

## Review Article

# Novel foods: an explorative study into their grey area

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European Union Regulation 258/97 defines novel foods as food products and food ingredients that have not been consumed to a significant degree in the European Union before May 1997. However, there are new foods that for some reason are not considered as novel foods, though we think that safety of these products is not always *a priori* established. We defined a ‘grey area’ which consists of such foods, and the present paper intends to raise awareness of this ‘grey area’ of unidentified novel foods. The grey area of novel foods is divided into two categories: (1) food products or ingredients for which the current Regulation leaves too much space for different interpretations and (2) food products or ingredients that are not novel according to the current Regulation, because the current Regulation contains gaps. These categories are illustrated by means of products already on the market in The Netherlands. We found about two dozen examples of products that had not been identified as novel foods according to the current Regulation, yet could be considered to be classified as novel foods and hence for which a safety evaluation (toxicological and/or nutritional) would be indicated.

### Novel foods: European Union Regulation 258/97: Grey areas: Food safety

Until 1997, consumption of traditional as well as new food products was generally assumed to be safe. Then, the food industry started to introduce more and more new products into the consumer market. This, in combination with the increase in worldwide production and trade flows of foods and the rise of modern biotechnology, gave rise to the introduction of European Union (EU) Regulation 258/97, in the present paper referred to as ‘the Regulation’<sup>(1)</sup>.

The Regulation was established to guarantee that new foods and food ingredients: (1) would not present a danger to the consumer, (2) would not mislead the consumer and (3) would not differ from food products or food ingredients for which new food products are a substitute to such an extent that normal consumption of those new products would be nutritionally disadvantageous for the consumer<sup>(2)</sup>.

According to the Regulation, novel foods are food products and food ingredients that have not been used for human consumption to a significant degree within the European Community before 15 May 1997 and fall in one (or more) of the categories below (quoted from EU Regulation 258/97<sup>(3)</sup>):

- (i) ‘foods and food ingredients with a new or intentionally modified primary molecular structure;
- (ii) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- (iii) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
- (iv) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances’.

Initially, foods and food ingredients containing or consisting of GM organisms and those produced from, but not containing, GM organisms were also considered as novel foods. However, since 18 April 2004 for these foods and food ingredients a separate Regulation is in force<sup>(4)</sup>.

**Abbreviations:** EU, European Union; HC, Health Council of the Netherlands (Gezondheidsraad).

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## Authorisation or notification

Novel foods have to be officially approved through the novel foods authorisation procedure before introduction on the European market. An application for authorisation contains a specification of the novel food, a description of the effects of the applied production processes, a description of the history of the organism used as a source, information on the anticipated intake, information from previous human exposure to the novel food, nutritional information, biological information, toxicological information, and information on labelling<sup>(5)</sup>.

In every EU country an organisation is authorised to review national novel foods dossiers, for example, the Ministry of Health and the Ministry of Agriculture. In the present paper such organisations are referred to as 'competent authority'. The producer must submit an application for authorisation to both the competent authority in one of the European member states and to the European Commission. 'A competent authority arranges for an assessment of the product for consumer safety. The safety assessment is performed on the basis of current scientific knowledge. The competent authority uses the safety assessment as a basis for reaching a national decision. All the other EU member states are then invited to assess the dossier of the applicant and the initial assessment from the competent authority. This assessment by the other member states is called a 'second opinion'. If a dossier raises so many questions that consensus between the member states is unachievable, the European Commission requests advice from the European Food Safety Authority (EFSA). The formal decision-making on authorizing a novel food takes place in the Standing Committee for the Food Chain and Animal Health and, if necessary, in the European Council of Ministers. Once authorised, the product may be sold across the European Union.'<sup>(6)</sup> The Regulation is currently under review<sup>(7)</sup> and our aim is to raise attention to some of the challenges.

If new foods or food ingredients are very similar to existing products, the company may follow a simplified (notification) procedure. Such a procedure evaluates substantial equivalence to existing foods or food ingredients (with regards to their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein)<sup>(5)</sup>. A 'history of safe use' of the comparable product is an important aspect underlying the principle of substantial equivalence<sup>(8)</sup>.

In practice, it is the producer who decides to characterise a food as a novel food and decides whether a new product should go through an authorisation or notification procedure. In each member state, an enforcement body has the responsibility to monitor these notifications, typically a national food safety authority.

## Rationale

Whereas most foods are clearly traditional foods and some are clearly novel foods, it is our concern that not all new foods or food ingredients for which safety of consumption remains to be established are recognised as novel food. We refer to such foods, which may pose a potential hazard and possible risk for public health, as the 'grey area of novel foods'. The presence of such foods caused us to raise a discussion on this topic.

Some discussion papers refer to gaps in the Regulation that could cause a grey area of concern. With regard to the terminology that is used within the Regulation, i.e. 'significant degree', it can be argued that 'significant' is a qualitative term, the interpretation of which may vary according to the (subjective) priorities of the applicant<sup>(9,10)</sup>. What is significant to one interest may be insignificant to another, despite objective facts. Furthermore, the European Commission has written a discussion paper<sup>(11)</sup> concerning comments on the current Regulation on novel foods. An important comment concerns the category 'foods and food ingredients to which has been applied a production process not currently used, where that new process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances'<sup>(3)</sup>. The main implementation issue in relation to this category is confusion about what exactly is meant by a 'significant change' in the composition or structure of foods, given that production processes always involve some change of this nature.

The present paper provides an overview of the problems and challenges that cause this grey area and illustrates these problems by means of several examples found on the Dutch market. It gives an overview of the grey area of novel foods on the Dutch market, as well as suggestions on how to correctly characterise these foods as novel foods.

Therefore, we addressed the following two questions:

- (1) To what extent does a grey area exist consisting of foods that have been introduced onto the market since May 1997 that could be classified as novel, but, however, have remained unidentified as such?
- (2) If such a grey area of novel foods exists, then what are its possible causes (and potential consequences and risks)?

## Methodology

Since to date there was no prior literature on the grey area of novel foods, we started with defining the grey area, followed by identifying food products that would fall within this definition. We listed unclarities related to the Regulation, which could form the demarcation of the grey area. Issues related to novel foods were based on the interpretation of the literature, food regulations and the opinion of experts. The following issues concerning the grey area were listed:

- Additives;
- Flavourings;
- Supplements;
- Fortified foods with vitamins and minerals;
- Herbal supplements;
- The term 'significant degree';
- Shift in target group;
- Traditional breeding methods;
- Growth stage of crops;
- Change in production process.

Next, a literature study was conducted to underpin a clear definition of the grey area of novel foods. Subsequently, we identified actual products that fall within the definition of the grey area.

During the course of our research, the Health Council of the Netherlands (HC) published a report in which they addressed a number of the issues we address in the present paper. From 1999 to 2004, the Netherlands Committee on Safety Assessment of novel foods (VNV; Veiligheidsbeoordeling Nieuwe Voedingsmiddelen) carried out a large number of dossier assessments of novel foods applications. Based on these findings, the HC had composed an advisory report on issues associated with the implementation of the Regulation and accompanying developments<sup>(12)</sup>. Apart from an overview of the current implementation of the Novel Food Regulation in general terms, the HC discusses issues of the Regulation and includes comments that largely concur with our notion of weaknesses of the Regulation. The HC did not provide, however, details on products. The HC report combined with own research forms the basis for the present paper.

#### *Food products and ingredients excluded from the present study*

To several foods and ingredients a regulation other than the Novel Foods Regulation applies, and we have excluded these from the present paper: additives; flavourings; supplements; foods fortified with vitamins and minerals; GM organisms.

**Additives.** Additives are defined as ‘any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food result, in it or its by-products becoming directly or indirectly a component of such foods.’<sup>(13)</sup> Examples of additives are preservatives, sweeteners and thickeners.

**Flavourings.** Flavourings are substances ‘used or intended for use in or on foodstuffs to impart odour and/or taste, and to source materials used for the production of flavourings’<sup>(14)</sup>. Art 1 (2) of Directive 88/388/EEC defines different types of flavourings, such as natural or artificial flavouring substances.

**Supplements.** Supplements are defined as ‘foodstuffs of which the purpose is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities’<sup>(15)</sup>. Food supplements were excluded from the present research, as this would open an in-depth investigation into all kinds of food supplements via a large variety of outlets.

**Foods fortified with vitamins and minerals.** European Regulation 1925/2006 concerns food products fortified with vitamins and minerals. It states that the European Commission will compose a repertorium of ‘legal’ vitamins and minerals and the conditions for their use. Vitamins and minerals that are already being used in a member state during the introduction of the Regulation are allowed to be used in that member state for 7 years after entering the market if the member state

provides the European Food Safety Authority with a safety report<sup>(16)</sup>. In addition to vitamins and minerals, EU Regulation 1925/2006 also deals with ‘other substances’ and provides for lists of substances ‘permitted’, ‘restricted’ or ‘under scrutiny’.

**Genetically modified organisms.** EU Regulation EU1892/2003 covers GM organisms and foods. Therefore GM organisms are also exempted from the present study.

#### *Determinants of the size of the grey area*

The Regulation includes two arbitrary characteristics that determine which new food products fall under this Regulation, which are directly linked to the size of the grey area of novel foods. These are the time line of 1997 and the European border.

**Time line of 1997.** To assess whether a food is novel, it has to be determined if the food product or ingredient has been significantly consumed in the EU before 15 May 1997. Foods that were consumed before this date are considered to be safe if no dangerous health effects were reported in the past. For new food products that enter the market after this arbitrarily chosen date, safety is not automatically assumed. If the Regulation had been implemented on an earlier or later date, more or fewer food products would be characterised as novel, respectively.

Example – probiotics and phytosterols:

Food products were enriched with probiotics before 1997. Therefore, new applications of probiotics do not need to follow the novel food procedure. Products with phytosterols on the other hand were first marketed in 2001 and were therefore considered as novel. New applications of phytosterols need to go through the authorisation or notification procedure. This would not have been the case if phytosterols had been introduced before 1997.

**European border.** Food products and ingredients are novel when they have not been used for human consumption within the EU<sup>(3)</sup>. This European border changes regularly. Can food products that are approved as novel food, or have a safe history of consumption in, for example, the USA or Australia be regarded as novel in the EU?

In the consideration of whether or not a food is novel, the EU border plays an important role. However, the number of EU members is not constant, since regularly new countries join the EU. As a result, if a food was already consumed in the new EU country before 15 May 1997, it can suddenly get a history of use in an EU country. With expansion of the EU, foods that were traditionally only consumed in a country that has just become a member state of the EU can be sold on the European market without the need for safety assessment of that food.

Example – phytosterols:

Phytosterols were introduced as blood cholesterol-lowering ingredients in the EU when Finland became a member in 1995. As a result these ingredients were consumed in an EU member state, whereas if Finland had not entered, they would have to be authorised as novel foods.

## **Results and discussion**

We identified two categories of food products forming a potential grey area of novel foods:

- (i) Food products or ingredients for which the current Regulation leaves too much space for different interpretations;
- (ii) Food products or ingredients that are not novel according to the current Regulation, because the current Regulation contains gaps.

Within these categories, subcategories have been defined. These categories and subcategories will be explained with examples. Below we discuss about two dozen examples that support the hypothesis that a grey area of novel foods does exist.

#### *Foods for which the current Novel Foods Regulation leaves too much space for different interpretations*

For some products it is difficult to classify them correctly as novel food or not, because the current Regulation leaves too much space for different interpretations on a number of aspects. These aspects will be discussed below.

*The term 'significant degree' related to consumption before 15 May 1997.* The Regulation states that the Regulation applies to 'food products and food ingredients that have not been used for human consumption to a significant degree within the community before 15 May 1997'<sup>(3)</sup>. However, a quantification of the concept of 'significant degree' is not provided.

For the following examples, it is clear that these products have been consumed outside the EU. However, it is difficult to determine whether these have been consumed to a 'significant degree' within the EU before May 1997.

Examples where the criterion 'human consumption to a significant degree' may be an issue:

- (1) Human consumption of camel milk is common in many Asian and African countries. It serves as a staple food of desert nomad tribes. Camel milk differs in composition from cows' milk<sup>(17)</sup>.
- (2) Teff is an important food grain in Ethiopia and Eritrea and less so in India and Australia. Traditionally, the grain is consumed in the form of bread-like pancakes. In Ethiopia, it accounts for about a quarter of the total cereal<sup>(18)</sup>.
- (3) The pitaya is the fruit of several cactus species, especially of the genus *Hylocereus*. Originally the fruit comes from Central and South America; however, the cacti are also cultivated in Southeast Asian countries and are also found in Taiwan, Okinawa, Israel and southern China. The species *Stenocereus gummosus* has been an important food source for native Americans.
- (4) The Acai berry originates from the acai palm, which is found in the Amazon region of Brazil. The juice and pulp of the acai berry are frequently used in fruit drinks.
- (5) Argan oil originates from the Moroccan tree *Argania spinosa*. Besides cosmetic application in skincare products, Argan oil is used for cooking. In 2002, Argan oil became a fashionable food in Europe and North America.
- (6) Vemma drink is a fruit juice available at Dutch health shops which contains mangosteen, a fruit from South East Asian tropical trees.

*The term 'significant changes' related to change in production process.* One of the categories of foods that the

Regulation applies to is: 'foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances'<sup>(3)</sup>. This definition is not always clear, since one could debate about the term 'significant changes'. This term is not quantified, which results in leaving room for different interpretations. Moreover, a problem with the change of production processes is that until it is investigated thoroughly (which is necessary for the authorisation procedure), it is unknown how much the composition differs from that of the original counterpart. However, this type of information is already needed before the authorisation procedure, at the state of consideration if a food product or ingredient is novel or not. In the current situation this information is only necessary in the authorisation procedure.

A discussion paper of the European Commission (2002) about the Regulation already mentions the issue of significant changes related to change in production process. It did not provide, however, concrete examples of products in this category.

Examples where the criterion 'significant changes related to change in production process' may be an issue:

- (1) In 2003, Mycryo was introduced as a powdered form of cocoa butter. Mycryo is produced by a cryogenisation process, in which liquid cocoa butter is cooled at an extremely low temperature to form it into a powder. In the chocolate industry, Mycryo is used to facilitate the crystallisation of chocolate and is also used in savoury preparations as a replacement for the usual cooking fats and in pastry as an alternative to gelatine. Though cocoa butter has already been used for a long time, its use in cryogenised form with its specific characteristics is new.
- (2) Tivall is a plant-based alternative to meat invented in Israel, and derived from wheat gluten and vegetable proteins. It is claimed that a unique and patented technology is used to transform selected ingredients into Tivall products. The production of Tivall is a 'secret' process, although it is known that wheat proteins and vegetable proteins are blended to form a base matrix. This meat-like matrix is fortified with vitamins and minerals and blended with a combination of vegetable oil, flavourings, spices, water and egg protein.
- (3) Quart mostly consists of mushrooms, but, however, also of 25% meat. Quart food products are hamburgers, schnitzels and filets. Quart products are made by combining meat-based processes with vegetable-based processes, which causes Quart products' nutritional value and metabolism to differ from real meat products. These processes themselves are not new. However, combining meat- and vegetable-based processes results in a new production process.
- (4) Valess products are meat substitutes based on a dairy concentrate of fresh milk and a vegetable substance to which ingredients have been added that create structure and taste. The production process of Valess is initially a dairy process, which is followed by a meat-based process.
- (5) PeptoPro is a sport drink that contains hydrolysed proteins. The use of proteins in ready-to-use sports drinks

was limited up to now as there were dissolution problems, as well as stability and digestive problems when complete proteins were used. Normal sports drinks contain water for rehydration, glucose and/or electrolytes. PeptoPro now adds hydrolysed protein in dissolvable form.

- (6) Vitaalbrood Pró-FIT contains a high level of  $\beta$ -glucan, a soluble fibre. The  $\beta$ -glucan comes from OatWell oat bran, which due to a special stabilisation process contains very high levels of  $\beta$ -glucan. The level of  $\beta$ -glucan in OatWell oat bran is about ten times as high as in a serving of rolled oats, oatmeal or oat flakes of the same size.

*Animal feed related to changed composition of foods.* Changes in the composition of an animal product due to a change in the composition of the animal feed are part of the problem category of interpretation of the Regulation. The HC already mentions this issue. The Netherlands Safety Assessments on Novel Foods Committee regards these products as novel, depending on the change of concentration and nature of components<sup>(12)</sup>. For the two following examples, it is questionable whether the changed composition is important enough to position the product within the grey area.

Examples – amended animal products:

- (1) The Columbus egg has a fatty acid composition that differs from eggs traditionally consumed because the feed for the chicken has a different composition from the feed that is traditionally given to chickens in the egg industry. The eggs are higher in *n*-3 fatty acids and lower in SFA.
- (2) In May 2005, Aurora cheese was introduced onto the Dutch market, which contains higher levels of conjugated linoleic acid and *n*-3 fatty acids than normal cheese. The basis for this cheese is milk produced by cows that are given special feed. This milk contains at least 10 mg conjugated linoleic acid per g fat and the proportion of *n*-3 to *n*-6 fatty acids is at least 1 to 3<sup>(19)</sup>.

*New varieties of organisms.* For products that consist of or are isolated from new plants or animals that are the result of traditional propagating and breeding methods, the criterion of whether or not to consider a product as a novel food is not clear. When using the species line as a criterion to call a product novel or not, foods from plant varieties are not regarded as novel. However, new varieties may have a different structure or composition and may therefore differ in their nutritional value, their level of undesirable substances, or in the way they are metabolised. Therefore, it has already been pointed out that in some cases the variety line is a more appropriate criterion for characterising a food as novel or not<sup>(12)</sup>. For the following examples, it is not clear whether they should be treated as novel according to the current Regulation.

Examples – new varieties of organisms:

- (1) Many different potato varieties exist and the composition of these varieties differs. For example, substances in potatoes that differ widely for different potato varieties are glycoalkaloids<sup>(20)</sup>. Since these substances are potentially toxic for humans, it is desirable that glycoalkaloid levels are evaluated before new potato varieties are released for consumption.
- (2) Bimi is a relatively new vegetable that looks like broccoli, but has a longer and more slender stem. There is a

year-round supply of bimi, mostly from Africa. The vegetable was developed using normal horticultural breeding techniques, without genetic modification: bimi is a cross between broccoli and china kale and contains high levels of glucosinolates.

- (3) The Santessa tomato is developed by a process of normal horticultural breeding techniques. This new tomato variety contains a higher level of lycopene than the traditional tomato.
- (4) From May 2007 onwards, besides white and green, also purple asparagus is available in the Netherlands. Purple asparagus (*Aspara pacific*) originated as a spontaneous mutation in northern Italy 300 years ago and with breeding programmes this purple asparagus is made commercially interesting now for farmers. Its purple colour comes from anthocyanins.
- (5) The golden kiwi originates from New Zealand and was introduced to Europe in 2000. The golden kiwi is a new cultivar group from the green kiwi and resembles the green kiwi in growth patterns and outward appearance. The golden kiwi is also used for juices.
- (6) Probiotics are ‘living micro organisms, which upon ingestion in sufficient numbers exert health benefits’. In the 1980 s, the Nordic countries received the first-generation probiotics, often including *Lactobacillus acidophilus* as the effective probiotic in fermented milks. In 1990, *Lactobacillus rhamnosus* was introduced to Finland, and shortly thereafter in Italy and the Netherlands. In 1994, *Lactobacillus casei*, Shirota strain, was introduced to the Netherlands by Yakult. Since 1994, many more products containing probiotic bacteria have entered the market. Today, a multitude of so-called probiotics are available throughout the EU, but actually not all of them fulfil the criteria set by the WHO expert group<sup>(21)</sup> requiring that for each probiotic both health benefits and safety should be scientifically substantiated. Although new probiotic products often contain bacteria from the same genus or even the same species, different varieties (strains) are used.

#### *Foods for which the current Novel Foods Regulation contains gaps*

This category deals with food products or ingredients that are not novel according to the current Regulation, even though the safety of consumption is not *a priori* established.

*Safety not assessed for new target groups.* New food products containing ingredients that have been used before 1997 and for which no harmful effects have been demonstrated are not novel foods. However, sometimes, existing products are aimed at a new target group, such as young children, pregnant women or the elderly. When in these target groups the physiological effects of these foods are unknown, the foods belong to the grey area. In this case, not the composition of the product determines the novel status, but the new marketing concept.

Examples where the criterion ‘target group of the product’ may be an issue:

- (1) Fristi Xtra is a probiotic drink that aims at a new, specific target group: children from the age of 1 year onwards.

Probiotic foods have been consumed to a significant degree before May 1997 and are therefore not characterised as novel. Though consumption of probiotics is generally considered to be safe for adults, the effects in children might be different. Adverse effects due to immunomodulation in young children cannot be ruled out yet<sup>(22)</sup>.

- (2) Different foods for infants and young children supplemented with probiotics and prebiotics are currently marketed in the Netherlands and most other European Community countries. Breast milk bifidobacteria and lactic acid bacteria are considered to be beneficial for health, but there is not much scientific information available on possible adverse effects of supplementary application in young children<sup>(22)</sup>. Prebiotics may function differently as they do not resemble breast milk oligosaccharides. Infants may form a group at risk for the adverse effects of probiotic and prebiotics due to, for example, immunomodulation, which may differ from the effects for adults.

*Growth stage of crops.* Except from synthetically produced food ingredients, most foods contain vegetable-based substances. These organisms may have a different composition during different growth stages of the crops. Since consuming crops while they are in a different growth stage than when they are normally consumed has unknown health effects, such products belong to the grey area, as is the case for the following examples.

Examples – new varieties of growth stages of crops:

- (1) Verjuice is an acidic juice, originally from France, made by pressing unripe grapes and it is used in salads as a sour substitute for vinegar and lemon.
- (2) White tea comes from the *Camellia sinensis* plant. The leaves are picked and harvested before they open fully, when the buds are still covered by fine white hair.
- (3) Broccocress is broccoli in a younger stage, more specifically, the sprout stage. Broccocress is a new product within the group of germ vegetables. Though the sprouts and mature broccoli originate from the same organism, the nutritional value differs. Sprouts, 3 d old, of certain crucifers including broccoli and cauliflower contain 10–100 times higher levels of glucoraphanin (the glucosinolate of sulforaphane) than do the corresponding mature plants<sup>(23)</sup>.

*Single product intake v. total ingredient intake.* The Regulation covers the application of a new product or ingredient and not of the total consumption of a specific ingredient. In addition, the total level of consumption of an ingredient is usually not taken into account in the case of a new application of a food that was already on the market. It is obvious that significantly altered intake may pose risks. Some examples are discussed below.

Examples – single product intake v. total ingredient intake:

- (1) Consumption of *n*-3 fatty acids may reduce the risk of CHD. Nowadays, many food products are enriched with *n*-3 fatty acids. However, with overuse of these fatty acids, negative health effects have been suggested<sup>(24)</sup>. The combination of the consumer's increased awareness of nutrition and health, and more products being enriched with *n*-3 fatty acids may result in a high total intake of *n*-3 fatty acids.

- (2) With an increasing number of probiotic food products and supplements entering the market, levels of intake of different probiotic bacteria may go up. As indicated earlier, adverse health effects of probiotics are unknown, and this is even more true of the health effects of high levels of intake and/or combination of different probiotic strains.

## Conclusion

The present paper aims to give a clear overview of the problems that give rise to the existence of the grey area and to illustrate these problems and challenges by means of several actual and clear examples. Currently, the EU and the HC point out that implementation of the current Regulation sometimes gives problems and may not always identify all new food products that can possibly harm consumer health. Even though virtually all parties admit that the current Regulation has weaknesses, until now, there has been hardly any systematic approach to solve these issues.

We have provided an overview of some of the challenges around the Regulation. It defines a grey area of novel foods and lists food products that are on the market in the Netherlands and some other countries in the EU in the autumn of 2007 for which the safety of consumption was not *a priori* established and which did not go through the authorisation or notification procedure for novel foods. Table 1 represents a reasoning for the existence of the grey area of novel foods, including the two categories demarcating the grey area in the present report, and provides an overview of potentially novel food examples. From Table 1, one can conclude that most of the potential novel foods discussed in the present paper owe their potential novel status to the Regulation, i.e. leaving too much room for different interpretation on a number of aspects, such as the quantification of the 'significant degree' of consumption of food products before 1997 and the quantification of 'significant changes' in the composition or structure of food products caused by new production processes. It is important that these aspects are identified and more closely defined when the Regulation is revised in the near future<sup>(7)</sup>.

In conclusion, the Dutch and European food markets contain food products that could actually be classified as novel foods, but remain unidentified as such. It is shown that such products do exist. If the existence of this grey area is acknowledged, the current list of EU novel foods would be much larger<sup>(25,26)</sup>. It is difficult to speculate on the size of the grey area of novel foods, especially since such a conclusion would rely on the definition of what would or would not fall into that area. For the purpose of the present paper, we have identified about two dozen types of grey area novel foods.

It should be emphasised that even though the present study indicates that the current Regulation may not identify all new foods, food ingredients or applications that enter the market, the conclusion from this should not be that the products mentioned in the present report are unsafe, but merely that for these products the safety (toxicological and/or nutritional) of consumption cannot automatically be assumed. In conclusion, the present overview indicates that the Novel Foods Regulation, currently being revised, should take this 'grey area' of novel foods into consideration. In any case

**Table 1.** Products on the market in The Netherlands in autumn 2007 that may or may not be considered to be novel foods, and are as such in a grey area

Grey area topics...	'Significant degree' related to consumption	'Significant changes' related to production process	Change in composition of a food product related to animal feed	Traditional breeding methods related to changed composition of foods	Marketing of 'old foods' to another target group	Marketing foods during another stage of their development
Novel Food Regulation leaves room for different interpretation or gaps in Novel Food Regulation	Camel milk Teff Pitaya fruit Argan oil Vemma drink Acai berry	Tival Mycryo Quart Valess Peptopro Vitaalbrood	Columbus egg Aurora cheese	Potato Probiotics Bimi Santessa tomato Purple asparagus Golden kiwi	Foods for infants and young children supplemented with probiotics Fristi Xtra	Broccocress Verjuice White tea

in addition to the suggestions of the European Commission<sup>(7)</sup>, follow-up studies, such as Post-Launch Monitoring<sup>(8)</sup> could be put in place in order to shed light on the intake and magnitude, if present, of potentially adverse health effects of these products.

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