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LEGAL INSTRUMENTS PROTECTING INNOVATIVE FOOD IN THE LIGHT OF THE REGULATION ON NOVEL FOODS IN THE EUROPEAN UNION

INSTRUMENTOS JURÍDICOS DE PROTECCIÓN DE LOS ALIMENTOS INNOVADORES, A LA LUZ DEL REGLAMENTO SOBRE NUEVOS ALIMENTOS EN LA UNIÓN EUROPEA

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Abstract

Innovative food is not only food resulting from the use of new technological methods, new production methods or food originating from new plant varieties. Novel food products are predominantly discoveries that are not subject to protection under industrial property law. Protection of such innovative discoveries becomes particularly important in the case of novel foods. The paper discusses regulations concerning novel foods, especially EU Regulation No 2015/2283. Regulations on novel foods provide for special solutions in order to ensure, although to a limited extent, protection of the innovative achievements applied in novel foods. These regulations are specific in nature as they protect not the product itself, but the scientific evidence and data provided to support an application for a permission to introduce novel foods. Despite certain concerns, these data protection measures should be assessed positively.

Keywords: data protection, novel foods, food safety, food security, new technologies, innovations in agriculture, traditional food from a third country

Resumen

Los alimentos innovadores no son sólo los que resultan del uso de nuevos métodos tecnológicos, nuevos métodos de producción o alimentos procedentes de nuevas variedades vegetales. Los nuevos alimentos son predominantemente descubrimientos que no están sujetos a protección en virtud de la legislación sobre propiedad industrial. La protección de estos descubrimientos innovadores adquiere especial importancia

en el caso de los nuevos alimentos. En este artículo se analizan los reglamentos relativos a los nuevos alimentos, especialmente el Reglamento UE nº 2015/2283. Los reglamentos sobre nuevos alimentos prevén soluciones especiales para garantizar, aunque de forma limitada, la protección de los logros innovadores aplicados en los nuevos alimentos. Estos reglamentos son específicos por naturaleza, ya que no protegen el producto en sí, sino las pruebas científicas y los datos proporcionados para respaldar una solicitud de permiso para introducir nuevos alimentos. A pesar de ciertas preocupaciones, estas medidas de protección de datos deben valorarse positivamente.

Palabras clave: protección de datos, nuevos alimentos, seguridad alimentaria, nuevas tecnologías, innovaciones en la agricultura, alimentos tradicionales de terceros países

SUMMARY

I. INTRODUCTION

Industrial property law provides for many instruments aimed at protecting innovations. In particular, its legal provisions enable patenting biotechnological inventions, i.e. innovations related to the production that consists of, or contains, biological material, or to the manner by which biological material is produced, processed or used.[1] An example of such inventions includes the isolation of biological material as well as new plant or animal varieties if the technical feasibility of the invention is not limited to a specific plant or animal variety or breed.[2] Although biotechnological inventions are subject to patenting under patent law, inventions that relate to plant varieties and animal breeds, or to purely biological methods of plant and animal breeding, are excluded from protection (Nowicka, 2017, pp. 50 et seq). Despite the above, there is a system protecting plant varieties *sui generis*[3] under EU and national regulations as well as the regulations of the Union for the Protection of New Varieties of Plants (UPOV) Convention. The rights provided for these laws are structurally similar to those arising from the patent, and therefore they called quasi-patent rights (Gawliczek, 2015, p. 38).

It should be pointed out, however, that innovative food is not only food resulting from the use of new technological methods, new production methods or food originating in new plant varieties. It may also have a typically agricultural origin and be food that is traditionally consumed in third countries

but which, due to the fact that it is not consumed in the EU, may be called innovative. For this type of food, the solutions provided for in industrial property law are not sufficient. New food products introduced to the market are primarily discoveries that are not at all protected by industrial property law, while such protection is particularly important in respect of novel foods. However, demonstrating the safety of such products requires significant research costs and a lengthy procedure.

The focus of the deliberations herein is the regulation of novel foods, and in particular EU Regulation No 2015/2283.[4] The aim of the reflection presented in this paper is to answer the question whether the regulations on novel food provide for specific instruments capable of protecting innovations and whether they are sufficient.

II. PLACING NOVEL FOODS ON THE EUROPEAN UNION MARKET

Further deliberations will require the explanation of the concept of novel food. Its definition, formulated in Regulation No 2015/2283[5] consists of two criteria that must be satisfied simultaneously. They are: the history of safe food use and the use of specific manufacturing processes (Amanor-Boadu, 2004, p. 611). Regarding the former, novel food is a food and food ingredients that have not been used for human consumption to a significant degree within the EU before 15 May 1997, irrespective of the dates of Member States' accession to the Union. It therefore consists of a temporal and quantitative element (van der Meulen & van der Velde, 2009, p. 64). According to the other criterion determining novel food, such food must belong to at least one of the ten categories of food which have been legally defined.[6]

The EU legislator has taken the view that the scope of Regulation No 2015/2283 that is currently in force should not be altered when compared to Regulation No 258/97 that was binding previously,[7] as reflected in the legally formulated definition of novel food. In the light of scientific and technological developments, it was necessary to correct, clarify and update the categories of novel foods. In principle, the substantive scope has remained unchanged since foods falling within the listed categories may belong to any of the four categories laid down in Regulation No 258/97.[8] However, the new definition is more precise and takes into account to a greater degree than before the technological progress (Stankiewicz, 2014, p. 7).

As K. Leśkiewicz points out, there are territorial food safety systems in place nowadays, which consist of food law institutions, standards and procedures

(2012, p. 180). The EU also has instruments capable of ensuring the safety of novel foods, and they include in particular a pre-market safety control system for novel foods that is preventive in nature (Kraus, 2001, p. 41). Although there is a general principle in EU food law that everything that is not prohibited by law is allowed, the "prohibition principle" is being increasingly applied. Consequently, the introduction of novel foods requires authorisation, otherwise the distribution of these foods is not allowed and considered illegal (Büscher, 1995, p. 21; Spranger, 2000, p. 111). This principle also applies to novel foods which cannot be placed on the Union market solely under the distributor's own responsibility,[9] but whose safety must be verified. It is worth emphasising that the obligation of the pre-market safety assessment was a certain novelty in the food law regulations (Bockisch, 2003, p. 391).

The novel food safety assessment system is based on an application procedure under which a food business operator intending to place a novel food on the EU market is obliged to obtain authorisation and an inclusion of the product in the Union's List of Novel Foods. The authorisations granted under this procedure are general in nature and binding on everyone. It should be noted that since it is the responsibility of the entity placing the food on the market to provide the proof of its safety in an application to the Commission,[10] it is the food business operator who performs the first risk assessment (Zbinden, 2009, pp. 11-12). The Commission may, should it deem necessary, to request EFSA[11] to issue an opinion on the impact that a given foodstuff may have on human health.[12] The exercise of this power allows for the reassessment of risks, this time by EFSA acting as the scientific backbone for risk management institutions (Szymecka, 2009, p. 170). Based on the risk assessment carried out by the applicant or, where appropriate, by EFSA, the Commission delivers a decision authorising the placing of novel foods on the Union market.

Regulation No 2015/2283 also provides for a simplified risk analysis process for traditional foods from third countries, namely for certain categories of novel foods defined in it as produced in a primary production.[13] The risk analysis process in this case is based on the demonstration of a history of safe food consumption in the country of origin. At the stage of preparation of the notification, the applicant must not only provide a product specification but also a specific comparison of the quality characteristics of the food, indicating the proposed conditions of use in the EU. The history of safe food use in a third country can only be attested by compositional data and a documented experience of a continued use of the food over a period of at least twenty-five years in the customary diet of a significant number of people in one or more third countries. The demonstration of a history of safe food use is

intended to demonstrate the overall safety of the food. After all, it is not certain that food that is considered safe and traditional in other parts of the world will be harmless to the EU population.[14] Therefore, the risk assessment is predominantly based on an analysis of the experience of consumption in third countries only.

The application and the accompanying evidence on the safety of traditional foods from third countries is assessed by the Commission, by EFSA and the Member States. The absence of contraindications from EFSA and any of the Member States is considered to constitute a favourable food safety assessment. However, even duly substantiated objections to the safety of a traditional food require an additional assessment,[15] and this is first of all carried out by the applicant whose application is reviewed by EFSA, taking into account possible risks to consumer health in the EU.[16] The EFSA opinion provides the basis for decisions authorising the placing of such foodstuffs on the European Union market.

It should be emphasised that there are high economic risks involved in submitting an application for the authorisation of novel foods on the Union market, and the applicant must already at the preparation stage of the relevant documentation verify the novel food's compliance with the requirements.

Innovation can only be implemented if there is a compromise between the innovator's profits and losses and the opportunities for other market participants to benefit from the achievements to date. It is about balancing the conflicting interests of competing entities. The procedure for the authorisation of novel foods generates significant costs, which some sources report as ranging from three hundred thousand to four million euros (Krakowiak, s.f.). On top of that, due to the general nature of the authorisations, the positive decision allows, in principle, not only applicants but also other operators to place novel foods on the EU market. This is why there are many legal instruments available in the existing law aimed at ensuring the economic protection of pioneers.

III. CONFIDENTIALITY OF APPLICATIONS FOR THE AUTHORISATION TO PLACE NOVEL FOODS ON THE EUROPEAN UNION MARKET

Regulation No 2015/2283, similarly to the earlier Regulation No 258/97, provides for the possibility of confidential treatment of certain information.[17] In such cases, applicants must indicate which elements of the information provided are to be treated as confidential and must provide a detailed statement

of reasons for the request for their confidentiality.[18] Where the Commission requests the opinion of EFSA, EFSA shall assess the confidentiality request submitted by the applicant.[19] Upon the request of an applicant, EFSA may grant confidential treatment only with respect to the following items of information where the disclosure of such information is demonstrated by the applicant to potentially harm to a significant degree its interests: the manufacturing or production process, including the method and its innovative aspects as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety; commercial links between the producer or the importer and the applicant or the authorisation holder, where applicable; commercial information revealing sourcing, market shares or business strategy of the applicant; and quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.[20] EFSA may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety; where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.[21] Where the Commission does not request EFSA's opinion, the Commission shall assess the confidentiality request submitted by the applicant.[22]

Furthermore, it is worth noting that applicants may also consult the Member State in which the novel food is first intended to be placed,[23] and the Member State may be asked to accept the confidential treatment of certain information contained in the application if its disclosure might harm the competitive position of the applicant.[24] To that end, it is necessary to identify the elements of the information submitted that are to be treated as confidential and to provide all relevant details to justify a request for confidentiality.[25]

The Member State must inform the applicant of its position as to which elements of information are to remain confidential. However, in this case again, the following data may not be subject to confidentiality: the name and address of the applicant, the name and description of the food, a summary

of the studies submitted by the applicant and, where appropriate, the analysis method.[26]

When a request for consultation is withdrawn, neither the Commission nor the Member States may disclose information in respect of which the food business operator has requested confidentiality.[27] Also, in the event that the food business operator withdraws its request for consultation, the information provided shall be kept confidential within three weeks of receipt of the notification.[28] This is especially important in the case when the decision is negative.

IV. PROTECTION OF SCIENTIFIC DATA CONTAINED IN APPLICATIONS FOR THE AUTHORISATION TO PLACE NOVEL FOODS ON THE EUROPEAN UNION MARKET

In the light of the regulations on novel foods, the analysis of legal instruments for the protection of innovative food should focus on solutions for the protection of scientific data included in the application for the authorisation to place novel foods on the EU market. The newly obtained scientific evidence and data must be used by the initial applicant only (Delewski, et al., 2016, p. 77). In other words, for a limited period of time such information may not be used by any subsequent applicant.[29] At the request of the applicant, supported by appropriate and verifiable information, the new scientific evidence or data on which the application has been based may not be used without the initial applicant's consent. Their protection may be granted for a period of up to five years provided the following conditions are met: (i) when the application was submitted, the newly developed scientific evidence or data were designated as proprietary, (ii) the initial applicant had the exclusive right to refer to them, and (iii) the authorisation could not have been granted without the submission of that scientific evidence or data.[30]

Where authorisation is granted on the basis of an application, and the list is updated on the basis of proprietary evidence, the entry should include additional elements such as the applicant's name and address, the date of inclusion of the novel food in the Union list and the end date of the data protection together with and information that the inclusion is based on proprietary evidence and protected scientific data.[31] The update also shows that during the period of data protection, only the applicant may place the novel food on the EU market unless a subsequent applicant obtains authorisation for that novel food without reference being made to the proprietary scientific evidence and the protected data, or the agreement of the initial applicant has

been procured.[32] However, the protection of the scientific data provided by the applicant should not prevent other applicants from seeking the inclusion of a novel food in the Union list either on the basis of their own scientific data or by reference to data protected upon the consent of the initial applicant.[33]

It should be pointed out that those rules do not apply to notifications and applications for placing traditional food from third countries on the Union market.[34] Nor shall renewed protection be granted to scientific evidence and data which are already protected or for which the protection period has expired.[35] The general five-year period of data protection granted to the initial applicant should not be extended to grant data protection to subsequent applicants.[36]

When the legislation on the protection of scientific data included in the application for the authorisation to place novel foods on the EU market is being analysed, the specific provisions on the protection of scientific data submitted in support of the application for authorisation of health claims cannot be ignored.

The binding regulations recognise the fact that many food business operators wish to make health claims on the labels of the products which they distribute. It is often in their interest to indicate the benefits flowing from the consumption of a new product launched on the market. The use of health claims is subject to the conditions laid down in separate legislation.[37] Given the purpose and scope of this paper, the analysis of the requirements and the admissibility of such labelling as well as the procedure for authorising the use of health claims is outside its scope, particularly since the use of health claims on novel foods is not subject to additional requirements when compared to those applicable to conventional foods. It should be noted, however, that also Regulation No 1924/2006 provides for the protection of scientific data that constitute the basis for granting authorisation.[38] For a period of five years from the date of the authorisation of health claims, proprietary scientific data and other data may not be used by other applicants.

It is important that, where an applicant seeks protection of scientific data relating to the same food in both the application for authorisation of a novel food and the use of health claims, the relevant periods of protection should run concurrently.[39] This is to be achieved by suspending the authorisation procedure for placing novel foods on the EU market.

The Commission will stay the authorisation procedure on request if data protection claims have previously been made in both procedures.[40] The stay of

the procedure does not prejudice the assessment of the food safety by EFSA,[41] but this period does not count as part of the deadline for the Commission to prepare a draft decision.[42] The stayed procedure will resume once the Commission has received the opinion of EFSA on health claims. From that moment on, the time limit for the Commission to prepare a draft decision will run afresh from the beginning.

Here, a doubt arises as to when the time limits for data protection start to run in both cases - whether this happens at the same time and for the same length of time, or whether one of the time limits is shortened due to a later issuance of a decision. When attempts to answer these questions are made, it must be assumed that a five-year period of protection for scientific data in support of a request for health claims starts as soon as the claims are properly qualified,[43] which means once the health claims have been authorised.[44] However, the suspension of the authorisation procedure for placing novel foods on the EU market is pending the submission of EFSA's opinion on health claims to the Commission, thus prior to the initiation of the comitology examination procedure, which is also required for the adoption of decisions on health claims.[45] This implies that the comitology procedure should be initiated in both cases, if not in parallel, then within a short period of time. This does not mean that decisions will be taken at the same time. In fact, there is no specific indication in the regulations adopted of when the Committee should deliver its opinion on the draft implementing act. What is only known is that it must deliver its opinion within the time limit laid down by the Chair according to the urgency of the matter.[46]

It should also be noted that if in both cases the application for information protection has been granted, the five-year period of data protection in support of an application for authorisation of a novel food may not exceed the data protection period in the health claim procedure,[47] and consequently it is considerably dependent on the former (Delewski, et al., 2016, p. 7). Therefore, if a decision on the use of health claims is taken earlier, the data protection period laid down in the decision authorising the placing of novel foods on the market should be shortened accordingly. This implies that the legislator assumes that the decision authorising the placing of novel foods on the market will not be taken earlier than the decision on the use of health claims. Unfortunately, this assumption is not confirmed in the existing legal provisions. Rather, it is assumed that the protection periods should run in parallel if both applications are positively assessed[48] and that in both cases authorisations will be granted (Loosen, 2016, p. 27). However, in view of the possible political aspect of the procedure for issuing an opinion, it is

necessary to propose that the regulation should be harmonised and that a precise moment of commencement of the period of protection of scientific data in both situations should be specified. Instead, rather than the desired "one door, one key" formula, the current solutions provide for a scheme of two doors and two keys, and that they will open at the same time may turn out to be only a mere assumption (Loosen, 2016, p. 28).

In line with the considerations to date, it must be concluded that the protection of scientific data must be distinguished from the confidentiality of applications. These are two separate institutions. One is to prevent the disclosure of confidential information, while the other is to guarantee a period of time during which other applicants may not rely on the data used by the initial applicant without his consent (Simpson, 2016, p. 310). The aim of the data protection regulations is therefore not to protect trade secrets but to stimulate research, development and innovation in agriculture and the agri-food industry, in particular by protecting the costly investment made by innovators while gathering information and data to support an application for the authorisation of novel foods (Simpson, 2016, p. 310). This is intended as an incentive for food business operators. However, the regulation does not indicate precisely which evidence or data may be considered as new (Gerstberger, 2008, p. 217). Neither does it provide for an exclusive right of reference to the proprietary scientific evidence or scientific data (Simpson, 2016, p. 309).

There are also opinions in the literature that the establishment of such a monopoly is inconsistent with the objectives of Regulation No 2015/2283, it does not serve to ensure food safety, and significantly impedes the free movement of goods, while applicants are entitled to other protection measures, such as patent protection or utility model protection (Gerstberger, 2005, p. 590). Their use would have a positive impact on the economy since it would allow other operators to market "essentially similar" products who, through licences granted, would share the costs of implementing the innovation (Gerstberger, 2005, p. 590). However, these opinions cannot be fully shared, as novel foods, including biological inventions, are not merely inventions, but also new plant varieties for which the law provides a specific sui generis protection model. They are also and first of all discoveries that are not subject to industrial property rights protection at all.

It should be noted that granting data protection will change the legal nature of the authorisation to place novel foods on the EU market. The decision will not be of a general nature, but will rather have a temporary, individual character. Therefore, according to the European Commission, such individual

authorisations will only be granted to applicants for really innovative foods.[49] In reality, in such a case the application of the solutions already adopted might be substantially limited.

The literature further stresses that the period of data protection provided for in Regulation No 2015/2283 is significantly shorter than the periods of data protection provided for in other EU regulations, such as Regulation No 528/2012[50] or Regulation No 831/2003[51] which provide for periods exceeding 10 years (Simpson, 2016, p. 311). A short period of protection may lead to a situation where the applicant's competitors might prefer to wait until the expiry of the protection period rather than obtain the consent of the innovator to use the proprietary data. As a result, even if the applicant will have the sole right to place the product on the market, without granting paid licences, he will not be able to recover the investment costs incurred (Simpson, 2016, p. 312).

V. CONCLUSIONS

The instruments available under industrial property law are insufficient to fully ensure the protection of innovations introduced by food business operators, as they only empower applicants to exercise such legal means as patent protection or utility model protection. When adopted, they may nevertheless bring about positive effects for the economy, as it will allow other operators to market similar products under licence and in this way share in the costs of implementing innovations resulting from granted licences, including compulsory licences. However, innovations on the food market are also plant varieties that enjoy a special *sui generis* protection, and in particular discoveries which are not subject to the provisions of industrial property law at all.

For those, regulations on novel foods, including Regulation No 2015/2283, contain specific provisions ensuring, even if only to a limited extent, the protection of innovative achievements in novel foods. These regulations are specific. They do not protect directly the product itself, but scientific evidence and data used to support an application for authorisation to introduce novel foods.

The protection period for new scientific data, during which the applicant may be the only one authorised to place novel foods on the EU market, is a positive solution. It may serve to stimulate research, development and innovation in agriculture and the agri-food industry, in particular by protecting the costly investments made by applicants in gathering information and data

to support the application for authorisation. It may also act as a stimulus and an incentive for the food sector.

However, this solution offers only a relative protection. This is because during the protection period (up to 5 years), newly developed scientific evidence or scientific data submitted in support of an application for a subsequent application cannot be used without the consent of the initial applicant, and a subsequent applicant will obtain exclusivity for placing the novel food on the market only if he provides new data and information, other than the confidential data already reported as confidential.

It should also be stressed that the five-year period of protection provided for in Resolution No 2015/2283, which is much shorter than in other legislative acts envisaging a similar solution, may not be sufficient for the initial applicant to recover at least part of the expenditure incurred. Too little account has been taken of the fact that the initial phase of product distribution includes as well a period of lower profits, as it takes time before customers familiarise themselves with a particular new food. Moreover, the innovator's competitors may prefer to wait rather than obtain paid licences from the applicant to use the authorisation granted.

And yet, these special measures do not prejudice resorting to other means of protecting innovations foreseen in separate regulations, including industrial property law. In fact, indirect protection of innovations may also be provided by protection rights from trademarks or industrial design registration, as well as geographical indications. These rights do not, however, protect the novelty of a product understood as novel food itself, but they allow to distinguish such food among competitors. Therefore, they serve more the marketing purposes than the protection of innovations.

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Notes

1 See Article 931 (1) of the Polish Act of 30 June 2000 – Industrial property law, Dz.U. of 2017, item 776 as amended, hereinafter referred to as IPL.

2 See Article 932 (1) of IPL. Compare Nowicka, 2017, pp. 75 et seq.

3 Compare Korzycka-Iwanow, 2000, p. 77 and Nowicka, 2017, pp. 51 et seq.

4 Regulation of the European Parliament and of the Council (EU) No 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p.1 as amended, hereinafter referred to as Regulation No 2015/2283.

5 See Article 3(2)(a) of Regulation No 2015/2283.

6 See Article 3(2)(a) of Regulation No 2015/2283.

7 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1 as amended, hereinafter referred to as Regulation No 258/97.

8 See Article 1(2) of Regulation No 258/97.

9 Streinz, 1998, p. 2.

10 Rehbinder, 1999, pp. 10 et seq.

11 European Food Safety Authority.

12 See Article 10(3) of Regulation No 2015/2283.

13 See Article 3(2)(c) of Regulation No 2015/2283.

14 Compare judgment of the CJEU of 16 January 2009, C#383/07 – M-K Europa GmbH & Co. KG against Stadt Regensburg, with the participation of: Landesanwaltschaft Bayern, ECLI:EU:C:2009:8.

15 See Article 15(2) of Regulation No 2015/2283.

16 See Article 17(2) of Regulation No 2015/2283.

17 See Article 23(2) of Regulation No 2015/2283.

18 See Article 23(2) of Regulation No 2015/2283.

19 In accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ EU L, No 31, p. 1 as amended. See Article 23(3) of Regulation No 2015/2283.

20 See Article 39(2) of Regulation No 178/2002.

21 See Article 23(4) of Regulation No 2015/2283.

22 See Article 23(5) of Regulation No 2015/2283.

23 If there is uncertainty about the legal status of a food intended to be placed on the EU market, potential applicants have the possibility to consult the Member State. The consultation procedure starts with an electronic application in the Member State where the food is to be placed on the market for the first time. For more on this see Article 4 of Regulation No 2015/2283 and Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 77, 20.3.2018, p. 6 as amended, hereinafter referred to as Regulation No 2018/456.

24 See Article 9(1) of Regulation No 2018/456.

25 See Article 9(2) of Regulation No 2018/456.

26 See Article 9(3) of Regulation No 2018/456 .

27 See Article 9(7) of Regulation No 2018/456.

28 See Article 9(5) of Regulation No 2018/456.

29 See Recital 30 to Regulation No 2015/2283.

30 See Article 26(2) of Regulation No 2018/456.

31 See Article 27(1) of Regulation No 2015/2283.

32 See Article 27(1)(d) and Article 26(2) of Regulation No 2015/2283.

33 See Recital 30 to Regulation No 2015/2283.

34 See Article 26(3) of Regulation No 2015/2283.

35 See Article 27(2) of Regulation No 2015/2283.

36 See Recital 30 to Regulation No 2015/2283.

37 These premises have been outlined in Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9 as amended, hereinafter referred to as Regulation No 1924/2006.

38 See Article 21 of Regulation No 1924/2006.

39 See Recital 31 to Regulation No 2015/2283.

40 See Article 28(1) of Regulation No 2015/2283.

41 Pursuant to Article 11 of Regulation No 2015/2283.

42 Pursuant to Article 12(1) of Regulation No 2015/2283.

43 Szostek, 2015, pp. 311 et seq.

44 See Article 21(1) of Regulation No 1924/2006.

45 See Article 15 of Regulation No 1924/2006.

46 See Article 3(3) of Regulation No 182/2011.

47 See Article 28(5) of Regulation No 2015/2283.

48 This assessment is done by EFSA.

49 Compare Commission Staff Working document: 'A Fitness check of the Food chain – state-of-play and next steps, SWD(2013)516 of 5 December 2013, p. 44.

50 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1 as amended.

51 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, 18.10.2003, p. 29 as amended.