"Does EFSA's lack of re-instruction by the Commission on the assessment of botanicals under Regulation (EC) 1924/2006 violate companies' rights and can companies continue to rely on the transitional provision under Art. 28 para. 5 HCR?"

Legal opinion commissioned by
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
and the
Bundesverband der Pharmazeutischen Industrie e.V. (BPI)

from

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In December 2021

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A. Starting point and introduction to the scope of the Health Claims Regulation

I. Legal basis: Regulation (EC) Nr. 1924/2006

The starting point for the legal question dealt with here is Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods of 20 December 2006.[1] It is about the content of the Health Claims Regulation and in particular about its implementation by the European Commission.

1. Purpose of the Health Claims Regulation

The purpose of the Health Claims Regulation (HCR) is to create uniform rules for the use of nutrition and health claims in order to ensure a high level of protection for consumers. This concerns claims for products that promise or suggest a health benefit, although they are not medicinal products. Art. 1 number 2 of the Directive 2001/83/EC[2] defines the term medicinal product as: „Any substance or combination of substances presented for treating or preventing disease in human beings".[3] Medicinal products are not goods and services in general, but healing instruments. As such, they are in a special context with regards to the protection of human beings. Medicinal products also serve a special purpose because the general public has a substantial interest in the development and existence of effective medicinal

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[1] Hereinafter referred to as the Health Claims Regulation; Moreover, provisions without reference to a law are provisions of this Regulation.

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Official Journal No. L 311 from November 28, 2001 p. 0067 - 0128.

[3] See also § 2 German Medicinal Products Act.

products with few side effects. Products offered in the food segment, which are – according to their own claim or according to customer expectations – therefore not medicinal products, may still be functionally close to medicinal products if they make health claims or arouse corresponding consumer expectations or satisfy existing expectations. If nutrition and health claims are made in advertisements or in the labelling of food products[4], it influences the expectations of consumers and very often represents a significant or decisive incentive to buy. Particularly given the influence of nutrition and health claims on consumers' purchasing decisions, the definition of permissible claims is intended to make it easier for consumers to be provided with reliable information to make an informed decision.[5]

The HCR is also intended to cause an internal market-oriented harmonization of laws in order to create the conditions for the free movement of goods. Differences between regulations on a national level that may affect intra-Community trade are thus to be equalized.[6] Furthermore, according to Recital 9, the adoption of the Health Claims Regulation with the application of the measures provided therein is also intended to create equal conditions of competition for the food industry and thus to serve fair competition in an open market economy.

[4] Recital 1, 36.

[5] Recital 9 and 10.

[6] Recital 2, 10 and 36.

2. Subject matter and procedure

The HCR is divided into five chapters. The first chapter deals with the subject matter, scope and definitions. Chapter 2 sets out general principles for the use of nutrition and health claims, while Chapter III then deals specifically with nutrition claims themselves. Specific conditions for health claims are found in the fourth chapter. The fifth and last chapter deals with general remarks and final provisions are formulated. The structure of the chapters already shows that the HCR refers to nutrition and health claims and their conditions of use. This is already addressed at the beginning in Art. 1 para. 1, 2 of Regulation (EC) No. 1924/2006. The only matter of relevance for the question of the suspended finalisation of the list and the lack of re-instruction to EFSA are the "health claims".[7]

The terms "claim" and "health claim" are defined in Art. 2 para. 2 no. 1 and 5 of Regulation (EC) No. 1924/2006. Accordingly, a "health claim" means

> [health claim] any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health; *[…]'*[8]

[7] It is true that the nutrient profiles provided for under Art. 4 para. 1 HCR have not yet been enacted either, cf. *Meisterernst/Haber*, WRP 2019, 413,414; however, these are not further relevant for answering the legal question.

[8] "Whether the term 'labelling' also includes non-linguistic communications can be left aside, because 'presentation' is also included. The term presentation also includes visual-pictorial-communications, in particular the entire appearance of the packaging, but also the appearance, i.e. the appearance of the food itself, e.g. its shape or color. Therefore, in individual cases, packaging in the shape of a heart could also be a health claim." (inofficial translation), cf. *Zipfel/Rathke* LebensmittelR, ed. by Rathke/Hahn, 179. EL March 2021, Veordnung (EG) 1924/2006 Art. 1 para. 8.

On the basis of this definition, it can therefore be assumed that the scope of application is broad, as intended by the Regulation;[9] in any case, the scope of application is not limited by the Regulation by way of the choice of legislative terms.

The HCR differentiates between different types of claims with regards to "health claims"[10] made in relation to health. On the one hand, these are claims relating to the reduction of disease risk[11], claims relating to children's development and health[12], and any others relating to health[13]. In addition to these differentiations according to Art. 10 para. 3 of Regulation (EC) No. 1924/2006, it is possible to make references about general, non-specific benefits of a nutrient or food to overall good health or health-related well-being.
The way in which the claim is presented affects the admissibility of the claim, its inclusion in a list of permitted claims, and the applicability of transitional rules. Health claims other than those referring to the reduction of a disease risk and to children's development and health are addressed in Art. 13 para. 1 lit. a)-c) of Regulation (EC) No. 1924/2006. It is stated in this norm:

> "(1) Health claims describing or referring to:
> a) the role of a nutrient or other substance in growth, development and the functions of the body; or

[9] *Delewski*, LMuR 2009, 41, 43.

[10] Since the claims are also addressed individually, but are significantly regulated in the fourth chapter, it is considered here that they fall under the term "health claim".

[11] Art. 2 para. 2 no. 6, chapter 4.

[12] Art. 13, 14, chapter 4.

[13] Art. 13 para. 1.

> b) psychological and behavioural functions; or
> c) without prejudice to Directive 96/8/EC, slimming or weight- control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,
> which are included in the list provided for in paragraph 3 may be made without undergoing the authorisation procedure laid down in Articles 15 to 19, […]"

For the claims mentioned in lit. a)-c) of Regulation (EC) No. 1924/2006, para. 1 together with para. 3 provide for the adoption of a list[14] of authorised claims without having to follow the procedure of Art. 15-19. [15] For claims referring to the reduction of a disease risk (lit. a) and claims referring to children's development and health (lit. b), Art. 14 para. 1 of Regulation (EC) No. 1924/2006 also provides for a list procedure for the inclusion of permitted claims in the Community list. However, this procedure is governed by Art. 15, 16, 17 and 19 of Regulation (EC) No. 1924/2006.

The respective procedures for the inclusion of claims in the respective list differentiate primarily with regards to the effort required: The procedure according to Art. 15-17, 19 of Regulation (EC) No. 1924/2006 can be described as more time-consuming.[16] In addition, the "initiators" for inclusion of a claim in the respective list are distinctively specified: While in the

[14] For the further evaluation, this list is important above all; however, the overall explanation of the possible procedures contributes to a better understanding and is needed in some places as a criterion to distinguish between them. Thus, the possible procedures are also explained here.

[15] In addition, there is also the procedure under Art. 18 for this type of claims under Art. 13 para. 5, if claims are based on new developed scientific evidence and/or include a request for the protection of proprietary data.

[16] Cf. *Delewski*, LMuR 2009, 41, 43.

procedure according to Art. 15-17, 19 an individual application for authorisation has to be submitted to the competent national authority (Art. 15 Regulation (EC) No. 1924/2006), the procedure according to Art. 13 para. 3 provides that the Member States submit to the Commission a list with the health claims to be evaluated (Art. 13 para. 2 Regulation (EC) No. 1924/2006). In this case, it is therefore not necessary for a company to submit an individual application requesting the inclusion of a claim in the list.

Nevertheless, both procedures provide for a scientific assessment of the relationship of the food to health, body functions, etc. before the health claim is included. For the claims relating to children and the reduction of a disease risk, this results from Art. 16 of Regulation (EC) No. 1924/2006; for other health claims, these requirements result from Art. 13 para. 3 of Regulation (EC) No. 1924/2006. In addition, this principle is also generally established in the provisions of Art. 5 para. 1 lit. a) and Art. 6 para. 1 of Regulation (EC) No. 1924/2006. Thus, a hearing or statement of the "authority" must take place in the procedure for the adoption of the list.

Authority is the European Food Safety Authority (EFSA) according to Art. 2 para. 2 no. 7 Regulation (EC) No. 178/2002. It is made clear by the HCR that the lists may not be adopted without prior involvement of EFSA, thus the Commission must consult EFSA in each case before adopting the lists.[17] In addition to the explicit regulations on scientific assessment in the provisions of the HCR, there are also indications of the

[17] Whether the Commission is then normatively or at least factually bound by EFSA's opinion is not relevant to the legal question.

importance of scientific assessment in the Recitals. According to Recital 17 of Regulation (EC) No. 1924/2006, the use of nutrition and health claims should be scientifically substantiated, meaning that all available scientific data should be taken into account and weighed. In particular for health claims, a uniform scientific assessment should take place at the highest possible standard; according to the legislator's intent, the evaluation should therefore be carried out uniformly by EFSA.[18] Only for the "other health claims" according to Art. 13 para. 1 lit. a)-c) of Regulation (EC) No. 1924/2006 a different type of assessment and authorisation shall be provided according to Recital 26. This consideration is reflected in the different procedural regulations according to Art. 13 and Art. 14 of Regulation (EC) No. 1924/2006. However, the scientific substantiation itself remains necessary under both procedures (as mentioned above).

EFSA's opinions or statements thus form the epistemic, science-based basis for the Commission's adoption of the list, but do not themselves have any legal effect on third parties.[19] They serve merely to prepare the Commission´s decision for the inclusion of the relevant data.[20] Based on this, the Commission shall then adopt the lists in accordance with the relevant procedures pursuant to Art. 25 para. 2 or Art. 25 para. 3 of Regulation (EC) No. 1924/2006.[21]

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[18] Recital 23 HCR.

[19] Cf. General Court judgment of 12.06.2015, T-334/12, para. 60.

[20] *Delewski*, LMuR 2009, 80, 82.

[21] The differences in the procedures are not relevant here; these refer, for example, to a possible right of veto of Parliament, cf. *Delewski*, LMuR 2009, 41, 48.

Overall, the adoption of the Health Claims Regulation led to a "paradigm shift" with regard to the requirements for the use of health claims. Before the Regulation was established, these could be used without any authorisation if there has been a scientific proof available; as a result of the new regulation, there has been a change from the principle of authorisation to the principle of prohibition with reservation of exceptions (preventive prohibition with reservation of authorisation).[22] Pursuant to Art. 10 para. 1 of Regulation (EC) No. 1924/2006, the following requirements therefore exist for the use of health claims:

> "Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14."

Based on the wording, it is clear that the inclusion of a health claim in the list of permitted claims according to Art. 13 and 14 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 shall be a fundamental element for permitted uses. The claim must actually have been positively listed in the relevant list, otherwise the use remains prohibited; the mere possibility of authorisation of a claim is not sufficient.[23] When making general health claims pursuant to Art. 10 para. 3 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006, the lists provided for in Art. 13 and 14 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 are also relevant for the permissible use of these claims, since the general claim must

[22] *Delewski*, LMuR 2009, 41, 42; *Kristin Oertl*, Update Health Claims-Verordnung, LMuR 2016, 1.

[23] *Delewski*, LMuR 2009, 41, 42.

contain at least one health claim authorised in the lists. The adoption of the lists provided for in Art. 13 and 14 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 also has a general effect according to Art. 17 para. 5 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006, namely that the authorised health claims can be used under the conditions specified therein by any food business operator and irrespective of who has individually applied for the authorisation in the procedure according to Art. 15-17, 19. An exception to the general effect exists only in the case that the use is restricted for data protection reasons according to Art. 21 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006.

From the overall context of the Health Claims Regulation, it can therefore be concluded that the adoption of the lists of authorised claims is of central importance for the use of health claims, as the inclusion in a list is a fundamental condition for the legal permissibility of use.[24] So far, the list approved by the European Commission contains comparatively few health claims. 1600 entries of a consolidated list of the applications received were finally evaluated and rejected.

> „For all other advertising claims applied for (approx. 2200, most of them for botanicals), the EU Commission has suspended the evaluation necessary for the implementation of the HCR since 2010. Thus, these claims can currently still be used without being evaluated,

[24] In addition, the general requirements according to Art. 3, 4 para. 1, 5, 6 para. 1 and para. 2 must also be fulfilled; however, these play only a minor role for the adoption of the list, since a scientific examination is provided for the inclusion of the claim in the list anyway.

> as long as they are not considered to be misleading on a case by case basis." (inofficial translation)[25]

Exceptions from the need to register on the list are provided for in the transitional measures. Art. 28 in connection with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 contains a number of transitional measures, some of which, however, no longer have any effect, e.g. Art. 28 para. 1 ("but not later than 31 July 2009"). For claims according to Art. 13 para. 1 lit. a), according to Art. 28 para. 5 in connection with Art. 10 I of Regulation (EC) No. 1924/2006, in addition to the existence of scientific evidence (cf. the claims of the HCR under Art. 5 para. 1 and Art. 6 para. 1), it is primarily required that these comply with the regulations of the respective Member States. For claims according to Art. 13 para. 1 lit. b) and lit. c) as well as Art. 14 para. 1 lit. b), the status before the adoption of the Health Claims Regulation in the Member States is decisive and also the further use is partly based on national law and otherwise on European Union law.[26]

3. Personal scope of application

The HCR is not a perfect example of a successful regulation; this already starts with the question of the material and personal scope of application. It is definitely in need of interpretation and specification which activities are covered by the HCR and to whom the regulation refers to. The starting point for answering these questions is Art. 1 para. 2 in connection with Art. 10 para.

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[25] https://wm.baden-wuerttemberg.de/de/service/presse-und-oeffentlichkeitsarbeit/pressemitteilung/pid/eu-verordnung-zu-health-claims-landesregierung-setzt-sich-fuer-verbraucher-und-hersteller-pflanzli/.

[26] *Conte-Salinas*, in: Holle/Hüttebräuker, HCVO, 1. edition 2018, Art. 28 para. 32.

1 of Regulation (EC) No. 1924/2006, which contains the following wording:

> „This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer."

In addition, subpara. 2 excludes certain claims from the scope of regulation; however, in para. 3, the scope of application is again extended to trademarks, brand names or fancy names, if the aspects mentioned therein are fulfilled. Therefore, the Health Claims Regulation does not provide a precise description of the subjects it refers to.[27]

In Art. 1 para. 2, Art. 10 I of Regulation (EC) No. 1924/2006, the criterion of "commercial communications" in the labelling and presentation or in the advertising of food is established for determining the scope of application. A communication is the deliberate transmission of data,[28] which is in any case commercial if it takes place within the scope of a commercial activity.[29] The characteristic of "commercial communication" is overall interpreted in a broad manner and can also comprise communications that are exclusively directed at medical professionals.[30] Thus, the scope of application includes any

[27] Cf. also *Leible/Schäfer*, WRP 2011, 1509, 1509.

[28] *Rathke/Hahn*, in: Zipfel/Rathke, Lebensmittelrecht, status 178. EL November 2020, 111. Verordnung Nr. 1924/2006, Art. 1 para. 4a.

[29] *Rathke/Hahn*, in: Zipfel/Rathke, Lebensmittelrecht, status 178. EL November 2020, 111. Verordnung Nr. 1924/2006, Art. 1 para. 5.

[30] Cf. *Kohser/Herzog*, GuP 2016, 178, 179.

health-related advertising made to the end consumer.[31] The scope of application with regards to the activities covered is rather broad and thus cannot be fully discussed here. However, based on the criterion of commercial activity, it can be assumed that companies make commercial communications because they will regularly use the claims with intend to increase their profit.

For the definitions of the terms "food", "food business operator", "placing on the market" and "final consumer", Art. 2 para. 1 lit. a) refers to Art. 2 and Art. 3 number 3, 8 and 18 of Regulation (EC) No.178/2002; for the definition of the term "food supplement ", Art. 2 para. 1 lit. b) refers to the definition in Directive 2002/46/EC. According to the wording of the provisions, it concerns products that can be consumed by human beings; food supplements are also included and are thus also covered by the scope of the Regulation. However, due to another regulatory regime than Directive 2004/24/EC, medicinal products, in particular herbal medicinal products, are not covered by the Health Claims Regulation.

The term food business operator covers natural and legal persons who are responsible for compliance with the food laws. In addition, associations can also be covered by the regulation in general.[32] Again, this reveals a broad scope of providers that are potentially bound by the Health Claims Regulation.

The Health Claims Regulation thus has a broad scope of application overall. Consequently, a large number of companies

[31] *Kohser/Herzog*, GuP 2016, 178, 179.

[32] *Leible/Schäfer*, WRP 2011, 1509, 1515.

have to observe the requirements for making health claims when advertising, labelling, etc. their products.

II. Status of implementation

Art. 1 para. 2 subpara. 2 and para. 4 HCR were amended by the Regulation (EC) 107/2008 of 15. January 2008 (Official Journal L 39 p. 8)

> „to provide the Commission with the power to adopt Community measures relating to the labelling and presentation of foods and the advertising of foods, to provide for derogations from certain provisions of Regulation (EC) No. 1924/2006, to establish and update nutrition profiles and the conditions and exemptions for their use, to establish and/or modify the lists of nutrition and health claims, and to adopt the list of foods for which claims are subject to restriction or prohibition." (inofficial translation)[33]

In the course of the implementation process of the Health Claims Regulation and thus in the course of the evaluation of health claims and issuance of the lists of such permitted claims, problems arose in connection with botanicals. Botanicals are plants and plant substances that claim to have a functional physiological effect.[34]

In this context, the Commission modified the implementation process[35] and adopted the list according to Art. 13 para. 3 of

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[33] *Zipfel/Rathke*, LebensmittelR, ed. by Rathke/Hahn, 179. EL March 2021, VO (EG) 1924/2006 Art. 1 para. 1.

[34] To the term in German: *Andreas Meisterernst*, Möglichkeiten der Vermarktung von Botanicals aus Sicht des Lebensmittelrechts, GRUR 2018, 482.

[35] Cf. Press releases from 27.09.2010, IP/10/1176; from 28.07.2011, IP/11/933; from 28.11.2011, IP/11/1460 and from 16.05.2012, IP/12/479.

Regulation (EC) No. 1924/2006 step by step – but initially without any content referring to botanicals. In the course of this practice, EFSA was even instructed explicitly to "suspend" the evaluation of botanicals until the problems regarding the evaluation of these substances had been resolved. Specifically, the problems that arose were, on the one hand, that the standard required for approval was often not met and that the interdependency between the claim and the food could not be sufficiently proven scientifically. On the other hand, a possible unequal treatment compared to registered herbal medicinal products was considered possible, since, in contrast to botanicals, no complete proof of efficacy is required for these; in the case of registered herbal medicinal products, a so-called traditional authorisation is granted, for which proof of efficacy can be considered plausible due to many years of medicinal application which is sufficient for the admissibility in medicinal use.[36]

The parallel to pharmaceutical law is remarkable here. Initially, natural medicines, i.e. traditional herbal remedies, also required scientific proof of efficacy, which in many cases is not available for them. With regard to sensitivities, cultural imprints and traditions, these medicines are used quite differently in the Member States in often deviating fields of application.[37] In correlation to foodstuffs with specific health claims, special regulations have been introduced for traditional herbal remedies in which the marketing authorization procedure is simplified and

[36] Cf. on the entire problem *Hüttebräuker*, in: Holle/Hüttebräuker, HCVO, 1. edition 2018, Art. 10 para. 19.

[37] *Heßhaus*, in: Kügel/Müller/Hofmann, Arzneimittelgesetz, 2. edition 2016, § 39 a para. 2.

a mere registration is considered sufficient, if the effect can be plausibly demonstrated on the basis of many years of use (§ 39a German Medicinal Products Act).

In the course of the evaluation process for the so-called botanicals, the Commission proposed two options to the Member States: The first option was to stay within the procedures provided for in the Health Claims Regulation; the second option was to create a new legal framework for botanicals, but this was predominantly rejected by the Member States.[38]

In 2012, as planned by the Commission, a partial list[39] pursuant to Art. 13 para. 3 of Regulation (EC) No. 1924/2006 on health claims was adopted[40], which mainly contained claims on permitted chemical substances, but - as planned - did not contain any statements on the majority of botanicals. The Commission's reflection process on the procedure with regards to botanicals is still ongoing; the botanicals, which are still pending, have not been scientifically evaluated by EFSA. Thus, there is a standstill for the adoption of further partial lists according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006.[41]

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[38] *Natz*, LMuR, 2016, 41, 45.

[39] Regulation (EU) 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health of 16.05.2012; Furthermore, in the course of time, other implementing regulations were enacted, e.g. regarding claims for children's development and health Regulation (EU) 440/2011.

[40] Cf. *Natz*, LMuR, 2016, 41, 42, 45.

[41] Thus, to answer the legal question regarding botanicals, Art. 13 para. 3 is the relevant provision; however, the claims under Art. 14 are still used in some places for justification, which is why they were explained above.

However, according to recitals 10 and 11 of the Regulation (EU) No. 432/2021, the transitional provisions remain applicable in particular for `botanicals´ until they have been included into the list of permitted claims, since they have not yet been evaluated. Nevertheless, transitional provisions can only claim this designation if their provisional status is not maintained ad infinitum.[42] To put it in a nutshell: Almost half of all health claims have not yet been evaluated because the European Commission has withdrawn the agency's mandate for the scientific evaluation of so-called "botanical health claims".[43] For more than 14 years, health claims about herbal substances (so-called botanical health claims) have not been scientifically evaluated contra legem. As a result, they may allegedly be used in food supplements on the basis of transitional provisions that have not been legitimized for such a long time.

This law-breaking inactivity is neither cured nor factually mitigated by the "major evaluation" (REFIT) of the HCR which was ordered by the European Commission. Its results were published in May 2020. The summary is meaningless and dilatory:

> „Since its adoption in 2006, the implementation of the Regulation remains incomplete. Nutrient profiles, that had to be set by January 2009, have not been established and health claims on plants and their preparations used in foods are not yet fully regulated. In addition, the situation in relation to health claims on plants and their preparations

[42] In more detail below B. IV.

[43] *Kristin Oertl*, Update Health Claims-Verordnung, LMuR 2016, 1 (5).

> has led to a broader reflection regarding the use of plants and their preparations used in foods.“[44]

This "broader reflection" is barely more than a cover-up for the politically intended inactivity to keep health claims on botanical food supplements in the market despite the lack of assessment.

The perspective provided for the evaluation of ensuring a high level of consumer protection in the future therefore also remains without any tangible substance:

> „The evaluation findings show that in the current situation consumers continue to be exposed to unsubstantiated health claims from the on-hold list and may believe that the beneficial effects communicated with the on-hold claims have been scientifically assessed and risk managed, whilst this is not the case.“[45]

It is not apparent in what way the Commission intends to fulfill its mandate.

> „Overall, the evaluation findings show that in the current situation the objectives of the Claims Regulation are not fully attained. Furthermore, the current rules of the Claims Regulation do not take into account the specific situation of plants and/or their preparations, which have a long traditional history of use linked to health benefits. It could be appropriate to explore the notion of 'traditional use' in

[44] Evaluation of the Regulation on nutrition and health claims, https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/evaluation-regulation-nutrition-and-health-claims_en.

[45] Commission Staff Working Document executive summary of the evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general framework for their use in foods, SWD(2020) 95 final, p. 2, https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/AUTRES_INSTITUTIONS/COMM/COM/2020/06-25/COM_SWD20200096_DE.pdf.

> the efficacy assessment of health claims on plants and their preparations used in foods together with the effects of the co-existence, on the EU market, of Traditional Herbal Medicinal Products on the same plant substances. In the light of the shortcomings highlighted above about the smooth functioning of the internal market and the possible openness to the notion of 'traditional use' to substantiate health claims on plants and their preparations, there are merits for further studying the potential harmonisation of the field of plants and their preparations, including the safety aspect."[46]

In other words: Political consultations and "reflections" prevail. The mandate of the HCR will continue not be fulfilled for an unforeseeable period of time.

III. Court proceedings before the European General Court and the European Court of Justice

The Regulation itself and also the issue of the lack of re-instruction of EFSA by the European Commission have already been the subject of proceedings before the General Court and before the Court of Justice of the European Union (CJEU). The aim here is to provide an overview of the content and decisions of the proceedings[47] to introduce the problem and to identify any statements that may be relevant for answering the legal question.

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[46] Evaluation of the Regulation on nutrition and health claims, https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims/evaluation-regulation-nutrition-and-health-claims_en.

[47] The decisions that have been made on the Health Claims Regulation and its implementation have not been comprehensively evaluated; rather, in order to create an overview, only the most frequently cited ones are discussed.

1. Procedure C-637/15 P

In an appeal before the CJEU in 2016[48], a Dutch company had sued for the annulment of the General Court's decision after the General Court had dismissed the action filed for a declaratory judgment[49] as inadmissible that the lack of re-instruction of EFSA on the evaluation by the Commission of the outstanding health claims for herbal substances pursuant to Art. 13 para. 3 of Regulation (EC) No. 1924/2006 is unlawful. The company bringing the action (plaintiff/appellant) was a manufacturer of medicinal products and food supplements that sold its products on the European market and made health claims for these purposes on the product labels and in advertising.

One of the justifications given by the General Court in the main proceedings was that the appellant lacked a legitimate interest in the proceedings. The appellant then based its appeal to the CJEU on the fact that, among other things, it had an legitimate interest in the proceedings and that the Health Claims Regulation offered the appellant and other food companies only insufficient protection as a result of the transitional measures and that the Commission's failure to act violated the Health Claims Regulation, Art. 41 of the Charter of Fundamental Rights of the European Union (CFR), Art. 168 TFEU, the principle of the effectiveness of the Regulation and the principle of *venire contra factum proprium*. The CJEU rejected the grounds of appeal because they were based in part on statements that the General

[48] CJEU judgement of 25.10.2016, C-637/15 P.

[49] In the alternative, an application was also filed for annulment of the Commission's letter of response to the applicant's letter in which it asked the Commission to act; however, this is irrelevant with regards to the legal grounds for the initial question.

Court had only examined for the sake of completeness[50]; in addition, the grounds cited were declared inadmissible or unfounded. Accordingly, the appeal proceedings were not successful overall.

All in all, no specific conclusions can be drawn from these proceedings for answering the legal question. The CJEU merely emphasized that it was undisputed that the Commission should have adopted the list by 31.10.2010 and that this was only partially done by Regulation No. 432/2012.[51]

2. Joint cases C-596-15 P and C-597/15 P

In a further appeal before the CJEU[52], two companies (plaintiffs/appellants) also appealed against the General Court's decision. One of the appellants, Bionorica SE, is a company that produces medicinal products and also sells them on the European market. It uses health claims for the labelling and advertising of its products. The second appellant was Diapharm GmbH & Co. KG - a company that operates as an international full-service provider for the healthcare industry. A major part of its business is advising companies on the use of health claims in food, in particular food supplements.

[50] Note: Aspects examined by the General Court only for the sake of completeness cannot, in the view of the CJEU, lead to the annulment of the decision in the appeal proceedings; grounds of appeal based on such aspects are ineffective.

[51] CJEU judgement of 25.10.2016, C-637/15 P, para. 73.

[52] CJEU judgement of 23.11.2017 in the joint cases C-596-15 P and C-597/15 P.

The General Court had declared both actions for failure to act regarding the Commission's failure to re-instruct EFSA on the evaluation of health claims on botanicals to be inadmissible in each case. The main reason given by the General Court was that the plaintiffs lacked the necessary legitimate interest in the proceedings, since neither of them had sufficiently explained why they would gain a definite advantage from the adoption of the list. In addition, the court pointed out that the Health Claims Regulation provides for extensive transitional provisions, which, moreover, could be more advantageous for the companies if the corresponding claims were included in the list as negatively evaluated, since they would then no longer be allowed to be used. It also rejected that the only partial adoption of the list would lead to the existence of unequal conditions of competition; similarly, the same is said to apply to an impairment of legal certainty. The CJEU upheld the grounds of appeal in part; however, as a result, it remained with the assumption that the appellants had no interest in legal protection.

In the case of Bionorica SE, which was found to produce only herbal medicinal products when the action was filed, the mere declaration of intent to enter the market for food supplements with the substances which were still to be evaluated was not sufficient for the CJEU to find a present interest. [53] For Diapharm GmbH & Co. KG, it was argued that, as a service provider, it was only engaged in activities that were not intended for its own use of the

[53] CJEU judgement of 23.11.2017 in the joint cases C-596-15 P and C-597/15 P, para. 113ff.

claims and thus upstreamed the manufacturing and the sale of the products covered by the Health Claims Regulation.[54]

Advocate General *Bobek*, however, had argued in his opinion that the legal interest of Bionorica SE should be awarded, since the company was potentially planning to enter the market with food supplements and, as a manufacturer of herbal medicinal products, was also in competition with manufacturers of herbal food supplements. The legal uncertainty caused by the lack of evaluation therefore affects the company's own business activities, so that there is a possibility of the company gaining an advantage as a result of EFSA's instruction by the Commission.[55]

Thus, an examination of the merits with more detailed information on the rights of companies was not made in this case either. However, the CJEU stated again in these proceedings that the Commission was obliged to instruct EFSA and to adopt a complete list by 31.01.2010[56] and also emphasized the lack of equivalence of the transitional arrangements compared to the list issued, in particular with regard to the need to comply with national regulations when using claims that have not yet been

[54] CJEU judgement of 23.11.2017 in the joint cases C-596-15 P and C-597/15 P, para. 98ff.

[55] In his opinion of 25.04.2017 Advocate General *Michal Bobek*, para. 29, 79ff.

[56] CJEU judgement of 23.11.2017 in the joint cases C-596-15 P and C-597/15 P, para. 56.

evaluated.[57] This was also emphasized by the Advocate General in his opinion.[58]

3. Other procedures

Another case before the General Court[59], dealt with the annulment of the Health Claims Regulation, Regulation No. 432/2012 and the Register of nutrition and health claims made on foodstuff published on the Commission's website. The plaintiff was a company that produces food supplements and dietetic foods and distributes them on the European market, as well as a professional association representing the interests of the companies. Both plaintiffs use health claims on a daily basis in the labelling and advertising of the products and had previously submitted information to the German authorities for submission to the Commission under Art. 13 para. 1-3. The General Court dismissed all of the applicants' requests as inadmissible and justified this, inter alia, on the grounds of the lack of direct concern required in the context of an action for annulment under Art. 263 para. 4 TFEU, because it had not been sufficiently demonstrated to what extent the applicants' legal position would be affected by the refusal to include the claims in the list.[60]

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[57] CJEU judgement of 23.11.2017 in the joint cases C-596-15 P and C-597/15 P, para. 87ff.

[58] In his opinion of 25.04.2017Advocate General *Michal Bobek*, para. 60ff. He also argued in favor of the admissibility of Bionorica SE's action and determination of this by the CJEU in the appeal proceedings; however, the proceedings was referred back to the General Court, meaning that no statements on the merits of the action for failure to act can be derived from the opinion, cf. para. 102ff.

[59] General Court judgement of 12.06.2015, T-334/12.

[60] General Court judgement of 12.06.2015, T-334/12, para. 28ff.

Furthermore, a decision was made in a proceeding on the effectiveness of Regulation 432/2012, with the incidental review of the Health Claims Regulation, where the action was declared admissible and an examination of the merits was conducted. In essence, it was stated there that the Commission had to adopt the list by 31.01.2010 after consulting EFSA on its evaluations, but that it was free to partially adopt already evaluated claims until then.[61] Regulation 432/2012 was considered to be effective; the same was considered for the Health Claims Regulation, since it does not violate the right to good administration, in particular the right to be heard, and the principle of legal certainty.[62] Further statements relevant to the legal question can only be partially taken from this procedure.[63]

4. Evaluation of the proceedings with regards to the answer to the legal question

Due to the predominant lack of examination of the merits in the proceedings, only limited conclusions can be drawn for answering the legal question. The admissibility of the proceedings mostly concerned the problem of whether the plaintiffs were directly affected or whether they had a legitimate interest in the proceedings. Sometimes this was denied with regard to the lack of entrepreneurial activity according to the

[61] General Court judgement of 12.06.2015, T-296/12, para. 59ff.

[62] General Court judgement of 12.06.2015, T-296/12, para. 165ff.

[63] For example, the applicability of Art. 41 CFR has already been denied due to the lack of an opening of the scope of protection, see General Court, judgment of 12.06.2015, T-296/12, para. 97ff. A violation of the principle of equal treatment was also rejected for lack of sufficient substantiation of the plaintiffs and not examined in more detail, cf. para. 113ff. The annulment of the suspended claims was not considered a suitable subject matter and, in the opinion of the General Court, could also not justify any benefits, cf. para. 199ff.

Health Claims Regulation or due to a lack of evidence of justification. In any case, the conclusion can be drawn that an affectedness by the HCR must be sufficiently demonstrated and not any person who is somehow active in the area of the food industry can draw an advantage from the further enactment of a list according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006. However, the general possibility of companies being affected and the admissibility of lawsuits is not negated by the decisions.[64]

Due to the inadmissibility of the proceedings, most of the decisions also contain no statements on the violation of corporate rights; they do not address the requirements of substantive subjective rights, which must therefore be determined and examined in greater detail in this context. The examination of the merits carried out in one proceeding did address substantive rights, but did not include an extensive examination and, in particular, did not make any statements regarding a right arising from the Health Claims Regulation itself. However, the decisions do contain statements on the legal assessment of the Commission's failure to act: There, the CJEU has made it clear that there was an obligation to adopt the complete list by 31.01.2010, which the Commission had not fulfilled. For this purpose, it had to instruct EFSA beforehand to carry out the evaluation of the pending herbal substances, which was also not done. This behavior was thus basically considered as a violation of the procedure provided for in Art. 13 para. 3 of Regulation (EC) No. 1924/2006.

[64] Cf. also *Gundel*, ZLR 2018, 55, 56.

B. Legal Assessment

The legal assessment is based on the question of the legal consequences of not issuing the additional list according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006. The focus will be on the scope of the binding effect of the Health Claims Regulation for the Commission and on the possibility of the infringement of company rights.

I. Binding of the Commission to the Health Claim-Regulation and legal assessment to the suspension of the evaluation by the Commission

As a regulation the Health Claims Regulation has a direct, binding effect.[65] It is also applicable law, which has not been repealed by the enactment of another legal act, by a court decision or due to a time limit.[66] Therefore, there is an obligation to comply, which cannot be waived due to an emergency situation.[67] The Commission was granted a wide margin of discretion in implementing the procedure set out in Art. 13 para. 1-3 of Regulation (EC) No. 1924/2006, so that, among other things, it did not have to adopt the list directly in its entirety but was initially allowed to adopt only a partial list (as happened).

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[65] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 9 para. 71.

[66] Cf. *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 11 para. 98, probably also *Natz*, LMuR, 2016, 41, 41, who also emphasizes the existence of clear requirements for the evaluation process in the Health Claims Regulation.

[67] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 11 para. 99.

However, the complete adoption of the list was excluded from this; in this respect, the wording of Art. 13 para. 3 of Regulation (EC) No. 1924/2006 with regard to the time limit of 31.01.2010 (”at the latest“) is clear. In addition, the HCR provides for a uniform procedure for the scientific assessment of health claims for herbal and other substances and establishes a uniform, highest possible standard of scientific assessment for all substances.[68] In the Regulation, only health claims other than those referring to the reduction of disease risk and to children's development and health, which are based on generally accepted scientific evidence, are subject to a different type of assessment and authorisation, which is also reflected in the different procedures under Art. 13 and 14 HCR.[69] According to Recital 30, other legitimate aspects may also be included in the examination, but this consideration only intervenes in the context of the examination process itself and does not permit the entire examination process to be omitted. Moreover, it can be assumed that the recital refers to the Commission's decree and not to EFSA's assessment process, as this is to be carried out solely according to scientific standards.

As the competent body for the adoption of the list according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006, the deadline set therein is addressed directly to the Commission, which did not observe it for the complete adoption and thus let it expire with regards to the herbal substances. As outlined above, the Health Claims Regulation makes it mandatory for EFSA to scientifically assess claims before the list of permitted claims can be adopted by the Commission. Therefore, after the suspension of the

[68] Recital 23.

[69] Cf. Recital 26.

assessment, the Commission first had to ask EFSA to start or continue the assessment. Only after this assessment can the list of permitted claims be issued at all and companies potentially benefit as a result. Neither was done in compliance with the time limit provided for in Art. 13 para. 3 of Regulation (EC) No. 1924/2006, with the result that the Commission infringed European Union law binding on it.[70]

In doing so, the Commission is not only violating the constitutional principle of lawful administration, but it is also endangering the legal interests that HCR is intended to protect, because the conduct creates significant gaps for the basis of rational scientific assessment of food, the importance of which the Court of Justice has recently reiterated.[71]

The suspension decision is already afflicted with a flaw of legal vagueness at the outset. There is - perhaps not surprisingly in view of the obvious illegality - no formal decision to suspend the assessment of botanicals - there is no known or published decision of the Commission to suspend the assessment. Only a press release is available. The May 16, 2012 memo

[70] Cf. also the CJEU, see above A.III; *Natz*, LMuR, 2016, 41, 46.

[71] „Article 5(1), Article 6(1) and (2), Article 10(1) and Article 28(5) of 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, as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008, must be interpreted as meaning that, under the transitional arrangements provided for in the latter provision, the burden of proof and standard of proof in respect of the health claims referred to in Article 13(1)(a) of that regulation are governed by Regulation No 1924/2006, which requires the food business operator concerned to be able to justify, by means of generally accepted scientific evidence, the claims which it uses. Those claims must be based on objective evidence which has sufficient scientific agreement.“ CJEU judgment of 10.09.2020, C-363/19, main conclusion number 1.

(MEMO12/346) acknowledges that approximately 2200, mainly so-called "botanical substances" are still awaiting completion of the authorisation procedure. Here the Commission thinks it can disregard the framework drawn by the HCR if it states:

> „There are also a number of claims that are on hold pending a final decision. These may continue being used under the conditions pertaining before adoption of the list of permitted health claims. This means they may remain on the market under the responsibility of the food business operator provided they comply with the claims Regulation and existing national provisions applicable to them.“[72]

Then follows the "notice" of suspension:

> „In September 2010 the Commission decided not to continue with the assessment of health claims for plant and herbal substances, the so-called "botanical" substances.“[73]

Although this notice is intended to claim legal effect within the scope of a regulation, it does not appear to have been drafted as a binding decision within the meaning of Art. 288 para. 4 TFEU and published in the required manner.[74] Rather, the Commission has informally set a legally significant, basically legislative measure - and then also justified it as if it were a legislator called upon to proclaim the primal legal act on its own:

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[72] Questions and Answers on the list of permitted Health Claims on food products,https://ec.europa.eu/commission/presscorner/detail/en/MEMO_12_346.

[73] Questions and Answers on the list of permitted Health Claims on food products,https://ec.europa.eu/commission/presscorner/detail/en/MEMO_12_346.

[74] See also the detailed presentation in: CJEU judgement of 23.11.2017, joint cases C-596/15 P & C-597/15 P (Bionorica und Diapharm/KOM), para. 16 ff.

> "Certain herbal substances can be present in the composition of both Traditional Herbal Medicinal Products (THMPs) and in foods. Different treatment can be given and different requirements apply to the same herbal substance, if it is included in a food product or a medicinal product. This could create discrimination on the market of herbal products and potential confusion for consumers. Since the Commission and Member States need more time to decide how to address this issue, it was decided to put these claims on hold."[75]

This decision to suspend the procedure by the Commission is not covered by any legal authority or by any legal power to act. The Health Claims Regulation does not provide for a suspension of the procedure, nor is this provided for in any other norm. Also, according to Art. 27 of Regulation (EC) No. 1924/2006, the evaluation is to be presented in 2013, which means that it will only take place after the lists have been issued. It is without precedent that a statutory mandate is aborted by the mere instruction of the Commission. The non-implementation of an explicit obligation of the Commission to act from Art. 13 para. 3 of Regulation (EC) No. 1924/2006 represents a violation of the principle of the rule of law underlying the EU, which has been ongoing for more than 10 years and can therefore ever since no longer be justified by technical difficulties of law enforcement, but is based on an unlawful decision of the Commission.

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[75] „Certain herbal substances can be present in the composition of both Traditional Herbal Medicinal Products (THMPs) and in foods. Different treatment can be given and different requirements apply to the same herbal substance, if it is included in a food product or a medicinal product. This could create discrimination on the market of herbal products and potential confusion for consumers. Since the Commission and Member States need more time to decide how to address this issue, it was decided to put these claims on hold." Questions and Answers on the list of permitted Health Claims on food products, https://ec.europa.eu/commission/presscorner/detail/en/MEMO_12_346.

Due to the necessity of the scientific review of the health claims by EFSA for the adoption of the list of permitted claims according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006, the following sections will refer to this inactivity and will only deal with the adoption of the list in some passages for a better understanding.

II. Standard for the existence of subjective rights in European Union law

An infringement of standards of European Union law cannot in itself constitute a specific violation of the rights of companies. Instead, it is necessary that subjective rights exist for the companies, which protect them precisely against omissions by the Union institutions.

In principle, both primary and secondary law can be considered for the establishment of subjective rights.[76] In Community law, the determination is not carried out entirely according to the same standards as in German law.[77] In accordance with the case law of the CJEU, a subjective right is generally considered to be established when the relevant provision has a direct effect.[78] For this, the standard must be sufficiently clear and its content must be unconditional;[79] in addition, the objective and protective

[76] *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 511.

[77] Cf. *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 510; see also the overview provided by *Ruffert*, DVBl 1998, 69, 69 ff.

[78] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 9 para. 16; see also *von Danwitz*, Europäisches Verwaltungsrecht, 1. Edition 2008, p. 511; *Lehnert/Pelzer*, ZAR 2010, 41, 42.

[79] *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 511.

purpose must also be taken into account when determining the subjective character.[80]

Overall, however, it should be sufficient that the standard protects typified overall interests (such as the functioning of the common market) and that the individual is factually affected.[81] Such a factual impact already exists if there are actual disadvantages with regard to the protected legal positions.[82] The reflexive protection of individual interests is already sufficient for the justification.[83] In this context, a provision may also give rise to a subjective right of the individual but may be depending on the observation of a time limit, even if this primarily serves to accelerate proceedings, since it is sufficient for the existence of the subjective character that actual disadvantages are suffered as a result of the disregard of the norm, which can be affirmed in the case of a missed deadline.[84]

III. Potential infringement of rights of companies

This section will now address in detail which rights companies may be able to invoke and whether these are then violated by the Commission's failure to act. The focus here will be on the Health Claims Regulation itself.

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[80] *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 513.

[81] *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 514.

[82] *Lehnert/Pelzer*, ZAR 2010, 41, 42.

[83] *Lehnert/Pelzer*, ZAR 2010, 41, 42.

[84] Cf. so *Lehnert/Pelzer*, ZAR 2010, 41, 43, who note this in relation to the deadline regulations of the Dublin II Regulation, but argue on the basis of the standards of European Union law in general. It is assumed here that the idea can be transferred in compliance with the principles for the establishment of subjective rights.

1. Scope of protection of the rights

In a first step, the scope of protection of possible relevant rights is explained here and applied to the legal question. Irrespective of the existence of secondary law, subjective rights under primary law will also be discussed here for the sake of completeness, although these can only be basically outlined due to the wide variety of forms they take.

a) Company rights under the Health Claims Regulation

The starting point for an infringement of the rights of companies can be the Health Claims Regulation itself. Due to the lack of re-instruction of EFSA by the European Commission, a violation of rights can only be considered if companies are granted individual rights in the Health Claims Regulation.

As already stated above, the Health Claims Regulation as a regulation has a direct effect and can thus in principle be the basis for the creation of subjective rights. It also applies unconditionally in terms of content and has a definite legal content. However, according to its meaning and purpose, the Health Claims Regulation would also have to cover corporate interests. In terms of content, the regulations in the ordinance primarily pursue two purposes: in the foreground is the safeguarding of consumer protection through the creation of a secure list of scientifically substantiated claims. In addition, the harmonization of the internal market and the creation of a level playing field are also clear objectives.

Company interests have therefore found their way into the purpose of the Regulation and are also to be protected through implementation of the measures provided for in the Regulation, or rather the economic position for the companies is to be improved. In this context, it must be noted that the Health Claims Regulation does not generally impose obligations on companies as such but has a factual and personal scope of application. However, this is - as already examined above - broadly defined and thus regularly covers all companies that make health claims in the advertising/labelling of their products. An advantage of the adoption of the list of permitted claims for companies can be that the claims are either positively accepted or, in the case of a negative, rejected due to the general effect according to Art. 17 para. 5 of Regulation (EC) No. 1924/2006. This applies to all companies and thus leads to a level playing field and legal certainty.

Companies must therefore demonstrate how they are affected by the adoption of the list and how their legal position is improved as a result. This can be done, for example, by explaining the use of the health claims and the activity on the market of food supplements. Following the case law of the CJEU and in particular the statements made there on individual concern, it can be assumed that a well-founded justification of the benefit must be provided. However, if the possibility of such a justification exists, the evaluation by EFSA must first be completed as a necessary prerequisite for the issuance of the list, so that the evaluation can be demanded from the companies.

As a counter-argument to this opinion, one could cite the different procedures according to the Health Claims Regulation: Only in the procedure according to Art. 15-17, 19 of Regulation (EC) No. 1924/2006 an individualization by a corresponding individual application obligation for the inclusion of the claim in the list is present, whereas the procedure according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006 does not provide for this. However, the general effect according to Art. 17 para. 5 refers to each of the lists and not only to the list according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006. In addition, it can also be assumed that the different procedures were also chosen for reasons of effectiveness, so that not every health claim has to be applied for individually. An individualization of the companies is therefore assumed in both procedures.

In particular, Art. 13 para. 3 of Regulation (EC) No. 1924/2006 also provides for a time limit for the implementation, so that the objectives provided for in the Health Claims Regulation are achieved by a certain date. In favor of the right of companies to comply with the deadline, it can be argued that the deadline serves the purpose of consumer protection[85], but also has a significant impact on business activities, since the issuance of the list is an essential prerequisite for the use of health claims.[86] In this context, it can be reiterated that while there are some transitional arrangements for health claims, these are not

[85] *Armbrüster*, Health Claims für Lebensmittel-Was geschieht mit den Botanicals? Zeitschrift für Phytotherapie, 41 (2020), 286ff.

[86] *Delewski*, LMuR 2009, 80, 89, who mainly refers to the deadlines in the approval procedure and the "applicant food operators" (inofficial translation of „antragstellenden Lebensmittelunternehmen“), but who does not seem to deal only with the procedure pursuant to Art. 15-17, 19, meaning that a general aspect of non-compliance with the deadlines in the HCR can also be inferred from his remarks.

equivalent to the actual enactment of the list.[87] For example, equal competitive conditions cannot be fully guaranteed by reference to compliance with national regulations. According to the opinion expressed here, the Health Claims Regulation gives companies the right to request instructions from EFSA to evaluate the pending health claims.

b) Rights under the Charter of Fundamental Rights and the European Convention on Human Rights

At the primary level, the fundamental rights of the European Union[88] under the Charter of Fundamental Rights (CFR) and the European Convention on Human Rights (ECHR) can be considered as subjective rights. Since the EU has not yet acceded to the ECHR, although this is provided for in Art. 6 para. 2 TEU,[89] the rights of the ECHR cannot be examined in isolation. In view of the reference in Art. 52 para. 3 CFR, however, they can be taken into account within the framework of the Charter of Fundamental Rights, so that rights of the same kind are addressed here in parallel.

It is undisputed that the Charter of Fundamental Rights is binding for the EU institutions, thus also for the Commission, pursuant to Art. 51 para. 1 sentence 1 CFR. The Charter of Fundamental Rights entitles not only natural persons but also legal persons, but it differentiates in the provisions between "persons" and "human beings" in the German version, so that legal persons

[87] See above III. 2.

[88] *Jarass*, in: Jarass, GRCh 4. edition 2021, Introduction para. 55.

[89] Cf. *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 38.

cannot be protected by provisions relating to the characteristic "human being".[90] However, this does not generally preclude companies from invoking fundamental rights.

The following rights can be considered here: freedom of expression under Art. 11 para. 1 CFR/Art. 10 ECHR, freedom to conduct a business under Art. 16 CFR, protection of property according to Art. 17 CFR/Art. 1 Protocol to the ECHR, equality before the law under Art. 20 CFR/Art. 14 ECHR and the right to good administration under Art. 41 para. 1 CFR. Within the scope of freedom of expression, commercial statements in the form of advertising are also covered;[91] the scope of protection of entrepreneurial freedom is generally broad and protects any form of economic activity.[92] The scope of protection of the right to property is opened up insofar as it concerns the protection of material objects or rights to claim; mere prospects of acquisition or market shares, on the other hand, are not covered.[93] Equality under the law includes the right to equal treatment of identical factual situations by the public authorities of the European Union.[94] The right to good administration ensures, among other things, that matters are dealt with expeditiously in the administrative activities of Union bodies.[95]

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[90] *Kingreen*, JURA 2014, 295, 298.

[91] *Calliess*, in: Calliess/Ruffert, EUV/AEUV 5. edition 2016, Art. 11 GRCh, para. 6.

[92] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 61.

[93] *Calliess*, in: Calliess/Ruffert, EUV/AEUV 5. edition 2016, Art. 17 GRCh, para. 6ff.

[94] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 66.

[95] *Jarass*, in: Jarass, GRCh, 4. edition 2021, Art. 41 para. 17.

At least in certain constellations, the CJEU has affirmed the obligation to act on the basis of fundamental rights.[96] Especially the manufacturers of herbal medicinal products suffer considerable competitive disadvantages due to the inaction of the Commission. Basically, it is up to the manufacturer to place the same herbal substance on the market either as a medicinal product or as a foodstuff: It is practically not a manufacturing decision but a marketing decision.[97] As long as a company in the case of food declaration is practically exempted from the proof by the interaction of suspension of the list compilation and the adoption of the transitional regulation from the proof of efficacy, it gains a tangible advantage over the one who puts the substance on the market as a medicinal product. This cannot be the intention of the European legislator, who has prescribed a coherent concept of consumer protection and the creation of a fair competitive relationship with the HCR and the corresponding provisions of pharmaceutical law.

This established coherent legal concept is disturbed by the obstructive, factually unjustified behavior of the European Commission. Since it is not only a matter of consumer protection, but also of fair competition in the open internal market, this has an impact on the position of the adversely affected company property and the freedom of trade or profession. The lack of equality has a subjective quality, because it has a direct impact

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[96] Cf. *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 31.

[97] *Meisterernst*, Möglichkeiten der Vermarktung von Botanicals aus Sicht des Lebensmittelrechts, GRUR 2018, 482 (484 f.).

on freedom rights. The reason for this is that manufacturers of medicinal products, especially herbal medicinal products, must - like medicinal products with chemically/synthetically defined active ingredients – pass detailed and costly authorisation procedures based on clinical studies in order to scientifically substantiate the effect and safety of their medicinal products offered on the market if they cannot be registered comparatively easily. Manufacturers of food supplements remain exempted from this, although they may claim substantially the same health effect for their products without having to prove this with scientific efficacy studies. Thus, they gain a clear competitive advantage at the expense of consumer protection, but also at the expense of regular competitors from the pharmaceutical sector, who then cannot offer their products at nearly the same low prices.

Meanwhile, this is gaining increasing practical weight. The markets between herbal food supplements in drugstores or general retail stores on the one hand and herbal medicinal products in pharmacies on the other are becoming intermingled. The suppliers of herbal medicinal products who have provided proof of efficacy and proof of safety by way of a marketing authorisation based on their own clinical studies, or whose efficacy and safety are recognized throughout the European Union as "traditional use herbal medicinal products" (THMP) due to proof of a long-standing tradition, suffer a considerable competitive disadvantage. This disadvantage of an omitted legal substantiation has a direct impact on competition, but also on consumer interests. Health claims (such as "calcium strengthens bones" (inofficial translation of „Calcium stärkt die Knochen“) "ginkgo promotes cognitive abilities" (inofficial translation of „Ginkgo fördert die kognitiven Fähigkeiten“) create health-related

expectations without providing information on more detailed conditions, correlations or dosages (as required by the Health Claims Regulation) because there is a lack of evaluation by EFSA for a large proportion of food supplements.

c) Rights arising from the fundamental freedoms

Fundamental freedoms also constitute subjective rights.[98] Due to the scope of the Health Claims Regulation on claims and advertising of products, the free movement of goods pursuant to Art. 34 TFEU is relevant here.

Sometimes it is already denied that the EU institutions are bound by the fundamental freedoms[99] and it is also argued that the fundamental freedoms, in contrast to the fundamental rights of the European Union, are primarily directed against the Member States.[100] In addition, the application of the fundamental freedoms is generally excluded if secondary law controls the exercise of the fundamental freedoms.[101] Accordingly, if there is final harmonization, there can be no recourse to the free movement of goods.[102] The applicability thus appears questionable in light of the harmonization of the rules on the use

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[98] *Ehlers*, in: Ehlers (ed.), Europäische Grundrechte und Grundfreiheiten, 4. edition 2014, § 7 para. 10.

[99] So *Kingreen*, in: Calliess/Ruffert, EUV/AEUV 5. edition 2016, Art. 34-36 AEUV para. 109.

[100] *Ehlers*, in: Ehlers (ed.), Europäische Grundrechte und Grundfreiheiten, 4. edition 2014, § 7 para. 13.

[101] *Ruffert*, in: Calliess/Ruffert, EUV/AEUV 5. edition 2016, Art. 288 AEUV para. 8.

[102] *Leible/Streinz*, in: Grabitz/Hilf/Nettesheim, Das Recht der Europäischen Union, 72. EL february 2021, Art. 34 AEUV para. 42.

of nutrition and health claims in the European Union, since even without the adoption of the lists of permitted claims, the use of these claims is governed by the requirements of the Health Claims Regulation. However, something different could result from the fact that the transitional provision in Art. 28 para. 5, which applies to the non-evaluated botanicals, refers to compliance with national regulations. Due to that reference, one could already deny a final harmonisation. If such a view ist taken, the free movement of goods can in any case be applied against the Member States. However, due to this only single provision regarding the application of national regulations, complete harmonisation could also be considered; then the free movement of goods could not apply in this respect.

d) Further rights

A violation of the fundamental rights of the German constitution (Grundgesetz) can generally only be invoked if there is no effective protection of fundamental rights at the level of the European Union.[103] The latter can, however, be assumed here. Rights can also be derived from the general legal principles of the EU, if necessary, since their content can be aimed at conveying claims to individual citizens.[104] Examples could be the protection of legitimate expectations and legal certainty.[105]

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[103] Cf. *Lehnert/Pelzer*, ZAR 2010, 41, 44.

[104] So *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 9, para. 44f.; Differing view *Ehlers*, in: Ehlers (ed.), Europäische Grundrechte und Grundfreiheiten, 4. edition 2014, § 14 para. 18.

[105] For the existence of the principles at the Union level, see *Herdegen*, Europarecht, 22. edition 2020, § 8 para. 21; however, no statement on the subjective character can be taken from these explanations.

2. Impairment of rights / unequal treatment of the same facts

There are tangible criteria for an impairment of the rights under the Charter of Fundamental Rights: An impairment can always be confirmed if the act has concrete, negative effects on the right in question.[106]

Due to the lack of re-instruction of EFSA by the European Commission, the scientific evaluation of health claims, which is mandatory for the adoption of the list, is missing. This impairs the rights of companies in terms of their entrepreneurial activity and the realization of the internal market. For small and medium-sized pharmaceutical companies, the legal uncertainty triggered by the inaction regarding permitted health claims is a serious problem. The different legal regulations for medicinal products and food supplements are a burden and disadvantage for pharmaceutical manufacturers. The development of a medicinal product entails a high financial risk. Without a final evaluation of the submitted health claims, companies refrain from developing corresponding medicinal products if they cannot exclude competition with manufacturers of food supplements, who continue to make use of a transitional provision that has become absurdly extended during the period of time lapsed. In the area of food supplements, competition is distorted because legal certainty exists only for chemical substances, not for herbal substances, while the Health Claims Regulation does not provide for a different approach to the evaluation of herbal and chemical substances. On the contrary, claims on herbal substances are not even mentioned as a separate category of claims that would require special considerations. In this context, it is important to

[106] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 21.

emphasize that the European legislator was aware of the different types of claims and provided special rules for some of them (e.g., for claims on the reduction of a health risk, Article 14). The fact that no special rules were adopted for claims on herbal substances shows that a special approach for them was not intended.

Similarly, products for which unevaluated claims are used gain an undesirable competitive advantage over medicinal products. As already indicated, there are many cases in which ingredients that are used in medicinal products can - in lower doses and under different conditions - also be used in food supplements.

With regards to the importance of the fundamental right to property and the freedom of occupation, it is primarily a matter of this unequal treatment, which, with continued inactivity, has an increasingly burdensome and thus more fundamental rights-intensive effect. The Commission's failure to act results in an impairment of the aforementioned rights, and the different treatment of non-evaluated and already evaluated botanicals triggered by the transitional provisions also constitutes unequal treatment that jeopardizes legal certainty.

3. Justification

Although the relevant rights in each case do not have a common justification, however, the requirements overlap partially or completely, which is why – in an overview – the essential aspects are examined together here. It is not possible to conduct a full examination here since this is also due to the manifold interactions between fundamental rights and fundamental

freedoms[107]. Fundamental rights of the European Union can serve as a legitimate interest[108] and also as a barrier to the restriction of fundamental freedoms.[109]. The criteria to be observed in this context are therefore extensive.

The Charter of Fundamental Rights provides for a precedence of law in Art. 51 par. 1 sentence 1. It requires that the conditions for an interference are regulated with sufficient precision in the legal basis.[110] In addition, the guarantee of content of essence (Art. 52 para. 1 sentence 1 CFR) and the principle of proportionality (Art. 52 para. 1 sentence 2 CFR) must be observed. In the context of proportionality, the activities of the European Union institutions are in any case reviewed for the actual promotion of the objective pursued by them.[111] The treaties do not contain any written legal requirement for the restriction of fundamental freedoms; sometimes the necessity of a legal basis for the restriction is rejected.[112] However, a general precedence of law for administrative interventions in the legal sphere of individual citizens can be derived from the principle of the rule of law enshrined in Art. 6 TEU, with the result that a legal basis must

[107] *Herdegen*, in: Isensee/Kirchhof (ed.), Handbuch des Staatsrechts, Vol. X 3. edition 2012, § 211 para. 24.

[108] Cf. *Kingreen*, JURA 2014, 295, 303.

[109] *Kingreen*, JURA 2014, 295, 303.

[110] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 22.

[111] *Oppermann/Classen/Nettesheim*, Europarecht, 9. edition 2021, § 17 para. 27.

[112] Like this *Kingreen*, in: Calliess/Ruffert, EUV/AEUV 5. edition 2016, Art. 34-36 AEUV para. 86.

exist in primary or secondary law.[113] As a result, with regard to the restrictions, the existence of a suitable reason and the existence of a legal basis are required in any case.

The Health Claims Regulation does not contain any explicit legal basis for restricting the rights of companies. The same applies to Regulation (EU) 432/2012, which does address the factual reasons for the suspension of the assessment of botanicals in the recitals but does not authorise this. However, the consumer protection laid down in Art. 12, 169 TFEU and Art. 38 CFR can be considered as a general reason for the suspension of the Commission's failure to act.[114] Indeed, the Commission has argued with respect to its failure to act that the reflection process on botanicals evaluation is intended to protect consumers.[115] Nevertheless, the question of whether the regulations embody a sufficient legal basis need not be answered conclusively here if there is already no suitable reason.

With regards to consumer protection, it must be noted that the suspension and the transitional provision lead to the fact that health claims are made to consumers that are not based on a scientific evaluation procedure.[116] In particular, this is not contradicted by the assumption that it is more difficult to provide

[113] *von Danwitz*, Europäisches Verwaltungsrecht, 1. edition 2008, p. 346ff.

[114] For example, consumer protection is recognized by the CJEU as an unwritten justification in the context of fundamental freedoms, cf. *Ruffert/Grischek/Schramm*, JuS 2021, 407, 410.

[115] E.g. the Commission's statement that the action serves consumers, as it safeguards the scientific examination of all claims that can be used in the market, cf. press release of 27.10.2010, cf. press release of 27.10.2010, IP/10/1176.

[116] *Natz*, LMuR, 2016, 41, 43.

sufficient data to substantiate health claims for herbal substances in foods than it is for fully authorised medicinal products containing herbal substances. On the contrary: If it is not possible to scientifically substantiate a particular claim, that claim clearly must not be used towards end consumers.

The Health Claims Regulation clearly provides for the necessity of scientific validation and evaluation by EFSA, which, by suspending the evaluation procedure by the Commission, deepens the existing uncertainties for consumers.[117] Again, the different treatment of herbal medicinal products and food supplements appears to be problematic, whereby the botanicals in the form of the latter may still be used without scientific examination by EFSA due to the transitional provisions. However, the consumer is often unable to distinguish between medicinal products and food supplements, so that there is a risk of confusion.[118] One could argue against this that in pharmaceutical law, the possibility of a traditional marketing authorisation does not require full proof of efficacy[119], which means that there can also be a possible health risk without scientific proof. However, a traditional marketing authorisation requires that the medicinal product demonstrably does not give rise to any risks according to Art. 16 c para.1 a) (ii) of Directive 2001/83/EC. In the discussion on the evaluation of claims for herbal substances, references have been made to the concept of traditional use in the field of medicinal products, which is laid

[117] *Natz*, LMuR, 2016, 41, 43, 45f.

[118] Cf. the consideration of the Bundesrat (German federal Council) in its decision of 12.02.21, Drs. 36/21, p. 4.

[119] Cf. *Rathke/Hahn*, in: Zipfel/Rathke, Lebensmittelrecht, status 178. EL november 2020, 111. Verordnung Nr. 1924/2006, Art. 5 para. 8i.

down in Chapter 2a of Directive 2001/83/EC. These references are misleading and do not change the clear legal framework for the evaluation of claims on herbal substances as laid down in the Health Claims Regulation. The term traditional use in Directive 2001/83/EC refers explicitly and exclusively to medicinal products. Medicinal products have specific functions and definitions and are subject to strict limitations in terms of their use, field of application and target group. In particular, unlike foods, they require prior authorisation and are subject to strict monitoring standards. For these reasons, foods and medicinal products are neither factually nor legally comparable, and a simple transfer of the concept of traditional use from one system to the other is not appropriate.

The period of approximately 30 years for the plausible proof of the efficacy of a traditional marketing authorisation is already very broad, thus there is potentially a long period of time for the discovery of possible risks. Furthermore, the Health Claims Regulation does not provide for a differentiated assessment of various claims, as is the case in pharmaceutical law. This idea also follows the concerns raised in the discussion of a different assessment standard for botanicals, since a different assessment standard for these also contradicts the express purpose of the uniform consumer protection anchored in the Health Claims Regulation.[120] Therefore, a promotion of consumer protection interests cannot be achieved by the suspension.

[120] *Rathke/Hahn*, in: Zipfel/Rathke, Lebensmittelrecht, status 178. EL november 2020, 111. Verordnung Nr. 1924/2006, Preliminary note (Vorb.) para. 7.

The Commission's lack of action is inconsistent with regards to the protection of consumers laid down in the Health Claims Regulation and Art. 12, 169 TFEU and Art. 38 CFR and cannot legitimize a suspension of the evaluation process by EFSA. Thus, a justification seems not possible regardless of the respective concrete requirements of the rights with regards to the protection of legitimate consumer interests.

IV. Loss of validity of the transitional provision of Art. 28 para. 5 HCR

1. No time limit exception ad infinitum: wording and purpose of the transitional provision

The previous investigation has shown that the politically unauthorised, unlawful decision of the Commission to prevent the compilation of lists for a large part of the botanicals and thus to keep the market for food with health claims open to manufacturers in an uncontrolled manner, results in a distortion of competition that restricts fundamental rights, above all to the detriment of pharmaceutical companies. This effect, however, only results from the combination of deliberate inactivity and the use of a transitional provision. The validity of the latter has already become doubtful due to the passage of time. The relevant provision of Art. 28 para. 5 of Regulation (EC) No. 1924/2006 reads as follows:

> „5. Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and

> without prejudice to the adoption of safeguard measures as referred to in Article 24."

The transitional provision of Art. 28 para. 5 HCR is based on the condition that the Commission actually evaluates and publishes the lists of health claims applied for under the HCR according to Art. 13 para. 3 Regulation (EC) No. 1924/2006. If the Commission suspends the evaluation of the health claims for a period of more than one year, it becomes already doubtful whether the transitional provision can claim validity.

In this context, it should be remembered that the objective of this Regulation when enacting the HCR was primarily to ensure a high level of consumer protection and to create a functioning internal market.[121] Adequate transitional measures should be created to allow business operators to adapt to the new legal situation.[122] Based on these two recitals, it can be assumed that the transitional provisions serve to balance business interests and consumer interests. The business interests and consumer interests, but also the interests of other, competing market participants[123], will become meaningless if no assessment takes place at all. The wording as well as the meaning and the purpose of the Regulation do not allow any other conclusion than that the evaluation is to be made promptly and actually; namely by the expiry of the clearly set deadline in Art. 13 para. 3 of Regulation (EC) No. 1924/2006, i.e. by 31.01.2010 at the latest.

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[121] Recital 36 VO (EC) No. 1924/2006.

[122] Recital 35 VO (EC) No. 1924/2006.

[123] See above B. III. 2.

Since the HCR obviously did not assume that the deadline would be exceeded, it also did not make any provision explicitly or implicitly ordering an extension of the validity of the transitional regulation beyond 31.01.2010.

In Art. 28 para. 5 of Regulation (EC) No. 1924/2006 there is at least no indication of an expiration date, but on the contrary, the HCR has explicitly provided for transitional provisions with a limited expiration date in other places, e.g. in Art. 28 para. 1 to 3. According to Art. 13, to which the transitional provision of para. 5 refers, para. 2 requires that the Member States shall provide the Commission with the list by 31 January 2008 at the latest. According to para. 3, the Commission should then adopt the corresponding lists with the authorised claims by 31.01.2010 at the latest. The Commission was thus granted a period of two years for the entire process, including the evaluation by EFSA. If one considered that this was a short period of time, one could have argued that exceeding the deadline by one year – which is still 50% of the period after the submission of the list proposals - does not eo ipso make the transitional regime invalid. This applies at least to those health claims for which an authorisation has been applied for, since the recital 12 of Regulation 432/2012 also only refers to these.[124]

In a relevant case before the General Court, the application of the transitional provision has not (yet) been declared contrary to European Union law. With regard to the infringement of the legal certainty resulting from the principle of the rule of law, the General Court ruled in the proceedings T-296/12 in 2015 - i.e. already more than six years ago - that the HCR does not yet

[124] Cf. *Meisterernst*, WRP 2019, 413, 418 para. 27.

infringe the principle of the rule of law with regard to the length of the transitional periods.[125] Today, in contrast, the transitional provision under Art. 28 para. 5 can no longer be applied.

Four years ago, the ECJ already objected to the continuing application of the transitional provision because no transitional provision can apply ad infinitum:

> „It is important to note that such a transitional situation, prolonged indefinitely beyond the period that ended, pursuant to Article 13(3) of Regulation No 1924/2006, at the latest on 31 January 2010, does not meet the requirements of that regulation, formulated in recital 23 thereof, according to which, in order to ensure a scientific assessment of the claims that is harmonised and of the highest possible standard, such assessments should be carried out by the EFSA (see, to that effect, judgment of 14 July 2016, Verband Sozialer Wettbewerb, C-19/15, EU:C:2016:563, paragraph 41).“[126]

Contrary to the CJEU's apparent assumption, however, there can be no discretion of the Commission to autonomously extend precise statutory time limits. If such a measure were considered possible, it would only be in situations of administrative emergencies and only in the event of immediate follow-on performance. It is in striking contradiction to the regulatory content of a transitional provision if it applies for an indefinite

[125] General Court, judgement of 12.06.2015 Case T-296/12, para. 208: „In the present case, the Court observes that, as indicated in recitals 10 and 11 in the preamble to Regulation No 432/2012, the claims which have been placed on hold continue to benefit from the legal rules which were applicable to them prior to the adoption of Regulation No 432/2012.“

[126] CJEU, judgement of 23.11.2017, joint cases C-596/15 P & C-597/15 P (Bionorica und Diapharm/KOM), para. 91.

period of time due to non-implementation of the standard required for its termination.

2. Union principle of the rule of law as a limit transitional continuation

The continued application of the exemption provision, which is accessory to the creation of the list, not only contradicts the HCR, but also the principle of the rule of law. This does not only apply to the principle of legal clarity, because the scope of construction and application of a provision ends where its meaning would be reversed.

The principle of the rule of law is enshrined in Art. 2 TEU.[127] It constitutes a value to which the Union and the Member States have committed themselves.[128] Although the wording is primarily addressed to the Member States, it also binds the Union and its institutions, including the Commission.[129] In addition to the aforementioned clarity of law, the principle of the rule of law in the Union includes, among other things, legal certainty, [130] the primacy of law with the binding force of sovereignty to this law.[131] The institutions of the Union are bound by the respective Union law within the framework of the hierarchy of norms.[132]

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[127] In addition, there are also provisions in Art. 19 para. 1 subpara. 2 TEU and Art. 47 para. 2 CFR, but these relate primarily to judicial proceedings. In addition, there are also simple-legal expressions.

[128] *Payandeh*, JuS 2021, 481, 481.

[129] *Payandeh*, JuS 2021, 481, 482/485.

[130] *Hilf/Schorkopf*, in: Grabitz/Hilf/Nettesheim, Das Recht der Europäischen Union, 73. EL May 2021, Art. 2 EUV para. 35.

[131] Scientific Service of the German Parliament (WD-Bundestag), elaboration PE 6 - 3000 - 7/16.

[132] *Payandeh*, JuS 2021, 481, 484.

The continued application of the transitional provision of Art. 28 para. 5 of Regulation (EC) No. 1924/2006 would even today not only conflict with the primacy of the HCR, but also lead to legal uncertainty. According to the recitals of the HCR, the intended scientific evaluation of health claims serves the creation of a functioning internal market, so that a legally secure basis for the use of the claims is to be created for companies. In addition, consumer interests are also to be protected by making a scientifically based evaluation of the substance and health. The continued applicability of Art. 28 para. 5 of Regulation (EC) No. 1924/2006 takes these interests into account in a rudimentary way at best: Consumer protection cannot be fully realized due to the lack of scientific assessment. It is true that the transitional provision itself stipulates that further use may only take place if the requirements of the HCR are met ("provided that they [the food business operators] comply with this Regulation") and thus consumer protection still seems to be taken into account in this respect. However, the scientific evaluation by EFSA is a core aspect of the Regulation and is rendered meaningless by the permanent application of transitional rules. The CJEU itself has emphasized the lack of equivalence of transitional arrangements and the adoption of the relevant lists in the joined cases C-596-15 P and C-597/15 P.

The conceptually marginal transitional provision, which is actually an exemption until the final evaluation of the authorisation capability, would become the "basic standard" for the use of the health claims that have not yet been evaluated if it were to continue to apply. This would also be contrary to the provision of Art. 10 para. 1 of Regulation (EC) No. 1924/2006 and the idea of a general prohibition of the use of health claims.

In addition, the CJEU made it clear in the joined cases C-596/15 P and C-597/15 P that due to the reference of the transitional rules to compliance with national rules, there would also be the possibility of contradictory results within one Member State.[133] Accordingly, the application of the transitional provisions may lead to a remaining legal uncertainty, which will become increasingly pronounced through permanent application. The creation of a uniform framework for all companies in the EU will thus be undermined.

3. Right to refer and obligation to refer within the meaning of Art. 267 TFEU

The HCR is directly applicable law in Germany and must be applied by the authorities and courts in the same way as national law. An application of Art. 28 para. 5 HCR meanwhile violates the principle of the rule of law, to which every authority and every court is bound, due to the time lapse; the norm should therefore no longer be applied. A court dealing with the matter will in any case refer this question to the CJEU, a court of last instance would be obliged to do so (Art. 267 TFEU).[134] As a regulation, the HCR has a direct, binding effect and must also be observed by the courts of the Member States. In addition, they are also bound by the Union's principle of the rule of law.

4. Consequences

[133] Para. 89.

[134] Cf. *Payandeh*, JuS 2021, 481, 486.

As a result, the prohibition of Art. 10 para. 1 of Regulation (EC) No. 1924/2006 applies directly to every health claim, unless an individual application for approval of a health claim has been approved by the EU Commission. According to Art. 10 para. 1 of Regulation (EC) No. 1924/2006, various requirements are established; a core requirement is that an inclusion has been made in one of the relevant lists. The principle of the HCR thus provides for a prohibition principle with a reservation of exceptions; before the adoption of the HCR, the principle of authorisation still existed for the use of health claims. An application must be made for each health claim, although it does not necessarily have to be made by the company intending to use it. At least in the procedures according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006, corresponding application lists are transmitted by the Member States. In addition, the lists basically have a general effect, i.e. if a substance has been authorised, it can be used by all companies, regardless of who submitted the application for inclusion. Unless a transitional provision intervenes, the non-evaluated health claim may no longer be used until the adoption of the authorisation list.

As already demonstrated[135] the validity of EU law under the rule of law can only be repealed, modified or suspended by an "actus contrarius" through due legislative process. The Commission is not empowered to simply extend the transitional provisions of a regulation; this requires a formal law with the participation of all institutions. The Commission did adopt Regulation 432/2012 on 16.05.2012, in which some of the health claims were authorised. The Regulation referred to does not contain any other statements on the repeal of Regulation 1924/2006; moreover, the HCR was

[135] See above B. I.

enacted by the European Parliament and the Council, so that the Commission is bound by it and can only be released from this binding effect by an equivalent legal act of the organs appointed for this legislation. The HCR 1924/2006 is thus still directly applicable law and binds the Commission.

C. Conclusion

1. The Commission was obliged to adopt the lists of permitted health claims according to Art. 13 para. 3 of Regulation (EC) No. 1924/2006 by 31.01.2010. The Commission has violated this obligation to evaluate not only by inactivity, but also by actively suspending the activities of EFSA. The resulting standstill in the evaluation of pending botanicals, which apparently extends into the future for an unforeseeable period, is not in line with the Health Claims Regulation. The HCR does not provide for a suspension of the procedure and requires that the evaluation should already be completed in 2010. The clear intention of the legislator, who wanted all health claims to be evaluated in a timely manner, is ignored by the Commission; its suspension order was *contra legem*.

2. The transitional provision under Art. 28 para. 5 of Regulation (EC) No. 1924/2006 is no longer applicable. The continued application of the exemption provision, which is accessory to the establishing of the list, would contradict both the wording and meaning of the HCR as well as the principle of the rule of law. The acquiescent administrative practice of the Commission can no longer be tolerated under the rule of law with regards to the binding nature of the law. The reason for this is that subjective rights of consumers, but also of manufacturers of herbal medicinal products, are violated because the unjustified continued application of transitional provisions privileges food supplement manufacturers over pharmaceutical manufacturers

of herbal substances, but also of chemical substances, without any objective reason.

3. The HCR gives the companies a legal advantage through the adoption of the corresponding list, which is affected by the omission. The suspension and failure to meet the deadline triggers a distortion of competition - contrary to equality - if the exemption pursuant to Art. 28 para. 5 of Regulation (EC) No. 1924/2006 should be treated as continuing to apply. This negative impact cannot be justified on the grounds of consumer protection. In addition, there is a multitude of other subjective rights at the primary level, which may also be violated depending on the interests at stake and the constellation of facts.

Companies therefore are affected by this and are infringed in their secondary and primary rights by the lack of re-instruction of the EFSA by the Commission on the evaluation of botanicals.

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