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The Novel Food Regulation

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While "innovations" are generally regarded positive, this does not necessarily apply to the food sector. New food products are regularly viewed with quite some suspicion and bias. This phenomenon also occurs when speaking about "Novel Food" as a legal category. Novel food is often reduced to foods from insects (that still cause many consumers to roll their eyes) or to controversially discussed substances like *cannbidiol* (which is at the borderline to drugs). What then remains unconsidered is the fact that Novel Food has not been established as a *chamber of horrors* but that it provides for a set of rules designed to guarantee the safety of our foods.

Novel Food is reality. The number of products and the amount of food consumed on the European Market are constantly growing. This development strikingly reflects both the availability and the demand for Novel Foods. Thus, irrespective of the public perception of the subject as such, there is definitely a high actual acceptance for Novel Foods.

On 1 January 2018 the legal framework concerning this elementary part of food law changed. This article focusses on the new legal setup and its consequences.

1. What is novel food? Why and how is it regulated?

The topic of "Novel food" is a topic of modern times. It is to be viewed in the light of new technologies, new foods, new diets and new necessities. The changes in the way society and science see food and growing possibilities concerning the manufacturing of food led to the regulation concerning Novel Food.

a) Legal Framework

With the development in technology in the 1980s, there was growing public concern especially with respect to genetically modified organisms ("GMOs") being used as food, in food or for the production of food. Thus the first Novel Food Regulation ("NFR"), Regulation (EU) No. 258/97, was aimed mainly at GMOs. Other forms of Novel Foods were not systematically included in the former NFR. A certain change occured in 2003 when the rules on GMOs were separated from the old NFR and were regulated in Regulation (EC) No 1829/2003 on genetically modified food and feed. From that time on the field of Novel Food became more relevant as an individual topic; metaphorically speaking it stepped out of the shadow of the GMOs.

The old NFR was applicable to new foods and food-related technologies until the end of the year 2017. After a decade of reform efforts and political back and forth, it was abolished and replaced by the new NFR. The new NFR, Regulation (EU) 2015/2283, was published in the official journal of the European Union on the 11 December 2015 and, according to Article 36, Subsection 1, it was to be implemented and entered into force on the 20th day after its publication. Thus it entered into force on 31 December 2015. However, it only became valid on 1 January 2018 (Article 36, Subsection 2), the same day that the old NRF was officially repealed (Art. 34, Sentence 1).

Some matters, however, were exempt from this general rule and became applicable on the day of implementation, 31 December 2015. This was the case, for example, concerning the rules on the competences between the EU and the Member States and the rules authorizing the European Commission to adopt implementing acts and measures. These implementing acts and measures themselves became valid no earlier than on 1 January 2018 which provided a coherent application of the NFR and these acts and measures. According to Article 34, Sentence 2, rules in other legal acts referring to the old NFR have to be read as references to the new NFR. Therefore, provisions outside the NFR did not need to be changed.

The new NFR also regulates the transition period between the old and the new NFR. In Article 35 the new NFR states for example that applications submitted before 1 January 2018 under the old NFR were to be treated as applications made under the new NFR. After some discussion during the legislative process, it was decided that foods that did not fall under the old NFR but would fall under the new NFR due to the changes made concerning the definition of Novel Food (see below), but were lawfully entered into the market, were allowed to remain in the market. In order to make use of this tran-

sition period, the persons responsible for the food had to file an application or notification (see below) which then enabled them to continue to market their products (at least) until a decision on their authorization was reached.

Since entering into force within the European Union – and thus being legally binding for all Member States – Regulation (EU) 2015/2283 defines what Novel Food is and how Novel Food is to be handled in the European Union. Alongside the new NFR there are four Implementing Acts and three Guidances issued by European Food Safety Authority (EFSA), which are relevant for the correct implementation of the new NFR and its processes. The following summary gives an overview of these documents and their content:

- Commission Implementing Regulation (EU) 2017/2468: lays down administrative and scientific requirements concerning traditional foods from third countries;
- Commission Implementing Regulation (EU) 2017/2469: lays down administrative and scientific requirements concerning applications referred to in Article 10 of Regulation (EU) 2015/2283;
- Commission Implementing Regulation (EU) 2017/2470: establishes the Union list of Novel Foods;
- Commission Implementing Regulation (EU) 2018/456: lays down procedural steps of the consultation process for determination of novel food status;
- EFSA Guidance on the preparation and presentation of an application for authorization of a Novel Food;
- EFSA Guidance on the preparation and presentation of the notification and application for authorization of traditional foods from third countries;
- EFSA administrative Guidance on the submission of applications for authorization of a Novel Food.

b) Novel food today

When comparing the definitions of "Novel Food" from the old NFR and the new NFR, similarities become apparent.

The new NFR defines "Novel Food" in Article 3, Sentence 2, letter a) as follows:

> 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession

of Member States to the Union, and that falls under at least one of the following categories:

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
(ii) food consisting of, isolated from or produced from microorganisms, fungi or algae; 11.12.2015 L 327/7 Official Journal of the European Union EN
(iii) food consisting of, isolated from or produced from material of mineral origin;
(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
– traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
– non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
(v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
(viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
(ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
– a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or
– they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.

Like the old NFR, the new NFR takes a two-tier approach on this definition. The first part of the definition is that the food in question has not been used significantly for human consumption within the European Union before 15 May 1997.

The second part of the definition requires the food to fall under one of the ten categories laid out in No. (i) to (x). This list of categories of Novel Food became significantly longer with the new NFR. Some categories

are nearly the same as in the old NFR (categories i, ii, vii), others show certain parallels to the old NFR (categories iv, v). Those Novel Foods that have no resemblance in the new NFR were usually either assigned to other categories of the old NFR-definition (categories iii, ix and partly viii) or were treated as Novel Food without being classified as belonging to any category at all (especially category x). One truly new category is category vi.

aa) Cut-off date: 15 May 1997

This important date concerning the first part of the definition of Novel Food originates from the old NFR. It is the date of implementation of the old NFR. In the old NFR, the definition was kept more open concerning the necessary history of consumption in the European Union. It stated in Article 1, Paragraph 2:

> This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories: (…).

With the exact date of 15 May 1997 being included in the definition of the new NFR, this requirement is now laid down clearer and, therefore, leaves hardly any room for wrong interpretation.

bb) Categories of Novel Food

The categories of the definition of Novel Food relate either to food or ingredients themselves or to manufacturing processes. As a consequence, the whole scale of foods and manufacturing processes may be subject to the NFR. However, many categories provide also for exemptions which, therefore, are highly relevant in practice. For example, category (vii) does not cover every food to which a novel process is applied to but only such food where the process «gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances».

2. WHAT ARE THE REQUIREMENTS FOR PLACING NOVEL FOOD ON THE EUROPEAN MARKET?

a) Union List

According to Article 6 NFR the European Commission establishes a Union List of authorized Novel Foods. This List was implemented through Commission Implementing Regulation (EU) 2017/2470. It contains those Novel Foods which have passed the authorization procedure and are therefore – if complying with the requirements set forth in this list – permitted to be place on the European Union market. This list contains the full range of foods and foodstuffs and represents a great variety of Novel Foods in all sorts of forms. Entries in the list cover food from primary production as well as complex processed food and food for general consumption as well as food for special group of consumers. This underlines the broad scale of Novel Foods and their possible use. The biggest part of the Union List consists of relatively "normal" foods and by no means represents the common association of Novel Food with overly "exotic" foods.

The Union List consists of two tables. The first table includes – next to the name of the Novel Food – information on conditions of use, additional specific labelling requirements and other requirements. The second table provides information on the specification, specific characteristics and/or the manufacturing process of the Novel Food.

Novel Foods that were authorized under the regulations of the old NFR were included in the Union List without further reviews or changes.

b) Authorization process

Many economic operators view the matter of "Novel Food" very negatively. The restrictive rules on "Novel Food" – to some people – hinder innovation. However, this view does not fully reflect the truth behind the processes and rules of the new NFR.

aa) Process on how to determine the status of the food in question

When it comes to a specific product, it needs to be decided whether or not it is a Novel Food. After all, this determines if the food may be placed on the market immediately or if an authorization is necessary. According to Article

4, Paragraph 1 NFR the food business operator who wants to place the food on the European Union market needs to verify if the food is considered Novel Food. There are no set rules by whom and how this verification needs to be carried out – apart from the definition of Novel Food in Article 3, Paragraph 2, Letter a) NFR. Also, there is no set consequence, if the business operator does not – fully – comply with his obligation to qualify his product.

In case the business operator is unsure about the Novel Food status, he consults the Member State where the product is intended to be placed on the market first (Article 4, Paragraph 2 NFR). However, again there are gaps concerning this rule: it is not defined when a business operator is deemed "unsure" or to what extent he needs to be sure about the qualification of the food in question. Neither is there a set consequence, if the business operator does not consult a Member State. If also the Member State is not able to qualify the respective food, other Member States or the European Commission can be consulted.

Since the NFR does not regulate the qualification process concerning the status as a Novel Food in detail, Commission Implementing Regulation (EU) 2018/456 provides further information and rules on this procedure. In its Article 1, the scope and subject matter of this Implementation Regulation is described as follows:

> This Regulation lays down rules for the implementation of Article 4 of Regulation (EU) 2015/2283 [the new NFR] as regards the procedural steps of the consultation process to determine whether or not a food falls within the scope of that Regulation.

According to the Implementing Regulation (EU) 2018/456, the consultation process begins by the business operator submitting an electronic consultation request to the Member State (Article 3, Paragraph 1) containing e.g. «a technical dossier», «supporting documentation» and «an explanatory note clarifying the purpose and relevance of the submitted documentation» (Article 3, Paragraph 2). Following this request, the Member State needs to verify the validity of the request without delay and can – if necessary – request further information from the business operator. Within four months of the verification of the validity of the request, the Member State then needs to give an answer on the status of the food in question. Should the Member State not be able to clarify the status of the food, it may consult other Member States and the European Commission. However, there are no specific rules when a Member State is required to consult other member states or the European Commission.

Once the Member State has concluded on the status of the food, it notifies the food business operator of its decision. This notification includes a justification of the decision and – in case the food is classified as "novel" – the Novel Food category under which it falls according to the definition of Article 3, Paragraph 2, letter a) NFR. While this notification by the Member State is relatively clearly regulated, the legal nature of this notification remains unclear.

After the member state communicated its decision to the business operator, the Commission needs to make the respective decision publicly available on its website.

bb) Public information on the Website of the European Commission

On the European Commission website (cf. https://ec.europa.eu/food/safety/novel_food/consultation-process_en) all foods that were subject to a consultation concerning their Novel Food status are listed. These foods are for example selenium enriched mushrooms (*Agaricus bisporus*), pine cone (Pinus sylvestris) syrup or polyporus umbellatus dehydrated mycelium powder. As of 11 March 2020, there are 35 foods listed on the website that were reviewed in order to clarify their status.

Alongside with the names of the foods, the website shows the decision made concerning each food, «Not novel when used as or in foods» or «Novel when used as or in foods». The list also provides a document containing the reasons for the decision for each food, as well as the category of food from the definition of Article 3, Paragraph 2, letter a) NFR that the respective food falls under in case it was deemed Novel Food.

As an example, selenium enriched mushrooms (*Agaricus bisporus*) were classified as Novel Food according to category (vii) («*food* resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances»). Although the used button mushrooms were consumed in the European Union before 15 May 1997, growing these mushrooms on enriched selenium substrates was not a known process in the European Union before that time. Because the circumstances of growing the mushrooms lead to a different composition of the product – higher level of selenium – this food was deemed "novel", since there is no history of consumption within the European Union of equally high-selenium-level mushrooms.

The Pine cone (Pinus sylvestris) syrup was not considered a Novel Food in the end. The applicant claimed that the food had been significantly used within the European Union before 15 May 1997 but failed to prove this claim. Therefore, the responsible Member State of Germany consulted other Member States concerning the history of use of this food. The Member States of Romania and Hungary were able to confirm that the syrup had been used before 15 May 1997, which led to this food being categorized as not novel.

cc) Procedural steps

If a food is considered a Novel Food, it needs to be authorized in order to be marketed in the European Union. The main focus of this authorization process is the question of the safety of the Novel Food. The rules concerning this authorization are laid down in Chapter III, Article 10 et sqq. NFR. The authorization process may be initiated by either the European Commission or via an application to the European Commission. After the application or the initiation of the process by the European Commission, the application is revised and, if necessary, a scientific opinion by EFSA is obtained. In case the Novel Food is being authorized, it will be added to the Union List.

aaa) Application

The formal application of a company or person, who would like to put the respective food on the European market, needs to contain the information set forth in Article 10, Paragraph 2 NFR. This includes the following:

(a) the name and address of the applicant;
(b) the name and description of the novel food;
(c) the description of the production process(es);
(d) the detailed composition of the novel food;
(e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
(f) where appropriate, the analysis method(s);
(g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

bbb) If necessary: Opinion by EFSA

According to Article 11 NFR the European Commission may ask for an opinion by EFSA in order to properly evaluate the eligibility for authorization. Once the opinion is sought by the European Commission, EFSA needs to give its opinion within nine months after the request.

ccc) Update of the Union List

In case of a positive decision regarding the authorization of a Novel Food, this newly authorized Novel Food needs to be included in the Union List. This is to be done within seven months from the decision regarding the application and is achieved through an Implementing act.
To the present day (11 March 2020), according to the Website of the European Commission there are 91 applications pending.

c) What happens after the authorization?

If a Novel Food is authorized to be placed on the European Union market, as a rule any food business operator can make use of the application. Before the new NFR existed, the authorization was only valid for the applicant and so only he was able to profit from it. Now, an authorization of a Novel Food means that anyone can market this authorized food – with the exceptions due to data protection (see below). However, in order to ensure the high level of customer security, there are certain rules and possibilities concerning the monitoring of authorized Novel Foods as well as obligations to inform the European Commission of important developments.

Article 24 NFR opens up the option for the European Commission to impose monitoring requirements regarding authorized Novel Foods due to safety issues. These requirements are generally imposed upon the applicant, who needs to comply with them. The Member States and their authorities are the ones to control out these monitoring requirements.

As a generally applicable rule, Article 25 NFR states that all food business operators who placed a Novel Food on the European market must inform the European Commission immediately if they learn about new scientific or technical information which might influence the evaluation of the safety of

use of the Novel Food or any prohibitions or restrictions imposed by a third country. The European Commission then provides this information to the Member States which then – if necessary – take the appropriate actions in their own responsibility.

3. EFFECTS OF THE NFR ON THIRD COUNTRIES

The NFR sets forth rules concerning Novel Food, which apply to all foods produced in the European Union and entered into the European Union. Section 2 of the NFR provides specific, simplified rules for traditional foods from third countries. This allows producers from third countries who would like to place traditional foods on the European Union market to avoid the authorization process of Article 10 NFR. Instead they can submit a mere notification of the intention to place a certain food on the European Union market to the European Commission. This notification to the European Commission necessarily includes information on the applicant as well as information on the food itself, for example the name and description of the traditional food, details on the composition of the traditional food, the country of origin, documented data regarding the history of safe food use in a third country and a proposal for the conditions of intended use and for specific labelling requirements.

The European Commission will forward this notification to the Member States and to EFSA. If there are no safety concerns about the food, the Commission authorizes the placing on the market and will update the Union List accordingly.

In case one Member State and/or EFSA object to the food being authorized due to safety issues, the applicant may file an application following the rules of Article 16 et sqq. NFR. The applicant then needs to provide further information, in addition to the information given alongside with the notification, in order to prove the safety of the food. This application is then forwarded to EFSA, which delivers an opinion on the food with regards to its safety. When reviewing the food, EFSA needs to take into account whether the applicant was able to prove the history of safe use for a period of at least 25 years of the food sufficiently and whether the composition or the conditions of use of the product bear a safety risk. Depending on the outcome of the opinion of EFSA, the Commission then needs to authorize the food via an Implementing act and update the Union List.

Until the present day (11 March 2020), there are 9 pending notifications concerning Novel Foods from third countries according to the Website of the Commission.

4. POSSIBLE BENEFIT: DATA PROTECTION

Chapter V of the NFR concerns the so called "Data Protection" regarding authorized Novel Foods.

Following a request of the applicant, scientific evidence or data concerning the authorized Novel Food may not be used for other applications for a period of five years, beginning with the date of authorization, unless the applicant of the authorized food gives his consent. Article 26, Paragraph 2 NFR states that data protection shall be granted by the Commission, if the following requirements are met:

(a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
(b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
(c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

If data protection is granted, information on this fact needs to be added to the Union List. The Union list then includes a remark that the authorization of the respective Novel Food was based on proprietary scientific evidence and scientific data which underlies data protection according to Article 26 NFR. It also needs to include the information that during the period of data protection the food may be placed on the market only by the original applicant, unless an application gets authorized without the use of the protected data. The Union List also mentions the end of the data protection period of 5 years.

The option of data protection is, however, not provided for foods that are placed on the European Union market under the simplified rules for traditional foods from third countries.

5. PENALTIES

Regarding penalties, the NFR states in Article 29:

> Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 January 2018 and shall notify it without delay of any subsequent amendment affecting them.

Therefore, the enforcement of the NRF is down to the Member States and their respective authorities concerned with food safety. These authorities monitor the food market and examine whether a food is novel and, if so, whether it is authorized and complies with the specification, conditions of use and further requirements of the Union List. If this is not the case, the respective authority will impose sanctions on food business operator by means of appropriate (and proportional) legal penalties.

6. HOW THE NFR AFFECTS AGRICULTURAL PRODUCTS

Since it does not differ between different foods, the NFR applies to food in general, including agricultural products. However, agricultural products may especially fall under the following categories of the definition of Novel Food according to Article 3, Paragraph 2, letter a:

(iv) (food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
– traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
– non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances
(v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
(vi) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.

These categories are especially relevant for the agricultural sector since they all refer to a production process concerning the food, which may lead to the food being Novel Food.

7. OUTLOOK AND BOTTOM LINE

After all, the new NFR is a complete set of rules fully governing the matter of Novel Food. It clearly assigns responsibilities not only to the applicant or food business operator but also the European Commission, the EFSA and the Member States with their respective authorities. Future will show, how this set of rules will be lived and to what extent the jurisdiction will be able to interpret these rules keeping its vision and the reality in mind and in balance.