Collaboration

Twenty years assessing novel foods in the European Union, 1997-2017

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Abstract

The application in 2018 of the new Regulation (EU) No 2015/2283 on novel foods has changed the regulatory framework and is a turning point which permits the evaluation of the results of the assessment and authorisation system used up until now.

For more than 20 years (1997-2017), Regulation (EC) No 258/97 has controlled the placing on the market in the European Union of novel foods and novel food ingredients. In this period, 125 novel foods have been assessed and authorised for marketing, and the substantial equivalence of around 90 novel foods has been assessed at the request of over 400 applicants. Of note among the novel foods which have been authorised are extracts and oils, and authorised uses include food supplements. In the case of the procedure for determining the substantial equivalence of a novel food to a previously authorised food, chia seeds are of particular note, followed by argan oil, phytosterols and Noni juice which, together, made up more than 60 % of all the notifications.

In spite of the efforts to create common assessment criteria and regulations via Regulation (EC) No 258/97 and Recommendation 97/618/EC, there has been a certain level of disparity among the different national assessment bodies. A large number of novel foods which received a favourable assessment from an assessment body in one Member State received safety objections from other Member States.

In any case, the experience gained from the assessment of novel foods over the past 20 years provides a fundamental base for embarking on a new stage with the application of the new Regulation No (EU) 2015/2283.

Key words

Novel food, assessment, authorisation, notification, substantial equivalence, Regulation (EC) No 258/97.

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1. Introduction

From a regulatory perspective, the concept of novel food appears in the European Union from the publication of Regulation (EC) No 258/97, which for more than 20 years (1997-2017), has regulated the placing of novel food and food ingredients on the market in the European Union (EU, 1997a). This Regulation applied to food and food ingredients which were intended to be marketed in the European Union but that, up until the date on which it came into force, 15 May 1997, had not been used for human consumption to a significant degree in the Union.

The application in 2018 of the new Regulation (EU) 2015/2283 on novel foods (EU, 2015) has changed the regulatory framework and is a turning point which will permit the evaluation of the results of the assessment and authorisation system used up until now.

In accordance with Regulation (EC) No 258/97, the applicant for placing the novel food or food ingredient on the market should submit a request to the Member State in which the product was to be placed on the market for the first time, who is required to conduct an initial assessment and issue the corresponding report. In the case of Spain, the competent authority for conducting the initial assessment was the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN).

If the initial assessment report was favourable and no objections had been submitted by the European Commission or other Member States, the Member State in which the application was submitted and assessed would inform the applicant that he might place the novel food or food ingredient on the market. In this case, the letter of authorisation from the member state was published on the European Commission Web page (SANTE, 2018).

If the initial assessment report was not favourable or objections were submitted by the European Commission or other Member States, the European Food Safety Authority (EFSA) would conduct a complementary assessment and the authorisation or refusal to place the novel food on the market was reflected in a European Commission Ruling. This Ruling was published in the Official Journal of the European Union and was also available in the compilation published on the Commission Web page (SANTE, 2018).

The marketing authorisations were granted specifically to the applicant, and therefore other operators wishing to market the same product were required to follow a simplified authorisation process in which they had to demonstrate that their product was substantially equivalent to a food consumed in the European Union prior to 15 May 1997 or to an authorised novel food. This simplified procedure could be used when the scientific evidence available and generally recognized, or an opinion delivered by one of the competent assessment bodies of one of the Member States, demonstrated that the novel food or ingredient was substantially equivalent to authorised foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

The applicant was required to notify the European Commission of the placing on the market of the equivalent product, and the notification was accompanied by the ruling from the competent assessment body or by the scientific data. In turn, the Commission sent the Member States a copy of this notification.

This paper has collected and assessed the information about the *applications* for assessment and authorisation of the novel foods or food ingredients, hereinafter *novel foods*, and about the

notifications of substantial equivalence of novel foods, hereinafter *substantial equivalences,* for the period 1997-2017.

The information about novel food authorisations and those which have followed the simplified procedure of substantial equivalence is taken from the public lists prepared by the European Commission, which include information from 1997 to December 2017 (SANTE, 2017a, b), and the authorisation Rulings and the letters of authorisation available on the Web page of the Directorate General for Health and Food Safety of the European Commission (SANTE, 2018).

In addition to the Union List of novel foods (EU, 2017), the lists published by the European Commission (EC lists) are the basis on which this paper has been written. Although these public lists do not contain all the novel food authorisations which were granted at the end of December 2017 and included in the new Union List of authorised novel foods which came into force in January 2018, the information which may be missing in the EC lists corresponds to a very small number of applications and does not significantly affect the assessment.

2. Assessment of novel foods 1997-2017

The assessment of novel foods should be in accordance with the requirements of Regulation (EC) No 258/97 in as far as they must not present a danger for the consumer, mislead the consumer, or differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

In order to facilitate the safety assessment of the foods and food ingredients, a number of guides to assessment have been published.

The Scientific Committee for Human Food of the European Commission set out certain recommendations concerning the information required to support the applications for the placing of a novel food on the market and the drafting of the initial assessment reports for these applications (SCF, 1997).

Subsequently Commission Recommendation 97/618/EC, of 29 July 1997 was published, concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 (EU 1997b).

This Recommendation establishes a scientific classification of novel foods according to whether they are pure chemicals or simple mixtures, complex novel foods or foods produced using a novel process. Depending on the class to which the novel food belonged, it was necessary to submit information regarding different aspects including the specification of the novel food, the effect of the production process, the history of the organism used as the source of the novel food, the anticipated intake/extent of use, the information from previous human exposure to the novel food or its source, and nutritional, microbiological and toxicological information.

With respect to the substantial equivalence of novel foods compared to others already on the market, the European Union (EU, 2013) and the United Kingdom (ACNFP, 2005) published guidelines for the presentation of information to demonstrate the substantial equivalence between a novel food or food ingredient and a food which has already been authorised. These guides serve as reference for both the applicants and the assessors.

3. Novel foods and novel food ingredients 1997-2017

3.1 Assessment of applications for authorisation for the placing on the market of a novel food submitted in the European Union

According to the EC List (SANTE, 2017a), in the period 1997-2017, 227 applications for initial assessment were submitted in the European Union pursuant to Article 4.2 of Regulation (EC) No 258/97. 64 of these applications appear in the List as in process and a further 155 were authorised (115, 74 %), refused (8, 5 %) or withdrawn (32, 21 %). In addition, another eight applications were for genetically modified organisms, which, on applying Regulation (EC) No 1829/2003 on genetically modified food and feed (EU, 2003), were excluded from the scope of application of Regulation (EC) No 258/97 and are not considered in this paper. The number of refusals is low. This is mainly due to the fact that, rather than receive a negative opinion, applicants preferred to withdraw their application. It is also necessary to consider the role of the national bodies who carried out the initial assessment, who advised applicants on how to submit a case thus avoiding, to some extent, the presentation of cases with little chance of success. 3 of these refusals were included in Rulings refusing authorisation to place the product on the market. These rulings indicate that the refusal is due to the fact that a significant consumption of the food was not demonstrated in the European Union prior to the entry in force of Regulation (EC) No 258/97 (EU, 2000), that the initial assessment report was negative (EU, 2001) or that the complementary assessment report from the EFSA was negative (EU, 2005).

The 115 applications which were authorised came from 22 different countries, including 9 which did not belong to the European Union, who submitted 37 % of these applications. The highest number of applications came from companies located in the United Kingdom and Germany, followed by the United States (Table 1).

Table 1. Country of the applicant for the assessment of authorised novel food

Country	Applications	Country	Applications
United Kingdom	16	Canada	4
Germany	12	Finland	4
United States	12	Holland	2
Belgium	10	Ireland	2
Japan	9	Italy	2
France	8	Sweden	2
Spain	7	Australia	1
Denmark	5	Austria	1
Israel	5	Chile	1
Norway	5	Croatia	1
Switzerland	5	Russia	1

The initial assessment applications which ended in an authorisation were submitted in 12 countries in the European Union, and 30 % of these were in the United Kingdom (Table 2). In this respect, in

addition to receiving applications from their own country, the United Kingdom assessment body received 44 % of the applications from countries not belonging to the European Union. These included the United States, Japan and Switzerland, probably due to the application language and the long experience of the assessment body in this country.

Table 2. Country in which the initial assessment of the applications for authorised novel foods was conducted

Country	Applications	Country	Applications
United Kingdom	35	Germany	4
Ireland	21	Spain	4
Holland	16	Austria	1
Belgium	12	Croatia	1
Finland	12	Denmark	1
France	7	Sweden	1

The average number of applications for initial assessment approved each year amounted to 6.4, with a minimum of 1 in 2002 and 2007 and a maximum of 18 in 2017, the last year of application for Regulation (EC) No 258/97. This probably served as a stimulus for submitting or completing applications prior to the entry in force of the new Regulation (EU) 2015/2283 (Figure 1).

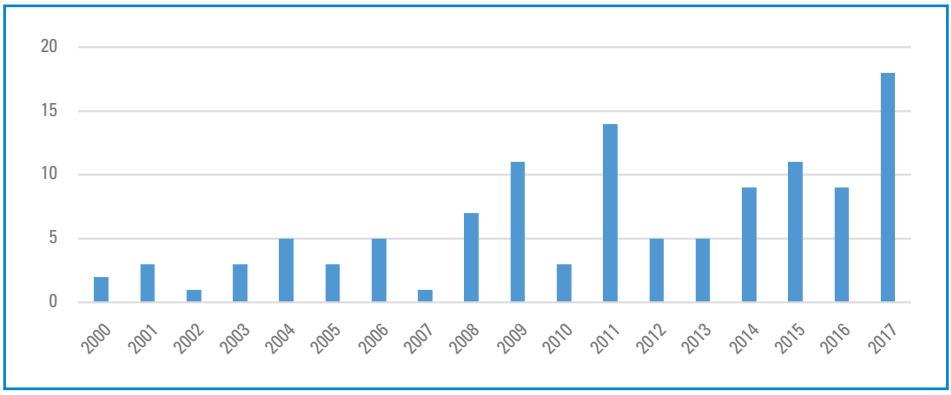

Figure 1. Year of approval of applications for authorised novel foods

Regulation (EC) No 258/97 established a time limit of 3 months for the completion of the initial assessment, although this time limit was extended if the applicant was asked to provide additional information. The time limits for the complementary assessment and publication of an authorisation were not fixed and could vary depending on the complexity of the case. The average length of the process, from the date of application to the date on which the authorisation was published, was 1 014 days, just under 3 years. However, this period was reduced for the cases submitted in the last 10 years (841 days) and 5 years (627 days).

Of the 115 applications authorised, only 25 did not receive objections from the Member States or from the European Commission and, therefore, were authorised via national letters of authorisation (Table 3).

Table 3. Novel foods authorised without objections

Year	Novel food	Assessor	Year	Novel food	Assessor
2005	D-tagatose	United Kingdom	2015	Vitamin K2	Ireland
2010	Guar gum	France	2015	Antarctic Krill (*Euphasia superba*) oil rich in phospholipids	Finland
2010	Sucromalt	Holland	2015	Chia seeds in non-alcoholic beverages	Ireland
2011	Arachidonic acid-rich oil from the fungus *Mortierella alpina*	Holland	2015	Phosphatidylserine from fish phospholipids	Finland
2011	Magnolia bark extract	United Kingdom	2016	Isomalto-oligosaccharide	United Kingdom
2011	Zinc L-pidolate	Ireland	2016	UV treated mushrooms (*Agaricusbisporus*)	Ireland
2011	Wheat bran extract	Belgium	2017	Chia seeds in fruit spreads	Austria
2012	*Schizochytrium* sp. oil rich in DHA and EPA	United Kingdom	2017	UV treated mushrooms (*Agaricusbisporus*)	Ireland
2012	Vitamin K2 (menaquinone)	Germany	2017	Memreeplus-40P, with phosphatidylserine and phosphatídic acid	Finland
2012	Antarctic oil (*Euphausia superba*)	Finland	2017	Lyophilization of *Tetraselmis chuii* in food supplements	Spain
2013	Methylcellulose	United Kingdom	2017	Chia seed in ready-to-eat meals	Spain
2014	Lyophilization of *Tetraselmis chuii*	Spain	2017	Chondroitin sulphate	Holland
2015	Dihydrocapsiate	United Kingdom			

On the other hand, 90 applications received objections, leading to the performance of a complementary assessment by the EFSA, except in those cases in which the applicant provided information which permitted the resolution of the objection posed by the Member States of the European Union, and the EFSA did not issue a report. When the initial assessment was favourable and no additional assessment was required from the EFSA, the average time of the procedure from the date of application to the date of publication of the authorisation was reduced to less than half (499 days compared to 1 165 days for the cases which received objections).

The Union List published at the end of 2017 in accordance with the new Regulation (EU) 2015/2283 (EU, 2017) included 125 authorisations compared to the 115 in the EC List. This difference is due to the fact that the most recent authorisations were included directly in the Union List, and the EU List also includes some novel foods which were authorised through substantial equivalence with other foods already existing in the market. This is the case of the microalga *Odontella aurita* and sacha inchi oil. Nevertheless, the difference is small and does not have a significant bearing on the assessment made.

The novel foods authorised up to 2017 include very varied products, ranging from foods traditionally consumed in countries not belonging to the European Union such as chia seeds (*Salvia hispanica*) to foods obtained by chemical synthesis such as monomethoxypolyethylenglicol as a gum base for chewing gum.

Of note are a number of extracts of products of vegetable (19), animal (2) or fungal (1) origin, totalling 18 % of the novel foods authorised up until 2017. Oils also make up a significant number of the novel foods authorised up to 2017 (18 %). In particular, oils of vegetable origin (for example Allanblackia, argan, chia, coriander or sacha inchi seeds), from microalgae (*Schizochytrium* and *Ulkenia*), and of animal origin (squid, *Calanusfinmarchicus*-arthropod zooplankton and krill crustaceans) or fungal origin (*Mortierella alpina*).

The novel food authorisations establish the conditions for use and, in particular, specify the category of food in which they can be used or included. Certain novel foods may be added to a large number of foods. For example, dihydrocapsiate can be added to 25 different categories of food. In these categories, food supplements are of note, as 58 % of the authorisations include the use of the novel food in food supplements.

The authorisations also include the specifications which must be met by each novel food, and which are included in the Union List (EU, 2017). The number of parameters for which specifications are established ranges from none (in the case of Noni fruit juice powder there is only 1 description) and 24 (betaglucans yeast and fucoidan extract from the seaweed *Fucus vesiculosus*). These parameters mainly include references to the composition but, sometimes, also refer to contaminants or undesirable substances.

The composition parameters include parameters relating to humidity, water or dry matter present in 78 % of the specifications. Proteins are present in 36 % of the specifications, followed by fats (21 %) and carbohydrates (18 %). Glucose appears in 7 % of the specifications and fibre in 10 %. Ash (34 %) and pH value (21 %) are also included.

As regards the parameters for undesirable substances, heavy metals stand out, being present in the specifications for 34 of the 125 novel foods in the Union List (EU, 2017). The lead content appears in the specifications for 28 novel foods, arsenic in 22 (2 of these as inorganic arsenic), mercury in 17 and cadmium in the specifications for 16 novel foods. In addition, in few cases have limits been established for extraction solvents and only on a very few occasions for pesticides, mycotoxins, PAH or components with a certain degree of toxicity such as anthraquinones.

Microbiological criteria are present in the specifications of 28 novel foods, in particular *Escherichia coli,* which appears in 21 specifications, *Salmonella* which appears in 19, *Enterobacteriaceae*

and *Listeria* in 7 and coliforms in 6. In addition, moulds and/or yeasts are included in 31 specifications. On some occasions, the specifications are fairly generic, for example: "absence of pathogenic agents" or "*Salmonella* and other pathogenic bacteria". Similar expressions but somewhat different are used such as "total aerobic microbial count", "total aerobic plate count" or "total aerobic bacteria", or they refer to "negative to test", without specifying the test.

The test methods to be used to determine some of these parameters are specified in some novel foods in a more generic manner, for example, Kjeldahl method, or with rather more precision, indicating the chromatographic conditions and the column type, or providing a reference to the specific method (AOAC, European Pharmacopoeia or method published in a scientific journal).

3.2 Assessment of applications for authorisation for the placing on the market of a novel food from Spanish companies

According to the EC List (SANTE, 2017a), 5 Spanish companies applied for and obtained authorisation to place a novel food on the market. In addition, 2 more applied for and obtained authorisation for an extension to the use of the previously authorised novel food. Therefore, 7 authorised applications came from Spanish companies, amounting to a total of 6 %.

In addition to these authorised applications, 1 application was withdrawn, another was left pending additional information and a third application fell under the scope of application of the new Regulation (EU) 2015/2283 as the assessment was not completed in 2017. This amounts a total of 10 applications submitted by Spanish companies.

Between 2003 and 2011, Spanish companies submitted their 3 applications for initial assessment in the United Kingdom but from 2011, all the applications were submitted in Spain (7). Moreover, 1 Swiss company also submitted their application in Spain.

Lastly, it should be noted that of the 115 authorised applications only 1 was submitted by a South American company (Chile).

4. Substantial equivalences 1997-2017

4.1 Assessment of notifications of the placing on the market of a novel food via substantial equivalence in the European Union

According to the EC List (SANTE, 2017b), in the period 1997-2017, 434 notifications of substantial equivalence of novel foods in the European Union were submitted in accordance with Article 3, point 4, of Regulation (EC) No 258/97, understood as notifications with an entry number different to that of the EC List. 11 of these notifications were for genetically modified organisms which, on applying Regulation (EC) No 1829/2003 on genetically modified food and feed were excluded from the scope of application of Regulation (EC) No 258/97 and are not considered in this paper. Therefore, the total number of notifications is reduced to 423. 15 notifications were submitted by different applicants and 22 applicants gave notification of various products. Moreover, 12 % were submitted by a company or consultancy on behalf of the applicant.

The EC List also includes other notifications referring to the placing on the market of phytosterols, and, in some cases, to Noni juice obtained from a company which already had a marketing autho-

risation. In these cases, the List of notifications includes a subscript with a letter to the number of the authorised notification. The 94 notifications of phytosterols of Noni juice provided by already authorised companies are not included in the 423 notifications mentioned above.

The 423 notifications came from 48 different countries, including 27 countries not belonging to the European Union, which formed 30 % of the notifications. The highest number of notifications came from companies located in Germany, followed by companies from France and Holland. Companies from China and the United States are prominent among the companies not belonging to the European Union (Table 4).

Notifications were presented in 19 countries of the European Union, 24 % of which were in Ireland and 18 % in France.

Table 4. Country of the notifier of the substantial equivalence of a novel food*

Country	Notifications	Country	Notifications	Country	Notifications
Germany	81	Ireland	11	Japan	5
France	46	Canada	10	Finland	4
Holland	28	Norway	10	New Zealand	4
United Kingdom	27	Denmark	8	Australia	3
Spain	23	Czech Republic	7	South Korea	3
China	21	Switzerland	7	Ecuador	3
United States	19	Argentina	6	Hungary	3
Austria	17	Chile	6	Mexico	3
Belgium	14	Morocco	6	Slovakia	2
Italy	13	Sweden	6	India	2
Poland	13	Bolivia	5	Peru	2
Brazil, Bulgaria, Cyprus, Costa Rica, Slovenia, Iceland, the Fiji Isles, Latvia, Lithuania, Panama, Paraguay, Dominican Republic, Senegal and Zimbabwe: 1 notification					

*When a notification includes several companies from different countries, each country is counted in the table.

The average number of annual notifications was 20. The first notification not related to a genetically modified organism was not presented until 2001, and the maximum number of notifications (79) was in 2016 (Figure 2). In 2017, the number of notifications, although very high, fell with respect to the previous year as the application of the new Regulation on novel foods implied that the authorisations became generic for the product, and were not linked to a specific company. This meant it was no longer necessary to present a notification of substantial equivalence.

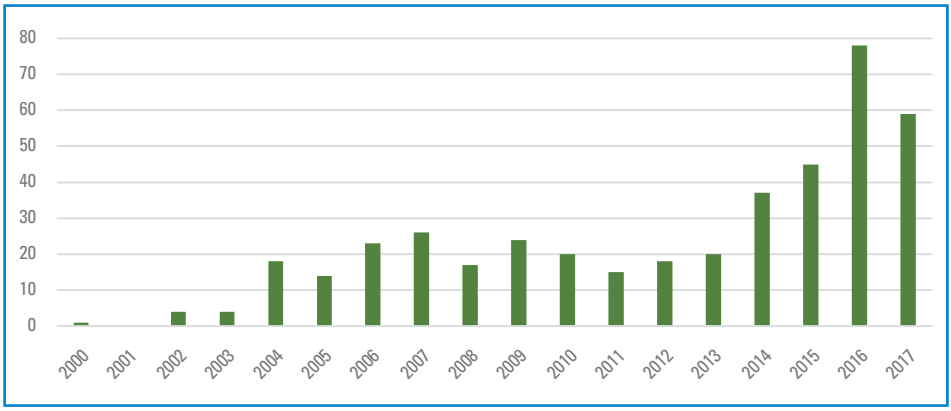

Figure 2. Year of notification of the substantial equivalence of novel foods

Approximately 90 different products were notified. The most frequently notified products were chia seeds, followed by argan oil, phytosterols and Noni juice which, in total, made up more than 60 % of the total (Table 5). The notifications did not always include all the authorised uses. For example, there are phytosterol notifications which include their addition to cheese, or yoghurt, and others which include all the authorised uses. Similarly, for chia seeds, the first notifications only listed their use as an ingredient in bakery products, but once their use had been authorised in other products, the notifications included these extensions to use.

Table 5. Novel foods most notified via substantial equivalence

Product	Notifications	%
Chia seeds	120	28
Argan oil	54	13
Phytosterols	43	10
Noni juice	40	10

Notifications were accumulated in certain years, probably due to the novelty of their introduction on the market and the existence of a higher demand for these products in the following years (Figure 3).

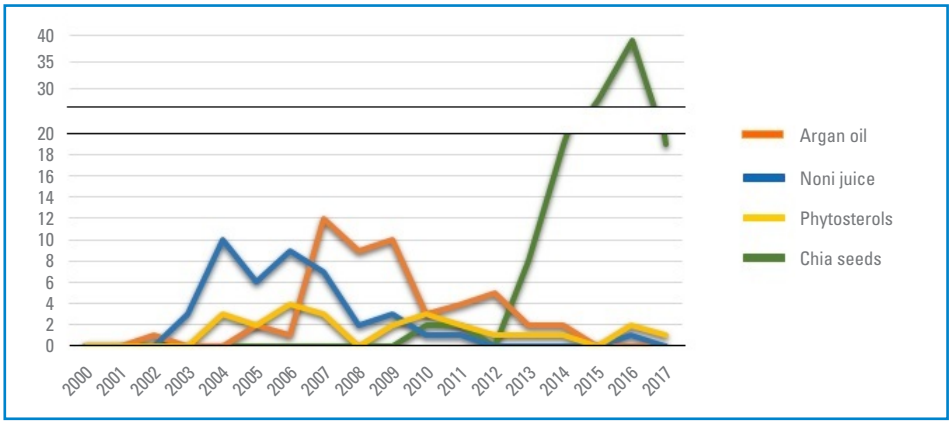

Figure 3. Annual variation of the four most notified novel foods

The notifications did not always refer to the same products marketed by different companies but, in some cases, established equivalences between products which were not identical with respect to their definition. For example, the microalga *Odontella aurit* was notified as the equivalent to authorised seaweeds, argan oil as the equivalent to other edible oils, sacha inchi oil to flax oil, basil seeds to chia seeds and the oil extracted from squid to tuna oil.

4.2 Assessment of applications for authorisation for the placing on the market of a novel food via substantial equivalence submitted by Spanish and South American companies

According to the EC List (SANTE, 2017b), 23 Spanish companies notified the placing on the market of a novel food via substantial equivalence, that is 5.5 % of the total 423 notifications. The applications were presented in Spain (74 %) and also in Belgium, Denmark, Finland and the United Kingdom. The majority were for chia seeds (57 %), followed by phytosterols (22 %) and Noni juice (9 %).

South American companies presented 29 notifications, equivalent to 6.9 % of the 423, from Argentina (6), Chile (6), Bolivia (5), Ecuador (3), Mexico (3), Peru (3), Brazil (1), Costa Rica (1) Panama (1), Paraguay (1) and the Dominican Republic (1). In some cases, the companies presented the notification together with other European or South American companies.

25 % of the notifications from South America were presented in Ireland and 18 % in Spain. Notifications were also presented in France (14 %), Finland (11 %) and the United Kingdom (11 %) and in Belgium, Denmark, Finland, Holland and Italy. Although initially the language would make the presentation of notifications in Spain easier, it should be noted that Regulation (EC) No 258/97 established that the presentation of the application to place a novel food on the market should be made in the country in which the product was to be placed on the market for the first time and that some of these companies had commercial links with European companies from other countries.

As in the case of Spanish companies, the majority of the notifications were for chia seeds (61 %), followed by phytosterols (11 %), noni juice (11 %) and sacha inchi oil (11 %).

5. Discussion

The novel foods regulation has enabled the assessment of the safety for the European consumer of novel food or food ingredients or foods which have never been consumed in the European Union and, consequently it has prevented exposure to possible emerging risks.

In spite of the efforts to create common assessment criteria and regulations via Regulation (EC) No 258/97 and Recommendation 97/618/EC, there has been a certain level of disparity in the criteria used among the different national assessment bodies. A large number of novel foods which received a favourable assessment from an assessment body in one Member State received safety objections from other Member States. Only 25 of these initial favourable assessments were confirmed by the remaining assessment bodies and did not receive any objections.

The substantial equivalence procedure also resulted in some disparity in the criteria as certain assessment bodies accepted the equivalence between products which are not exactly identical or for broad categories of food while others were more restrictive and only accepted equivalences between identical products from different producers.

The evaluation system applied since 1997 did not differentiate between food which had a long history of safe use outside the European Union and completely new products which might pose more doubts regarding their safety and require a more in-depth assessment. The time limits for the assessment and authorisation were long but it should be remembered that, on many occasions, these time limits depended on the applicant as they could take some time to provide the additional information required during the assessment process.

The specifications for the novel foods which were assessed and authorised vary considerably as regards the number and type of parameters. For some plant products, such as seeds, the specifications initially established might have been for specific conditions of cultivation and did not adequately consider the possible seasonal, geographic or climatic variations. As a result, on assessing the substantial equivalence of one of these new foods compared to one already authorised, some values for certain parameters would often be outside the specification. To the contrary, the identification of the species using morphological or genetic means was barely included in the specifications except in certain cases such as that of the microalga *Tetraselmis chuii*, the identification of which using molecular biology methods is given in the specifications.

One question which was established in the majority of novel foods authorised (approximately 90 %) are certain specific requirements for additional labelling, usually referring to the name of the novel food.

The inclusion of test methods in the specifications was not usual. Although, in principle, the specification of a method may be of use for the control authorities, the advances made in analytical techniques may mean that these methods become obsolete after a certain time. One important question is the need to ensure that the standards which permit the analysis of all the parameters are available, especially those which affect food safety, as is the case of the anthraquinones in the noni concentrate or pure, to enable the competent authorities to make the relevant controls.

Although the accreditation of the tests conducted by the applicants in accordance with the ISO/IEC 17025 (ISO, 2017) standard were not a requirement of Regulation (EC) No 258/97, and nor were

they listed in Recommendation 97/618/EC, it was a way of guaranteeing the quality of the test data provided with a case. Nevertheless, sometimes, for some of the more unusual determinations, the applicants had difficulty finding laboratories whose scope of accreditation covered them. In these cases, the option was to facilitate the validation of the method used and the quality controls applied.

In the case of the monitoring of good laboratory practices for certain tests, Recommendation 97/618/EC only required these with respect to the studies of possible allergenicity and the nutritional information. However, logically, these might be considered necessary in the toxicological tests.

In any case, the experience gained from the assessment of novel foods over the past 20 years provides a fundamental base for embarking on a new stage with the application of the new Regulation (EU) 2015/2283.

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