulation’s implementation (Art. 26 – 29)
- Transitional and final provisions (Art. 30 – 35)

Nonetheless, this current EU food additive regulation is the result of an evolution that can be traced back many decades ago since the early years of the European Union and the emerging concept of "food additive" coming from the Codex Alimentarius Commission (CAC):

![Figure 2. History of the Regulation (EC) No 1333/2008](image)

The Figure 2 not only describes the predecessors (direct and indirect ones) from the current EU food additive regulation, but also shows the interaction between them regarding how they were repealed and "condensed" into the following legislations.
In addition to the Regulation (EC) No 1333/2008, the European Union also establishes food additive’s specifications concerning their origin, purity and how to identify the substance. The current regulation on food additive’s specifications is the Regulation (EC) No 231/2012, which contains every single specification from the food additives listed in the Regulation (EC) No 1333/2008. However, the establishment of specifications had been a common practice as shown in the following Table 1, concerning the food additives being approved by the pieces of legislations historically depicted on Figure 2:

<table>
<thead>
<tr>
<th>Legislation approving food additives</th>
<th>Legislation establishing the specifications for the approved food additives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive 89/107/EEC on Foods additives in general</td>
<td>-&gt; (Not applicable)*</td>
</tr>
<tr>
<td>Directive 94/36/EC on Colours</td>
<td>-&gt; Directive 95/45/EC</td>
</tr>
<tr>
<td>Directive 95/2/EC on Food additives other than colours and sweeteners</td>
<td>-&gt; Directive 96/77/EC</td>
</tr>
</tbody>
</table>

Note (*): The Directive 89/107/EEC indicates only the general requirements and principles that a food additive shall fulfil, without approving specific food additives within its document. Therefore, it does not refer directly to any legislation on food additive’s specifications.

Nevertheless, similarly to the history of EU food additive regulation, all the EU legislations on specifications depicted in Table 1 took the Codex Alimentarius Commission as a reference, which had been executing this task since 1967 (CAC, 1967).

And lastly, food additives are approved by the common authorization procedure described in Regulation (EC) No 1331/2008, which also involves the approval of substances like food enzymes and flavourings. Before this legislation, the Directive 89/107/EEC also addressed the food additive’s approval on its Article 5, but not in a comparable extend as in the current Regulation (EC) No 1331/2008.
III. What is the legal basis (legal evidences) for the existence of EU “borderline” food additives?

As depicted in the problem statement, the concept of “EU borderline food additives” is proposed for gathering those substances which classification as food additives or non-food additives are debatable. Because the European Union Legislation is the one defining whether a substance applies as a food additive or not, it is coherent to establish as a first question whether the EU legislation allows the existence of these borderline additives and how. As elaborated in the theoretical framework (Section II), the Regulation (EC) No 1333/2008 is the current regulation concerning on how food additives are governed within the EU. Consequently, evidences should be found in this piece of legislation leading to the existence of these EU borderline food additives.

3.1. Legal Basis Nº1: Grey-areas on the food additives definition

The Article 3, paragraph 2a of the Regulation (EC) No 1333/2008 establishes the following first paragraph within its definition:

“‘food additive’ shall mean 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;...”

As a first look, the question of “What are food additives?” appears to be really straightforward to answer. Food additives are substances that present three main characteristics at the same time: 1. they are not normally consumed as a food or ingredient, 2. being intentionally added for a technological purpose 3. resulting them or their by-products to remain as components of the food. Anything not fulfilling with the definition cannot be considered as a food additive. In theory, there should not exist any room for substances difficult to classify or carrying confusion. However, a more exhausting reflection of every single element on this definition will expose blurry components leading to non-specific descriptions on what a food additive is, which hereinafter will be called as “definition’s grey areas”.

First, the words “not normally consumed as food” on the definition bring logically the suspicion of an existing grey-area for classifying a substance as a food additive or not: It will be possible to formulate the question of “Up to what extend a substance can be considered or not as normally consumed as food?” In the EU list of food additives it is possible to find substances that may challenge this principle. For example, rosemary had been a spice used in culinary applications since ancient times (Baines & Seal, 2012), and clearly being consumed as food, but nowadays its extract had been approved on the EU as a food additive “Extracts of rosemary (E392)” (Baldwin, 2011), a similar case happens to paprika that despite of being also used as a spice (CAC, 2001) its extract obtained approval as food additive “Paprika extract (E160c)”, or even the existence of caramel as “Plain caramel E150a” (Regulation (EC) No 1333/2008). All this cases, being substances normally consumed as food that ended up on the EU food additives positive list. These facts might suggest that it is not possible to make a “clear cut” between what is and not normally consumed as food according to the definition.

About the statement on “whether or not the substance has nutritive value”, it suggests the possibility of existing food additives with nutritional properties. However, it would not create a grey-area because according to this expression, the nutritional value is not conditioning the food additive’s nature of the substance.

Regarding “the intentional addition for a technological purpose”, the “technological purposes” are already established in legislation. The same regulation (EC) No 1333/2008 on the paragraph 2c states that the technological functions of a food additive are reflected on the list of “functional classes” by including sweeteners, colours, preservatives, antioxidants, and others, which are depicted on the Annex I of the same document. Therefore, it should not create a grey-area. Nonetheless, it is important to mention that a technological purpose is not an exclusive characteristic of “food additives”. Along the
human history, there had been many food ingredients being used on preparations due to their technological properties. The use of food salting as a preservation technique before the existence of refrigeration (Henney et al, 2010), the elaboration of jams and jellies for keeping fruits properly (Number, 2002), or the use of turmeric (Curcumin E100) or alfalfa (chlorophyll) as natural food dyes (Baines & Seal, 2012) are all good illustrations of the use of food ingredients for technological purposes. In those cases, the classification as a food additive or not would rely on condition of “not normally being consumed as food”, already identified as a “grey-area”.

Continuing with the analysis, by reflecting on the phrase “Intentional addition”, the following question may come out: Is it possible to have a food additive non-intentionally added to a food which ends up into a technological effect on it? The purpose of incorporating a food additive into a food is for bringing desired organoleptic properties not technically or economically possible without their addition (Article 6(1) of Regulation (EC) No 1333/2008), for example, the lack of a specific colour effect, considerable reduction on its shelf life, or a non-recognisable texture or consistency of the product, among others. The incorporation of a non-intentional food additive would cause a larger distance from the desired properties or in the best situations, no effects on the properties. Consequently, there cannot exist a “non-intentional” addition of a food additive bringing a substantial technological effect in a product.

The grey area related to the “technological purpose” will appear by challenging the phrase regarding where this technological purpose should take place in the product. As the definition states, the technological purpose will take place in the manufacture, processing, preparation, treatment, packaging, transport or storage. Nonetheless, there exist substances like food enzymes that perform a technological purpose within some of the depicted steps despite of not being considered as food additives. These substances perform a large variety of reactions within food processing, like for example α-amylase on the starch hydrolysis on bread-making, papain and bromelain on protein hydrolysis for meat tenderization or chymosin on casein hydrolysis for coagulation of milk in cheese making (Whitehurst and van Oort, 2010). Despite of this, there are only two enzymes approved as such: Invertase (E1103) used on the production of invert syrup for confectionary (Aburigal et al, 2014) and Lysozyme (E1105) on wine industry for preventing spoilage (Carstens et al, 2014). It is not possible to establish the reasons at this point concerning why the earlier substances are not food additives in comparison to the last two just by following the definition.

And finally, about “whether the substance or its by-products remains or not in the food”, there exist substances that remain mainly unchanged within the food product until consumption as the majority of foods additives, including for example emulsifiers and sweeteners. But there are some others that experiment substantial degradation on the product like colorant carotenoids (Carle & Schweiggert, 2016) due to factors like light, oxygen or temperature, or like food enzymes (Whitehurst & van Oort, 2010) undergoing denaturalization after exposure to high temperature, extreme pH or high salt concentrations. Both cases are producing by-products due to those reactions; the first one involves the creation of “substances from degradation” meanwhile in the second one, the molecule changes its shape and internal chemical bonds leading to a loss of enzymatic activity. In other words, what remains on the food are “side-molecules” of those initial substances. However, the grey-area comes to the surface by considering that in the first case the original substance is classified as a food additive, while in the second case not.

So as a pre-conclusion of this analysis, from the characteristics describing a food additive: the “not normally consumed as food”, “the place in which the technological purpose takes place” and “the existence of remaining product or by-products” are the main source of grey-areas. Nevertheless, there is a remaining analysis to the food additive’s definition regarding it exemptions’ part:

“... The following are not considered to be food additives:
(i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties;
(ii) 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;
(iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;
(iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin);
(v) chewing gum bases;
Most of the items mentioned on the exemptions above are listing concrete substances that are accurately defined by science. This is the case of monosaccharides, disaccharides or oligosaccharides (i), products containing pectin (iv), dextrins and starches (vi), ammonium chloride (vii), blood plasma, edible gelatin, protein hydrolysates, milk protein and gluten (viii), other aminoacids than glutamic acid, glycine, cysteine and cystine (ix), caseinates and casein (x), and inulin (xi). Apart from that, some of them refer to well define products on the market like chewing gum bases (v) or coating materials (iii).

However, the complications come by analysing the remaining item (ii), it establishes that dried or concentrated foods and flavourings for food manufacturing which posses "aromatic, sapid or nutritive properties plus a secondary colouring effect" must not be classified as food additives. This situation brings room for the following grey-area: How to determine in a substance which property from an aromatic/sapid/nutritive or colouring is the primary or secondary one?

In conclusion, after analysing the whole definition, the grey-area statements which generate these debatable substances would be -as depicted in the Table 2- the "not normally consumed as food", "where the technological purpose take place", "the existence of remaining product or by-products" and from the exemptions, the "foods with aromatic/sapid/nutritive properties together with a secondary colouring effect". Those are the definition’s grey areas leading to EU borderline food additives.

Table 2
Summary of Grey-areas from the Food additive’s definition on Regulation (EC) No 1333/2008.

<table>
<thead>
<tr>
<th>Elements from the definition</th>
<th>Grey area: Yes or No?</th>
<th>Argument</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;not normally consumed as a food in itself and not normally used as a characteristic ingredient of food&quot;</td>
<td>Yes</td>
<td>It does not specify a &quot;clear cut&quot; between what is and what is not normally consumed as food.</td>
</tr>
<tr>
<td>&quot;whether or not it has nutritive value&quot;</td>
<td>No</td>
<td>It is not an excluding statement.</td>
</tr>
<tr>
<td>&quot;the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food&quot;</td>
<td>No</td>
<td>An unintentional addition of a food additive will bring unwanted properties on the final product.</td>
</tr>
<tr>
<td>&quot;in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food&quot;</td>
<td>Yes</td>
<td>The technological purposes are listed.</td>
</tr>
<tr>
<td>&quot;results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods&quot;</td>
<td>Yes</td>
<td>Some substances that –apart from fulfilling the other food additive's criteria- perform technological purposes as described are not considered as food additives.</td>
</tr>
</tbody>
</table>

From definition's exemptions:

| "(i) 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;" | Yes | Difficulties on defining whether the colouring effect is primary or secondary. |
| The rest of exemptions | No | They are concrete substances being accurately defined by science or the market. |

As it could be described, the first legal basis for the borderline additive's existence lies on the lack of precision of the food additive's definition.

3.2. Legal Basis Nº2: Elements in Regulation No 1333/2008 evidencing food additive’s overlap with other substances

The regulation No 1333/2008 shows along its content the closeness that food additives possess regarding other food substances also regulated within the EU.

(vi) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amyloitic enzymes;
(vii) ammonium chloride;
(viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;
(ix) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function;
(x) caseinates and casein;
(xi) inulin;“
3.2.1. **Scope-related elements of overlapping**

The regulation’s scope (article 2) lists the substance categories that can possibly play the role of a food additive:

> "2. This Regulation shall not apply to the following substances unless they are used as food additives:
> (a) processing aids;
> (b) substances used for the protection of plants and plant products in accordance with Community rules relating to plant health;
> (c) substances added to foods as nutrients;
> (d) substances used for the treatment of water for human consumption falling within the scope of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (2);
> (e) flavourings falling within the scope of Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods]."

The paragraph indicates that in case a substance -from (a) to (e)- is used as a food additive, then the regulation No 1332/2008 applies to it, and as indicated further in the regulation, this substance must be approved on the Community list (Article 4(1)) and used under specific conditions detailed on it. This paragraph not only shows the proximity existing between the food additives and the substance categories involved from (a) to (e), but also the expression “unless they are used as food additives” implies that the food additive's classification of a substance is related to its use; making it able to be linked to other substance’s categories depending on its purpose.

Additionally to the last paragraph, the regulation on its paragraph 2(3) explains a temporarily overlap of possible food enzymes currently being scoped as food additives until the community list of food enzymes is adopted:

> "3. This Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No 1332/2008 [on food enzymes], with effect from the date of adoption of the Community list of food enzymes in accordance with Article 17 of that Regulation."

From the mentioned substances -2(2)(a) to (e) and 2(3)- being overlapped with food additives, in case the concept of EU borderline food additives is aimed for only scoping to substances from the specialty food ingredients industry, the categories (b) on plant protection substances and (d) on water treatment substances need to be excluded from the current analysis. The related argument for this exclusion is that plant protection products are used during primary production of food, and water treatment products -according to Directive 98/83/EC- are applied before the points of compliance where the water is still not considered as “food” regarding the Article 2 of regulation (EC) No 178/2002. Therefore, the remaining overlaps from the scope for the specialty food ingredient industry would involve only the categories of processing aids, nutrients, flavourings and food enzymes.

3.2.2. **Non scope-related elements of overlapping**

Apart from the food additive’s overlap focused on the scope, the regulation also shows several evidences along its content describing the proximity of the food additive classification to other substances.

As a starting point, the Recital (5) suggests the existence of food additives performing flavouring or nutritional functions, in which those cases they should not be considered as food additives:

> "... 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."

Furthermore, lines below preparations of foods or other natural sources material should be considered food additives if they experimented a “selective extraction” and resulting into having technological effect on a final food:

> "...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"

About the already analysed definition (Article 3(2)(a)), it is possible to identify that most of the found grey-areas are also highlighting the closeness of food additives with other foods.
Later, the Article 12 about the changes that an already approved food additive can suffer on its production method or starting materials, it is indicated that food additives can be prepared by the use of nanotechnology:

“When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.”

Food products elaborated under new techniques such as nanotechnology are governed by the novel food regulation (EC) Nº 258/97 and proximally repealed by the regulation (EU) Nº 2015/2283, which both confirm in their articles 2 the existence of food additives with “novel” characteristics by explicitly excluding them from both novel food’s regulations.

Finally, the regulation realized explicitly on Article 13 the overlap with substance coming from genetically modified organisms (GMOs) scoped on the Regulation (EC) No 1829/2003:

“1. A food additive falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes II and III in accordance with this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.”

Nevertheless, by reflecting on Article 13, this last overlap differs from the previous ones on the fact that this category does not make a substance to compete with its food additive’s nature; a substance can be a food additive and coming from a GMO source at the same time. Consequently, by excluding the GMO category, the remaining overlaps non-related to the scope of the regulation involve flavourings, nutrients, foods (in general) and novel foods. Having regard that “food in general” will collect all the foods not falling within a specific substance category into a one large group.

### 3.3. Legal Basis Nº3: Interpretation decisions

On the paragraph 19(c) of the Regulation No 1333/2008, it is established that decisions such as the applicability of a substance within the food additive definition will be executed according to the indications on the Article 28(2) of the same regulation:

“Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 28(2) whether or not:
(a) a particular food belongs to a category of food referred to in Annex II; or
(b) a food additive listed in Annexes II and III and permitted at ‘quantum satis’ is used in accordance with the criteria referred to in Article 11(2); or
(c) a given substance meets the definition of food additive in Article 3.”

According to this Article 28(2), the interpreting process should be performed according to Articles 5, 7 and 8 from Council Decision 1999/468/EC, document that is repealed by the Regulation (EU) No 182/2011 (Articles 5,10 and 11). However, both documents indicate that "the related committee" should carry the interpretation decisions: In this case the Standing Committee on Plants, Animals, Food and Feed (SCPAFF).

By containing an “interpretation article”, the regulation No 1333/2008 realises the potential situations whether the classification of a substance as a food additive or not would not be clear.

### 3.4. Concluding on the legal basis for the existence of EU borderline food additives

As elaborated along this research question, the food additive regulation No 1333/2008 contains the following elements supporting the idea of a blurry border between the "food additives" group of substances and the "other substances" (non-food additives): From the grey-areas spotted on the definition, continuing to the overlapping with other substance categories in which food additives are legally expected to border (i.e. processing aids, nutrients, flavourings, etc) and finishing with the
existing **room for interpretation** on the food additive’s definition from the Standing Committee on Plants, Animals, Food and Feed (SCFAFF).

Therefore, it is possible to legally define a EU borderline food additive as:

“A substance which **classification** between the possibilities of a food additive or a non-food additive is **difficult or debatable**, because of the substance’s characteristics fulfilling with at least one of the following conditions from the Regulation (EC) Nº 1333/2008:

(i) the substance falls into the grey-areas of the food additive’s definition,
(ii) the substance belongs to the overlapping substance’s categories depicted in that regulation or
(iii) the substance’s classification needs further interpretations from the SCFAFF”.

And for defining the EU borderline food additives for the context of the specialty food ingredients industry, the overlapping substance categories should exclude the plant protection products and water treatment substances, leaving the following remaining substances in which a EU borderline food additive can fall into:

1) **Food Additive (FA), or**
2) **Non-food additive substances like**: Processing Aid (PA), Food Enzyme (FE), Novel Food (NF), Food in General (FG), Nutrients (NU) and Flavourings (FA).
IV. What is the relevance of classifying these EU “borderline” food additives for the specialty food ingredients industry?

4.1. Reason Nº 1: Different regulatory outcomes from the possible legal statuses of the EU borderline food additives

By following the achieved legal basis for the EU borderline food additives, the substance within the specialty food ingredients industry can fall within the following substance’s categories:

1) Food Additive (FA), or
2) Non-Food Additive substances like:
   - Flavouring (FL)
   - Processing Aid (PA)
   - Food Enzyme (FE)
   - Novel Food (NF)
   - Foods in general (FG)
   - Nutrient (NU)

Because these substance’s categories are ruled within the EU by different pieces of legislation, it is reasonable to expect different established conditions that may trigger also different advantages and disadvantages between each other to the specialty food ingredients industry. For instance, it was explained in the section II the way on how the EU legislation establishes the conditions of use, labelling, specifications and authorization of food additives. In that sense, by analysing the applicable pieces of legislation to the other possible categories of a EU borderline food additive (PA, FE, NF, FG, NU, or FL), it should be possible to develop and depict the differences.

For obtaining an initial perspective of which regulations govern the identified substances categories, the EU Commission website on its “Food safety overview” section (EU Commission, 2017a) mentions the respective applicable legislation. The obtained legislation is arranged in the following Table 3:

<table>
<thead>
<tr>
<th>Substance category</th>
<th>Legislation defining the substance and its use</th>
<th>Legislation defining their authorization procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulation (EU) No 2283/2015</td>
<td>Regulation (EU) No 2283/2015</td>
</tr>
<tr>
<td>Foods in general (FG)</td>
<td>Regulation (EC) No 178/2002</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>Nutrients (NU)</td>
<td>*Directive 2006/125/EC</td>
<td>EU commission - &quot;Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods&quot;</td>
</tr>
<tr>
<td></td>
<td>*Directive 2002/46/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Regulation (EC) No 953/2009</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Directive 2006/141/EC</td>
<td></td>
</tr>
</tbody>
</table>

(*) According to the "Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods" from the European Commission (EU Commission, 2004).

Nevertheless, some modifications to this Table 3 must be done, in light of the following information:

- According to the presentation called “Food processing aids in the European Union” from the Mr. Jerome Lepeintre, Minister Counsellour for Health & Food Safety (EU Commission, 2016a), processing aids in the EU are classified into “food enzymes”, “extraction solvents” and “other processing aids”.

- For the extraction solvents authorization, it is recommended by the same EU commission website to follow the common authorization procedure (Regulations (EC) No 1331/2008 and No 234/2011) despite of not being explicitly indicated.
- According to the definition of food enzymes in Article 3(2)(a) from Regulation (EC) No 1332/2008 not all the food enzymes are processing aids, consequently it is necessary to divide this category into two sub-groups: inside processing aids and outside.

- And finally, novel foods in the new regulation (EU) No 2015/2283 are divided into “novel foods and traditional foods”.

Therefore, the previous Table 3 should be adjusted as follows:

### Table 4
**Modified chart on legislation applicable to the substances categories from EU borderline food additives.**

<table>
<thead>
<tr>
<th>Substance Category</th>
<th>Legislation defining the substance and its use</th>
<th>Legislation defining their authorization procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>***Other processing aids</td>
<td>Regulation (EC) No 1333/2008</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>****Traditional Foods (New)</td>
<td>Regulation (EU) No 2283/2015</td>
<td>Regulation (EU) No 2283/2015</td>
</tr>
<tr>
<td>Foods in general</td>
<td>Regulation (EC) No 178/2002</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>Nutrients</td>
<td>*Directive 2006/125/EC</td>
<td>EU commission - &quot;Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods&quot;</td>
</tr>
<tr>
<td></td>
<td>*Directive 2002/46/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Directive 2009/32/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Regulation (EC) No 953/2009</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Directive 2006/141/EC</td>
<td></td>
</tr>
</tbody>
</table>

(*) According to the "Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods" from the European Commission (EU Commission, 2004).

(**) According to EU Commission Website on the authorization of extraction solvents. (EU Commission, 2017b)

(****) According to Presentation "Food processing aids in the European Union" from the Mr. Jerome Lepeintre, Minister Counsellour for Health & Food Safety (EU Commission, 2016a).

(****) According to the new Novel Food Regulation (EU) No 2015/2283.

From the legislation described in the Table 4, conditions to those substances were identified and after the advice from Mr. Geert de Rooij (Annex IV) - currently the Regulatory affairs manager for the Federation of the Dutch Food and Grocery Industry (FNLI)- they were "clustered" into the categories: "Application", "Post-application obligations with authority", "Conditions for production" and "Conditions for Commercialization” as shown in the following Table 5, which elaboration is explained on detail in the Annex II of this research.

### Table 5
**Summary of the regulatory conditions differing between the EU borderline food additives elaborated in Annex II**

<table>
<thead>
<tr>
<th>Substance’s categories</th>
<th>Cluster Nº 1: Application</th>
<th>Cluster Nº 2: Post-application obligations with authority</th>
<th>Cluster Nº 3: Conditions for production</th>
<th>Cluster Nº 4: Conditions for commercialization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Additives</td>
<td>Time: 4.5 (2.5-8) years</td>
<td>- New scientific/technical information</td>
<td>- Regulated specifications for Food Additives</td>
<td>- Levels of use (mostly)</td>
</tr>
<tr>
<td></td>
<td>Success Rate: 25.7 - 46.4%</td>
<td></td>
<td>- Food additives allowed for Food Additives</td>
<td>- Detailed labeling</td>
</tr>
<tr>
<td></td>
<td>Cost: € 115,700</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Confidentiality: Not for safety relevant elements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraction solvents</td>
<td>Time: 2.8 years</td>
<td>---</td>
<td>- Regulated specifications</td>
<td>- Labelling in foods only in case of allergens</td>
</tr>
<tr>
<td></td>
<td>Success Rate: No data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cost: € 115,700</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Confidentiality: Not for safety relevant elements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Enzymes</td>
<td>Time &amp; Success Rate: No data</td>
<td>- New scientific/technical information</td>
<td>- Regulated specifications for Food Enzymes</td>
<td>- Labelling in foods only in case of allergens</td>
</tr>
<tr>
<td></td>
<td>Cost: € 115,700</td>
<td></td>
<td>- Food additives allowed for Food Enzymes</td>
<td>- Detailed labeling as product itself</td>
</tr>
<tr>
<td></td>
<td>Confidentiality: Not for safety relevant elements</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Cluster Nº 1 on “Application” involves the process from the applicant for submitting a dossier to the authority (the EU Commission or the Member State depending on the procedure) containing information related to the substance’s safety for food application in order to allow this authority to decide on granting or not the permission to this substance for being used in the market. Parameters like the time of the authorization’s process, success rate, costs and property rights involved on the submitted data (Confidentiality & Data protection) are evaluated. For this cluster, food additives have the longest average authorization’s process taking 4.5 years, a success rate of 35.7-46.4%, a high cost of > €115,700, with the authority keeping confidentiality on the dossier’s information not relevant for safety evaluation according to their decision and no data protection is granted (due to the non-exclusive nature of the authorization).

The categories of extraction solvents, food enzymes, novel foods (under the current regulation), nutrients and flavourings present similar features as the food additive’s application, varying in terms of time and success rate but all of them showing high costs for the dossier elaboration. However, a comparable difference starts to be shown for the novel foods under the new regulation entering in force in 2018 by bringing a data protection for 5 years since the authorization to the scientific/toxicological submitted information developed by the applicant. Nevertheless, the categories showing considerable benefits in comparison to the food additives are the traditional foods (from the new novel food regulation) by not needing the mandatory development of scientific/toxicological data on the dossier which means an investment higher than €115,700, and the foods in general and processing aids by not being required undergoing an application procedure.

Concerning the Cluster Nº 2 on “Post-application obligations”, this refers mostly to the scientific data on the product’s safety that can appear after obtaining the authorization, which the applicant has the responsibility for communicating to the authority. As the food additives, most of the other categories present this feature exempting the extraction solvents, other processing aids and foods in general.

The Cluster Nº 3 on “Conditions for production”, the substances are divided in two main groups:
- The substances like food additives, extraction solvents, food enzymes, nutrients and flavourings, which processing and product’s characteristics are regulated by specifications
(allowing the addition of food additives for specific use in food additives, food enzymes, nutrients and flavourings respectively).

- The substances considered as "whole foods" (such as novel foods and foods in general) consequently needing to fulfill with contaminants & pesticides and added substances applicable to them (addition of i.e. food additives, flavourings, food enzymes to those foods).

And finally, the Cluster Nº 4 regarding "Conditions of Commercialization", regulations may restrict the substance's trade in terms of level of use, property rights for commercialization (being an exclusive or non-exclusive authorization to the applicant), substance's labelling, and the possibility for health/nutritional claiming.

Regarding the levels of use, regulations establish maximum amounts -and also minimum amounts, in case of nutrients- for adding the substance into determined food categories (such as dairy foods, fats and oils, cereals, etc). Food additives are generally restricted in this sense, unless the authority's risk assessment will allow it to be added in "quantum satis" (addition for reaching the expected purpose without misleading the consumer). The similar situation applies to flavourings (but "quantum satis" is the trend), to nutrients (which are always restricted), to novel foods (occasionally restricted) and is expected to apply also to food enzymes (which positive list is still not published yet). Nevertheless, it is important to mention that the establishment of limits on a substance will depend on the risk assessment executed by European Food Safety Authority (EFSA) and the later decision of the EU Commission; consequently, it is a feature that will depend on a case-by-case analysis. The only categories exempted for limits of use are the processing aids and foods in general.

In terms of property rights for commercialization granted by authorization, most of the categories attached to a non-exclusive authorization implying the substance's commercialization not restricted to only the applicant. However, the novel foods under the current regulations and the future submissions of novel foods under the new regulation (involving developed scientific/toxicological data) are restricted to only the applicant.

For labelling, most of the categories like food enzymes, novel foods, foods in general or nutrients must be labelled in their food applications, and following specific requirements for their sale as a product itself to the food manufacturers or directly to the consumers. In case of food additives, they follow mainly the same tendency but they must be labelled using its functional class plus the specific name or E number for their presence in food products. And regarding flavourings, the labelling is less specific by only allowing the use of the general description “flavourings” or their sub-groups as defined in Regulation (EC) Nº 1334/2008. For processing aids, their labelling on food products is mandatory only if they cause allergies or intolerances.

Finally, for health/nutritional claiming, it is possible only for novel foods, foods in general and nutrients because the purpose of a food additive, food enzyme, processing aid and flavouring is related to a technological/flavour effect.

As depicted in lines above, food additives involve different regulatory outcomes in comparison to the non-food additive options. From an application's point of view, having a substance the status of a traditional food, other processing aids or food in general is more convenient rather than having a food additive. As mentioned, the traditional food status means saving money on the dossier elaboration. However, the last two status by being excluded from an authorization, they do not only involve saving time of an application, but also time for preparing a dossier, which in case of toxicological studies, they can take months and even years to perform and obtain the desired data. This save of time is also evidenced in case the companies are willing to innovate on new food applications for the related substance: For substances conditioned to an authorization, the companies should apply for and "extension of use" for the food categories not already included in the authorization; meaning additional time and costs for elaborating and submitting a dossier, and waiting for the authority’s decision on this procedure.

This absence of authorization process is also relevant in relation to avoid the post-application obligations with the authority, because the new scientific data or restrictions to the substance can bring the possibility for them to modify and restrict more the already established level of uses in the granted authorization. This disadvantage is well exemplified by the re-evaluation process of food additives (Article 32 Regulation (EC) Nº 1333/2008) to the substances submitted before 20 January of 2009, in which the EU Commission periodically ask the producers this data.
In terms of the conditions of productions, it is difficult to state that a food additive -because of being defined by specifications- would involve a production being more or less complicated than a novel food or a food in general, which is conditioned to fulfilling with regulations on contaminants or pesticides. Factors like the specific kind of food additive (i.e. a polymer, food extract or a synthetic molecule from petrochemical origin) or its production process (such as extraction, fermentation, chemical reaction) varies between substances to substances. Furthermore, for “food-like” products, they can belong to different food categories which at the same time will involve different maximum limits of contaminants or pesticides; this, without mentioning the fact that further specific regulations -not possible to mention on the Table 5- may apply depending on the product’s nature. Therefore, the regulatory conditions on the production will be relevant for a company’s decision once the specific substance is identified.

Lastly, regarding the conditions for commercialization, the conditions of use established for food additives and the other categories would be a constrain for the companies to innovate on new food applications (as depicted on while discussing the application) which can mean using the substance in new food categories not expected by the authority. Additionally, in terms of authorization’s exclusiveness, a novel food status would protect the applicants’ investments by bringing them the exclusive rights for commercializing the substance. For a substance with a non-exclusive authorization (i.e. food additives), the investment done by the applicants for building a dossier would not mean for them a competitive advantage among their sector, unless they would have this competitive advantage in other features i.e. exclusive contracts with costumers, process patents or larger scale production allowing them to produce a more convenient product in comparison to their competitors, etc. Regarding labelling, the regulatory requirements for a food additive involves also the use of a functional class plus its specific name or E number, which according to the market trends depicted in Section II, probably would not be in-line with the “natural” and “clean label” appearance desired for a food product in case it ended up having an “artificial” sound. And finally on health/nutritional claims, they would not be expected for substances with more technological/flavouring effects.

This section had established within the EU borderline food additives that the food additive status possesses different regulatory consequences among the possible non-food additive status; some of them as notorious disadvantages like the related costly & time-consuming application process (with the possible “extensions of use” due to the levels of use on food categories), the non-exclusive feature of the authorization and the related post-application obligations, and other implications on the production conditions and labelling which depends on the substance’s nature to be named as disadvantages or not. **However, as a general conclusion, it is reasonable to consider the food additive’s status generally as a less attractive category, which could be chosen by taking into account the substance’s characteristics and how it might limit the possibility of classifying it among the other options of categories from the EU borderline food additives.**

4.2. **Reason Nº 2: The uncertainty of legal status as an obstacle for innovation within the specialty food ingredients industry**

As depicted in the Section II, the specialty food ingredients industry has the responsibility of developing products capable to fulfil with the market trends such as improving the sustainability and avoiding waste in food production, contributing to healthier diets and healthy ageing, and making possible the design of convenient and safe foods. For achieving this purpose, in case of the companies belonging to the Federation of European Specialty Food Ingredients Industry, they dedicates 3-8% of their turnover to research and development, reaching a total among those companies an average of €2 billions in R&D per year (EU Specialty Food Ingredients, 2014a).

Nonetheless, this process of product development is far from being only a straightforward design of an ingredient and its release to the market. Several assessments take place before the actual selling of the ingredient and thus start generating a turnover (Figure 3).
The Figure 3 depicts how product’s launching evolves from the opportunity and feasibility study up to the market saturation, in which the turnover practically does not exist before the product’s launching and is just noticeable after the product’s sales “take off”.

However, in these processes, one determining factor eroding confidence and discouraging investment on these innovations is the uncertainty, which is identified as such by the Federation of European Specialty Food Ingredients Industries on its document called “Innovation Dialogue- Can the EU regulatory environment help deliver food innovation?” (EU Specialty Food Ingredients, 2016b) They indicate that this procedural uncertainty is “compounded by the legal uncertainty as to the legal status of food ingredients and the need to seek authorisation”.

In the context of EU borderline food additives established on this research, this procedural uncertainty is particularly true. The concept of a EU borderline food additive in this research implies the substances which classification as a food additive or non-food additive is debatable and difficult, in which the non-food additive options could be a PA, FE, NF, FG, NU or FL presenting different regulatory outcomes in comparison to a food additive as recently discussed in the previous Section 4.1.

These different regulatory outcomes among the EU borderline food additives not only affect the "launching time" from a product development (Figure 3) by bringing uncertainty on whether the substance will need authorization or not as suggested by the federation, but also they shape the "take off" slope and the "saturation point" from the graph. For instance, a substance restricted to specific food categories such as a food additive will imply a limitation on its food applications and consequently less food products in the market containing the substance; meaning fewer revenues for the company producing the substance. Or a substance applicable as a novel food with an exclusive authorization (from 2018 onwards) would experiment a more accelerated "take off" in the first years because the applicant company would fully bear the rights for commercialization and having no competitors due to the data protection of 5 years. Or a substance obtaining the status of a food additive with a functional class of, for example, “acidity regulator”, “emulsifier”, “sequestrant”, possibly making the substance not suitable for a “clean label” and by doing this, bringing the substance’s turnover to a lower “saturation point” for not being able to reach the food products belonging to the "natural trend" or the market.

**Consequently, for the EU borderline food additives in the context of food innovation: Having more predictability (less uncertainty) on the legal status of a substance potentially to be developed would bring more tools to the decision-makers for considering a more realistic turnover vs. time curve of this innovation process and therefore having access to a better “feasibility picture” for investing or not on this development.**

4.3. **Reason Nº3: The EU Commission realising classification as problem within the authorization procedure for specialty food ingredients**

In 24 June 2016, a workshop between the EU policymakers and industry was held in Brussels (EU Specialty Food Ingredients, 2017b) for discussing the regulatory challenges on food innovation. Within the event, Mr Wim Debeuckelaere - Head of Sector on Food Additives, Food Enzymes and Flavourings at the Commission Directorate-General for Health and Food Safety (DG SANTE) - on his presentation (EU Commission, 2016b) acknowledged the food improvement agents (substances belonging to the specialty food ingredients sector) as “essential for food innovation”. **Nevertheless, within the problems**
lengthening their authorization processes such as not completed dossiers, not sufficiently justified/explained technological needs by applicants or administrative procedures in general, Mr Debeuckelaere identified substance’s classification as one of those element by stating “the scope under which legislation the substances fall is not clear”; fact that results being in-line with the Federation of European Specialty Food Ingredients Industries as explained in the previous Section 4.2.

However, Mr Debeuckelaere considers that the classification problems do not come from the legislation, but instead he prefers to address them by improving the related guidance - currently available in shape of documents clarifying legislation and situations of pre-submission in ad-hoc basis according to him- by setting them as one part of the next tasks from the EU Commission within the regulatory challenges on food innovation, in which stakeholders will be involved (EU Specialty Food Ingredients, 2017b).

4.4. Reason Nº 4: Limited current classification efforts from private sector

Only some associations belonging to the specialty food ingredients sector -most of them at the same time members of the Federation (EU Specialty food ingredients, 2017c) - are addressing the classification of substances within the framework of EU borderline food additives. These are the cases of the Natural Food Colours Association (NATCOL, 2017), the European Technical Caramel Association (EUTECA, 2015), the European flavours Association (EFFA, 2015) and the Association of Manufacturers & Formulators of Enzyme Products (AMFEP, 2009) publish their positions and guidance to their own company members on substance’s classification. These associations and their publications are summarized in the following table:

Table 6
Positions and guidance from European associations on specialty food ingredients on the classification of substances falling into the EU borderline food additives

<table>
<thead>
<tr>
<th>Association</th>
<th>Date</th>
<th>Classification Issue</th>
<th>Related EU borderline food additives</th>
</tr>
</thead>
<tbody>
<tr>
<td>NATCOL</td>
<td>2005</td>
<td>Position Paper: Food</td>
<td>FA - FG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ingredients with</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>colouring properties</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td></td>
<td>Decision tree</td>
<td>FA - FG</td>
</tr>
<tr>
<td>2008</td>
<td></td>
<td>Selective Extraction</td>
<td>FA - FG</td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td>Guidance notes on</td>
<td>FA - FG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the classification of</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>food extracts with</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>colouring properties</td>
<td></td>
</tr>
<tr>
<td>EUTECA</td>
<td>2015</td>
<td>Decision tree</td>
<td>FA - FG and FL</td>
</tr>
<tr>
<td>EFFA</td>
<td>2015</td>
<td>Guidance document on</td>
<td>FA - FL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the EC Regulation on</td>
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<tr>
<td></td>
<td></td>
<td>Flavourings</td>
<td></td>
</tr>
<tr>
<td>AMFEP</td>
<td>2009</td>
<td>Regulatory classification</td>
<td>FA - FE (not as PA) and FA - FE (as PA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of food enzyme uses as</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>processing aid, additive</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>or ingredient</td>
<td></td>
</tr>
</tbody>
</table>

As depicted in the Table 6, the guidance of these associations is limited in some cases for only bringing advisory to the ingredients companies (members of these associations) how to declare (label) these ingredients, for transmitting this information to their costumers (the food manufacturers). Some of the publications are directly guidance documents elaborated by the EU Commission such as “The guidance notes on the classification of food extracts with colouring properties” (NATCOL) and Guidance document on ”Classification of flavour enhancers and flavouring substances with modifying properties” (EFFA).
However, in terms of ingredients innovation, the EU Commission in 2016 is still indicating the classification as an issue, as detailed in previous Section 4.3 despite of being these guidance examples released since 2005 by the private sector.

4.5. Reason Nº5: The Standing Committee on Plants, Animals, Food and Feed (SCPAFF) interpreting cases of non-proper use of food additives

As mentioned on the "Legal Basis Nº3" in Section III, the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) is requested to bring their interpretations on the classification of substances within the Regulation (EC) Nº 1333/2008 as indicated on its paragraph 19(c). As consequence, the current research also appointed to review on their entire published meetings on the sections "Toxicological Safety of the Food Chain" and "General Food Law". The identified cases are depicted in the following Table 7:

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Title of discussion</th>
<th>Description</th>
<th>Related EU borderline food additives</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 14th of 2006</td>
<td>Spinach extract with high levels of nitrates used in sausages</td>
<td>Some manufacturers of meat products were detected to be using standardised spinach extracts containing high levels of nitrates. Additionally, the producers labelled the product as not containing food additives. In this meeting, this practice was considered by the Member States as a deliberate use of a food additive because it would be intended for a technological purpose as preservative in the final food (the sausages). As a consequence, the committee stated that such use should comply with the food additive and food labelling legislations.</td>
<td>FA - PI</td>
</tr>
<tr>
<td>June 21th of 2016</td>
<td>Use of copper sulphate (CuSO4) in cucumber preparation</td>
<td>The case refers to the use of a substance for creating a food additive in situ in the food. Producers requested an opinion on a process for retaining the green colour of cucumbers meant for preparing milk products. The process involves the immersion of cut cucumbers into a water solution of copper sulphate (CuSO4) followed by a solution draining, a wash step in water and a heat treatment. This process allows the copper ions from the CuSO4 solution to combine with cucumber's chlorophylls for producing copper complexes of chlorophylls. Regarding this situation, the Committee concluded unanimously that the process described to formation of copper complexes of chlorophylls (E 141(i)) in situ not naturally present in cucumbers. Considering that neither CuSO4 nor copper complexes of chlorophylls are allowed in cucumber preparations, this process constitutes a non-authorised food additive use.</td>
<td>FA - PA</td>
</tr>
<tr>
<td>June 21th of 2016</td>
<td>Use of alkalising substances in processing of cocoa products</td>
<td>The use of alkalising substances in processing of cocoa products was discussed regarding their role as processing aids or food additives. Substances like calcium carbonate (E 170), carbonates (E 500 – 504), hydroxides (E 524 – 528) and magnesium oxide (E 530) are often added to the cocoa nibs in a reaction vessel before roasting in order to (i) increase the dispersability in aqueous solutions, (ii) reduce bitterness in taste and (iii) change the colour of cocoa powers. According to this, the committee concluded that the resulting by-products of those substances (i.e. mineral salts) still present in the product create a remaining effect on it. And considering that those substances are recognized in the related food category according to the Regulation (EC) No 1335/2008. Therefore, they are considered as food additives in cocoa powders.</td>
<td>FA - PA</td>
</tr>
</tbody>
</table>

The cases listed in the Table 7 involve the use of substances considered as infringing the EU food additive's regulations by this SCFAFF. These substances, by needing interpretation from the SCFAFF, they apply as EU borderline food additives according to the elaborated definition in previous Section III.

Therefore, by achieving the classification of EU borderline food additives, food manufacturers will have more certainty on how to use specialty food ingredients falling as EU borderline food additives and consequently avoiding the mentioned infringement situations; increasing in this way their trust on applying these ingredients on their products.

4.6. Concluding on the relevance for the classification of EU “borderline” food additives for the specialty food ingredient industry

For the specialty food ingredient industry, the relevance of classifying EU border line food additives relies on the consequent capacity to predict the regulatory status of a substance being developed within those companies, in the following ways:

1. A company developing an ingredient can visualize beforehand the regulatory behaviour of the substance not only before the launching (by calculating the impact in terms of time involved before perceiving revenues, dossier-building expenses and chances for being approved), but also by depicting the constrains that the substance will experiment in the market (labelling, level of uses, exclusive/non-exclusive authorization or allowed ways of use); meaning this “regulatory behaviour” one of the factors drawing the path of the total revenues that the project of developing a food ingredient can produce, important for decision-makers.
EU “borderline” food additives: Their legal basis and classification for the Specialty Food Ingredients Industry

2. The whole specialty food ingredient sector can benefit from obtaining their products a higher level of trust from their customers (the food manufacturers) by being them able to avoid infringements from a wrong use.

Considering that the EU Commission is aware on the limitations that classification issues causes to food innovation up to this date (on lengthening authorization procedures) -issues that persist despite the current effort of the private sector (EFFA, NATCOL, EUTECA, AMFEP)- and the relatively more openness of the EU Commission to improve the guidance –with stakeholders- rather than modifying the legislation.

There would be an opportunity for the specialty food ingredient industry to encourage the development of classification guidance on these EU borderline food additives jointly with the EU Commission, taking into account that the already done efforts made by the private sector on their own are still being limited up to this date.

This joint work should bring priority for the development a guidance document clarifying the legislation -working as an “a priori” tool- rather than a pre-submission procedure (making the latter possible as a complement). The reason for establishing this priority is the possibility for addressing with the first option the regulatory analysis of an ingredient development in an earlier stage.

By having a guidance document, the developers can have the “regulatory directions” before starting with the ingredient’s formulations on lab-scale tests (even in the “concept” stage of the ingredient). However, with a solely pre-submission procedure, all -or part of- the ingredient characteristics should be already
set for allowing the authority to evaluate the ingredient; meaning that more steps in the ingredient’s development had already been performed. In situations of non-favourable decisions from the authority on these pre-submissions, a re-design of the product will cost more to the company in comparison to an “earlier detection” done with a guidance document. Nevertheless, there could also exist a still valid scenario of having both measures implemented; allowing the pre-submission procedure to “detect” non-favourable conditions for the companies just in case the guidance document would result limited for classifying the specific ingredient being developed by the company.

Finally, developing a classification guidance document will allow detecting the conditions for all the potential cases of EU borderline food additives identified in Section III, consisting on the debatable situations between food additives (FA) vs. non-food additives (PA, FE, NF, FG, NU and FL). Being those possibilities largely superior to the cases already addressed in Table 6. By doing this, the document will be covering all possibilities of guidance; situation that would benefit a company possibly working in this moment on an EU borderline food additive, which might not be solved yet by neither the existing guidance (from the private sector nor the EU Commission).
V. What are the conditions and principles for classifying the EU “borderline” food additives?

As concluded in the previous section, the specialty food ingredients industry may have the opportunity for developing a guidance document for the classification of EU borderline food additives due to the shared interest from the EU Commission.

Nonetheless, for the elaboration of a guidance document, it is crucial to understand first the conditions and principles in which the EU borderline food additives behaves. This means, according to the developed definition from Section II:

(i) How exactly the “grey-areas” sizes are from the food additive’s definition in which the substance can fall into.

(ii) Which are the conditions for classifying the substance into a FA or a non-FA (as PA, FE, NF, FG, NU or FL)

(iii) Which is the classification’s rationale used by the SCFAFF and how it can be based on legislation.

And finally, if among the studies from (i) to (iii) it is possible to visualize “patterns”, to formulate and propose principles on their regulatory behaviour.

5.1. Deep-analysis of the grey areas sizes from the food additive’s definition

The grey-areas identified from the food additive’s definition in Section III are the following ones:

1. “not normally consumed as a food in itself and not normally used as a characteristic ingredient of food”
2. “in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food”
3. “results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”
4. “(ii) 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;”

For figuring out how their sizes are, it is important to search on their related literature – among these literature, the predecessors of the food additive’s legislation depicted in Section II- in order to find hints or guidance on how to interpret these grey-areas, and if possible, to narrow them.

5.1.1. Grey Area Nº1: “Not normally consumed as food”

It was discussed about how the definition by itself is not able to make a “clear cut” between what is normally consumed as food and what is not. The way on how this statement is formulated can bring the research to question itself about how this phrase could emerge into the current regulation.

The history of this phrase does not limit itself to the current Regulation (EC) No 1333/2008 or its predecessor the Directive 89/107/EEC, it actually comes from the Codex Alimentarius Commission (CAC). The Codex Alimentarius Commission (CAC) is the body created by both the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) in the 1960’s, which during the years became the single most important international reference point in terms of foods standards (Codex Secretariat FAO, 2006). Between the years 1965-1973 (CAC, 1965, 1968-1970, 1972-1973), the Codex Committee on Food Additives (CCFA) from the Codex Alimentarius Commission was engaged on developing a definition for food additives, and around those years there were already discussions about whether some substances should be considered as ingredients or food additives (i.e. monosodium glutamate) or issues like considering including food ingredients within the guidelines on
food additives (CAC, 1968). The designed definition, and the one which is still in force (Codex Alimentarius, 2016) is described as follows:

“For the purposes of the Codex Alimentarius “food additive” means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods. The term does not include “contaminants”(i) or substances added to food for maintaining or improving nutritional qualities.”

Despite of this achievement, the real discussion took place in their 20th meeting (CAC, 1988) when the CCFA was working on establishing the International Number System (INS) for identifying food additives for food labelling purposes (similarly to the E-number system in EU). In this point, the CCFA found difficult to identify by the definition which substances should be considered as such for being included on the INS. As a consequence, the Secretariat of the CCFA elaborated a paper named CX/FAC 89/21 “Interpretation of the Codex definition of Food Additives – Certain Foods considered as Foods or Food Ingredients” (CAC, 1989c). In this paper, the committee concluded that the decision whether a substance should be considered a food or food additive depends on consumptions patterns, which varies from country to country; consequently, every case should be considered separately. Due to this reason, they also indicated that the elaboration of a guideline on this matter was not possible.

As it could be depicted, the origins of this phrase only limit itself to reinforce its subjective characteristic. And until today, there is no other supporting document bringing further approaches, leaving this grey gap to remain intact.

5.1.2. Grey Area Nº2: “Where the technological purpose takes place”

Regarding this grey-area, the problem lays on the openness of where the technological purpose has effect along the food-value chain. The definition scopes the manufacture, processing, preparation, treatment, packaging, transport or storage; however, in practice substances like food enzymes are mainly not considered as food additives, just with the exemption of Invertase (E1103) and Lysozyme (E1105).

Back to Codex Alimentarius -as the origins of the current EU definition-, food enzymes were a matter of discussion for considering them or not as food additives (CAC, 1977-1978). This issue was addressed within the context of the elaboration of a new category of substances used in food production called “processing aids”. Substances that in practice play different roles on food industry such as food safety enhancers by reducing potential contamination in food during processing (antimicrobials), facilitating agents for easier removal of impurities (flocculants), as pH control agent, as catalysts, or clarifying agents between other functions (IFIC, 2017).

The working group on this committee (CAC, 1977) defined those substances – which terms remain unchanged within the current document CAC/GL 75-2010 “Guidelines on Substances used as Processing Aids” (Codex Alimentarius, 2010)- in that meeting as follows:

“A processing aid is a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product”.

The important fact on this codex discussion was that, this same working group considered those substances being already included as food additives by definition, and a separate definition was needed mainly for specifying these substances. This close relationship between them (food additives and processing aids) was evidenced years later during the committee’s task for making an inventory of processing aids. The related working group of this committee stated that many food additives were also used as processing aids within the meaning of the definition (CAC, 1989a), fact that still can be confirmed nowadays on the latest version of this proposed inventory (CAC, 2013). For example, one of the substances involved in this processing aid’s inventory is Sodium Carbonate, which is listed as an agent for treating boiler water, but at the same time considered as a codex food additive INS 500(i). Within the context of water treatment for food production, this substance avoid the formation of Calcium
sulphate, responsible of deposits formation on water (GE, 2017), but at the same time, within the context of food formulation of many product categories, it performs the role of a food additive with the function of “alkali” (JECFA, 2002) (Codex Alimentarius, 2016).

In the EU, a similar definition to codex for processing aids is established at the Regulation (EC) No 1333/2008 on its Article 3, paragraph 2b. Both definitions are compared in the following Table 8:

<table>
<thead>
<tr>
<th>Food additive’s definition</th>
<th>Processing aid’s definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>“food additive’ shall mean 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…”</td>
<td>‘processing aid’ shall mean any substance which: (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;”</td>
</tr>
</tbody>
</table>

The only substantial differences –in terms of technological functions as highlighted in Table 8- between processing aids and food additives are, first, processing aids limit their technological effect on the treatment or processing of the food, instead of reaching the final product as the food additives, and second, the processing aids showing themselves as unavoidable residues (difference that will be analysed in the next section).

Additionally, the same Regulation (EC) No 1333/2008 on its numeral 6 support the technological effect’s limitation of processing aids by stating:

“Substances not consumed as food itself but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation."

By this moment, it is already clear that the processing aids, in contrast to the food additives, are substances that limit their technological effect until the final product, but not including it. However, for addressing the specific case of food enzymes, about the reason why all of them instead of Invertase (E1103) and Lysozyme (E1105) are included as food enzymes, a more recent document within the EU brings the specific explanation.

In 2014, the European Commission developed a guideline called “Guidance document on criteria for categorization of food enzymes” (EU Commission, 2014a). This document acknowledges that food enzymes like Invertase (E1103) and Lysozyme (E1104) are provisionally considered as food additives. This is stated due to the Article 2 par 3 from Regulation (EC) No 1333/2008 indicating that once an Union List of Food enzymes is adopted – which is currently under construction (EU Commission, 2016c)- both enzymes will stop being considered as food additives, and consequently, they will remain as food ingredients.

Later, the document proposes a decision tree –see Figure Nº 1- for defining whether a food enzyme will be considered as “processing aid” or an “ingredient” (considering “ingredients” as the final category of substances like Invertase (E1103) and Lysozyme (E1105) after the creation of the mentioned EU list). This decision tree is built under the following principles of the substance’s effect on the food (EU Commission, 2014a):

1. “Whether the food enzyme or its residues still perform a technological function in the food as marketed or as prepared by the consumer and thus creating an on-going effect”.

2. “If the food enzyme is no longer functioning after food processing but the effect remains on the food as marketed the categorisation of the food enzyme as an ingredient or as a processing aid is more difficult”.

Substances falling within the first principle are clearly used as ingredients, however, regarding the second one, the guidance brings a deeper approach for the categorization.
Finally, the guidelines show examples of the application of this decision tree by describing how substances apply as “food ingredients” or “processing aids”. It mentions the case of Invertase (E1103) in confectionary, being concluded as “food ingredient” due to it enzymatic reaction that performs along the storage of the product, the same as Glucose-Oxidase in bottle beverage by removing oxygen from headspace of bottle after sealing, and lastly, food enzymes considered as “processing aids” like Pectinases/hemicellulases in vegetable oil extraction, some food enzymes in bread and the same Glucose-oxidase but used in liquid egg in which effects only remain on the process because they end up being separated or destroyed during it.

As depicted in Figure 6, the document with its decision tree helps the applicant to reduce the existing uncertainty on food enzymes’ categorization between a “food ingredient” and “processing aid”. The remaining grey-area in this kind of substances locates for food enzymes that reaches the Question Nº6 of the decision-tree: Corresponding to food enzymes that are present in the final product and not as a carry-over component, not irreversibly denatured or degraded in the manufacture, processing or treatment and which tend not (or not enough) to perform a technological function in the food as marketed, or as prepared by consumers.

Additionally, the food enzyme’s situation remains coherent with the “processing aid” and “food additive” definitions by, first, stressing on the principle of performing or not an effect in the food as marketed, and second, considering the context of specific use for elaborating the classification. The document also brings examples following this decision-tree like the food enzymes on dough for bread mixes meant for home preparation, which results being considered as “ingredients” instead of “processing aids” because they are marketed as dough for the costumer, or the case of Glucose-oxidase which for bottled beverages is an “ingredient” but a “processing aids” for liquid eggs production. Nonetheless, by being
tested Invertase (E1103), Lysozyme (E1105) and Glucose-oxidase in the decision-tree and resulting all of them reaching the Question N°6 as "ingredients", it is not clear why the first two are "food additives" and the last one not. The current research can only suspect that by being Invertase (E1103) and Lysozyme (E1105) approved in 1998 and 1995 respectively as "food additives" (Directive 95/2/EC and 98/72/EC), the regulation (EC) No 1332/2008 -from 2008- could not address them. Furthermore, there is no reference of any other enzyme -apart from Invertase (E1103) and Lysozyme (E1105)- being submitted according to the European Data Base System (EU Commission, 2017c).

In conclusion, regarding where the technological purpose takes place on the product, the Codex Alimentarius and EU references suggest if substance's technological effect does not reach the final product, then the substance should be considered as a processing aid, otherwise it will be a food additive. It is important to clear out that this should be the expected outcome as long as the substance fulfills with the other conditions on the definition. And regarding the specific case of food enzymes, the grey-area is reduced up to the substances reaching negatively the Question N°6 of the related guidance document (see paragraphs above). About the specific cases of Invertase (E1103) and Lysozyme (E1105), this research suspects that, in principle, they should belong to the category of "food enzymes as ingredients" (instead of "food additives") according to the EU guidance document.

5.1.3. **Grey Area Nº3:** "The existence of remaining product or by-products"

By analysing the EU definitions of Food Additives vs. Processing Aids (see Table 9) –similar to the Table 8 but with different highlighting- both shows different points of view regarding the substance’s permanence in the final product.

<table>
<thead>
<tr>
<th>Food additive’s definition</th>
<th>Processing aid’s definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;food additive’ shall mean 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;...&quot;</td>
<td>&quot;processing aid’ shall mean any substance which: (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfill a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;&quot;</td>
</tr>
</tbody>
</table>

For food additives, the definition suggests the presence or expected presence of the substance or its by-products on the final product, meanwhile for processing aids; there is a lighter possibility for resulting it or its derivatives on the final product. Nonetheless, the processing aids add specific conditions for this situation: they should be present as 1) residues, 2) they should be unintentional but technically unavoidable and 3) do not present any health risk. From a grey-area perspective, a reflection can be performed on whether they are sources or not of them.

First, the fact of **"not presenting any health risk"** does not represent a grey-area between processing aids and food additives, because the health risk of the latters are also assessed according to the Article 1 of Regulation Nº 1331/2008:

> "This Regulation lays down a common procedure for the assessment and authorisation (hereinafter referred to as the common procedure) of food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs (hereinafter referred to as the substances), which contributes to the free movement of food within the Community and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests..."

Regarding the **"unintentional but technically unavoidable presence"**, the reflection of "unintentional addition", which the research made on Section III, relates to the principle of a consequent distorted effect on the final product’s organoleptic properties. Consequently, the permanence of that substance in the final product should not represent a positive effect on its properties. And the **"technically unavoidable presence"** should be sustained by the current existing food processing methods on the market. Therefore, this expression also does not bring a source of grey-area.
About the compared possibility of presence in the final product between food additives and processing aids, both implies the existence of technical arguments for supporting that presence: The first one by stating “reasonably expected to result” and the second one –literally- by “unintentional but technically unavoidable presence”. Nonetheless, this last one stress on the “unintentionally” and “unavoidability”, meaning those elements a substantial difference between the two definitions.

Finally, about the remaining expression “residue”, it is established by Oxford Dictionary (Oxford, 2017) as “A small amount of something that remains after the main part has gone or been taken or used” and supported by the secondary definition on “A substance that remains after a process such as combustion or evaporation”. Cambridge Dictionary (Cambridge, 2017) brings a similar but “consolidated” definition: “the part that is left after the main part has gone or been taken away, or a substance that remains after a chemical process such as evaporation”.

For bringing these definitions into context, it is relevant to reflect on the already mentioned ways on how processing aids works on food industry as: disinfecting agents (antimicrobials), removers of impurities (flocculants), pH controllers (acids & bases), as catalysts (enzymes) between other functions (IFIC, 2017). These substances result being (partially) removed, non-active anymore or being degraded during the food process. These are also the cases of proteins in wine for clarification (Marchal et al, 2002) being flocculated together with the yeasts and separated from wine by gravity, the use of sodium hypochlorite for vegetables disinfection (Nakanishi et al, 2013) with the consequent degradation of this substance into chlorine gas (OSU, 2011) or -the already mentioned at the beginning- food enzymes (Whitehurst & van Oort, 2010) for several reactions in food and undergoing denaturalization after exposure to high temperature, extreme pH or high salt concentrations in the production process. In other words, these substances are used for food processes in which main part has gone, been taken or used.

Nonetheless, by comparing with the processing aids, food additives also can experiment degradation. For example, “antioxidants” such as BHA (E320) and BHT (E321), Propyl gallate (E310), Tocopherols-rich extracts (E306), or Extracts of rosemary (E392) (Baines & Seal, 2012) progressively become consumed while they interact with food by protecting them from oxidation during the shelf-life, or the already mentioned carotenoids as “colours” (Carle & Schweiggert, 2016) in which factors like light, oxygen or temperature causes the formation of derivate compounds with less colour intensity. In this point, the formulated question could be: After a certain amount of time on the shelves, can it be considered that those remaining food additives are “residues” from the original amount added before product’s packaging? For instance, at the moment in which a consumer purchases a food product near the expiration day, it would contain only “residues” from the initial amount of those food additives.

In that sense, the expression of “residues” could apparently be considered as a grey-area between these two kinds of substances. However, by tanking into account the “intentional presence” and -the one from the last grey area- the “technological purpose in the final product”, this situation is completely solved: Substances like “antioxidants” and “colours” are meant to be present on the final product in comparison to processing aids, because of they still perform an effect on the final product. The remaining amount of “antioxidants” is still protecting the product during the shelf life, and the remaining “colours” in the product are perceivable to the consumer while purchasing.

As it could be described, the residues still performing a technological function on the final product makes the substance to be a food additive instead of a processing aid. Nevertheless, from this reflection, a remaining question is possible to be elaborated. Due to the limitations of the research, it could not be possible to confirm the existence of a processing aid remaining intact on the final product’s composition (and not as “residues”), in that case: Would it still be considered as a “processing aid”? Yes, the argument for keep considering this processing aid as such will come by confirming that the substance - despite of being present in the original amounts- does not perform a technological function on the final product. Additionally to this, the substance’s purpose on the process must be confirmed and despite of being present in the original amounts, the absence of health risk should be supported.

As a conclusion, the grey-area identified on the existence of the remaining substance or by-products from the food additive’s definition is eliminated by the establishment of the substance’s category of processing aids; because this last one states that although performing a role during the process, the remaining substances should not perform any technological effect on the final product, additionally to having an unintentional and technically unavoidable presence in the final product.
5.1.4. Grey Area Nº4: “Foods with aromatic/sapid/nutritive properties together with a secondary colouring effect”

Following up with the last identified source of grey area, substances belonging to this grey-area were already aimed back in time by previous regulations within the European Union. Their story began with the Council Directive of 23 October 1962 on “colouring matters”, which was oriented to establish an approved list on these substances under specific criteria of purity. Despite of not setting an actual definition on what a "colouring matter" was, but instead the directive on its Article 3 set paprika, turmeric, saffron and sandal-wood as examples on what it considers as "a substance used on foodstuffs because of their aromatic, sapid or nutritive properties with a subsidiary colouring property".

Nevertheless, It was not less than thirty years later that the European Union decided to define colours used in foodstuffs by the approval of the Council Directive 94/36/EC. In its article 2, the directive defined those substances as the ones adding or restoring colour in food, including natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food (as the current EU food additive’s definition does). Additionally, the directive included the concept of a “selective extraction” for considering preparations as “colours” (concept that is also present in recital (5) of the current Regulation (EC) No 1333/2008):

“Preparations obtained from foodstuffs and other 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 Directive.”

And lastly, this Directive 94/36/EC later on its article 3 also defines what was not considered as “colours”:

“Foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron...”.

Within those thirty years that occurred between the Council Directive of 23 October 1962 and Council Directive 94/36/EC, it is clear that three elements were introduced: the colour’s definition, the concept of "selective extraction" and the exclusion of aromatic/sapid/nutritive substances with a secondary colouring effect. Therefore, it is reasonable to expect that some events should happened between those thirty years letting the incubation of those three mentioned elements, which can bring hints for understanding this grey-area.

Within this range of time, the Codex Alimentarius Commission started to experiment discussions on cases related to these substances. In 1977 (CAC, 1977), the Committee on Fish and Fishery Products requested to the Committee on Food Additives their position on how the first one was dealing with some ingredients of processed fish products. In this request, the Committee on Fish and Fishery Products had been considering within the scope of their products that spices were food ingredients; meanwhile spice oils and extracts as food additives, matter in which the Committee on Food Additives agreed with. Nonetheless, it was not before 1989 on the already mentioned in a previous section the CX/FAC 89/21 “Interpretation of the Codex definition of Food Additives – Certain Foods considered as Foods or Food Ingredients” (CAC, 1989c) where the committee addressed properly this problem. Within this document, the secretariat collected both committee’s and its expert group (JECFA-Joint Expert Committee on Food Additives) views along the time on the matters involving their criteria for classifying these food extracts.

The collected views on possible factors determining a “food” or “food additive” status like the "degree of processing" which led this committee to classify Turmeric as food and processed Eucheuma seaweed as additive, a “type of use” exemplified by the beet-red (concentrate of juice from beet-root) which was considered as “food” in the context of colour enhancement for beet products meanwhile as a "food additive" when this concentrate was used as colorant for other food products, and finally the "concentration of vegetable juices" considered by the committee on leading the loss of naturalness and a consequent higher attention to the reactants involved on the related concentration process, conducted them to formulate the following consensus:

“When a substance normally consumed as food undergoes processing, such as preparation into different components, extraction and/or chemically modified substance is used for some technological purpose in a food other than that from which it is derived, the substance is a food additive rather than a food/food ingredient”.

\[\text{[Master	in	Food	Safety	Law:	Master	Thesis]}\]
In this point, the Codex Alimentarius Commission acknowledged the condition of food extracts as "food additives" in case their technological purpose differs from the original food. However, they did not specify further guides on how this extraction should be carried out. Due to this lack of further hints from the Codex Alimentarius Commission, the research consequently focuses on digging into current references in the EU.

Arriving back to the current EU Food additive's regulation, the document on its Annex I indicates what "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".

Statement that emulates -almost identically- it repealed Council Directive 94/36/EC. Additionally, this current Regulation (EC) No 1333/2008 on it recital 5 also took elements from the article 2 of the same repealed directive (and mentioned paragraphs above) to state its interpretation regarding food extracts:

"...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..."

This recital suggests that substances having the purpose of imparting flavour, taste or nutritional qualities into a food should not be considered as food additive. Later, it also mentions examples of foods that despite of playing technological functions should be also exempted from being food additives such as sodium chloride, saffron for colouring and food enzymes. And lastly, -the part coming from Council Directive 94/36/EC- substances resulting from a "selective extraction" of foods and other natural sources should be considered food additives if they are intended to bring a technological effect on the final product. Considering that this "selective extraction" must be relative to the nutrient or aromatic constituents, as also indicated previously in the Annex 1 on the same Regulation (EC) No 1333/2008.

Concerning this "selective extraction", it was not before 2013 that the document "Guidance notes on the classification of food extracts with colouring properties" (EU Commission, 2013) from the European Commission appeared to explain this concept with a more objective approach. This guidance of 2013 took these already mentioned interpretations from the recital (5) of Regulation (EC) No 1333/2008 plus a development on a selectivity criteria for creating a tool for facilitating the classification of those extracts into Food ("Colouring food") or Food additive ("Colour") which can be summarized on its own decision tree (Figure 7) showed as follows:
This decision tree uses the definition's exemption (a)(ii) as a question in the first step "Q1", later the nature of the source material whether it is a food or not based on the mentioned recital 5 as the second step "Q2", continuing with a third step "Q3" about whether the substance was a result of a selective extraction or not, and finally for "Q4" the substance is considered selectively extracted and recognizing in this moment the status of "food additive", the confirmation is requested on whether is an approved additive listed in the European Union (Regulation (EC) No 1333/2008) according to the requirements of specifications (Regulation (EC) No 231/2012). The possible outcomes of a substance through the decision tree can be a "Food or Flavouring", "Colouring food", "Approved Colour" and "Not approved Colour".

Within this decision-tree, "Q3" was the only step that required an extra argument not available from an interpretation of Regulation (EC) No 1333/2008 by needing a development of the criteria for a selective extraction. The developed selectivity criteria (depicted in Figure 8) establish a mathematical proportion between the pigment's concentration in the extract (primary extract) versus the concentration present in the source material. These calculations can be executed by two different methods: Based on nutritive constituents (Fn) and another on aromatic constituents (Ff), which the guideline named as "enrichment factors".

Figure 8. Enrichment Factor Ratios (EU Commission, 2013)
their classification first in Fn rather than Ff. This because Ff is related to aroma compounds, which can be present in the form of many different substances varying between food products causing the tests to be more specific (Reinhart, 2014). Nevertheless, the EU Commission considered the relevance of performing Ff in cases where there is a need for assessing the aroma compounds content on an extract (EU Commission, 2013). The guidance reminds the user that in case the extract from a food material stops retaining the same characteristics of the source material (such as colour, nutritive or aromatic properties) despite of not fulfilling with the selective extraction, the decision on whether the extract applies or not as a food additive ("Colour") will be analysed case by case according to a procedure depicted on the Article 19 (c) of the Regulation (EC) No 1333/2008 (EU Commission, 2013).

Nonetheless, it is relevant to reflect on whether this guidance document actually is answering the question on How to determine in a substance which property from an aromatic/sapid/nutritive or colouring is the primary or secondary one? By analysing the guidance document, it assumes that the question is straightforward to answer by only mentioning it as the first question "Q1" of the flowchart in Figure 7.

Reinhart (2014) on his article named "Colouring Foods versus Food Colours" also reflects on how this question ends up after this guidance document. On the Section 3 of his article about "Flavourings with secondary colouring effect", he proposes that this "Q1", on whether an extract has a primary or secondary colouring effect, should be done on a case-by-case basis. He exemplifies this idea by the case of a spinach extract:

"...If, for example, a spinach extract is used for a compound food because of its (primary) colouring effect (e.g. spinach extract in green fruit gums or in green candies) it is an extract with colouring properties which has to be classified by the Guidance notes on the classification of food extracts with colouring properties either as a Colouring Food or as an additive colour (approved or not approved within the EU).

If the spinach extract is used for a compound food because of its (primary) aromatic effect (e.g. spinach extract in a spinach soup) it is a flavouring with a secondary colouring effect and therefore outside the scope of Regulation (EC) No 1333/2008. In this case the spinach extract has to be designated as a flavouring (see Article 18, paras. 2, 4 + Annex VII, Part D of Reg. (EU) 1169/2011) and labelled accordingly..."

A small observation is worth to be done on this statement: Reinhart (2014) indicates in this quote that the second case (spinach extracts as flavouring) is the one not applying within the scope of Regulation (EC) No 1333/2008, however he is implying later that both "Colouring Food" and "Food Colours" are scoped within Regulation (EC) No 1333/2008. Nonetheless, it is important to clarify that a substance being a "colouring food" is not scoped by the Regulation (EC) No 1333/2008. This because the Article 2 of Regulation (EC) No 1333/2008, indicates that the regulation only applies to food additives. In fact, both the regulations and guidance document establishes the "Colouring Foods" not as food additives.

After making the observation and reflecting on his article, it is possible to perceive this guidance document as an accurate tool for classifying a colouring food extract on situations whether it is clear for the user that the extract has a primary colouring effect (in other words, a "YES" on the Q1 of the flowchart) for classifying it as a "Colouring Food" or "Colour", with only a blurry situation in which despite of the extract is not fulfilling with the selective extraction, it stops retaining anymore the same characteristics of their source material (explained in that section on cases in which both questions C1 and C2 are answered with "NO"). However, in terms of narrowing the initial grey area by clarifying the situations whether an aromatic/sapid/nutritive or colouring characteristic is predominant, Reinhart –by using the example of the spinach extract- only refers to a case-by-case analysis regarding the context in which this substance would be used.

5.1.5. Spin-off: "Foods with aromatic/sapid/nutritive properties together with a secondary technological effect"

As the title of this section suggests, this research will adapt the last definition’s grey-area into a broader situation: What if the word "colouring" is replaced by "technological"? In this way, the previous grey-area would expand into food extracts with all the other possible technological properties like preservation, emulsifying, antioxidants and others. Similar to the colouring food extracts, those dried/concentrated substances showing aromatic/sapid/nutritive properties with a secondary technological effect would be susceptible for being classified within food additives or other categories.
Substances performing technological functions like yeast extracts as flavour enhancers (by containing high amounts of glutamic acid and 5'-ribonucleotides), or extracts of sage, oregano or tea as antioxidants (due to the presence of phenolic compounds) that are already considered as foods, or substances like the monk fruit (*Siraitia grosvenorii*) working as a high potency sweetener which may enter to the EU after approval as a food additive or not (Baines & Seal, 2012) would be related within this additional definition’s grey-area.

Furthermore, and more relevant, within the current EU approved list there is a plant normally consumed as food and extracted for ending up being registered as a food additive due to its antioxidant properties on food: The Extract of Rosemary (E392). Its story started in 1998 and narrated by Baldwin (2011) explaining the use of a rosemary extract as antioxidant on food without any prior approval, which was detected by the French authorities. After a discussion between EU member states at the related standing committee (The Standing Committee on Foodstuffs), it was concluded that this substance was selectively extracted, deodorized and deliberately added for that technical purpose. Therefore the substance was declared as banned until a proper revision from the Scientific Committee of Foods (SCF) -the predecessor of the current European Food Safety Authority (EFSA) - could be performed. This decision triggered the reaction of producers in the UK who grouped together for setting a study aiming to identify a criterion for differing an “additive rosemary extract” from a “flavouring rosemary extract”. The outcome of this work was a criterion based on a ratio proportion of two characteristics substances on those extracts: carnosic acid and carnosol. However, a debate on the establishment of a threshold related to it took place within all the extract manufacturers, which ended up with the majority of them already satisfied after the agreed threshold allowed them to sell the extracts as flavourings without the food additive status. Nonetheless, the remaining four companies willing to have a product within this status worked together to prepare a dossier. The application started by a fully submission in 2001 to the SCF and finally obtaining an opinion from EFSA in 2008, which cause its approval on 2010 as a food additive by the Directive 2010/67/EU.

About this last illustrative example, it is possible to analyse it from the perspective of this spun off grey-area. Rosemary extracts have flavouring and antioxidant properties, but due to the context of use that was detected by the Standing Committee in Foodstuffs, it was established –for those uses- that the antioxidant property was predominant. Again, as the previous grey-area of foods with aromatic/sapid/nutritive properties together with a secondary colouring effect, this case is consequently similarly defined by a case-by-case analysis regarding the context in which this substance would be used.

The logic would also suggest the opportunity of adapting the “colouring food extracts” guidance notes on the classification of food extracts with technological properties. However, for supporting this idea, it is relevant to find evidences related to its practical and legal feasibility.

According to the recital 5 of the Regulation (EC) No 1333/2008, it allows food extracts for performing other types of technological effects rather than only colouring:

“...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...”

This statement brings openness to apply all functions by not only generalizing the type of effect as “technological”, but also establishing “pigments” as only one example of constituents that are matter of a selective extraction. As a consequence, this research considers that the recital could possibly work as a sort of “suggestion” from a legal perspective of this principle’s application for not being limited to colouring food extracts.

From a practical approach, the “extracts of rosemary” case shows a food extract aimed for a technological function on foodstuffs in which the criterion for defining a “cut” between its status of “food” or “additive” had to be developed entirely by the industry itself during those years. Nevertheless, the current research could contact Mr Baldwin himself who during those years performed the position of Secretariat for the European Rosemary Extract Producers Group throughout the approval process for these rosemary extracts (Baldwin, 2011). According to the communication of November 18th of 2016 (Annex V of this research), apart from confirming that during those years the Standing Committee of Foodstuffs lacked of any specific criteria for defining whether a substance was “selectively extracted,
deodorized and deliberately added for a technical function”, He explained that the “Guidance notes on the classification of food extracts with colouring properties” – document that appeared years later- shared the same principles with this rosemary extract case.

5.1.6. Final conclusions and comments from the research on grey-areas sizes from the food additive’s definition

After performing the literature research on the involved grey-areas, the obtained "sizes" are summarized in the following Table 10:

<table>
<thead>
<tr>
<th>Identified sources of definition’s grey-areas</th>
<th>Initial grey-area (Before research)</th>
<th>Relevant Research’s findings</th>
<th>Remaining grey-area (After research)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“… not normally consumed as a food in itself and not normally used as a characteristic ingredient of food…”</td>
<td>It does not specify a “clear cut” between what is and what is not normally consumed as food.</td>
<td>Codex Alimentarius Commission could not define objectively what is “not normally consumed as food”.</td>
<td>It remains unchanged. Narrowing was not possible.</td>
</tr>
<tr>
<td>“… in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food…”</td>
<td>Some substances that –apart from fulfilling the other food additive’s criteria- perform technological purposes as described are not considered as food additives.</td>
<td>Substances’ category of processing aids: Not having technological effect reaching the final product. Food enzymes are classified by EU guidance document into: Ingredients or Processing Aids.</td>
<td>Processing aids’ category eliminates grey-area. Exemption: Remaining grey-area on food enzymes reaching the EU Guidelines with a negative outcome in the Question Nº6.</td>
</tr>
<tr>
<td>“… results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods…”</td>
<td>Substances that also can be considered to remain in the product –apart from fulfilling the other food additive’s criteria- are not considered as food additives.</td>
<td>Substances’ category of processing aids: the residues do not have a technological effect reaching the final product.</td>
<td>Processing aids’ category eliminates grey-area.</td>
</tr>
<tr>
<td>“(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacture of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;”</td>
<td>Difficulties on defining whether the colouring effect is primary or secondary.</td>
<td>EU guidance document for classifying colouring food extracts into: “Food or flavouring”, “colouring food”, “approved colour” or “non-approved colour”. Reinhart (2014) as an author discussing this guidance document.</td>
<td>It remains unchanged. Narrowing was not possible. It is related to a case-by-case analysis on the context of use.</td>
</tr>
<tr>
<td>“(iii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacture of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary technological effect;”</td>
<td>Difficulties on defining whether the technological effect is primary or secondary. (Similar to the case above)</td>
<td>Baldwin (2011) explaining the history of the Rosemary Extract approval as E392.</td>
<td>It remains unchanged. Narrowing was not possible. It is related to a case-by-case analysis on the context of use.</td>
</tr>
</tbody>
</table>

From the table, it is possible to appreciate cases in which the grey area size is eliminated, reduced or remains unchanged from how it is stated on definition. Consequently, the resulting remaining grey-areas of the definitions involves the statement “not normally consumed as food”, which is “per se” subjective as indicated by Codex Alimentarius Commission, how to define a colouring/technological effect as primary or secondary which there is no further indications on literature nor legislation, and finally, food enzymes reaching negatively the question Nº6 of the decision-tree from its EU guidance document, because the EU Commission recognised themselves that the decision should be taken in a case-by-case basis.

5.2. Analysing the borderline conditions among the possible substance’s categories

The food additive’s regulation (EC) No 1333/2008 includes the interactions and borders that a “food additive” have with other substance categories as elaborated in Section III. Regarding these interactions, the regulation establishes them between the "food additive" status vs. one "non-food additive" status (PA, FE, NF, FG, NU or FL) as conceptualized in the following Figure 9:
Consequently, the strategy for addressing the borderline conditions among the substance’s categories - involving historical references and current guidance to legislation - will follow this concept.

5.2.1. Borderline conditions between Food Additives and Processing Aids

As defined in the previous Section 5.1, the main differences between a food additive and a processing aid is the “place” of the technological effect, not only performed by the initial substance added during the food manufacturing but also its residues or derivatives. The substance or its residues/derivatives playing a technological effect reaching the final product is a "food additive" and the one having only technological effect on the process a "processing aid".

Nonetheless, the research found an article entitled “Lysozyme: Just an additive or a technological aid as well” by Giangiacomo et al. (1992) in which it is proposed that Lysozyme in cheese place a role as a technological aid (processing aid) by shortening clotting time and allowing higher yields meanwhile having a recognized “food additive” effect on cheese’s preservation.

This article of Lysozyme in cheese brings the research to analyse whether a substance playing both roles (food additive and processing aid) will have to obtain also both regulatory statuses or end up with only one of them for this specific application (cheese).

As indicated in 4.1 about the regulatory outcomes, the difference between a food additive and a processing aid lies on the first one being conditioned to an approval procedure, restrictions of use, authority monitoring and labelling declaration on a food product (the processing aid only labelled in case it involves a declarable allergen). In case a substance playing the role of both food additive and processing aid would have to "hypothetically" choose for a processing aid as a unique regulatory status, it would involve an elimination of regulatory constrains carried by the status of a food additive.

However, by analysing the definitions of food additives and processing aids (see Tables 8 or 9 from the previous Section 5.1), the discussions is solved by the expression “and do not have any technological effect on the final product” from the processing aid’s definition. This expression excludes any possibility that a processing aid would perform a technological effect on the final product, and because the food additive’s definition involves a technological purpose "in the manufacture, processing, preparation, treatment, packaging, transport or storage", it also allows a food additive to be considered as performing an effect in both stages "in the process and final product" or solely "in the final product".

As a consequence, a substance performing both roles as food additive and processing aid (as the proposed example of the lysozyme in cheese), it actually would be performing only a role of a food additive with a type of effect involving both process and final product. It would not be considered as a processing aid, because the processing aid’s definition explicitly excludes any technological effect in the final product.

Therefore, the borderline between a processing aid and a food additive will be the principle of a "technological effect in the final product" and under the following conditions: If the substance performs only a technological effect in the process, it is a “processing aid”; otherwise if the substance performs a 1) technological effect in the final product or 2) a effect in the process plus an effect in the final product, it will be a “food additive”.

Figure 9. Visual concept on how the food additives in Regulation (EC) Nº 1333/2008 interact with other substance categories (PA, FE, NF, FG, NU or FL)
5.2.2. **Borderline conditions between Food Additives and Food Enzymes (that are not Processing Aids)**

As mentioned in the Section 5.1, the “Guidance document on criteria for categorization of food enzymes” (EU Commission, 2014a) allows the user to classify food enzymes into the categories of processing aids or “ingredients” (which implies “food additives” and “food enzymes” under the meaning of this research). In a section of this guidance document called “food enzymes in the EU”, it is explained that the only two food enzymes Invertase (E1103) and Lysozyme (E1105) considered as food additives will be no longer considered as such and transferred to the Community list on food enzymes once this one will be published.

Considering also that food enzymes are already being evaluated for elaborating such community list according to the document “Food enzyme applications submitted to the Commission within the legal deadline (from 11 September 2011 to 11 March 2015)” (EU Commission, 2016c), it is possible to contemplate the idea of no other future food enzymes are being considered to undergo a food additive’s authorization.

**Regarding these evidences, the borderline between food additives and food enzymes (that are not processing aids) is currently reduced to only Invertase (E1103) and Lysozyme (E1105) being considered as “food additives” until the food enzymes community list will be published.**

5.2.3. **Borderline conditions between Food Additives and Foods in general**

By analysing the legal basis of the EU borderline food additives in the Section III, it was noticed that both food additives and foods could perform a technological effect in a food product and the main difference between them was the characteristic of “not normally consumed as a food”. However, as it could be demonstrated in the last Section 5.1, this “not normally consumed as a food” characteristic was no further developed and its Codex Alimentarius Commission’ origins acknowledged the subjective nature on it.

Among these substance existing in the “not normally consumed as a food” blurry line between food additives and foods, the research found substances like, for example, the Plain Caramel (E150a) playing the role of food additive and food in products which classification was proposed by EUTECA (The European Technical Caramel Association mentioned in Section 4.3) in the document entitled “EUTECA decision-tree” (EUTECA, 2015). This document guides the caramel users (food manufacturers) to define whether the substance they are adding to their food products is a food additive (“Caramel colour I, E150a”) or a food (“burnt sugar”) as described in the flowchart in Figure 10:

![Figure 10. Flowchart for classifying food additive (“Caramel colour I, E150a”) or a food (“burnt sugar”) (EUTECA, 2015)](image-url)
ISO 4120:2004 “Sensory analysis – Methodology – Triangle Test”) to determine whether the caramel influences the overall food product’s taste. This flowchart proposes the production method (Q1) as a main decision to define the product as a food additive (“Caramel colour I, E150a”), and in case it does not have it, an existing influence of the caramel on the food product taste (Q2) will qualify it as a food (“burnt sugar”). EUTECA, in order to solve the classification problem, introduces the concepts of production method and sensory test as principles.

A special group of substances belonging also to this borderline between food additives and foods, are the technological food extracts that were identified in the last Section 5.1 of this research as “colouring food extracts” and their spin-off version, the “other food extracts with other technological functions than colouring”.

Regarding the colouring food extracts, they classify those substances into “colouring food” or “food colour” depending on the principles on whether the source material is a food, and whether the extraction is selective or not. This already explained decision-tree could effectively classify, for example the spirulina extract, an algae extract obtained from Arthospira platensis bringing a blue or green colour to their food applications (FAO, 2008). It was found that the resulting selective extraction of the spirulina (based on nutritive constituents) was around 1 – 2,4, making this extract to be classified as “colouring food” instead of a “colour” (a food additive) (Reinhart, 2014).

About these guidance notes on the classification of colouring food extracts, it is worth discussing about an article entitled: “Legislative update: how food colours are currently differentiated from colouring foods and how the EU legislative review might change this” from Romero & Di Mario (2014) on how these guidance notes solve the classification problem of the mentioned borderline substances. The relevance for discussion lies on how their authors conclude on the specific conditions in which this happens.

As a first conclusion, the authors state that “a characteristic food or food ingredient, which is traditionally used as such, will always be a colouring food, irrespective of the purpose for which it is added”. The authors could not specify in the conclusions whether the “characteristic food or food ingredient” that they mean is 1) the resulting "colouring food" or 2) "the source for obtaining a colouring food after extraction". This clarification is relevant because they mean two totally different statements. In case the authors mean the “characteristic food or food ingredient” as the resulting colouring food (1), then they would be correct because a “food colour” is a food additive, which by definition is “not normally consumed as a food”. However, in case they mean the “characteristic food or food ingredient” as "the source for obtaining a colouring after extraction" (2), then the authors would be obviating the situation of a potential selective extraction. According to the guidance note (see Figure 7 of the Section 5.1), this selective extraction would make the resulting extract to qualify as an “food additive” - despite of coming from a characteristic food traditionally used as such as proposed- that in case it is not already been listed as such in the Regulation (EC) No 1333/2008, it should undergo an authorization before using it.

The second conclusion about "a substance which is not used as a characteristic food or food ingredient and which - at the same time - serves a colouring purpose needs to be considered as a food colour, thus requiring an EU approval in order to be marketed", has the same treatment as the first conclusion. In case the authors refers the “substance not being a characteristic food or food ingredient having colouring purpose” as the resulting “food colour”, they would be right because the guidance notes decision tree (Figure 7) directly qualifies it as a “food additive” by leading the substance from Q2 to Q4. On the other hand, in case the authors refer a “substance not being a characteristic food or food ingredient having colouring purpose” as the “source for obtaining a food colour after extraction”, this statement would be excluding the possibility of having a “food source” producing a “food colour”. Furthermore, the guidance notes on its last part Annex IV describes as an example the situation in which a carrot root extract would be considered an "colouring food" or "food colour" whether they fulfills or not with the selective extraction.

Finally, the authors indicate as third and forth conclusions that "any extract with a threshold value for selective extraction >6 would need the EU-wide authorization" and “irrespective of the scientific soundness of choosing a particular quantitative threshold for the demarcation of borderline cases, such a clear-cut demarcation tool will provide with legal certainty in most cases and, thus, should be welcomed". Both statements describe the nature of the proposed “selective extraction”, the first one refers to the consequences of an food extract having a factor >6 and already depicted on the Figure 7 of
this research, on the second one, the expression “legal certainty in most cases” would refer the only limitations in which the substance stop having the same characteristics of the food source despite of not fulfilling the “selective extraction”. Nevertheless, it is important to mention that the whole decision-tree “per se” do not create a clear-cut, because before applying the selective criteria in “Q3”, the user have to deal with “how to define a colouring/technological effect as primary or secondary” in “Q1” and then with the “not normally consumed as food” in “Q2” (in the shape of whether or not the source material is normally consumed as food within EU), which are two grey-areas defined in previous Section 5.1. The only situations in which answering the question “Q2” would be irrelevant are when the extract will overpass the “selective criteria”, making it automatically a “food additive” (approved or needing approval).

As described in paragraph above, this research considers that Romero & Di Mario (2014) needs to clarify most of their conclusions. Nevertheless those were helpful for reflecting and depicting on specific outcomes possible to obtain from the guidance notes on colouring food extracts.

Despite of already depicting in the current and previous sections about the effectiveness of the guidance notes on colouring food extracts for classifying substances into “colouring food” and “food colours”, it is still not clear on how to address the first question of the related decision-tree: how to determine that the aromatic/sapid/nutritive properties or the colouring effect of an extract is the primary or secondary reason for being incorporated during food manufacturing. The previous case of the caramel classification by EUTECA proposes the use of a blind test under the ISO standard: ISO 4120:2004 for identifying whether the taste is the main effect (over the colour) that the caramel bring to the food product, which would result into a appropriate proposal –despite of being elaborated by the private sector- for approaching the predominance of the effect on the colouring food extracts.

Regarding the other technological food extracts (reminding that “colouring” is one type of technological function), the previous Section 5.1 described the point of view of Mr Baldwin (2011) on the rosemary extract approval as food additive “E392”. By being the Extracts of Rosemary (E392) a food extract for performing an antioxidant function on fatty foods, it suits perfectly within the group of technological food extracts.

Mr Baldwin (2011) on his communication of November 18th of 2016 (Annex V of this document) indicated that the rosemary extract’s classification as food additive showed the same principles as the guidance notes on colouring food extracts. Nonetheless, by simulating the classification of the rosemary’s extracts through the guidance notes’ decision-tree, it is possible to realise the selective extraction criteria (Q3) as a potential incompatible step for non-colouring extracts. The current extraction criteria was exclusively designed from colouring food materials like alfalfa, carrot, grape, spirulina, spinach, tomato among others, as depicted in the technical report of the Joint Research Centre from the EU Commission entitled “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) No 1333/2008) or colouring foods” (EU Commission, 2015). For using of the current selective criteria on a non-colouring food extract, confirming its “applicability” would be necessary; otherwise it would be appropriate to develop another selective criteria for non-colouring food extracts.

Nevertheless, considering that the rosemary extract was approved as a food additive by developing first a proposal of specifications within the food industry for differing the "food additive" extract version from the “food” extract version, it would be also another solution for classifying the technological food extracts. The only difference between the “specifications” and the “guidance notes” strategies will be that in the “guidance notes” strategies, by establishing a “selective criteria” for classifying technological food extracts, the outcomes would be 1) “food or flavouring”, 2) “technological food” (instead of “colouring food”) or 3) “food additive”, making possible that the extracts falling into the last two categories “technological food” and “food additives” are allowed primarily for technological purposes. On the other hand, in the “specifications” strategy, by establishing specifications for the “food additive” version of the extract instead of using a “selective criteria”, the concept of a “technological food” would not exist anymore; leaving the classification into only two options, the 1) “food or flavouring” and the 2) “food additive”. Consequently, it would only allow the extracts falling into the “food additive” category to perform a primary technological effect on the food product; conclusion that Mr Baldwin also considers on his article on how of the rosemary extract was approved as food additive: "...What this means is that where rosemary extracts are added primarily as an antioxidant, this can only be done legally if you meet the specifications laid down in the Regulation".
Lastly, as the same way of the colouring food extracts, the classification of other technological food extracts would also have to face the problem on how to determine that the aromatic/sapid/nutritive properties or the technological effect of an extract is the primary or secondary reason for being incorporated during food manufacturing. However, for a technological food extract classified solely by a food additive’s specification, it would not experiment this problem because the specifications (as depicted in the rosemary extract approval) would define the predominant use of the extract.

For concluding on the depicted cases, the borderline conditions between food additives and “foods in general” (which in the current research are foods not including PAs, FE, NF, NUs, and FLS) are mainly defined by the blurry expression of “not normally consumed as food” coming from Codex Alimentarius Commission in which there no exist further guidelines applicable to it (grey-area that remained on the previous section 5.1).

Nonetheless, within these substances, the ones presenting aromatic/sapid/nutritive properties together with a colouring effect are currently possessing guidance in only the following two cases:

- For caramel colours, a proposal from the association EUTECA based on the use of sensory tests for classification among the flavouring or technological effect.
- For colouring food extracts, under the use of a selective criteria for their extraction. However, the limitation of this colouring food extracts relies on the current lack of guidance for defining on which of the aromatic/sapid/nutritive property or technological effect is primary or secondary as “Q1” (also a grey-area that remained on the previous section 5.1), and in cases in which the “selective criteria will not be >6, with the “Not normally consumed as food “ in “Q2”, differing in this way from the caramel colours situation.

Consequently, for these substances having aromatic/sapid/nutritive properties together with a colouring effect, the capacity for defining the “predominant effect” is crucial, in which the proposal of applying a sensory test is worth to be further evaluated by the authority.

And finally, from the technological food extracts (the spin-off version of the colouring food extracts), the conditions for their classification would be the use of a “selective extraction criteria” similarly to the colouring food extracts, or establishing “specifications” as explained with the Extracts of Rosemary (E392). The latter presents the advantage of not having to deal with decisions on “Q1” and “Q2”, because these specifications automatically divides the “food” extracts from the “additive” extracts.

5.2.4. Borderline conditions between Food Additives and Novel Foods

As defined in regulations (EC) No 258/97 and (EU) No 2015/2283, “Novel Foods” differ from “Foods in General” by not being consumed into a significant degree within the EU before 15 May 1997, therefore addressing their borderline conditions with food additives should be a straightforward application of the previous section (FA vs. FG) with only considering the date of the substance’s introduction into the EU as an additional aspect. However, there exist additional particularities in this borderline worth for mentioning and developing in the current section.

Everything began in the same 20th meeting (CAC, 1988) of the Codex Committee on Food Additives and Contaminants (CCFAC) from the Codex Alimentarius Commission, in which the revision of the food additives’ definition was requested. In the paragraph number 180 of that meeting’s minute, it was indicated that the Netherlands informed the Committee about the existence of substances consequence of developments on the area of nutrition and biotechnology (such as fat and sugar replacers during that time) and agreed to prepare a paper for the Committee for the next meeting. The paper presented was entitled CX/FAC 89/19 “Novel food constituents in relation to the codex definitions of food and food additive” (CAC, 1989b) and introduced officially for the first time the term “novel food”.

This paper CX/FAC 89/19, apart from shaping the EU definition of “novel food” by proposing them as “foods or food ingredients produced from sources of microbial, plant or plant origin, which foods or ingredients have hitherto been used for human consumption or which have been consumed in only small amounts”, it also acknowledged their possible classification - in that time - as “foods” or “food additives”.

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This closeness between “novel foods” and “food additives” was even clearer by the already mentioned paper CX/FAC 89/21 "Interpretation of the Codex definition of Food Additives – Certain Foods considered as Foods or Food Ingredients" (CAC, 1989c), which together with the CX/FAC 89/19 were meant to be discussed on the next 21st meeting of the CCFAC. The paper CX/FAC 89/21, apart from debating on the food additive’s definition, it mentioned on its paragraph 11 about certain substances traditionally identified as “food additives” starting to be used as major components of new foods on confectionary exceeding the 95% on dry weight basis and brought the example of Sorbitol (E420) and other polyols, and Xanthan (E415) and other gums. The Committee in this paper acknowledged (paragraph 13) that in both cases, the substances no longer fulfilled their technological functions by being present as a major component in the food and further considered interpreting those situations as dealing with “new foods” (paragraph 14).

This interpretation of a “food additive being considered as a novel food” led the research to dig into the whole list of Novel foods being currently approved in the EU (EU Commission, 2017) and found the following food additives approved as novel foods:

<table>
<thead>
<tr>
<th>No</th>
<th>Year</th>
<th>Substance</th>
<th>EU decision</th>
<th>Country of application’s submission</th>
<th>Applicant Company</th>
<th>Food additive’s characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2006</td>
<td>Lycopene from Blakeslea trispora</td>
<td>2006/721/EC</td>
<td>United Kingdom</td>
<td>Vitatene Antibiotics SAU</td>
<td>Food additive E160d(iii) in the EU.</td>
</tr>
<tr>
<td>2</td>
<td>2009</td>
<td>Lycopene</td>
<td>2009/348/EC</td>
<td>The Netherlands</td>
<td>BASF</td>
<td>Food additive E160d in the EU.</td>
</tr>
<tr>
<td>3</td>
<td>2009</td>
<td>Lycopene</td>
<td>2009/362/EC</td>
<td>Ireland</td>
<td>DSM Nutritional Products Ltd.</td>
<td>Food additive E160d in the EU.</td>
</tr>
<tr>
<td>4</td>
<td>2009</td>
<td>Lycopene from Blakeslea trispora</td>
<td>2009/365/EC</td>
<td>United Kingdom</td>
<td>Vitatene</td>
<td>Food additive E160d(ii) in the EU.</td>
</tr>
<tr>
<td>5</td>
<td>2009</td>
<td>Lycopene oleoresin</td>
<td>2009/355/EC</td>
<td>United Kingdom</td>
<td>Ottaway &amp; Associates Ltd</td>
<td>Food additive E160d(ii) in the EU.</td>
</tr>
<tr>
<td>6</td>
<td>2013</td>
<td>Synthetic zeaxanthin</td>
<td>2013/49/EU</td>
<td>The Netherlands</td>
<td>DSM Nutritional Products VML</td>
<td>A food additive recognised by Codex Alimentarius (2017) as INS 1512(i). In EU, it could fulfil the requirements of a food additive.</td>
</tr>
</tbody>
</table>

The purposes of approving those substances as novel foods are due to their health effects marketed by their applicants, such as the Zeaxanthin as food supplement having an antioxidant role on protecting the retina and lens (DSM, 2017a) and the Lycopene by preventing of heart diseases and as antioxidant by protecting the body from free radicals (DSM, 2017b).

By analysing the every single of these EU Commission’s decision authorizing those substances as novel foods, there were always and statement excluding the approval of those substances for technological purposes (colouring):

<table>
<thead>
<tr>
<th>Substance</th>
<th>EU Decision</th>
<th>Statement on technological effect’s exclusion from the granted Novel food authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lycopene</td>
<td>2009/348/EC</td>
<td>“…However, this requirement under the present Decision, applies to the use of lycopene as a novel food ingredient and not to the use of lycopene as a food colour, that falls within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.”</td>
</tr>
<tr>
<td>Lycopene</td>
<td>2009/362/EC</td>
<td>“…However, this requirement under the present Decision, applies to the use of lycopene as a novel food ingredient and not to the use of lycopene as a food colour, that falls within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.”</td>
</tr>
<tr>
<td>Lycopene from Blakeslea trispora</td>
<td>2009/365/EC</td>
<td>“…However, this requirement under the present Decision, applies to the use of lycopene as a novel food ingredient and not to the use of lycopene as a food colour, that falls within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.”</td>
</tr>
<tr>
<td>Lycopene oleoresin</td>
<td>2009/355/EC</td>
<td>“…However, this requirement under the present Decision, applies to the use of lycopene as a novel food ingredient and not to the use of lycopene as a food colour, that falls within the scope of Council Directive...”</td>
</tr>
</tbody>
</table>
As a conclusion for the borderline conditions between the food additives and novel foods, evidencing the main purpose of the substance.

Claimed.

This regulation refers that the food manufacturer would like to communicate on the product’s label.

Additionally to the conditions for authorisation, there exist other substances with the potential of playing technological purposes on food products, such as Isomaltulose (Decision 2005/581/EC) like sweetener (O’Donnell and Kearsley, 2012), Trehalose (Decision 2001/721/EC) also like sweetener (Ohtake and Wang, 2011) or Ice Structuring Protein Type III HPLC 12 as a processing aid (Decision 2009/344/EC) between others. However, those substances cannot be considered as food additives under the EU legislation, because they belong to the listed exemptions from the food additive’s definition or they belong specifically to other substances categories.

Despite of being clearly defined that food additives being approved under novel food authorizations do not scope their technological functions, it is also thinkable that by using them for “novel food” purposes, at the same time, they would be creating a technological effect on the food product, i.e. colouring.

Under that scenario, establishing the “predominant effect” -which was needed in the previous section for the borderline of food additives with foods in general- between the novel food purpose and the technological effect would be needed.

As a starting point, it is relevant to acknowledge that the novel food authorizations on these substances in Tables 11 and 12 established 1) a specific purity criteria, 2) maximum level of use in specified food categories and even 3) specifications on how to label the substance in foodstuffs. Those three conditions would make this substance to differ from their food additive’s version from the “novel food” version in case it possesses both types of authorizations. For example, there would be the possibility that the substance is allowed for being added as “novel food” in certain food categories and levels differently than its addition as a “food additive”. Moreover, for the consumer it would be easier to determine the predominant function of the substance by reading on the food product’s labelling: the mentioned food additive’s authorised as novel foods are requested for being labelled without the use of their E-numbers.

Additionally to the conditions for authorization, in case the novel food posses a positive health’s effect that the food manufacturer would like to communicate on the product’s label, then the Article 5(1) of Regulation (EC) No 1924/2006 on nutritional and health claims establishes the related conditions:

“(b) the nutrient or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or

(ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; ...

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;”

This regulation refers as “significant quantity” to a substance’s minimal amount in the product -and in the reasonably expected quantity to be consumed- able to produce the nutritional/physiological effect claimed. Apart from a possible claim on the food product, this “significant quantity” could also differ from the substance’s quantity for producing a desired technological effect on a product and in this way evidencing the main purpose of the substance.

As a conclusion for the borderline conditions between the food additives and novel foods, it can be implied that in case a substance is approved as a “novel food”, such approval will not
cover its uses as a “food additive” in case of existing (i.e. Lycopene), or with the potential to exist (i.e. Zeaxanthin). In other words, by authorizing its use under this scheme, the substance is recognised as “not being used as food additive” for the specified applications. Consequently, in a specific application of the substance, one category disables the existence of the other one, meaning the need of setting a “predominance” between a technological function and another effect (being exemplified in this case by a “health effect”).

For substances having both types of authorizations, setting the “predominance” would result straightforward to perform; the related conditions (purity criteria, food category & levels and labelling requirements) helps to identify which is the “predominant purpose”. However, for other situations, the “significant quantity” for a nutritional/physiological effect should be taken into consideration for identifying the existence of a “health effect”.

5.2.5. **Borderline conditions between Food Additives and Nutrients**

The relationship between food additives and nutrients was clarified at the first time by the Codex Alimentarius Commission at the Codex Committee on Food Additives (CCFA) on its 17th meeting (CAC, 1984). On the paragraph 40 of the meeting’s minute, the Committee confirmed that substances, which were nutrients “per se”, were not included in the definition of food additives. The only previous statement regarding this topic within the codex was the already mentioned codex food additive definition elaborated during the years 1965-1973 (and still in force) establishing that a food additive, “whether or not it has nutritive value”, is intentionally added for technological purposes in food products. By connecting the two statements, for codex it is acceptable the existence of food additives with nutritional value, but not nutrients “per se”.

Within the EU context, the definition on food additive is a “descendant” from the Codex definition (as elaborated on the Section 5.1.), implying in the same way the possibility of a food additive on having nutritional value within the EU context. Nonetheless, in comparison to codex, there exist an additional element in the EU legislation coming from the recital (5) from the Regulation (EC) No 1333/2008 clarifying this relationship between a nutrient and a food additive in a better way than the codex:

> “...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.”

By contrasting the EU food additive’s definition suggesting the possibility of existing food additives with “nutritional value” (“whether or not it has nutritive value”) against this recital (5) that eliminates a food additive to be considered as such in case performing a “nutritional purpose”, **It is possible to conclude that the substance’s “nutritional intentionalty” (purpose) within a food product is the one defining its categorization as a “non-food additive” substance instead of its nutritional value. Furthermore, in terms of effect’s predominance, this recital indicates the clear position of the nutritional purpose over the “food additive” one. Meaning that in case it is identified that the substance is performing a nutritional purpose no matter of an existing parallel technological effect, the substance should be considered a nutrient.**

From this point it is clear to split the analysis into two objectives, first, addressing the existing substances possible for being food additives and nutrients, and second, assessing the ways on how to determine an existing nutritional purpose within a “food additive” use of a substance.

For the first objective, by taking into consideration the definition of “nutrients” as defined in Article 2(2)(s) of Regulation (EC) No 1169/2011 on food information to consumers: “…protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in point 1 of Part A of Annex XIII to this Regulation, and substances which belong to or are components of one of those categories”, and comparing the existing lists of approved food additives (Regulation (EC) No 1333/2008) versus the approved nutrients indicated on the five pieces of legislation involving nutrients (Directive 2006/141/EC, Directive 2006/125/EC, Regulation (EC) No 953/2009, Directive 2002/46/EC and Regulation (EC) No 1925/2006) referred on the “ADMINISTRATIVE GUIDANCE ON SUBMISSIONS FOR SAFETY EVALUATION OF SUBSTANCES ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN THE MANUFACTURE OF FOODS” (EU Commission, 2004), the current substances being able to perform both food additive and nutrient functions are depicted as follows:
As VITAMIN C: L-ascorbic (E300), acid sodium-L-ascorbate (E301), calcium-L-ascorbate (E302), and L-ascorbyl 6-palmitate (E304ii)

As VITAMIN B2: Riboflavin (E101i), riboflavin 5′-phosphate, sodium (E101ii)

As VITAMIN E: DL-alpha-tocopherol (E307)

As described in all those five pieces of legislation, the purity criteria of those substances should fulfil with the requirements provided on Community legislation. Regarding this point, the nearest document defining those substances is the Regulation (EC) No 231/2012 on food additive's specification. Therefore the purity criteria are not obstacle for food additives in order to perform as nutrients.

And for the second objective, for spotting this nutritional purpose within the food product from a "seeming" food additive's use of the substance, the differences on their regulatory conditions may help on this process. As a first difference, similarly to the previous case of novel foods vs. food additives, the food categories for the substance's use as a food additive (Regulation (EC) No 1333/2008) would differ from the allowed ones as nutrients (Directive 2006/141/EC, Directive 2006/125/EC, Regulation (EC) No 953/2009, Directive 2002/46/EC and Regulation (EC) No 1925/2006).

Later, in comparison to food additives, nutrients are conditioned for being added up to a maximum amount but also to fulfil a minimum one. For instance, the Regulation (EC) No 1925/2006 on the addition of vitamins and minerals to food establishes that the total amounts of vitamins/minerals present (naturally present plus added amounts) must not exceed maximum established amounts (Article 6(1)), however, at the same time it establishes that the addition shall result into the presence of a "significant amount" within the food product (Article 6(6)).

Regarding this "significant amount", it is referred in this Regulation (EC) No 1925/2006 on its Article 6(6) to the Directive 90/496/EEC, which is the repealed directive from the current Regulation (EC) No 1169/2011 on food information to consumers. The Regulation (EC) No 1169/2011 on its Annex III sets the meaning of "significant amounts" for vitamins and minerals:

"2. Significant amount of vitamins and minerals

As a rule, the following values should be taken into consideration in deciding what constitutes a significant amount:

— 15 % of the nutrient reference values specified in point 1 supplied by 100 g or 100 ml in the case of products other than beverages,
— 7.5 % of the nutrient reference values specified in point 1 supplied by 100 ml in the case of beverages, or,
— 15 % of the nutrient reference values specified in point 1 per portion if the package contains only a single portion,"

These "significant amounts" for vitamins and minerals allow them to be declared on the nutritional labelling on food products (Article 30(1) of Regulation (EC) No 1169/2011) as follow:

"The mandatory nutrition declaration shall include the following: ...(f) any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII."

Addressing the "significant amounts" of other nutrients apart from vitamins/minerals (i.e. proteins, fats, fibre, etc.) -which at the present do not involve any existing food additives- is only available within the context of nutritional claims (Annex from Regulation (EC) No 1925/2006) like, for example, a requirement of a min of 20 % from the total energy of a food shall be proteins to claim it as "High Protein", or 3 g of fibre on 100 g of product (or 1.5 g per 100 kcal) to state "Source of Fibre", and also vitamins and minerals (which "significant amounts" for nutritional labelling allow them for nutritional claiming as "Source of -mineral/vitamin name-"), among others. These amounts allowing nutritional claims are also "significant amounts" according to the Article 5(1) of the same Regulation (EC) No 1924/2006 (see previous discussion on "Borderline conditions between Food additives and Novel foods").

The resulting borderline conditions between food additives and nutrients are allowed by the following three aspects:

1) The existing overlapped substances between the lists of food additives and nutrients within the EU legislation;
2) A shared purity criteria meaning that both food additive and nutrient lists are referring to the same substance;

3) And finally, the existence of a substance’s nutritional purpose (“nutritional intentionality” instead of “nutritional value”) on the food product which eliminates the option for a food additive classification, according to recital (5) of regulation No 1333/2008.

For this last aspect (3), the nutritional purpose can be identified by the differences on regulatory conditions like: 1) food categories in which the substance is applied and the levels of use and 2) by bringing special attention to the existence of “significant amounts” present in the nutrients which can be manifested by the nutritional labelling and/or claiming.

5.2.6. Borderline conditions between Food Additives and Flavourings

The very first discussion surrounding the identity of flavourings whether they are food additives or not took place in the “Ad-hoc” working group on flavourings from the CCFA committee from the Codex Alimentarius Commission (CAC, 1977). This “Ad-hoc” working group presented a report to the Committee during their 11th meeting including among other topics in agenda related to flavourings-their views regarding the considerations of flavourings as food additives.

The working group considered that the concept of “food additive” was not suitable for flavouring substances consisting of extracts of plant parts (natural flavours), single substances isolated from these extracts, natural flavouring substances and the synthetic equivalents of the latter (nature-identical flavouring substances). Therefore, the working group supported the idea of treating some flavourings as food additives instead of introducing the concept of flavourings as a type of food additives.

This tendency is reflected nowadays on the EU legislation concerning the Article 2(e) from Regulation No 1333/2008 as depicted in Section 3.2 (“Legal basis Nº2”):

“2. This Regulation shall not apply to the following substances unless they are used as food additives:
(a) processing aids;
(b) substances used for the protection of plants and plant products in accordance with Community rules relating to plant health;
(c) substances added to foods as nutrients;
(d) substances used for the treatment of water for human consumption falling within the scope of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (2);
(e) flavourings falling within the scope of Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods].”

According to this article, the substances applying as “flavourings” from the Regulation (EC) No 1334/2008 are the ones that can play the role of “food additives”. This regulation (EC) No 1334/2008 on its article 1 classifies these substances into four categories, being “flavourings” only one of them:

“1. This Regulation shall apply to:
(a) flavourings which are used or intended to be used in or on foods, without prejudice to more specific provisions laid down in Regulation (EC) No 2065/2003;
(b) food ingredients with flavouring properties;
(c) food containing flavourings and/or food ingredients with flavouring properties;
(d) source materials for flavourings and/or source materials for food ingredients with flavouring properties.”

And these “flavourings” are defined latter in Article 2(a) from the same regulation as follows:

(a) ‘flavourings’ shall mean products:
(i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;
(ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof;

In other words, the EU legislation acknowledges that only substances within the definition of “flavourings” have the potential of being used as food additives, instead of all the substances with flavouring properties described in Regulation (EC) No 1334/2008; similar outcome as the depicted from the “Ad-hoc” working group of the CCFA back in 1977 from the Codex Alimentarius Commission.
Within these flavourings in the EU, there is a subcategory that was found to be particularly close to food additives, consequently the EU Commission elaborated a document for guiding on their classification entitled “Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer” (EU Commission, 2014b). These guidance notes explain the characteristics differing these two categories of substances, the methods for classifying substances into those categories and the regulatory consequences involved.

Regarding the flavourings substances with modifying properties (scoped by the Regulation (EC) No 1334/2008), the guidance notes define them as substances able to change the individual characteristics of the flavour of a food including effects like increasing, decreasing, or changing the perception of individual relevant sensorial characteristics of flavour. Additionally, the guidance notes describes some situations on how flavouring substances with modifying properties performs:

1) impact the time onset and duration of the perception of specific aspects of the flavour profile and/or
2) reduce specific flavour off-notes, for example decrease metallic flavour and/or
3) intensify specific flavour characteristics, for example increase the perceived fruitiness and/or
4) reduce specific flavour characteristics, for example reduce bitterness.”

Meanwhile, about flavour enhancers (scoped by the Regulation (EC) No 1333/2008), the guidance notes depict their purposes for addition to food:

"- to amplify the existing taste and/or odour of a foodstuff, and/or
- to increase the overall perception of all flavour characteristics, and/or
- to increase a single flavour perception so significantly that it is out of balance relative to the modification of the other flavour characteristics."

As examples of both categories, the guidance notes mentions the Monosodium glutamate (E 621) as a flavour enhancer due to its effect on enhancing the flavour of proteins in food products. However, for a flavour substance with modifying properties, the guidance notes chooses a more complex example: the Neohesperidine DC. This substance is an authorized flavouring substance under Regulation (EC) No 1334/2008 (at a level of up to 5 mg/kg) due to its property of increasing specific characteristics. Nonetheless, this substance at the same time is a food additive (E959) under Regulation (EC) No 1333/2008 playing the role of a flavour enhancer (at a level of up to 5 mg/kg) and as a sweetener (at a level of up 10 mg/kg to 150 mg/kg).

And finally, for defining the categories of these substances, the guidance notes proposes the performance of an expert panel study on the sensory profiles by tasting samples with and without the substance for the specific food application. For this task, the guidance also suggest the following ISO standards on training the expert panel and establishing the sensory profile:

ISO 3972: Sensory Analysis- Methodology – General Guidance for establishing a Sensory Profile
ISO 13299: Sensory Analysis – Methodology – Method of investigating sensitivity of taste

As a conclusion for the borderline conditions between the food additives and flavourings, it is possible to state that the borderline is limited between food additives and the substances defined as “flavourings” according the Regulation (EC) No 1334/2008. By analysing the guidance notes on the classification of flavour enhancer and flavouring substances with modifying properties, it is also possible to appreciate the relevance of the “context of use” for classifying a substance (being depicted along this research in almost every section): In this opportunity, Neohesperidine DC is able to perform different functions not only depending on the food application, but also in the amount in which this substance is added. Lastly, these guidance notes represent an “official” document suggesting the perform of sensory test for classifying substances concerning its effect; being notice that a similar strategy was proposed by the private sector in case of EUTECA on the Caramel’s classification.

Other borderline conditions apart from the existing between flavour enhancer and flavouring substances with modifying properties were not established yet. However, an approach by a sensory test similarly to the caramel’s classification from EUTECA could lead to a solution in those cases.
5.2.7. **Concluding from the borderline conditions among the possible substance's categories**

After identifying all the borderline conditions (PA, FE, NF, FG, NU and FL), the following proposed principles could be elaborated describing their behaviour in front of a food additive:

**The "Predominant Effect" principle:**
This proposed principle rises from the repeated situations in which a substance might be well known to have a technological effect from previous situations (or being listed as food additive), but capable to show additionally a health/nutritional/flavouring effect or a technological effect not reaching the final product. This principle was exemplified by the Lysozyme in cheese (FA vs. PA), the technological/colouring food extracts or the Caramel colours (FA vs. FG), the Zeaxanthin (FA vs. NF), food additives as Vitamins C, B2 and E (FA vs. NU) or the flavouring substance with modifying properties vs. a flavour enhancer (FA vs. FL). Those situations can be classified into substances which their “Predominant effect” need to be assessed and those which not.

The situations not needing of tests to classification are depicted as follows:

1. For a substance producing technological effects reaching the final product together with some not reaching it, the FA status will be over a PA status (i.e. the Lysozyme in cheese).
2. For a substance being a FE, it will not be a FA (due to the upcoming FE positive list).
3. For a substance showing nutritional/health properties together with a technological effect, a “Significant Amount” (as defined in Regulation (EC) No 1924/2006 and 1925/2006) producing a nutritional/health labelling and claiming will make them prevail over a technological effect; this because it was found that a “nutritional purpose” eliminates the option of a “food additive” classification as suggested by recital (5) from Regulation (EC) Nº 1333/2008, and a “health effect” excluded the Zeaxanthin to be considered as a food additive on its novel food authorization for those cases.

For substances showing flavouring properties together with a technological effect, an assessment would be needed. Sensory tests seems to be promising as a method for further development and proposal to the authority, which were already used on the “Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer” by the EU Commission.

**The "Composition” principle:**
Situations in which a specific composition of the substances decides its classification occurred in the colouring or technological food extracts (FA vs. FG). The specific component’s proportions as classification criteria are achieved by establishing a “decision-tree with a selective extraction” or by “specifications”, being the first one a “semi” clear-cut by being a classification depending on a existing technological effect as “predominant” at the beginning of the decision-tree, meanwhile the second one being a “full” clear-cut by allowing only the use of extracts fulfilling with them to work as food additives.

**The "Context of Use” principle:**
Along the analysis of the existing borderlines, there were cases in which the substances possess many features like nutritional, physiological (health), flavouring or technological for the process or the final product. In case of being two, or more together at the same time, one of them will be the most “valuable” determining in this way its purpose for addition. For instance, the Caramel Colours having flavouring and technological property (colour), or Zeaxanthin by showing health effect as antioxidant and a technological property (colour).

Nevertheless, the "value" of this substance’s feature will be higher or lower among the others that co-exist on it, and this will depend on the process steps needed to transform a food into the final product, or the other components that would be present together with the substance in the final product’s formulation. For example, the capacity of modifying the pH of a substance would be relevant for setting the conditions for processing steps such as precipitation/separation/fermentation among others, however, for a separate use, it can also help to keep the pH of a final product along it shelf-life; this substance in the first case would be a processing aid and in the second situation a food additive with a possible functional class of “acidity regulator”. For the Caramel colour explained by EUTECA, the relevance of its “flavour” or “colour” would depend on the product formulation: In case the caramel “flavour” is not possible to be perceived due to the presence of, for example, strong herbs and flavourings within the formulation, the colour would be a more relevant feature that the caramel can bring to this formulation, and consequently, showing the relevance of the sensory test’s proposed from EUTECA.
In this way, the substance’s categorization is not only conditioned to a possible compositional specification or substance’s identity, but also to their specific applications -as depicted- in which they are referred in this research as the “Contexts of Use”.

The "Not normally consumed as food” principle:

More than a principle, it can be considered as a limitation, however, it is the only way for classifying a substance between a “food additive” and a “food in general” in case it has a technological function; because of the definition "per se". Therefore, the substances within this borderline that do not have to deal with this principle are only the ones which further classification criteria had already been developed such as the caramel colours by its sensory tests, and the technological food extracts in case they are defined by specifications.

5.3. Understanding the SCFAFF interpretations

For finalizing the study of the conditions and principles of the EU borderline food additives, the rationale of the SCFAFF in the cases depicted in Section IV will be analysed, expecting the conclusions on them to enrich and improve the already proposed principles in last Section 5.2.

5.3.1. Spinach extract with high levels of nitrates used in sausages

According to the records of the Standing Committee on the Food Chain and Animal Health (SCFCAH) – former SCFAFF- in Brussels on December 14th of 2006 (EU Commission, 2006), some manufacturers of meat products were detected to be using standardised spinach extracts containing high levels of nitrates. Additionally, the producers labelled the product as not containing food additives. In this SCFAFF meeting, this practice was considerate by the Member States as a deliberate use of a food additive regarding the technological purpose of preservation in the final food. As a consequence, the SCFAFF stated that such use should comply with the food additive and food labelling legislations.

Within the food industry, nitrates are known to perform preservatives functions in meat products (Campden Technology Limited, 2010) and they were already approved as food additives among those years by the Directive 95/2/EC (predecessor of the current Regulation (EC) No 1333/2008) as sodium nitrate (E251) and potassium nitrate (E252). Therefore, it is reasonable that the presence in high amounts of them in an ingredient (spinach) to be added in a final meat product (a sausage) would have this purpose.

Unluckily, no further records were found by this research confirming whether (1) this nitrate was added to the spinach extract by a supplier or (2) their presence in high contents was due to selection or other techniques applied to the spinach as a plant. For illustrating this last possibility, Campden Technology (2010) on its report for the Department for Environment, Food & Rural Affairs of United Kingdom (DEFRA) depicted examples in which vegetables naturally high on nitrates (i.e. celery, lettuce and beets) can be added in form of powders, juice or concentrates together with nitrate-reducing bacterial cultures in order to gradually produce nitrite on the food which preserved the meat product matter of application.

Regarding the first possibility of a direct addition of nitrates to the spinach extract (1), the argument for the non-compliance would be straightforward to elaborate: According to the Directive 95/2/EC Annex III Part C, the addition of E251 or E252 was not allowed for food products others than cured meats or some types of cheeses. The only possibility for allowing is in cases in which this extract is solely meant for production of cured meats or some types of cheeses, according to the Article 3 1(c) of the same directive. Under this possibility, the meat manufacturer would still have to fulfil with the article 6 4(c)(ii) of Directive 2000/13/EC on food labelling by declaring this nitrates on their meat products, due to their technological effect on the final product as preservatives; making automatically the claim "not containing food additives” on their labels an infringement.

On the other hand, for the presence of nitrates beforehand on the spinach as a plant (2), a similar direct approach to the Directive 95/2/EC would result complicate to perform, because this legislation did not contemplate situations in which a food additive is already present in a food ingredient without any addition. Consequently, under this situation, it would be coherent to look for pieces of legislation related to the Directive 95/2/EC in order to find possible explanations for this case.
The Directive 95/2/EC on its Article 1 refers to the Directive 89/107/EEC concerning main aspects of food additives. At the same time, this Directive 89/107/EEC on its Annex II (5) indicates that food additives must comply with the approved purity criteria for being added to food. Concerning this purity criteria, the research found that the Directive (EC) 96/77/EC addressing purity criteria for food additives other than colours and sweeteners was applicable.

This Directive (EC) 96/77/EC establishes –among other additives- specifications for nitrates (E251-252), setting for this purpose specific parameters like minimal concentrations, maximum contaminant content, and description. By taking into account that these specifications allow a food additive for being added to foodstuffs, and the “spinach extract” is not a recognized way –according to this directive- for adding nitrates into foodstuffs, consequently it is finally possible to interpret the addition of nitrates in the form of a spinach extract as an infringement of the purity criteria. Moreover, additionally to this reflection, it is also feasible to argument that by containing this spinach extract high amounts of nitrates; the extract will become “not normally consumed as a food”. This “not normally consumed as food” feature due to the high content of nitrates, plus the acknowledged technological effect of preservation may bring the spinach extract its final status of a “food additive”. However, the first argument regarding purity criteria is fully objective due to the use of specifications as grounds, in comparison to the second one appealing to a grey-definition such as “not normally consumed as food” as elaborated at the beginning of this Section V.

5.3.2. Use of copper sulphate (CuSO4) in cucumber preparation

This case from June 21th of 2016 refers to the use of a substance for creating a food additive in situ in the food. Producers requested an opinion on a process for retaining the green colour of cucumbers meant for preparing milk products. The process involves the immersion of cut cucumbers into a water solution of copper sulphate (CuSO4) followed by a solution draining, a wash step in water and a heat treatment. This process allows the copper ions from the CuSO4 solution to combine with cucumber’s chlorophylls for producing copper complexes of chlorophylls. Regarding this situation, the Committee concluded unanimously that the process described to formation of copper complexes of chlorophylls (E 141(i)) in situ not naturally present in cucumbers. They stated that due to neither CuSO4 nor copper complexes of chlorophylls are allowed in cucumber preparations, this process constitutes a non-authorised food additive use.

Apart from considering that the addition of both CuSO4 and copper complexes of chlorophylls are forbidden on cucumber preparations according to Regulation (EC) No 1333/2008, it is specially relevant to reflect on how this resulting food additive copper complexes of chlorophylls (E 141(i)) appeared on the food product (the cucumbers). Despite that the Regulation (EC) No 1333/2008 do not specify “the act of addition” of a food additive as a requisite for its presence in a foodstuff (that can happen also indirectly in food by the principle of “carry-over” depicted in its Article 18), the “creation” of copper complexes of chlorophylls (E 141(i)) within those cucumber preparations can also be interpreted as an infringement of the “purity criteria” requisite, similarly to the previous case on “Spinach extract with high levels of nitrates used in sausages”. This copper complexes of chlorophylls (E 141(i)) present in cucumber preparations are not fulfilling with the purity criteria established by Regulation (EC) No 231/2012.

The mechanism for supporting the purity criteria’s argument is based on the Article 4(5) of Regulation (EC) No 1333/2008 indicating the specification’s fulfilment of Regulation (EC) No 231/2012 in order to allow a substance to be use as food additive according to Article 4(1) of Regulation (EC) No 1333/2008. In case this substance do not fulfil with the purity criteria, the substance is also not following the Article 4(5) of Regulation (EC) No 1333/2008, and consequently, the Article 5 from the same regulation regarding “Prohibition of non-compliant food additives and /or non-compliant food” will apply, stating that “No person shall place on the market a food additive or any food in which such a food additive is present if the use of the food additive does not comply with this Regulation”.

5.3.3. Use of alkalisising substances in processing of cocoa products

In June 21th of 2016, it was also discussed the use of alkalisising substances in processing of cocoa products regarding their role as processing aids or food additives. Substances like calcium carbonate (E 170), carbonates (E 500 – 504), hydroxides (E 524 – 528) and magnesium oxide (E 530) are most often added to the cocoa nibs in a reaction vessel before roasting in order to (i) increase the dispersability in
aqueous solutions, (ii) reduce bitterness in taste and (iii) change the colour of cocoa powders. According to this, the committee concluded that the resulting by-products of those substances (i.e. mineral salts) still present in the product create a remaining effect on it. And considering that those substances are recognized in the related food category according to the Regulation (EC) No 1333/2008. Therefore, they are considered as food additives in cocoa powders.

In this situation, the processing aids added cause an effect in the final product, therefore - as also being elaborated on in this research - they are “food additives” in the current context of use.

5.3.4. Concluding from the SCFAFF interpretations

From the SCFAFF rationale on the "food additive" categorization of the discussed substances under their depicted situations, it is possible to state the following conclusions:

1. There are reasons to believe that the “purity criteria” in Regulation (EC) No 231/2012 can explain the discussion on the "Spinach extract with high levels of nitrates used in sausages“ and the "Use of copper sulphate (CuSO4) in cucumber preparation". The Regulation (EC) No 1333/2008 indicates that food additives can be added to foods only if they follow the compositional specifications in Regulation (EC) No 231/2012. Consequently, by the "spinach extract with nitrates" and the "in-situ creation of copper complexes of chlorophylls" not being standardized ways for adding E251-252 and E141(i) depicted by Regulation (EC) No 231/2012, they result of infringements of Regulation (EC) No 1333/2008.

2. The discussions on the “Use of alkalisng substances in processing of cocoa products” and the "Use of copper sulphate (CuSO4) in cucumber preparation“ show the relevance of taking care of the technological effects from the by-products in the final product. The substances in this case, the substances were assumed to be working as processing aids. However, due to the effects of the substances’ by-products in the final product, they were concluded to be playing the role of food additives (as indicated in the food additive’s definition).

These conclusions contribute to the proposed principles in Section 5.2 on the following aspects:

1. It was shown that for substances applying as “existing food additives” (as shown in the spinach extracts with nitrates), the purity criteria is a requirement deciding on whether these substances are infringing the food additive’s legislation or not. Consequently, similarly to the EU guidance document on food colouring extracts discussed in Section 5.2, the requirements would consist on fulfilling with both Regulations (EC) No 1333/2008 and 231/2012.

Consequently, this contribution could be extrapolated also for indicating that in case the classification of these EU borderline food additives ends up determining a substance playing the role of an “already approved ones”, these are conditioned to the fulfilment of aspects like a “purity criteria”, “foods categories & levels” or “specific labelling requirements” applying to the category, as shown for the cases of FA, NF and NU.

2. Within the “Predominant effect” principle, it had been already discussed that a technological effect reaching a final product prevails over the one reaching only the production process. However, it is also important to remember taking into account the by-product’s effect in these situations.

5.4. Concluding on the conditions and principles for classifying the EU borderline food additives

From this section, all the three characteristics defining a EU borderline food additive were analysed. Starting with the grey-areas of food additive’s definition, in which their sizes were reduced to only the expressions of “not normally consumed as food” and “how to define a colouring/technological effect as primary or secondary”, plus the food enzymes reaching negatively the question Nº6 of the decision-tree from its EU guidance document.
Those two first expressions were also involved on the borderline conditions between the food additives and the non-food additive’s categories (PA, FE, NF, FG, NU and FL) during the analysis of the different substance’s cases and supporting guidance literature for establishing the proposed principles of “Predominant Effect”, “Composition”, “Context of Use” and “Not normally consumed as food”.

And finally, the analysis of SCFAFF interpretations contributed to the proposed principles by remembering taking into consideration the by-products effects of the substances, and in case the classifications ends up into a “already approved substance” the related requirements for the substance must be followed in order to avoid infringements.

After performing the whole evaluation, the resulting principles (and omitting exemplifications) are described as follows:

The “Predominant Effect” principle:
The substance (or its by-products) that is capable to show a technological effect reaching the final product additionally to a health/nutritional/flavouring effect or a technological effect not reaching the final product will possess a predominant effect among the mentioned leading to its classification.

Situations needing tests to identify the “Predominant Effect”:
1. For substances showing flavouring properties together with a technological effect.
Sensory tests are the method. They need further development for proposing them to the authority.

Situations NOT needing tests to identify the “Predominant Effect”:
1. For a substance (or its by-products) producing technological effects reaching the final product together with effects performing only in the production process, the FA status will be over a PA status.
2. For a substance being a FE, it will not apply as FA.
3. For a substance showing nutritional/health properties together with a technological effect, a "Significant Amount" (as defined in Regulation (EC) No 1924/2006 and 1925/2006) producing a nutritional/health labelling and claiming will make them prevail over a technological effect.

The “Composition” principle:
Specific composition of the substances decides its classification. It is currently present in two forms: "specifications" or "selective extraction", having the first one the advantage over the second one on not entering into "grey-area questions" during its application for classification.

The “Context of Use” principle:
From the different features that a substance (or its by-product) can possess like nutritional, physiological (health), flavouring or technological (for the process or the final product), the most "valuable" one - determining the purpose for its addition on food- will vary depending on how the 1) production process or 2) the final product’s formulation are, and consequently, defining the categorization of the substance for that use.

The “Not normally consumed as food” principle:
"Not normally consumed as food" is the main characteristic (from the food additive’s definition) for classifying a substance between a "food additive" and a "food in general" category, in case this substance shows a technological function.

As indicted previously, in case those principles produce a classification into an "already approved substance" (in a positive list), it should also fulfill applicable conditions, such as "purity criteria", "food categories & levels" or "specific labelling requirements".

Finally, the remaining "unpredictable" situations from the analysed conditions and principles are reduced to:

• Case-by-case situations on colouring food extracts: For extracts not having selective extraction but stop keeping the properties of their food source.
• Case-by-case situations on food enzymes: For food enzymes reaching negatively the question N6 of the decision-tree from its EU guidance document.
• Substances depending exclusively from the assessment on their "not normally consumed as food" feature.
VI. Borderline food additives’ principles & conditions into practice: The resulting integrated classification’s Decision-Tree

The proposed principles and conditions for classifying the EU borderline food additives were developed in the previous section, consisting on the existence of a “Predominant Effect”, “Composition”, “Context of Use” and “Not normally consumed as food” as principles ruling the classification, and complemented by guidelines on handling already approved substances and limitations for classification.

These proposed principles and conditions should have the target of producing a guidance document on legislation for classifying these EU borderline food additives, which uncertainty – as depicted in Section IV - lengthen authorization procedures, impacting negatively the specialty food ingredients sector in terms on food innovation. Being this guidance document a preferred way for approaching the EU Commission and improving this situation as suggested by Mr Debeuckelaere himself, the Head of Sector on Food Additives, Food Enzymes and Flavourings at the Commission Directorate-General for Health and Food Safety (DG SANTE). (EU Specialty Food Ingredients, 2017b)

In order to produce a proper guidance document, these proposed principles and conditions should be organized and translated into a tool simple enough to be followed by specialty food ingredients companies. Therefore, the format of a decision-tree is suitable for a practical use of the classification. Working this decision-tree as a “funnel” by collecting all the findings elaborated in the current research.

The objective of this decision-tree is assessing any substance considered as an EU borderline food additive according to this research into one of the established possibilities (FA, PA, FL, NF, FG, NU or FE). The proposed principles and conditions should be translated into questions starting from the most straightforward and natural to answer for the user to the more specific ones. Additionally, considering that the conditions and principles were elaborated between the interactions of food additive’s status and the non-food additives (as depicted in the visual concept on Figure 9), the decision-tree should be built considering the food additives as the vertebral spine.

The first challenge for elaborating this decision-tree is locating the proposed principles and conditions along it. It is reasonable to expect that the “Context of Use” principle would be present in every single decision, because of the dependency of a classification on the specific process/ formulation as depicted in Section V, and the “Predominant Effect” principle being applied only for decisions in which the substance would have more than one potential effect. Meanwhile the “Compositional” principle should be applied on situations in which after confirming the substance’s effect under context of use, the composition criteria will define it as a food additive or not (as seen for the food extracts). And finally, due to the subjective characteristic of the “Not normally consumed as food” principle, it should be established only for decisions in which the use of the other three principles had already been exhausted.

Taking into account the substance’s classification among the 6 categories (FA, PA, FL, NF, FG, NU or FE) and having FA as a vertebral spine of the decision-tree, the first decision would be on separating the possible substances in two groups: the ones that are already approved food additives and the ones which are not; making this decision a straightforward question to the user by only making him/her to verify their presence on the related positive list. Within these substances being present in the positive list, it will be relevant to determine which is their “Predominant Effect” under the “Context of Use”. Consequently, making them to fulfil with their applicable legislation in terms of the effect that they perform.

From the substances not belonging to the food additive’s positive list, the decision-tree can exclude the substances not performing a “technological effect at the final product (TFFP)” under the “Context of Use” as a second decision, which is the main characteristic from food additives according to its definition. Those excluded substances -not longer being possible to be food additive- can be further classified in terms of their “predominant effect” under the “context of use” in a similar way to the first decision.
Later, from this group of substances showing a TFFP under the "Context of Use", it is necessary to address on whether or not this TFFP is primary or secondary, excluding as a third decision the substances not having a TFFP as primary within the "Context of Use". And similarly to the previous decisions, those excluded substances -not longer being possible to be food additive- should be further classified in terms of their "Predominant Effect" under the "Context of Use".

Finally, the remaining substances showing TFFP as a primary function under the "Context of Use" can have the substance categorizations of FA, FE, NF or FG. In this point, the "Predominant Effect" principle is not useful anymore, because the technological effect is already identified as predominant. Consequently, the "Compositional" principle should take place in shape of the specific classification's criteria being developed for specific substances –and explained during this research– as the "Food Enzymes" guidance document, the technological/colouring food extracts and the substances being explicitly excluded by the definition; this in order to leave the remaining cases under the judgement of the "Not normally consumed as food" principle.
Figure 11. Flowchart for classifying EU borderline food additives

In this way, the principles and conditions can be properly addressed by the user from the most straightforward decision (being or not in the food additive’s positive list) to the most complicated one (being or not “Not normally consumed as food”), resulting on the flowchart illustrated in Figure 11 containing 11 questions. It is important to mention that this decision-tree would be only one of the possible combinations in which the questions can be displayed.
This Decision-tree for classifying the EU borderline food additives appeals several times to the "Predominant Effect" principle (as explained lines above). Being the application of this principle required in the questions Nº2, Nº4 and Nº6 of the flowchart in Figure 11. Therefore, the proposed "Predominant Effect" in this research should be translated also into another decision-tree for making it easier to follow by a user.

Figure 12. Flowchart for the "Predominant Effect" on the classification of EU borderline food additives

The Figure 12 contains the formulated "Predominant Effect" depicted in two main paths: for situations in which there is only one existing effect for assigning the substance’s role according to the "Context of Use" (useful for Q2 reaching the grey-coloured box B1 and for the Q4 reaching the grey-coloured box B4), and for situations in which there exist a "TFP" on the final product, leading to the discussion on whether it is primary or secondary in front of other effects (useful for Q2 reaching the grey-coloured box B1 and Q6 reaching the grey-coloured box B5).

It is relevant mentioning that the concluded substance’s role achieved by this decision-tree should be properly assessed on the fulfilment of applicable legislation in terms of factors like definition, allowed food categories and levels, specific labelling, between others, as concluded in Section V. In case the substance is not fulfilling with the applicable legislation within this "Context of Use", the user should apply for the respective authorization as a new fully registration of the substance or its extension of use to this "Context of Use" correspondingly.

For both Figures 11 and 12, specific terms are applied which had been listed in the following Table 13. These terms consist on definitions directly extracted by legislation that had been used as such along the performed research ("Food Additive", "Food Enzyme", Flavouring", "Novel Food", "Nutrient" or "Processing Aid"), some terms are adapted ("Not normally consumed as food", "Significant Amount", "Technological Function") or completely proposed (i.e. "Contest of Use", "Food Extract", "Food in general").
Finally, after depicting the "Predominant Effect" on Figure 12 and listing the definition involved in Table 13, descriptions -referring information belonging to those Figure 2 and Table 3- are described in Table 14 for the white and grey-coloured boxes from the flowchart of Figure 11 for classifying EU borderline food additives.

Table 13

<table>
<thead>
<tr>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Context of Use&quot;</td>
<td>Specific production process or food formulation in which a EU borderline food additive (or its by-products) performs a nutritional, physiological (health), flavouring or technological (in the process or final product).</td>
</tr>
<tr>
<td>&quot;Flavouring&quot;</td>
<td>As defined in Article 3(2)(a) of Regulation (EC) No 1334/2008.</td>
</tr>
<tr>
<td>&quot;Food Additive&quot;</td>
<td>As defined in Article 3(2)(a) of Regulation (EC) No 1333/2008.</td>
</tr>
<tr>
<td>&quot;Food Enzyme&quot;</td>
<td>As defined in Article 3(2)(a) of Regulation (EC) No 1332/2008.</td>
</tr>
<tr>
<td>&quot;Food Extract&quot;</td>
<td>Extract which primary source is a substance falling into the definition of &quot;food&quot; according to Article 2 of the Regulation (EC) No 178/2002.</td>
</tr>
<tr>
<td>&quot;Food in general&quot;</td>
<td>EU borderline food additive falling into the definition of &quot;food&quot; (according to Article 2 of the Regulation (EC) No 178/2002) without being included on the substance's categories of &quot;Food Additive&quot;, &quot;Nutrient&quot;, &quot;Flavouring&quot;, &quot;Food Enzyme&quot;, &quot;Novel Food&quot;, and &quot;Processing Aid&quot;.</td>
</tr>
<tr>
<td>&quot;Not consumed normally as food&quot;</td>
<td>Expression extracted in the context of &quot;food additive&quot; and &quot;processing aid&quot; definitions in Article 3(2)(a) and Article 3(2)(b) correspondingly from Regulation (EC) No 1333/2008.</td>
</tr>
<tr>
<td>&quot;Novel Food&quot;</td>
<td>It involves the definition of &quot;Novel Food&quot; in Article 1(2) Regulation (EC) Nº 258/97 or Article 3(2)(a) Regulation (EU) Nº 2015/2283 and &quot;traditional food from third countries&quot; in Article 3(2)(c) Regulation (EU) Nº 2015/2283.</td>
</tr>
<tr>
<td>&quot;Nutrient&quot;</td>
<td>As defined in Article 2(2)(a) of Regulation (EC) No 1169/2011: &quot;Protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in point 1 of Part A of Annex XIII to this Regulation, and substances which belong to or are components of one of those categories&quot;.</td>
</tr>
<tr>
<td>&quot;Processing Aid&quot;</td>
<td>As defined in Article 3(2)(b) of Regulation (EC) No 1333/2008.</td>
</tr>
<tr>
<td>&quot;Significant Amount&quot;</td>
<td>The nutritional/health effect is claimed and highlighted according to Regulations (EC) No 1924/2006 and No 1925/2006.</td>
</tr>
<tr>
<td>&quot;Technological Function&quot;</td>
<td>Function that a food additive performs in a foodstuf belonging to the options depicted in the Annex 1 from Regulation (EC) No 1333/2008 (referred by the Article 3(2)(c) of the same regulation).</td>
</tr>
</tbody>
</table>

Table 14

<table>
<thead>
<tr>
<th>Description</th>
<th>WHITE-COLOURED BOXES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptions A1, A2 and A3</td>
<td>The Figure 12 (Flowchart for the &quot;Predominant Effect&quot; on the classification of EU borderline food additives) must be applied.</td>
</tr>
<tr>
<td>Description A4</td>
<td>In case the substance is mentioned within the listed exemptions from the Food additive’s definition (Article 3(2)(a) from Regulation (EC) No 1333/2008), it cannot be considered as a food additive.</td>
</tr>
<tr>
<td>Description A5</td>
<td>It is possible that a food extract can have more than one technological function reaching the final product. In case one of the functional aspects is a colouring one, it should be classified according to the “Guidance notes on the classification of food extracts with colouring properties” (EU Commission, 2013) because having a colouring function results on the only requirement for applying such guidance notes.</td>
</tr>
<tr>
<td>Description A6</td>
<td>The substance should be analysed in a case-by-case basis to define is the substance is &quot;Not normally consumed as food&quot; or not.</td>
</tr>
</tbody>
</table>

GREY-COLOURED BOXES

<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptions B1, B4 and B5</td>
<td>Those grey-coloured boxes indicates the possible substance’s categories allowed for this step after applying the Figure 12 (Flowchart for the &quot;Predominant Effect&quot; on the classification of EU borderline food additives) on the previous boxes A1, A2 and A3 respectively.</td>
</tr>
<tr>
<td>Description B2 and B3</td>
<td>The substance is fulfilling/ not fulfilling with the Regulation (EC) No 1333/2008 in the specific &quot;Context of Use&quot;.</td>
</tr>
<tr>
<td>Description B6 and B10</td>
<td>The substance is not a food additive, leaving the categories of &quot;Novel Food&quot; and &quot;Food in general&quot; as the only two possible categories. In case the substance do not fulfills as a &quot;Novel Food&quot; regarding the Regulation (EC) Nº 258/97 or Regulation (EU) Nº 2015/2283, then the remaining option would be the &quot;Food in general&quot;.</td>
</tr>
<tr>
<td>Description B7</td>
<td>The substance is a &quot;food enzyme&quot; as defined in Article 3(2)(a) of Regulation (EC) No 1332/2008. Additionally, it will be considered as an &quot;Ingredient&quot; according to the “Guidance document on criteria for categorization of food enzymes” (EU Commission, 2014a), because the option of being a &quot;processing aid&quot; would be already discarded by the previous Description A2.</td>
</tr>
<tr>
<td>Description B8</td>
<td>By using the decision-tree of “Guidance notes on the classification of food extracts with colouring properties” (EU Commission, 2013) from its second question (because the first one is the &quot;Q6&quot; from this decision-tree), the substance can be classified into:</td>
</tr>
</tbody>
</table>

- "Colouring Food", which can belong to a "Novel food" or a "Food in general" by applying the Descriptions B6 or B10. |
- "Colours", which belongs to a "New Food additive" needing to undergo an authorization procedure before being used. |

The only case-by-case situation for deciding the extract's classification –as depicted by the guidance notes- is when
the extract is not presenting a “selective extraction” but it stop having the characteristics of the source.

Description B9  In case of having a food extract with only non-colouring technological functions, the decision-tree needs established specifications or confirmed selective extraction criteria in order to finishing classifying among a “New food Additive”, “Novel food” or “Food in general”, similarly to the Description B8.

Description B11  The substance will be classified as a “new food additive” needing to undergo an authorization procedure before being used.

In this way, the findings obtained and consequently formulated as principles and conditions in Section V can be applied in a more straightforward manner, making them suitable for addressing the “food additive” or “non-food additive” status (PA, FE, NF, FG, NU or FL) of any substance under determined situations. Task that would not be possible to perform by reading the proposed conditions and principles as such, at least not for an sporadic or moderate user like a personnel within Quality, Research and Development or Regulatory affairs departments in the specialty food ingredients companies, which are the target users bearing with the classification problem – “on the field” – of these EU borderline food additives.
VII. Discussion: Limitations, Opportunities & Challenges of the integrated classification’s Decision-Tree on EU borderline food additives

As having the decision-tree already defined from the research’s findings, special attention should be given to resulting decision-tree’s constrains and characteristics leading to the opportunity of performing further developments on legislation involving the specialty food ingredients sector.

7.1. Inherent grey-areas within the already established EU guidance notes

The elaborated decision-tree appeals in specific situations to already elaborated EU guidance notes such as the “Guidance document on criteria for categorization of food enzymes” (EU Commission, 2014a) and “Guidance notes on the classification of food extracts with colouring properties” (EU Commission, 2013), which acknowledged themselves on having situations for executing a decision in a “case-by-case” basis, being located for the food enzymes guidance note on the negative answer to the Question Nº6 of its decision-tree and for the colouring food extract guidance note on cases in which there is not selective extraction but the extract stop having the same properties as its food source.

7.2. Classifying non-colouring technological food extracts

The decision-tree is currently “reserving” a place for the technological food extracts motivated and exemplified by the Extracts on Rosemary (E392). Their classification currently lacks of an established mechanism for differing them among the categories of “Food Additives”, “Novel Foods” and “Food in general”.

Developing this classification mechanism –whether by “specifications” or “selective criteria”- should be a matter of concern due to the current market trend on “more natural ingredients” depicted in Section II. It is reasonable to expect that further developments on food extracts on the market as a way for approaching to this trend would involve exploiting other plant properties not necessarily within the technological function of colours, as exemplified by the Extracts of Rosemary (E392).

Furthermore, this current limitation on how to assess a non-colouring technological food extract would carry additional complications in case, in a near future, a food extract having both colouring and non-colouring technological functions is discovered or developed. Within the proposed Decision-tree for EU borderline food additives in Figure 11, the food extracts having a colouring property should be automatically treated by the colouring food extract decision-tree regardless the existence of co-existing non-colouring technological effects (see Figure 7). This scenario should also be taken into account for further improvements.

7.3. No capacity for deciding conditions in-between substances

Due to the initial problem statement based on classifying food additives from non-food additives, and the consequent definition’s proposal of a “EU borderline food additive” from the Regulation (EC) No 1333/2008, the resulting classification decision-tree is not possible to address situations for “in-between substances”, as visualized in the concept of Figure 13.
7.4. The development of a “Sensory test” guidance document

In this research, it was mentioned that the only established ways for addressing the predominance between a flavouring and a technological effect are sensory tests for the official “Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer” (EU Commission, 2014b), and a proposed (but not official) for the caramel colours by EUTECA. Consequently, methodologies for further applications should be proposed and evaluated, being the Colouring food extracts as the first cases identified by the need to establish this predominant effect on their first question (Q1) on their decision-tree (See Figure 7).

Furthermore, in both of the existing cases, the classification criteria are dealing with the predominance between a flavouring effect vs. a “non-organoleptic” technological function (influencing on food’s colour or texture). There will exist situations in which the “predominant effect” should be decided in situation between a flavouring effect vs. a “non-organoleptic” technological function (such as preservation, carriers, packaging gases, propellants, between others). The methodology for development should also figure out how to determine the predominance.

7.5. New technological functions

As indicated in this research, the Regulation (EC) Nº 1333/2008 on its Article 9 establishes the possibilities in which a technological function can take place in a food application. Nevertheless, it also allows on its paragraph 2 the inclusion of new technological functions in relation to how technology improves along the time:

“2. Where necessary, as a result of scientific progress or technological development, the measures, designed to amend non-essential elements of this Regulation, relating to additional functional classes which may be added to Annex I shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).”

Within the current list of technological functions (“functional classes”), it is already possible to appreciate an addition of a new functional class called “contrast enhancer” by the Regulation (EC) No 510/2013 modifying the Regulation (EC) Nº 1333/2008. This “contrast enhancer” consists on the capacity of a substance to help on distinguishing the depigmentation produced on the external surface of fruits or vegetables on predefined parts (by techniques like the laser treatment) by imparting colour following interaction with certain components of epidermis.

Under these situations of new technological functions, the elaborated decision-tree on EU borderline food additives allows the user to appeal always to the current list of functional classes to define whether a
technological function is already recognised or not by the EU. In case that a user have to face a “potential" new technological function within the decision-tree, deciding on whether it is or not a new one will not depend on the user. The user should communicate it to the authority, which should address this decision as established on the already mentioned paragraph 9(2) from Regulation (EC) No 1333/2008.

7.6. The “Not normally consumed as food” principle and future “sui-generis” types of food additives

On the same meeting of the SCFAFF from the discussion on “Spinach extracts containing high levels of nitrate used in sausages” taking place in Brussels on December 14th of 2006 (EU Commission, 2006), the standing committee on a discussion named “Criteria for the use of microbial cultures as food additives” received a draft paper detailing when the use of cultures would be considered as food additive with a preservation property.

Despite of this discussion not reaching further decisions from the standing committee up to this date, it clearly shows how the variety of substances performing technological function and being “Not normally consumed as food” can expand in the future. Consequently, in terms of the decision-tree for classifying EU borderline food additives, this “Not normally consumed as food” principle – currently being “Q11” – would be always "pushed" up to the end –as visualized in Figure 14- by every new “sui-generis” food additive being discovered with the evolution on food technology along the time.

Figure 14. Visualization on how the “Not normally consumed as food” principle will be “pushed” to the end of this decision-tree with the upcoming developments on food ingredients

This behaviour of the “Not normally consumed as food” principle as a “big-box” criteria containing all the substance’s possibilities not being discovered or tested within this decision-tree is consequence of its subjective nature, as depicted from its origins in the Codex Alimentarius Commission (CAC, 1989c). In front of this subjectivity, the EU Commission might have the possibility to evaluate the elaboration of a guidance document on this principle, probably in a similar way to the one explaining the meaning of "Human consumption into a significant degree“ (EU Commission, n.d.) created for bringing a better understanding of the Novel food’s definition from Regulation (EC) No 258/97.
VIII. Conclusions

- Proposing a definition of these EU borderline food additives allows the establishment of an objective approach for assessing these substances.

"A substance which classification between the possibilities of a food additive or a non-food additive is difficult or debatable, because of the substance’s characteristics fulfilling with at least one of the following conditions from the Regulation (EC) No 1333/2008:

(i) the substance falls into the grey-areas of the food additive’s definition,
(ii) the substance belongs to the overlapping substance’s categories depicted in that regulation or
(iii) the substance’s classification needs further interpretations from the SCFAFF”.

Being in this way possible to depict their characteristics such as its presence on the EU food additive’s definition in shape of grey-areas, on the interactions of the food additives with other substances along the food additive’s regulation and finally in their need to be discussed by the SCFAFF. These proposed characteristics led this thesis to frame the research into answering - with the available literature and references - on how the classification of these substances happens. Consequently, without defining these EU borderline food additives, their classification would not be possible to achieve.

- The “grey-areas” of the food additive’s definition plus the rules that the food additives follow during their interaction with other substances and the legal analysis for the SCFAFF decisions, all of these elements being supported by available literature and references, could allow this research to formulate the following principles and conditions that the EU borderline food additives obey:

The “Predominant Effect” principle:
The substance (or its by-products) that is capable to show a technological effect reaching the final product additionally to a health/nutritional/flavouring effect or a technological effect not reaching the final product will possess a predominant effect among the mentioned leading to its classification.

Situations needing tests to identify the "Predominant Effect":
1. For substances showing flavouring properties together with a technological effect.
   Sensory tests are the method. They need further development for proposing them to the authority.

Situations NOT needing tests to identify the "Predominant Effect":
1. For a substance (or its by-products) producing technological effects reaching the final product together with effects performing only in the production process, the FA status will be over a PA status.
2. For a substance being a FE, it will not apply as FA.
3. For a substance showing nutritional/health properties together with a technological effect, a "Significant Amount" (as defined in Regulation (EC) No 1924/2006 and 1925/2006) producing a nutritional/health labelling and claiming will make them prevail over a technological effect.

The “Composition” principle:
Specific composition of the substances decides its classification. It is currently present in two forms: “specifications” or “selective extraction”, having the first one the advantage over the second one on not entering into "grey-area questions" during its application for classification.

The “Context of Use” principle:
From the different features that a substance (or its by-product) can possess like nutritional, physiological (health), flavouring or technological (for the process or the final product), the most "valuable" one -determining the purpose for its addition on food- will vary depending on how the 1) production process or 2) the final product’s formulation are, and consequently, defining the categorization of the substance for that use.

The “Not normally consumed as food” principle:
"Not normally consumed as food" is the main characteristic (from the food additive’s definition) for classifying a substance between a “food additive” and a “food in general” category, in case this substance shows a technological function.
These principles are complemented by indications of remaining grey-areas defined into "case-by-case" basis, and the indication of fulfilling applicable conditions to the substance in order to avoid infringements.

- The motivations of the specialty food industry for being able to classify these defined EU borderline food additives (substances difficult to classify) are reducing the uncertainty affecting innovation in this sector (because of the different regulatory consequences of the possible substance's categories) and bringing a higher level of trust to their costumers (the food manufacturers) on how to use them properly in order to avoid infringements. According to this need and the relative openness of the EU commission to improve their guidance documents in comparison to modifying regulation, the proposed principles and conditions on the classification of EU borderline food additives -which had been translated into a decision-tree in Figure 11- can inspire the elaboration of a guidance document for presenting to the EU commission in order to allow the specialty food ingredients industry to have a tool for assessing the regulatory status of these substances in an early stage of a food ingredient development before the step of dossier submission to the authority.

- The reason for transforming the proposed principles and conditions of EU borderline food additives into the decision-trees depicted on Figure 11 and 12 is the need to make them directly applicable for an sporadic or moderate user like a personnel within Quality, Research and Development or Regulatory affairs departments in the specialty food ingredients companies, which are the target users bearing with the classification problem "on the field" of these EU borderline food additives. Nevertheless, the decision-tree also allows to visualize existing limitations for its full application such as the "location" of the inherent grey-areas, the way "under construction" for the non-colouring technological food extracts (which should be improved due to the current natural trends in the market), the need for a full-development of the "sensory test" for all the possible cases (being identified their need first on the colouring food extracts). Elements that the specialty food ingredients industry could develop jointly with the EU Commission in case they decide to work on this decision-tree.

- Special attention should receive the "Not normally consumed as food" principle in this research. Its subjective nature coming from the discussions in the Codex Alimentarius Commission (Document CX/FAC 89/21), and "tested" in the elaborated decision-tree on Figure 11 by pushing it up to the end of it (and for the next types of substances in the future), makes it an obstacle not possible to dodge on the way for achieving a fully predictability on EU borderline food additive's classification.
IX. Further research opportunities from these proposed EU borderline food additives

9.1. Next steps for the Decision-tree on the classification of EU borderline food additives

After building the decision-tree and a later discussion on it, it was possible to identify elements needed for allowing it to properly address the classifications or to reach a higher performance on this task.

9.1.1. Improving the classifications of non-colouring technological food extracts

Being this currently an "under construction" path as demonstrated with the decision-tree and a potential source of new food ingredients fulfilling with the “natural” current trend, addressing specific cases of extracts within this group and how to classifying them would contribute to the certainty on their innovation as depicted in Section III.

9.1.2. Addressing the conditions of the in-between substances

As visualized in the Figure 13, further researches can be performed on defining how are the in-between borderlines from the substances involved on these EU borderline food additives.

9.1.3. The development of a "Sensory test" guidance document

Considering that for the "Predominant effect" determination only two specific cases were formulated, a research can be done on proposing a methodology for the remaining cases involving a flavouring vs. a technological effect reaching the final product.

9.1.4. The development of a "Not normally consumed as food" guidance document

Being identified the "Not normally consumed as food" principle as a problematic element on these substance’s classification due to its inherent subjectivity, researching on how to address this matter with a more objective treatment such as the guidance on "Human consumption into a significant degree" (EU Commission, n.d.) for the Novel food’s definition from Regulation (EC) No 258/97 could bring hints for a possible application.

9.2. Spin-off approaches from the classification’s decision-tree for EU borderline food additives

Additionally to the current research on EU borderline food additives, the same methodology could be applied for different situations:

9.2.1. Research on other EU borderline substances

The current research focused on addressing the classification of substances as food additives and non-food additives. However, a similar approach can be performed by locating other substances as into the central position such as “EU borderline nutrients” or “EU borderline Processing Aids” and so on as depicted in the Figure 15.
9.2.2. Research of the Borderline food additive on an international legal framework

These EU borderline food additives research can be extrapolated to define grey-areas between substances classifications in other legal frameworks such as Codex, USA, Australia, Canada, Japan, China, ASEAN community, or Latin-America region.

9.3. What if the EU legislation is changed? Reducing substance's categories for a consequent reduction on grey-areas and borderlines

As depicted in Section III, Mr Debeuckelaere -Head of Sector on Food Additives, Food Enzymes and Flavourings at the Commission Directorate-General for Health and Food Safety (DG SANTE)- considered that the problems causing substance’s classification to food innovation do not come from the legislation, and consequently, he prefers the option of improving the related guidance documents (EU Specialty Food Ingredients, 2017b). Around this restriction, the current research focused on studying and formulating a proposal under this frame. Nevertheless, by intentionally obviating the EU Commission’s preference, it would be possible to formulate proposals and possibly test them for solving the classification problem. From this perspective, and by using this performed research as a starting point, one approach could be easily proposed: The reduction of substance’s categories for a consequent reduction on grey-areas and borderlines.

It was noticed along the current research that every category involved on the EU borderline food additives implies at the same time the creation of borderlines between the food additive category and the other ones. Therefore, a hypothesis can be established on the basis of a categories’ reduction implying also the reduction of frontiers causing grey-areas.

One possible approach for reaching this reduction is converging the substances requiring undergoing an authorization procedure (FA, NF, FE, NU, FL) due to the similarities on their risk assessment (as depicted in Annex II of this research). However, this attempt would have to exclude Flavourings (FL) and Nutrients (NU), due to their labelling consequences, being the first ones declared without specifying them (as “flavourings”) and the second ones having an impact on the nutritional labelling and claiming.

This remaining unification of FA, NF and FE could be supported by the Codex Alimentarius commission document CX/FAC 89/21 being discussed in Section V of this research. This document would indicate the existing priority for Codex Alimentarius Commission to perform a risk assessment over determining the existence of a technological function by stating “…in some situations, a substance acceptable as food may be considered as food additive to allow setting of specifications in order to ensure microbiological purity and control of chemical contaminants”. This, in addition to the existing closeness between the Food Additives and Novel foods and the relevance of the risk assessment over their classification acknowledged on the document CX/FAC 89/19 also analysed in Section V.

“Since, by definition, novel foods or food ingredients do not have a history of use, a toxicological evaluation is generally desirable before they are admitted to the market. Such a safety assessment should be possible irrespective whether the novel product is classified as a food or as a food additive. In fact, the question arises if the toxicological evaluation should be a major factor in deciding whether the novel ingredient is a food substance or an additive.”
This category’s convergence would possibly end up reaching a similar perspective of the GRAS authorization in the US in the sense of approving the substances primarily in terms of a risk-assessment rather than a technological function by covering substances having or not that function: for example, Citric acid esters of mono- and diglycerides as GRN No. 511 (for technological purposes in infant formulas), Dried citrus pulp GRN No. 487 (as a processing aid and technological purposes reaching final product in foods), Oat protein GRN No. 575 (protein source for foods), or Canola protein isolate GRN No. 683 (as protein source and technological purposes in several food applications) (FDA, 2017). In this way, the “Not normally consumed as food” principle found on this research might not be needed anymore: In case the risk-assessment would show the lack of necessity to establish restriction, the substance could be considered as "food in general" (FG). Leaving the “Predominant Effect” and “Context of Use” to deal with the remaining borderline situations between this converged group of FA+FE+NF with the remaining categories (FA, PA and NU) as visualised on the Figure 16.

![Figure 16. Visualization on how the categories' convergence could be achieved](image)

Nonetheless, by converging these categories FA, NF and FE, there would exist the risk of moving these categories to the field of the EFSA's guidance documents for dossier elaborations. It is important to mention that within the those guidance documents, the substances should also be classified in terms of their nature, such as being chemical substances (single or mixtures), foods consisting of/isolated from/produced from microorganisms, fungi, algae, material of minerals, plants, animals or being nanomaterials (EFSA, 2012 and 2016a). Furthermore, depending on the substance's characteristics some steps within the risk-assessment could vary like in the case of Novel foods applying as “Traditional foods from third countries” that by having “history of consumption”, the scientific/toxicological studies are not mandatory for them (EFSA, 2016b). Consequently, instead of reducing the borderlines, they would be only moved to a dossier elaboration discussion. Therefore, this converging proposal would need to be addressed with the proper extension for being able to conclude on this matter.

Furthermore, in terms of international trade, modifying these EU regulations in comparison to only elaborating guidance documents would involve potential observations to the EU in terms of Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (MSF) agreements from the other member states of the World Trade Organization (WTO), because of the consequently “distancing” of the EU legislation from the established Codex Alimentarius Guidelines (WTO, 2017). The Codex Alimentarius Commission on its CODEX-STAN 192/1995 (Codex Alimentarius, 2016) establishes the definition and categorization of food additives, which in this proposal for the EU, this categorization would be converged into a bigger group also joining "Novel Foods" and "Food Enzymes", causing the EU to distance itself from an recognised standard (CODEX-STAN 192/1995) as such by the TBT and MSF agreements from the WTO.
X. References

General references


EU "borderline" food additives: Their legal basis and classification for the Specialty Food Ingredients Industry

[Master in Food Safety – Food Safety Law: Master Thesis]


Giangiacomo, R., Nigro, F., Messina G., & Cattaneo, T.M.P. (1992). Lysozyme: Just an additive or a technological aid as well?. Food Additives & Contaminants, 9:5, 427-433, DOI: 10.1080/02652039209374094 http://www.tandfonline.com/ejournals/toc/1/92/7625039209374094?needAccess=true#hROCoCwL3d3dy50YW5kZm9ubGluZ355jzh0U2xwcml9Me55aWlyYXJ5Lnd1c35ubC5jcyE5SmRmLzEwLjEwODAvMjI2MTt1MkxvMDk5ZGV0TGQbWmV3EFyY2yzcz1ICc1QEBAMA


JECFA. (2002). SODIUM CARBONATE.


http://pubs.acs.org.ezproxy.library.wur.nl/doi/abs/10.1021/jf0105539


https://www.jstage.jst.go.jp/article/bbb/77/6/77_120087/_article


http://nchfp.uga.edu/publications/nchfp/factsheets/food_pres_hist.html


https://www.researchgate.net/publication/49851694

https://mycotopia.net/index.php?app=core&module=attach&section=attach&attach_id=1134238

Oxford (2017). Residue
Retrieved March 27, 2017 from https://en.oxforddictionaries.com/definition/residue

http://www.jstor.org/stable/24326032?seq=1#page_scan_tab_contents


Retrieved July 31, 2017 from https://www.wto.org/english/tratop_e/coher_e/wto_codex_e.htm
**Codex Alimentarius Commission meetings (CAC)**


<Not available on the website>


<Not available on the website>


**Codex Alimentarius Commission (2013).** FA/45 INF/03 - Information document for the 45th ccfa- inventory of substances used as processing aids (gpa), updated list. Codex committee on food additives and contaminants 45th session. Beijing, China, 18-22 March 2013.


**EU Legislation**


to those that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L 269, 14.10.2009, p. 9.

EU "borderline" food additives: Their legal basis and classification for the Specialty Food Ingredients Industry

[Master in Food Safety – Food Safety Law: Master Thesis]


XI. ANNEXES
11.1. ANNEX I: Communication with Mr Geert de Rooij from 29 May 2017

Re: Wageningen University - Moises Chong (Food safety Law)

Chong Sakiara, Moses

Mon 5/29/2017 2:26 PM

geroot@frit.nl <geroot@frit.nl>,
<ch.hartemink, ralf@hartemink@wur.nl>

Dear Mr. de Rooij,

Thank you very much for your approaches, I will adjust my draft list into a new version according to your comments.

- About the reason for the different classifications:
  I am creating a "decision tree" describing the conditions in which a substance difficult to classify will end up being one (or more) of the described categories (food additive, novel food, nutrient, processing aid, flavouring, regular food). The list per se is part of my thesis for showing how these regulatory classifications may carry different outcomes to the companies in terms of investments (dossier building), time and marketing of ingredients. And therefore, a motivation for building a decision-tree for these "border-line additives".

- I will re-structure the items according to the calibers you are depicing.

Indeed, I will share with you the final version of the list as you requested, including the final decision tree I am developing for classifying these "border-line additives".

Thank you again Mr de Rooij for your valuable guidance,

Best regards,

Moises Chong

From: Geert de Rooij <geroot@frit.nl>
Sent: Monday, May 29, 2017 1:24 PM
To: Chong Sakiara, Moises
Cc: Hartemink, Ralf
Subject: Re: Wageningen University - Moises Chong (Food safety Law)

Dear Moises Chong,

The attachment shows a very interesting comparison of possible differences between the legal possible definitions of certain substances.

I have the following remarks:
- You do not describe (in the mail or attachment) what is the reason for the different categorization, that is itself the first hurdle for companies to take and subsequently one that entitle all relevance as it is sometimes used to avoid complex authorization procedures.
- Would you consider to priorities and cluster the list of differences? For instance application for authorization and data required are closely linked.
- Much of the differences listed are of regulatory origin; however the last one is company's own, I suggest you make
that more explicit as it is of a different caliber.
- under item 5 government procedures, you can make a differentiation between what is necessary for governments to do and what is necessary for companies (Post market surveillance under the NF legislation and need scientific data under the Additives legislation).

Of a slightly different page is the total cost of an application under the additives legislation is often below 200k euro, while a NF application can run up to 1500k euro and begin the first often done in approximately 2 to 3 years, the NF application can easily accrue the 5 year period.

Greetings Geert

-----Oorspronkelijk bericht-----
Van: Chong Sakiha, Moises [mailto:moises.chongtsakihara@wur.nl]
Verzonden: maandag 22 mei 2017 16:01
Aan: Geert de Rooij <gderooj@fmi.nl>
CC: Hartemink, Ralf <ralf.hartemink@wur.nl>
Onderwerp: Wageningen University - Moises Chong (Food safety Law)

Dear Mr. de Rooij,

Good morning, nice to meet you,

My name is Moises Chong, Master Student from Wageningen University on Food Safety Law. Professor Ralf Hartemink kindly brought me your contact. If possible I would like to ask you for your valuable regulatory opinion on my thesis research.

I am currently working on food additives that are difficult to classify as such because they appear to be on the “border” between food additives and other food substances like enzymes, novel foods, flavourings, processing aids or even with common foods. For example, foodstuffs with colouring properties that are not classified as food additives, enzymes approved as food additives, novel foods that are also food additives etc. I am calling these food additives as “borderline additives”.

My objective with this thesis is identifying all these “borderline spots” on the EU legislation and mapping all the conditions in which those “borderline substances” can occur.

For establishing the motivations or why this research would be important, I am stating that a substance falling within a food additive classification will carry different “regulatory outcomes” in comparison to the possibility of being classified as processing aid, novel food, food enzyme, nutrient, etc.

The “differences of regulatory outcomes” between these substances in comparison to a food additive that I could identify by my own are, for example, differences on dossier requirements, different times of procedures, different limitations on application on food products once it is approved, etc. Therefore, I am considering that developing a map in advance about the conditions whether a “borderline substance” falls into one classification or another could bring an “a priori” regulatory picture to food companies for further innovations on food ingredients.

I would like to ask for your valuable opinion on whether the listed “differences of regulatory outcomes” are correct or whether I would be missing additional ones. I only could gather the listed ones from my perspective obtained by working on food industry on my home country (Peru), because no academic literature I could find at the University regarding this topic.

Thank you very much for your time and support Mr. de Rooij.
Re: Wageningen University - Moises Chong (Food saf... - Chong... http://webmail.wur.nl/owa/#viewmode=ReadMessageItem&It...

Best Regards,

Moises Chong
11.2. ANNEX II. Regulatory conditions differing between the EU borderline food additives

The following annex depicts all the clusters converging into the Table 5 from the Section III of this research.

Cluster Nº1: Application

The application is a procedure in which the authority (the EU Commission or the Member state depending on the procedure) brings permission for the commercialization of the related substance. For obtaining the permission, the applicant must submit a dossier containing information related to the substance’s safety for food application. This cluster focuses on depicting the differences between authorizations in terms of time, success rate, costs and property rights on the submitted data.

1. Time and success rate of applications

A dossier evaluation from its submission until the authority’s decision -whether they approve the substance or not- is a process that takes months and even years, and which outcome will not always involves the authorization as a result. The following Table 1 describes the summarized data obtained after a study detailed in the Annex III of this research on this matter:

<table>
<thead>
<tr>
<th>Substance Category</th>
<th>Number of successful applications (Nº)</th>
<th>Average time for a successful application (years)</th>
<th>Range of time for a successful application (years)</th>
<th>Successful Rates (%)</th>
<th>Number of submitted substances (Nº)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Additives</td>
<td>10</td>
<td>4.5</td>
<td>2.5 – 8</td>
<td>35.7 – 46.4</td>
<td>28</td>
</tr>
<tr>
<td>Extraction Solvents</td>
<td>1</td>
<td>2.8</td>
<td>(No data)</td>
<td>(No data)</td>
<td>1</td>
</tr>
<tr>
<td>Food Enzymes</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
</tr>
<tr>
<td>Other Processing Aids</td>
<td>(No application is needed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Enzymes (Which are not Processing Aids)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
</tr>
<tr>
<td>Novel Foods (Current)</td>
<td>152</td>
<td>3</td>
<td>1.3 – 5</td>
<td>&gt; 37.8</td>
<td>402</td>
</tr>
<tr>
<td>Novel Foods (New)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
</tr>
<tr>
<td>Traditional Foods (New)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
<td>(No data)</td>
</tr>
<tr>
<td>Foods in general</td>
<td>(No application is needed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrients</td>
<td>8</td>
<td>*3.1</td>
<td>*1.6 – 6.5</td>
<td>72.7</td>
<td>11</td>
</tr>
<tr>
<td>Flavourings</td>
<td>2</td>
<td>2.0</td>
<td>1.2 – 2.8</td>
<td>20 - 50</td>
<td>10</td>
</tr>
</tbody>
</table>

*Note [3]: The data belongs only to the time between the EFSA’s scientific risk assessment and the approval in the positive list. A full time measurement starting from the company’s application was not possible to perform due to lack of information on the submission date.

2. Costs for the applications

The costs of application procedures can be divided into three categories: 1) Registration fees, 2) Working hours/person 3) Dossier.

The registrations fees for most of the authorization procedures are free of charge. Food additives (FA), Food Enzymes (FE) and Flavourings (FL) procedures were clarified by Mr Jaap Kluijhooft from Précon Food Management B.V. on his communication from 4 August 2017 (Annex IV of this research), and NU procedure fee is not confirmed by the EU Commission. However, for Novel Foods, authorizations fees are established for every country under the current regulation, being for the Netherlands the amounts of € 2,068 for notifications and € 10,500 for a full application as established by the Medicine Evaluation Board (MEB, 2017). Regarding the new novel food regulation, there is still being analysed the existence of payment and its mechanism. And the working hours/person represents the salary of the persons involved on the elaboration and submission of the authorization dossier, which amount would depend on the dossier’s complexity and how the company or consultancy office is organized.
However, for the costs related to the dossier, they depend on the requirements established for every substance’s category as depicted in Table 2.

Table 2: Elements on Application’s dossiers from EU Borderline food additives depicted on their related guidelines.

<table>
<thead>
<tr>
<th>Dossier’s element</th>
<th>I. Regulatory background</th>
<th>II. Substance’s identity</th>
<th>III. Production process</th>
<th>IV. Compositional data</th>
<th>V. Product’s specifications</th>
<th>VI. History of use</th>
<th>VII. Proposed use</th>
<th>VIII. Nutritional information</th>
<th>IX. Toxicological information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sec. 2</td>
<td>Sec. 3</td>
<td>Sec. 2</td>
<td>Sec. 3</td>
<td>Sec. 2</td>
<td>Sec. 3</td>
<td>Sec. 2</td>
<td>Sec. 3</td>
<td>Sec. 3</td>
<td>Sec. 3</td>
</tr>
<tr>
<td>2.8</td>
<td>3.6</td>
<td>1.3</td>
<td>1.4</td>
<td>2.8</td>
<td>1.3</td>
<td>2.8</td>
<td>2.2</td>
<td>2.2</td>
<td>2.1</td>
</tr>
<tr>
<td>1.1</td>
<td>2.1</td>
<td>3.1</td>
<td>Sec. 1, Sec. IV, V, VI, VII</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
</tr>
<tr>
<td>1.3</td>
<td>2.3</td>
<td>3.3</td>
<td>Sec. 1</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>Sec. 2</td>
<td>1.5</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td>2.6</td>
<td>3.4</td>
<td>2.7</td>
<td>2.7</td>
<td>2.7</td>
<td>2.7</td>
<td>2.7</td>
<td>2.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sec. 4</td>
<td>Sec. 3</td>
<td>Sec. 4</td>
<td>Sec. 4</td>
<td>Sec. 3</td>
<td>Sec. 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.8</td>
<td>2.9</td>
<td>2.4</td>
<td>2.4</td>
<td>2.6</td>
<td>2.6</td>
<td>2.1</td>
<td>2.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.10</td>
<td>2.11</td>
<td>2.10</td>
<td>2.11</td>
<td>2.11</td>
<td>2.11</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:

(9) The requirement is optional.

The Table 3 describes the elements I to V contained in the toxicological section of the dossier from the substance's categories, in which the Extraction Solvents, the Novel Foods under the new regulation, Nutrients and Flavourings are following the same toxicological structure of the Food Additive. For this group of substances, the specific analysis methodologies are detailed. Being for the Food enzymes only specified for “Genotoxicity” but still requested for the rest of the sections, and for the current Novel Food regulation requested but not specified in all the sections. Nevertheless, the “Traditional Foods from third Countries” (New regulation of Novel foods), indicate that the toxicological analysis and information (complementing the information on the “History of Use”). Consequently, from the substance categories depicted, the requirement structures can be divided into two groups the “food additive-like” categories and the “food enzymes”. However, what those two types have in common are the division of their analysis strategies by “tiers”, in which a substance shows to have adverse toxicological effects in the first tier, it should undergo the tests on the second tier.

Considering the explained “tier” structure and the only available reference of costs for toxicological analysis coming from Rovida & Hartung (2009), it is possible to build the Table 4:
This Table 4 shows how companies in both type of analysis structures (food additives-like and food enzymes) will have to expend minimum € 115,700 in case the substance’s toxicological characteristics do not bring it to the second tier. In conclusion, and due to the limitation on cost information, it can be stated that the whole application (authorization fees + working hours/person + dossier) would cost > € 115,700.

3. Property rights involved on the submitted data

Property rights involved on the submitted data mainly consist on whether this data developed by the own company would belong to the open public or not (Data Protection) or whether the authority would keep secrecy on it during it evaluation (Confidentiality). The following Table 5 describes how this matter is treated along the substance’s categories within the EU borderline food additives:
Substances falling as FA, FE, FL, NU, “Traditional foods from third countries” or Extraction Solvents would not present “Data protection” because their authorization will be open for every producer willing to market the substance, meanwhile the companies submitting Novel food dossiers under the new regulation will be granted 5 years of data protection on their developed scientific/toxicological data from the date of authorization, fact that was not possible with the current novel food regulation (Brookes, 2007). Regarding the confidentiality of the dossier information, this is only granted to the non-safety relevant aspects and the applicant should request this confidentiality treatment; being the authority the one deciding on this matter. This confidentiality is applicable to all the substances submitting an authorization dossier.

### Table 5

Property Rights from the submitted data on applications dossiers for EU borderline food additives

<table>
<thead>
<tr>
<th>Classification of EU borderline food additive</th>
<th>Fact Nº1: Information that shall not be Non- Confidential</th>
<th>Fact Nº2: Applicant shall justify the requested confidentiality of information</th>
<th>Fact Nº3: Commission decides on the information’s confidentiality</th>
<th>To the newly developed scientific evidence or scientific data supporting the application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Additive, Food Enzyme, Flavouring &amp; Extraction Solvents (1)(2)</td>
<td>1. Name &amp; Address of applicant.</td>
<td>Yes</td>
<td>Yes</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td></td>
<td>2. Name and clear description of substance.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Justification of use.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Information relevant for the assessment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Where applicable, analytical method(s).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 years from the date of authorization (Art. 26.1).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novel Food (Current) (3)</td>
<td>(Not Specified, it is indicated that confidence measures should be implemented) (Art. 10)</td>
<td></td>
<td></td>
<td>(No data protection) (9)</td>
</tr>
<tr>
<td>Novel Food (New) &amp; Traditional Food (New) (3)</td>
<td>1. Name and address of the applicant.</td>
<td>Yes</td>
<td>Yes</td>
<td>For Novel Food</td>
</tr>
<tr>
<td></td>
<td>2. Name and description of the novel food.</td>
<td></td>
<td></td>
<td>For Traditional Food</td>
</tr>
<tr>
<td></td>
<td>3. Proposed conditions of use of the novel food.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Summary of the studies submitted by the applicant.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Results of the studies carried out to demonstrate the safety of the food.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Where appropriate, the analysis method(s).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Any prohibition or restriction imposed in respect of the food by a third country. (Art. 23.4.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrient (3)</td>
<td>(Not Specified, the applicant is only encouraged to make public as much information as possible) (Section 3)</td>
<td></td>
<td></td>
<td>(Not applicable)</td>
</tr>
</tbody>
</table>

**Notes:**


Cluster N°2: Differences on post-application obligations with Authority between the substances categories:

Substances obtaining an authorization will have to bring updated information concerning new scientific/technical information or even new restrictions or prohibitions applied to the substance, which would be of safety relevance to the authority. The Table 6 describes these requirements for all the substance categories for EU borderline food additives.

Table 6
Post-application obligations with the authority after obtaining the permission

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>II. The substance’s producer/user shall inform about: Any prohibition/restriction in a 3rd country.</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>(Art. 25)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>III. Member state should request to the food producer to which the substance is applied: Information on the product’s placing/withdrawn from the market.</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>(Art. 14.5)</td>
<td>---</td>
</tr>
</tbody>
</table>

Notes:

The Table 6 shows the tendency of bringing scientific/technical data to the authority to most of the substance’s categories, being the new novel food regulation requested to bring also further prohibitions/restrictions from other countries to the substance. Within this context of requesting updated information to the producers, the EU Commission with EFSA performs a re-evaluation process of approved food additives (Art. 26 of Regulation (EC) No 1333/2008) which would bring to the food additive the modification of their approved conditions (such as food categories and levels).
Cluster Nº3: Differences on conditions of production between substances categories:

Substance being identified among the categories of EU borderline food additives will show also different requirements impacting on the way of producing them.

<table>
<thead>
<tr>
<th>Substance Category</th>
<th>Processing aids allowed in the substance’s production</th>
<th>Food Additives allowed for addition to the substance</th>
<th>Contaminants applicable to the substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction Solvents</td>
<td>(Not applicable)</td>
<td>(Not applicable)</td>
<td>(Not specified)</td>
</tr>
<tr>
<td>Other Processing Aids</td>
<td>(Not applicable)</td>
<td>(Not applicable)</td>
<td>(Not specified)</td>
</tr>
</tbody>
</table>

These substances can be classified in two groups: the ones being regulated by “specifications” such as FA, PA, FE, NU and FL in which the substance production features are defined only for it such as the possibility of use of diverse substances like processing aids, and the level of contaminants. And the ones being “complex foods” such as NF or FG in which substances on their productions and contaminant levels are widely established and applied to those products in terms of what "food categories" do they belong to. Finally, for the specific case of food additives, this difference on those two groups is also noted in the Regulation (EC) No 1333/2008 in which the food additives from Annex II are applied to the “complex Foods” (NF or FG) and the Annex III to the substances defined by "specifications" (FA, PA, FE, NU and FL).

Cluster Nº4: Differences on conditions of commercialization between substances categories:

Finally, the substance’s categories present conditions affecting its commercialization such as restrictions for their use in food products in shape of food categories and level, is this authorization exclusive or non-exclusive to the applicant, labelling and possible claims.
The Table 8 shows the different frequencies in which these substances have restrictions going from rarely restricted for the Flavourings (due to their small amounts needed for having an effect on food products) up to the Nutrients being always restricted (due to the existence of minimum and maximum levels). In terms of authorization exclusivity, the novel foods are the only ones belonging to the applicant. Regarding the substances labelling within food products and as a product itself (sold as a product itself or within a food product), Flavourings are the less restricted by not needing to be labelled in food product (except when they involve allergens) and Flavourings not needing to be specific. Finally for existing nutritional/health claims, they are applicable to food-like substances such as (NF, FG) and Nutrients.

### Table 8

<table>
<thead>
<tr>
<th>Substance Category</th>
<th>Substance's conditions of use in food (level of use)</th>
<th>Authorization of a property rights involved on commercialization</th>
<th>I. On food products to consumers</th>
<th>II. For direct selling to consumers</th>
<th>III. For selling to food manufacturers</th>
<th>Possibility for nutritional/health claiming (sold as a product itself or within a food product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Additives (1)(2)</td>
<td>Generaly restricted</td>
<td>Open</td>
<td>Yes</td>
<td>Yes</td>
<td>(Similar to II)</td>
<td>---</td>
</tr>
<tr>
<td>Food Enzymes (2)(3)</td>
<td>---</td>
<td>---</td>
<td>In case of allergens</td>
<td>---</td>
<td>(Similar to II)</td>
<td>---</td>
</tr>
<tr>
<td>Processing Aids (2)(3)</td>
<td>---</td>
<td>---</td>
<td>In case of allergens</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Food Enzymes (2)(3) (Which are not Processing Aids)</td>
<td>Expected to be Generally restricted</td>
<td>Open</td>
<td>Yes</td>
<td>Yes</td>
<td>(Similar to II)</td>
<td>---</td>
</tr>
<tr>
<td>Novel Foods (2)(3)(5)(6) (Current)</td>
<td>Occasionally restricted</td>
<td>Only for the Applicant</td>
<td>Yes</td>
<td>Yes</td>
<td>(As I and II)</td>
<td>Possible</td>
</tr>
<tr>
<td>Novel Foods (2)(3)(5)(6) (New)</td>
<td>Occasionally restricted</td>
<td>Only for the Applicant in case of protected data</td>
<td>Yes</td>
<td>Yes</td>
<td>(As I and II)</td>
<td>Possible</td>
</tr>
<tr>
<td>Traditional Foods (2)(3)(4)(6) (New)</td>
<td>Occasionally restricted</td>
<td>Open</td>
<td>Yes</td>
<td>Yes</td>
<td>(As I and II)</td>
<td>Possible</td>
</tr>
<tr>
<td>Foods in general (2)(3)(6)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>Possible</td>
</tr>
<tr>
<td>Nutrients (2)(5)(7)</td>
<td>Always restricted</td>
<td>Open</td>
<td>Yes</td>
<td>But not specific</td>
<td>Yes</td>
<td>---</td>
</tr>
<tr>
<td>Flavourings (2)(3)(8)</td>
<td>Rarely restricted</td>
<td>Open</td>
<td>Yes, but not specific</td>
<td>Yes, but not specific</td>
<td>---</td>
<td>(As I and II)</td>
</tr>
</tbody>
</table>

**Notes:**


11.3. ANNEX III. Differences on time & success rate of new substances’ applications from companies among the possible classifications of EU borderline food additives

This Annex III describes the data being summarized in the Table 1 of Annex II.

Being noticed that a borderline food additive may fall into the classification of a FA, PA, FE, NF, FG, NU or FL, the following brief study has the objective of assessing the time and success rate of new substances’ applications from companies among those substance’s categories.

For achieving this objective, the proposed methodology consists on analysing the applications of new substances made by companies under the current applicable legislations. The relevance of limiting the study on approved or rejected substances up to only the ones performed under the current legislations is avoiding considering the substances authorized under conditions that do not exist anymore.

For the assessment of approved substances, the methodology in the current study involves the revision on the modifications of the related “positive list” from the legislations. These modifications belong to substances submitted by companies as “single” applications, because in case of having modifications with “bulk” approval of substances, the resulting time calculations of their approvals would not be realistic. Regarding the time calculation, the “finish date” is the date of the legislation’s modification involving the positive list, and the “starting date” is the submission date also indicated in the same modification. In case the “starting date” is not indicated on the modification, the related risk assessment’s request from the EU Commission to the EFSA works as a “EFSA’s starting date”. These risk assessment requests done by the EU commission to the EFSA can be found on the EFSA’s website for “register of questions” (see figure 1) by typing the related “keyword” of the substance to search.

Figure 1. EFSA’s register of questions (http://registerofquestions.efsa.europa.eu/roqFrontend/login?0)

These risk assessment requests indicate information on the substances’ identity, the company submitting the application and the dates in which the letter is sent by the EU Commission and also the one in which EFSA acknowledges the receipt (see Figure 2). The current study considers the first date between those as the reference because of scoping a slightly more realistic time for a calculation, but in case it is not possible, the second date is taken. This would not be a considerable problem due to the fact that both dates only differ in approximately one week between them.

Figure 2. Example of a scientific risk assessment by the EU Commission to the EFSA
This EFSA’s website for “register of questions” is also suitable for identifying the substances which risk assessments do not reflect the modification of the positive lists with the addition of the related substance; meaning that those substances are “not successful applications or still in progress”. Therefore, the “success rate” that this brief study can perform is on the basis of calculating the approved substances’/("approved substances” + “not successful or in progress”) x 100%.

I. Food Additives

The Table 1 includes the all the new substances submitted by companies since the publication of Regulation (EC) No 1333/2008, which were officialised as additions of the positive list by modifications of the regulation. Regarding the Table 2, it is elaborated by searching risk assessment’s requests on the EFSA’s register of questions under the keywords of “as a food additive” and “on a food additive” and excluding the risk assessment’s requests from the substances approved on the related positive list.

Table 1.

<table>
<thead>
<tr>
<th>No</th>
<th>Req 1333/2008 modification</th>
<th>Food Additives</th>
<th>Applicant</th>
<th>No of request from the EU Commission</th>
<th>Submission date (month/day/year)</th>
<th>Publication date (month/day/year)</th>
<th>Time between submission and publication (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>M28 7/30/2013</td>
<td>Stigmasterol-rich plant sterols (E 499)</td>
<td>Diageo plc.</td>
<td>(not available on the website, The applicant was found by the related EFSA’s scientific opinion)</td>
<td>2/11/11</td>
<td>7/30/13</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Note

Reasons for not including the following modifications on the positive list of food additives:


M5 11/31/2011 The assessment was started by the former Scientific Committee on food (SCF), (ref. SCIENTIFIC COMMITTEE ON FOOD, CS/ADD/EDUL/167 final, 17 June 1999, "Opinion on STEVIOSIDE AS A SWEETENER (adopted on 17/6/99)", EUROPEAN COMMISSION)

M7 3/80/2012 Edition of the positive list regarding food additives containing Aluminum.

M20 2/25/2013 Regarding iron oxides and hydroxides (E 172) Hydroxy propyl methyl cellulose (E 464) and polysorbates (E 432-436) only suffering modifications on their uses.

M35 12/74/2013 Brilliant Black BN, Black PN (E 151) is only renamed as "Brilliant Black PN (E 151)".

M45 9/57/2014 Removal of montan acid esters (E 912) from the positive list.

M54 9/2015/649 The application was submitted by a country (Germany) instead of a Company.

Food Additives

The Table 1 includes the all the new substances submitted by companies since the publication of Regulation (EC) No 1333/2008, which were officialised as additions of the positive list by modifications of the regulation. Regarding the Table 2, it is elaborated by searching risk assessment’s requests on the EFSA’s register of questions under the keywords of “as a food additive” and “on a food additive” and excluding the risk assessment’s requests from the substances approved on the related positive list.
Table 2: Substances submitted as new food additives for the positive list of Regulation (EC) No 1333/2008 not accepted by EFSA or which risk assessment still not being reflected as a modification of the related positive list.

<table>
<thead>
<tr>
<th>No</th>
<th>No of request from the EU Commission</th>
<th>Substance’s name</th>
<th>Applicant</th>
<th>EFSA Scientific Opinion (Date of research: 23-05-2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>DG SANCO/E3/AAP/gb (2013)308432</td>
<td>Anthrapen</td>
<td>Natural Red s.r.o.</td>
<td>Not accepted</td>
</tr>
<tr>
<td>3</td>
<td>DG SANCO/E3/DC/gb(2011)58885</td>
<td>Calcium lignosulfonate (40-65)</td>
<td>DSM Nutritional Products France</td>
<td>Published (26/07/2011)</td>
</tr>
<tr>
<td>4</td>
<td>DG SANCO/E3/WDB/gb(2012)1036027</td>
<td>Chlorine Gas</td>
<td>Knick and Clean</td>
<td>Published (16/02/2016)</td>
</tr>
<tr>
<td>5</td>
<td>DG SANCO/E3/Bl(2010)335230</td>
<td>Dihydroquercetin</td>
<td>ROSFIS-JSC Amedis</td>
<td>Not accepted</td>
</tr>
<tr>
<td>7</td>
<td>DG SANCO/E3/WDB/gb/530886 D</td>
<td>glycerol esters of tall oil resin</td>
<td>Georgia-Pacific Chemicals LLC</td>
<td>Published (6/2/2011)</td>
</tr>
<tr>
<td>8</td>
<td>DG SANCO/E3/MW/km D 531216 (2007)</td>
<td>Gum acacia modified with octenyl succinic anhydride</td>
<td>TIC GUMS, Inc</td>
<td>Published (31/03/2010)</td>
</tr>
<tr>
<td>10</td>
<td>DG SANCO/E3/WDB/km (2013)</td>
<td>Kopal</td>
<td>Walburg GmbH Industrielackfabrik</td>
<td>Not accepted</td>
</tr>
<tr>
<td>12</td>
<td>DG SANCO/E3/C0/qp(2011)1263216</td>
<td>Medium viscosity mineral oils</td>
<td>CONCAWE</td>
<td>Published (13/03/2013)</td>
</tr>
<tr>
<td>16</td>
<td>SANTE.E2/WDB/km (2016)</td>
<td>Curdlan</td>
<td>Intertek Scientific &amp; Regulatory Consultancy on behalf of MC Food Specialties Inc.</td>
<td>In progress</td>
</tr>
<tr>
<td>17</td>
<td>SANTE.E2/AAP/km (2017)</td>
<td>Glucosylated steviol glycosides</td>
<td>PureCircle</td>
<td>In progress</td>
</tr>
<tr>
<td>18</td>
<td>SANTE.E2/AAP/km (2016)</td>
<td>Low-substituted hydroxypropyl cellulose (L-HPC)</td>
<td>Association Management &amp;Regulatory Services on behalf of SE Tylose</td>
<td>In progress</td>
</tr>
</tbody>
</table>

Results:

According to the Table 1, the average of time needed is **4.5 years (2.5 – 8 years)**. And by comparing the Table 1 vs. the table 2, the resulting success rate ranges between **35.7 – 46.4 %**. These numbers assuming the extremes that those three “in progress” substances from Table 2 are going to be all rejected (10/(10+18) x 100% = 35.7%) or all approved (13/(10+18) x 100% = 46.4%).

II. Extraction Solvents (Processing Aids)

Apart from the Food Enzymes applying as Processing aids, the remaining type of this category involving an authorization procedure are the "Extraction Solvents". The Table 3 shows the unique substance being approved after the publication of the Directive 2009/32/EC.
Table 3. Substances submitted by companies as new extraction solvent according to the Directive 2009/32/EC.

<table>
<thead>
<tr>
<th>No</th>
<th>Directive 2009/32/EC modification</th>
<th>Extraction Solvent Name</th>
<th>Applicant</th>
<th>No of request from the EU Commission</th>
<th>Submission date to EFSA (month/day/year)</th>
<th>Publication date (month/day/year)</th>
<th>Time between submission and publication (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M1</td>
<td>Dimethyl ether</td>
<td>AKZO NOBEL Chemicals Holding GmbH</td>
<td>DG SANCO/E3/MW/km D 531005 (2007)</td>
<td>11/7/07</td>
<td>8/16/10</td>
<td>2.8</td>
</tr>
</tbody>
</table>

Results:

Due to only existing one substance being submitted since the publication of the Directive 2009/32/EC and because no other substance appeared on the EFSA’s register of questions by entering "extraction solvent", it was not possible to calculate neither time nor success rate. The only value of 2.8 years comes from the only available example.

III. Food Enzymes

The EU Commission document on "Food enzyme applications submitted to the Commission within the legal deadline (from 11 September 2011 to 11 March 2015)" (version 4 from 25 July 2016) gathers all the applications being made for the elaboration of the food enzyme’s positive list that will be published according to the Article 4 from Regulation (EC) No 1332/2008.

Results:

This EU Commission document indicates that the positive list is still in progress, consequently, all the submitted substances for a food enzyme approval are also still in progress. Therefore, it is not possible to calculate neither time nor success of rate.

IV. Novel Food

The EU Commission website possess a list of the novel foods application in which their status are also indicated. The Table 4 summarises this information by evaluating the list version from 17-03-2017. Regarding the time calculation from the successful applications, Brookes (2007) on its briefing paper called "Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector" for the Confederation of the Food and Drink Industries of the European Union (CIAA) & the Platform for Ingredients in Europe (CIE) indicates as average time as 3 years, ranging between 1.3 – 5 years. This tendency was confirmed also from 2007 onwards by reviewing the novel food list version from 17-03-2017. It is important to mention that the novel food application under the new regulation (EU) No 2283/2015 will enter in force in 2018. Consequently, the current data available of applications belongs to the regulation (EC) No 258/97.

Table 4

Status of all the novel food dossiers being submitted until the date within the European Union. (Date version of data: 17-03-2017)

<table>
<thead>
<tr>
<th>Status of the already submitted Novel food dossiers since 1997</th>
<th>Dossiers</th>
<th>Amount</th>
<th>Percentage from total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusal/withdraws</td>
<td>36</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>&quot;Not applicable&quot;</td>
<td>1</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Approved/no objections</td>
<td>152</td>
<td>37.8</td>
<td></td>
</tr>
<tr>
<td>In progress (the oldest from 2000, youngest is 2017)</td>
<td>213</td>
<td>53.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>402</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Additionally to the 402 applications, there exist two belonging to “extensions” of use from approved novel foods. These two applications are not part of the calculations due to not involving the application of a new substance.
Results:
The average of time needed is approx. 3 years (1.3 – 5 years).
Regarding the success rate, in case all the 213 “In progress” applications indicated on the Table 4 ends up being refused/withdrew, the minimum success rate would be 37.8%. The limitation for calculating the maximum success rate is that the “in progress” applications range from 2000 up to 2017.

V. Food in general
"Foods in general” within the study refers to “food” under the Article 2 from Regulation (EC) No 178/2002, which do not fall into the specific categories of FA, PA, FE, NF, NU or FL. However, there no exist authorization procedures applying to it.

Results:
There is no applicable authorization procedure for those substances.

VI. Nutrients

Table 5
New nutrients as “single approvals” in modifications of regulations involved on the “ADMINISTRATIVE GUIDANCE ON SUBMISSIONS FOR SAFETY EVALUATION OF SUBSTANCES ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN THE MANUFACTURE OF FOODS”.

<table>
<thead>
<tr>
<th>No</th>
<th>Modification</th>
<th>Substance</th>
<th>Applicant</th>
<th>No of request from the EU Commission</th>
<th>Submission date received by EFSA (month/day/year)</th>
<th>Publication date (month/day/year)</th>
<th>Time between submission and publication (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Modification 119/2014</td>
<td>chromium enriched yeast</td>
<td>IA Food Consulting on behalf of Precise Ingredients</td>
<td>SANCO/E4/AK/ib</td>
<td>7/18/11</td>
<td>2/7/14</td>
<td>2.6</td>
</tr>
<tr>
<td>5</td>
<td>Modification 119/2014</td>
<td>chromium(III) lactate tri-hydrate</td>
<td>Agrobac</td>
<td>SANCO/E4/YA/ko</td>
<td>1/20/11</td>
<td>2/7/14</td>
<td>3.1</td>
</tr>
<tr>
<td>6</td>
<td>Modification 2015/414</td>
<td>(6S)-5-methyltetrahydrofolic acid, glucosamine salt</td>
<td>WTC Consulting GmbH on behalf of GNOSIS GmbH</td>
<td>SANCO/E5/AK/bs</td>
<td>9/14/12</td>
<td>3/12/15</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Table 6

<table>
<thead>
<tr>
<th>No</th>
<th>Substance</th>
<th>Applicant (Company)</th>
<th>Purpose</th>
<th>EFSA’s published Opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Heme iron (blood peptonates)</td>
<td>APC Europe S.A.</td>
<td>Foodstuffs and food supplements</td>
<td>27/04/2010</td>
</tr>
<tr>
<td>2</td>
<td>Iodized ethyl esters of poppy seed oil</td>
<td>Bunge Europe</td>
<td>Foodstuffs</td>
<td>7/03/2013</td>
</tr>
<tr>
<td>3</td>
<td>Phosphoryl Oligosaccharides (POs-Ca®)</td>
<td>Glico Nutrition Co., Ltd.</td>
<td>Foodstuffs, food supplements and foods for special medical purposes</td>
<td>17/06/2016</td>
</tr>
</tbody>
</table>

Results:

From the table 5, the average of time needed is **3.1 years (ranging from 1.6 – 6.5 years)**. Unluckily, this data belongs to only the measuring between the EFSA risk assessment and the publication on the positive list and not starting from the application submitted by the company. And from both tables 5 and 6, the success rate of **72.7%** (72.7% = 8/(8+3) x 100%).

VII. Flavourings

The Table 7 includes the two new substances submitted by companies since the publication of Regulation (EC) No 1334/2008, which were officialised as additions of the positive list by modifications of the regulation.

The other substances’ approvals added in the positive list by the other modifications belongs to an evaluation programme according to the Regulation (EC) No 2232/96, in which the substances are clustered into "Flavouring Group Evaluations (FGEs)". Therefore, they are not included for avoiding deviations on the time calculation of the successful applications.

Table 7

<table>
<thead>
<tr>
<th>No</th>
<th>Reg. 1334/2008 modification</th>
<th>Flavourings</th>
<th>Applicant</th>
<th>No of request from the EU Commission</th>
<th>Submission date (month/day/year)</th>
<th>Publication date (month/day/year)</th>
<th>Time between submission and publication (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M9 2016/54</td>
<td>gamma-glutamyl-valyl-glycine (FL-no: 17.038)</td>
<td>Ajinomoto Co. Inc.</td>
<td>SANCO.E3/SH/sec (2013)</td>
<td>3/21/13</td>
<td>1/19/16</td>
<td>2.8</td>
</tr>
<tr>
<td>2</td>
<td>M10 2016/55</td>
<td>3-{[4-amino-2,2-dioxido1-H-2,1,3-benothiadiazin-5-(y)oxy]-2,2-dimethyl-N-propylpropanamide (FL-no: 16.128)}</td>
<td>Firmenich</td>
<td>SANCO.E3/SH/km D (2011)</td>
<td>11/12/14</td>
<td>1/19/16</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Regarding the Table 8, it is elaborated by searching risk assessment’s requests on the EFSA’s register of questions under the keywords of “new flavouring” and excluding the risk assessment’s requests from the substances approved on the related positive list.
Table 8

Substances submitted as new flavourings for the approved list of Regulation (EC) No 1334/2008 which risk assessment still not being reflected as a modification of the related approved list.

<table>
<thead>
<tr>
<th>No</th>
<th>No of request from the EU Commission</th>
<th>Substance’s name</th>
<th>Applicant</th>
<th>Information received by EFSA (month/day/year)</th>
<th>EFSA’s Scientific Opinion (Date of research: 23-05-2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>SANTE.E2/MGR/md(2016) 7592145</td>
<td>Naringenin (CAS: 480-41-1)</td>
<td>Interquim S.A.</td>
<td>12/19/16</td>
<td>In progress</td>
</tr>
<tr>
<td>3</td>
<td>SANTE.E2/MGR/md (2016) 7593120</td>
<td>1-Methylnaphthalene, FL 01.014</td>
<td>International Organization of the Flavour Industry (IOFI)</td>
<td>12/19/16</td>
<td>In progress</td>
</tr>
<tr>
<td>4</td>
<td>SANTE.E7/MGR/aa (2015)</td>
<td>2-(4-Methylphenoxo)-N-((3H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl) acrylamide</td>
<td>Keller and Heckman LLP</td>
<td>12/7/15</td>
<td>Additional data request</td>
</tr>
<tr>
<td>6</td>
<td>SANTE.E7/MGR/aa (2015)</td>
<td>(E)-3-(2,4-Dimethoxyphenyl)-N- [2-(3- methoxyphenyl)-ethyl]- acrylamide</td>
<td>Firmenich</td>
<td>4/20/15</td>
<td>Additional data request</td>
</tr>
<tr>
<td>7</td>
<td>SANCO.E7/MGR/aa (2015)</td>
<td>(S)-1-[3-[(4-amino-2,2-dioxido-1H-benzo[c][1,2,5]triazin-3-yl)oxymethyl]piperidin-1-yl]-3- methylbitan-1-one</td>
<td>Keller and Heckman LLP</td>
<td>1/26/15</td>
<td>Additional data request</td>
</tr>
<tr>
<td>8</td>
<td>SANCO.E3/SH/km (2012)</td>
<td>3’-[(3,5-dimethylisoxazol-4-yl)methyl]-1H-pyrazol-4-yl-]&lt;[-(3- hydroxybenzoyl)imidazolidine-2,4-dione.</td>
<td>Firmenich</td>
<td>9/28/12</td>
<td>In progress</td>
</tr>
</tbody>
</table>

Results:

According to the Table 7, the average of time needed is **2.0 years (1.2 – 2.8 years)**. There existed only 2 substances involved. And by comparing the Table 7 vs. the table 8, the resulting success rate ranges between **20 – 50%**. These numbers assuming the extremes that those three “in progress” substances (with additional data requested) from Table 8 are going to be all rejected (2/(2+8) x 100% = 20%) or all approved (5/(2+8) x 100% = 50%).
11.4. ANNEX IV. Communication with Mr Jaap Kluifhooft from 4 August 2017

RE: Wageningen University - Moises Chong (Food safety Law)

Jaap Kluifhooft <jkluifhooft@precon-food.nl>
Fri 8/4/2017 9:10 AM
Cc: Chong Sakihara, Moises <moises.chongsakihara@wur.nl>; Meulen, Bernd <bernd.vandermeulen@wur.nl>

Dear Moises,

There is no fee authorization fee involved in the applications for Food additives, Food Enzymes, Favouring and Nutrients.

See also:

With kind regards
Jaap Kluifhooft
+ 31 (0)6 - 1906.6442
jkluifhooft@precon-food.nl

Précon Food Management B.V.
Reguliererring 16a, 3981 LB Bunnik
Postbus 26, 3980 CA Bunnik
+ 31 (0)30 - 656 60 10
www.precon-food.nl

-----Oorspronkelijk bericht-----
Van: Chong Sakihara, Moises [mailto:moises.chongsakihara@wur.nl]
Verzonden: zaterdag 22 juli 2017 14:58
Aan: Jaap Kluifhooft <jkluifhooft@precon-food.nl>
CC: Meulen, Bernd <bernd.vandermeulen@wur.nl>
Onderwerp: Re: Wageningen University - Moises Chong (Food safety Law)

Dear Mr Jaap,

Thank you very much for the meeting last Friday.

Regarding your comment about the lack of any “Authorization fees” for:
Food additives, Food Enzymes, Flavourings and Nutrients.

I would like to kindly ask you to confirm me by answering this mail in order to have it as a record for my thesis.

Thank you very much for your support Mr Jaap,
 Regards, Moises.

From: Chong Sakhara, Moises
Sent: Wednesday, July 19, 2017 12:23 PM
To: Jaap Kluijffoort
Cc: Meulen, Bernd vander
Subject: Re: Wageningen University - Moises Chong (Food safety Law)

Perfect Mr. Jaap, I will be there.

Regards, Moises

From: Jaap Kluijffoort <jkluijffoort@precon-food.nl>
Sent: Wednesday, July 19, 2017 8:39 AM
To: Chong Sakhara, Moises
Cc: Meulen, Bernd vander
Subject: RE: Wageningen University - Moises Chong (Food safety Law)

Dear Moises,

I could be available for a Skype conference this Friday afternoon 21 July from 14.00hr. onward.
My Skype-address/name is: jaap.kluijffoort@outlook.com

With kind regards
Jaap Kluijffoort
+31 (0)6 - 1906.6442

-----Oorspronkelijk bericht-----
Van: Chong Sakhara, Moises [mailto:moises.chongsakhara@wur.nl]
Verzonden: dinsdag 18 juli 2017 17:43
Aan: Jaap Kluijffoort <jkluijffoort@precon-food.nl>
CC: Meulen, Bernd vander <bernd.vandermeulen@wur.nl>
Onderwerp: Re: Wageningen University - Moises Chong (Food safety Law)

Dear Mr Jaap, good afternoon,

I am glad to hear from you, please do not worry about the delay.

Regarding my thesis, I am in the final stage and my presentation will be in August 29th.

The list that I attached in our last communication was a proposal about the elements that companies developing food ingredients will take into consideration as "regulatory consequences" from the resulting substance's classification from their developments; being the substance classification a status of "Food additive", "Novel food", "Nutrient", "Flavouring", "Food Enzyme" or "Processing aid". Regarding this list, I have already talked to a RA manager from the FNL and he advised me to "clusterize" the regulatory consequences, which I later grouped as regulatory outcomes affecting 1. the application, 2. substance's production, 3. Responsibilities with the Authority"
RE: Wageningen University - Moises Chong (Food saf... - Cham...  https://webmail.wur.nl/owa/#viewmodel=ReadMessage&... 

and "4. Commercialization".

However, the assessment of the "regulatory outcomes" to the companies developing food ingredients is only one part of my thesis. My thesis is called "EU borderline food additives: Legal basis and classification for the food ingredient industry", in which I address all those substances that are difficult to classify as food additives and non-food additives in order to explain them and mapping all the conditions for their classification. And for explaining the relevance of this research for the food ingredient industry, I am dedicating one section for explaining that their final classification of these substances as food additives or other non-food additives (such as novel foods, nutrients, flavourings, processing aids, food enzymes) involves potential "pro and cons" as consequences of their regulatory classification (consequences in "application", "substance production", "responsibilities with the Authority" and "Commercialization") which is a matter of concern for new food ingredients for development.

I would definitely like to have a short skype conference with you to hear some comments about my thesis and share some findings.

Best regards,

Moises

From: Jaap Kluijffoort <jkluijffoort@precon-food.nl>
Sent: Friday, July 14, 2017 2:45 PM
To: Chong Sakihara, Moises
Cc: Meulen, Bernd vander
Subject: Wageningen University - Moises Chong (food safety Law)

Dear Moises Chong,

First my apology for not reacting sooner on the email you have sent me a few weeks ago. Unfortunately I received your email during a hectic period to, just before my holiday period, so it ended up in my "to-do/read" email box.

After Bernd van der Meulen asked my last November to help you with some of your questions, I expected a call/message shortly after that. But that didn't come, so I had a kind of 'forgotten' you.

I suppose that you are about to start your thesis and the document you sent me is a kind of 'working plan' for your thesis, is that correct?
Maybe it would be an idea to have a short teleconference to discuss your paper?

With kind regards

Jaap Kluijffoort
+31 (0)6 - 1906.6442
jkluijffoort@precon-food.nl
(cid:image003.png@01D1157C.860CF860]
(cid:image002.png@01D20A95.25E860DC0]
RE: Wageningen University - Moises Chong (Food saf... - Chon... https://webmail.wur.nl/owl/#viewmodel=ReadMessageItem&It...

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www.precon-food.nl <http://www.precon-food.nl/>

[cid:image001.png@01D20A95.25E86DC0] <https://www.linkedin.com/company/precon-food-management-bv>
[cid:image004.png@01D20A95.25E86DC0] <https://twitter.com/preconfoodnews/>

-----Oorspronkelijk bericht-----
Van: Chong Sakihara, Moises <mailto:moises.chongsakihara@wur.nl>
Verzonden: maandag 22 mei 2017 16:11
Aan: Jaap Kluijffoxt <jkluijffoxt@precon-food.nl>
CC: Meulen, Bernd vander <bernd.vandermeulen@wur.nl>
Onderwerp: Wageningen University - Moises Chong (Food safety Law)

Dear Mr. Kluijffoxt:

Good morning, nice to meet you,

My name is Moises Chong, Master Student from Wageningen University on Food Safety Law. Professor Bernd van der Meulen kindly brought me your contact. If possible I would like to ask you for your valuable opinion on my thesis research.

I am currently working on food additives that are difficult to classify as such because they appear to be on the "border" between food additives and other food substances like enzymes, novel foods, flavourings, processing aids or even with common foods: For example, foodstuffs with colouring properties that are not classified as food additives, enzymes approved as food additives, novel foods that are also food additives, etc. I am calling these food additives as "borderline additives".

4 de 7
4/8/17 14:38
My objective with this thesis is identifying all these “borderline spots” on the EU legislation and mapping all the conditions in which those “borderline substances” can occur.

For establishing the motivations on why this research would be important, I am stating that a substance falling within a food additive classification will carry different “regulatory outcomes” in comparison to the possibility of being classified as processing aid, novel food, food enzyme, nutrient, etc.

The “differences of regulatory outcomes” between these substances in comparison to a food additive that I could identify by my own are, for example, differences on dossier requirements, different times of procedures, different limitations on application on food products once it is approved, etc. Therefore, I am considering that developing a map in advance about the conditions whether a “borderline substance” falls into one classification or another could bring an “a priori” regulatory picture to food companies for further innovations on food ingredients.

I would like to ask for your valuable opinion on whether the listed “differences of regulatory outcomes” are correct or whether I would be missing additional ones. I only could gather the listed ones from my perspective obtained by working on food industry on my home country (Peru), because no academic literature I could find at University level regarding this topic.

Thank you very much for your time and support Mr. Kluijffoert

Best Regards,

Moises Chong
RE: Wageningen University - Moises Chong (Food saf... - Chen... https://webmail.wur.nl/oWA/#/viewmodel=ReadMessageItem&... 

From: Meulen, Bernd vander
Sent: Sunday, November 13, 2016 5:14 PM
To: jkluifhooff@precon-food.nl<brmailto;jkluifhooff@precon-food.nl>
Cc: Chong Sakihara, Moises
Subject: Additives

Dear Jaap,
Thank you.

Dear Moises.
Mr. Jaap Kluijfhooft is very experienced in food additives. I am sure he will be able to answer some of your questions.

Kind regards,
Bernd

B.M.J. van der Meulen
Professor of Food Law
Wageningen University
Postbox 8130 - 6700 EW Wageningen
Tel. +31 317 - 484159 (sect.)
E-mail: Bernd.vanderMeulen@wur.nl<brmailto:Bernd.vanderMeulen@wur.nl><mailto:Bernd.vanderMeulen@wur.nl%3emailto:Bernd.vanderMeulen@wur.nl>

Further information:

6 de 7
Nederlandse Vereniging voor Levensmiddelenrecht:

Wageningen University, Law and Governance Group offers a specialisation Food Safety Law. For information see Master Food Safety Law http://www.law.wur.nl/UK'Master:+Food:+Safety:+Law/
11.5. ANNEX V. Communication with Mr Nigel Baldwin from 18 November 2016

RE: Request of information about “Regulatory Insight: Inside Rosemary’s Approval”

Nigel Baldwin Intertek <nigel.baldwin@intertek.com>
Fri 11/18/2016 11:15 AM

To: Chong Sakihara, Moises <moises.chongsakihara@wur.nl>; *CP Global Health Environment Web Info <web.cp@hes@intertek.com>
Cc: Meulen, Bernd vander <bernd.vandermeulen@wur.nl>

Dear Moises,

Thanks for the email.

The answer to your question is no, not at all and that took many years to evolve within the industry. If you look at the EU specification for e392 you will see that it is now defined but that came later. You may also be aware of this more recent document produced to guide the colourings people, https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_additive-eu-rules.pdf. The same principles apply.

Hope this helps.

Kind regards,

Nigel

Nigel Baldwin BSc CSci
Director of Scientific & Regulatory Consulting Europe
Intertek Scientific & Regulatory Consultancy

--- Original Message ---
From: Chong Sakihara, Moises <moises.chongsakihara@wur.nl>
Sent: 17 November 2016 23:21
To: Nigel Baldwin Intertek; *CP Global Health Environment Web Info; Nigel Baldwin Intertek
Cc: Meulen, Bernd vander
Subject: Request of information about “Regulatory Insight: Inside Rosemary’s Approval”

Dear Mr. Baldwin,

Good morning,

I am pleased to write to you. My name is Moises Chong, a thesis student from Prof. Bernd van der Meulen (on copy in this communication) in Wageningen University and Research (The Netherlands) on the master specialization of Food Safety Law.
On my thesis, I am currently working on explaining the "Regulatory paths" that companies can follow in front of substances, which appears to be on the "threshold" between the concepts of Food Additives and Common Foods.

During this research, I was really glad to find on the web your article "Regulatory Insight: Inside Rosemary’s Approval" from "The World of Food Ingredients APRIL/MAY 2011" (see annex), in which you explain that the Standing Committee (around 1998) confirmed that Rosemary extracts should be considered as food additives in cases where they were selectively extracted, deodorized and deliberately added for the purposes of keeping food fresh.

I apologize for the following specific question, but I would be extremely grateful if you could bring me information about if the Standing Committee had in that moment an specific "criteria" for defining whether a substance was selectively extracted, deodorized and deliberately added for this technical function, or on the other hand, if the "criteria" in this case was the ratio mentioned on the article and proposed by the industry. This information will be really helpful for my research.

Thank you very much for your support Mr. Baldwin,

Yours sincerely,

Moises Chong

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