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LEGAL AND REGULATORY NEWS

RECENT DEVELOPMENTS REGARDING HEALTH CLAIMS AND FURTHER NEWS ON EUROPEAN FOOD LAW

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CONTENT

This issue of our newsletter focuses on REGULATION (EU) No 1924/2006 and the latest national developments regarding health claims. The articles present national case law on health claims and botanicals as well as national particularities in connection these topics. The newsletter in general aims at providing a useful compendium on this topic with open access.

A very warm thank you to our colleagues from all over Europe for their contribution to our newsletter. It is a pleasure to work with you.
And now, we hope you enjoy reading.

Bärbel Ines Hintermeier, LL.M. & Prof. Dr. Alfred H. Meyer

Health claims: Belgian case law and administrative practices

Authors: Aude Mahy & Aleksandra Sanak

In the past years, an increasing number of food products bearing reference to nutritional and/or health characteristics were placed on the market in Belgium. Although Regulation 1924/2006 on nutrition and health claims made on foods (NHCR) was adopted to harmonise the applicable legal framework in Member States, it has already raised practical difficulties which led Belgian courts to deliver their judgments. Decisions have also been issued by the Jury for Ethical Practices in Advertising (JEP), an independent self-disciplinary body in Belgium. In parallel, the national authorities in Belgium have developed various guidance and interpretative documents regarding nutrition and health claims intended for food business operators in order to help them to better understand and correctly apply certain provisions of Regulation 1924/2006.

This article presents recent Belgian case law and decisions as well as administrative practices in the context of health claims.

CASE LAW

1. Vivaqua case

A few years ago, Vivaqua, a public company involved in the production and distribution of drinking water in the Brussels-Capital Region, published a brochure to promote the consumption of tap water. The brochure included various statements claiming positive and healthy effects of consuming tap water. The Royal Federation of Water and Soft Drink Industry (FIEB/VIWF) and Nestlé Waters Benelux NV brought an action against Vivaqua. The question was whether a brochure issued by a public company with no commercial goals could fall within the scope of the NHCR or not. Indeed, the various statements made by Vivaqua – should they fall within the scope of the NHCR – would be regarded as illegal. They contained various nutrition and health claims not authorised by the Regulation.

The Court of Appeal of Brussels (5 February 2013, Ann. Prat. Comm., 2013, p. 90) decided against Vivaqua and considered that the communications made by a public company fall within the scope of the NHRC since the brochure aims to promote the consumption of tap water and hence its sale to consumers.

This having been considered, the Court of Appeal examined the statements referring to health included in the brochure in light of Regulation 1924/2006 and provided the following reasoning:

The claim: « *A low dose of fluorine protects against tooth decay. Too much fluorine can, however, cause stains on the teeth and weaken them. It can also cause damage to various organs (liver, kidneys, brain) and make the skeleton more fragile. In our country, [Belgium] the fluorine concentration is fixed at 1.5 mg per liter of drinking water - a standard that takes into account the use of fluorinated toothpaste.* » (free translation from Dutch).

This statement claimed that tap water contains fluorine which presents both **positive and negative effects** on human body, and its consumption must not exceed certain levels. Surprisingly, according to the Court of Appeal, this statement was not a health claim because it did not give the impression that tap water is suitable to prevent tooth decay due to the presence of fluorine. It also did not imply that any particular quantity of tap water would contain a certain portion of fluorine. On the contrary, in the Court's view, the brochure made it clear that tap water contains fluorine which may have good and bad effects on health and that the concentration of fluorine must remain below a certain level, taking into account the use of fluorinated toothpaste. The Court also did not consider that the allusion to changes in body functions may inspire any fear in consumers and concluded that it did **not constitute a health claim**. The Court therefore did not order Vivaqua to remove such statement.

The claim: *«Water, source of life and health»* (free translation from Dutch): the Court of Appeal ruled that this statement was **not a health claim** because it was only the title of the brochure and related to water in general. One may wonder whether the Court would have decided differently today since the EU Court of Justice has given in the meantime a broad interpretation of the concept of 'health claim' in the case which related to, among others, 'easily digestible' claim (Judgment of 6 September 2012, Deutsches Weintor, ECLI:EU:C:2012:526).

The claim: *«The water of Vivaqua [...] is a source of all kinds of elements which are essential for the proper functioning of the body»* (free translation from Dutch): the Court was of the opinion that such statement **constitutes a health claim**. Article 10.3 of Regulation 1924/2006 requires that any reference to general, non-specific benefits of food for overall good health or health-related well-being be accompanied by a specific health claim included in the lists of claims established according to Articles 13 and 14 of Regulation 1924/2006. This was not the case of the claim at stake which therefore breached Regulation 1924/2006.

2. Ferrero vs Delhaize case

Another interesting judgment regarding health claims was passed by the Court of Appeal of Brussels in the case Ferrero vs Delhaize in 2017 (2 June 2017, ICIP-Ing.Cons., n°3, 2017, p. 594). In 2013, Delhaize launched a brand new hazelnut bread spread without palm oil. The launch of this product was surrounded by a huge marketing campaign emphasising the beneficial effects of such a product without palm oil. Ferrero, producer of the widely-known hazelnut and cacao bread spread, Nutella, filed a complaint against various statements communicated by Delhaize in its campaign and, in particular, in connection to health claims.

One of the Delhaize's press releases promoting its new hazelnut bread spread included the following statements: *«Better for health and for the planet»* (free translation from French) and, about the negative effects of palm oil: *«To this health impact can be added an environmental impact»* (free translation from French), as well as recommendations by a health professional.

In the opinion of the Court of Appeal, the indication that palm oil-free hazelnut bread spread is *«better for health»* **suggests a relationship between that product and health.** Consequently, this constitutes a health claim and breaches Regulation 1924/2006 by suggesting that the new hazelnut bread spread has general beneficial effects (it contributes to a better health maintenance) while not being accompanied by a specific health claim as required by Regulation 1924/2006 (Articles 10.2, 13 and 14). The recommendations by a health professional which were included in the contentious press release were also judged by the Court of Appeal as contrary to Regulation 1924/2006 (Article 12 (c)) even though the person referred to acted as Director Quality & Food Safety for Delhaize and not a medical doctor.

Finally, the Court ruled that the **statement on negative effects of palm oil which contribute to the development of obesity and cardiovascular diseases was unlawful** because it implied doubts about the safety and/or adequacy of other foods, i.e. other hazelnut bread spreads containing palm oil such as, for instance, Nutella (Article 3 (b) of Regulation 1924/2006).

3. Jury for Ethical Practices in Advertising (JEP)

The Jury for Ethical Practices in Advertising (JEP) is an independent self-disciplinary body in Belgium with the mission of ensuring that advertising practices are fair, truthful and socially responsible. The remit of JEP is advertising by means of social media (including TV, radio, Internet, posters, etc.), direct mail and e-mail. Its decisions are based on legislation, self-disciplinary codes and the consolidated ICC Code on Marketing and Advertising. Summaries of decisions are freely accessible on JEP's website (www.jep.be).

Jet Import cases

In 2015, JEP decided on a complaint against a radio commercial advertising the energy drink 'Red Bull' (JET IMPORT - 05/08/2015). The commercial consisted of statements *«My memory is so bad; help me»* and «*Well, then drink a Red Bull; we bet it works?*» (free translations from French). According to the complainant, the commercial encouraged young people to consume the energy drink to improve their memory.

JEP analysed the commercial in light of Regulation 1924/2006 as to whether it contained or not a lawful health claim. It decided, based on the opinion of the Federal Public Service Public Health, Food Safety and Environment, that the commercial indeed included a health claim which referred to the ability of concentration and memory. In its decision, JEP underlined that **a simple fact of suggesting or implying a health effect is sufficient to constitute a health claim** in the meaning of Regulation 1924/2006. JEP further explained that, although the claim was not prohibited due to, at the time, pending authorisation for claims regarding attention and concentration for caffeine, it has to refer to the substance for which it is authorised (or pending – namely caffeine) and not to the product as such (Red-Bull). The evoked effect is indeed due to the presence of caffeine in the product. JEP concluded that the commercial breached Regulation 1924/2006 and ordered to adapt the commercial accordingly or, failing to do so, to stop its broadcast.

Two years later, in 2017, in a similar case (JET IMPORT – 29/11/2017), JEP considered that the statements included in the commercial constituted health claims because they stated, suggested or implied a relationship between the advertised product and health. In JEP's opinion, the claims were general health claims and had to be accompanied by specific claims (Article 10.3 of the NHCR) referring to the substance for which they are authorised or pending. This was not the case of the commercial. JEP concluded that the commercial did not comply with the NHCR and had to be modified or removed.

ADMINISTRATIVE PRACTICES

1. National guidelines and interpretative documents

Food legislation and policy is developed in Belgium by the Federal Public Service Public Health, Food Safety and Environment (FPS Health). The FPS Health also publishes guidelines and interpretative documents intended to help food business operators to better understand and apply food legislation. The following guidelines have been developed by the FPS Health in the area of nutrition and health claims:

- Guidelines regarding the flexibility of the wording for health claims (November 2014);
- Status and use of nutrition and health claims (April 2017);
- FAQs regarding certain provisions on nutrition and health claims (July 2017).

The Federal Agency for Safety of Food Chain (FASFC), in charge of control policy and enforcement in the entire food chain, also drafts and publishes interpretative documents in the form of administrative circulars which aim at providing food business operators with clarification, explanation or interpretation of food legislation. In 2017, the FASFC published a Circular on claims made on foods (Reference PCCB/S3/CDP/930320).

The abovementioned documents can be helpful for food business operators who wish to use health claims on their products. However, these guidelines and interpretative documents are not legally binding. The ultimate interpretation of the legislation on nutrition and health claims lies with the EU Court of Justice.

It is worth noting that the authorities in Belgium adopt in general an open approach and are willing to provide guidance and/or interpretation of legislation to food business operators who seek to ensure compliance with food legislation. Proactivity of food business operators in this respect may, therefore, be advantageous.

2. Controls and sanctions

In case of non-compliance with food labelling or advertising requirements, including nutrition and health claims, food business operators in Belgium expose themselves to various sanctions that can be imposed by the Federal Public Service Economy (FPS Economy), the FASFC and the national courts. In 2016, a new protocol was concluded between the FASFC and the FPS Economy which clarifies control powers with regard to labelling, advertising and the composition of food to avoid inspection overlaps. The division of inspection powers between the two authorities has also been included in a Circular published by the FASFC in 2017 (Reference PCCB/S3/CDP/1463259).

According to the protocol, the FASFC is responsible for controls regarding public health and food safety issues, while the FPS Economy controls composition, labelling, designations, misinformation and economic fraud regarding foodstuffs. The inspections on nutrition and health claims are the task falling under the supervision of the FASFC. Overall, the key for food business operators to reduce administrative or criminal liability issues is prevention. When deciding on liability, Belgian authorities usually take into account prevention strategies (see guidelines, interpretative circulars).

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Placing the Foodstuffs with Nutrition and Health Claims on the Market of the Republic of Croatia

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1. Introduction:

With the entry of the Republic of Croatia into the European Union (the «**EU**»), the state had overtaken the obligation to harmonize its existing legislation with the EU, including, *inter allia*, food law related legislation. One of the challenging tasks with respect to the aforementioned field of law was enforcement of the Regulation (EU) No 1924/2006 (the «**Regulation**») into the national legal system, since it brought much stricter legal framework and big changes for the food business operators. The respective Regulation was implemented into Croatian legal system by means of the Act on Nutrition and Health Claims and Nutrients Enriched Food (*Zakon o prehrambenim i zdravstvenim tvrdnjama te hrani obogaćenoj nutrijentima, Official gazette no 39/2013*) as well as the Ordinance on the requirements for entering the monitoring programme and the implementing programmes for the monitoring of food supplements, foodstuffs with added vitamins, minerals and other substances and foodstuffs with nutrition and health claims (*Pravilnik o uvjetima za uvrštavanje u program monitoringa i provođenje programa monitoringa dodataka prehrani, hrane kojoj su dodani vitamini, minerali i druge tvari i hrane s prehrambenim i zdravstvenim tvrdnjama, Official gazette No 83/2013*; the «**Ordinance on Monitoring**»).

The Act on Nutrition and Health Claims and Nutrients Enriched Food concerns the general implementation of the Regulation (establishing competent authorities and their tasks, official controls, administrative measures and fines), whereas the Ordinance on Monitoring refers to the conditions of placing the food attributed with nutrition and health claims on the market of the Republic of Croatia.

Other conditions regarding the labelling, advertising and presentation of food with nutrition and health claims are governed with the Regulation (EU) No 1169/2011, Regulation (EU) 432/2012 and Act on Providing The Information Regarding Food to the Consumer (*Zakon o informiranju potrošača o hrani, Official Gazette No 56/2013, 14/2014, 56/2016*). All the aforementioned conditions apply to all forms of commercial communication (e.g. web pages, information leaflets and booklets, posters, any form of writing, oral, image advertising, etc.).

The general responsibility for the enforcement of the abovementioned laws and regulations lies with the Ministry of Health of the Republic of Croatia. The power to investigate infringements and impose fines is mainly vested with Sanitary Inspections (*sanitarna inspekcija*) as a special unit set up within the Ministry of Health.

2. Nutrition and Health Claims Particularities in Croatia

Health claims imply that there is a relationship between a product and a health condition, whereas nutrition claims state, suggest or imply that a food has particular nutritional properties. In general, adding nutrition and/or health claims to the label of the food product is optional, however, if added, they must neither attribute the food with the properties such as prevention, therapy or treatment of the disease, nor in any way imply to such properties of the food. Each claim should be worded in a particular way and should not by its content, graphics or other signs and/or claims mislead the consumer.

Additionally, health claim must always be stated for the nutrient, food or category of food for which it is approved and not for the entire product containing such claim. This is mentioned specifically because, before Croatia joined the EU, foodstuffs on the Croatian market had the stated purpose which pertained to the whole product and Croatian Ministry of Health had been in charge for rendering decisions on the approval of the purpose of such products. The validity of rendered decision was five years from the date of issue. However, after 30 June 2013, stricter obligations were imposed to the food business operators and consequently the abovementioned practice of attributing the food with the specific purpose had to be abolished, whereas any added claim had to be connected to a particular active substance of the food, in accordance with the provisions of the Regulation (EU) 432/2012.

Furthermore, whenever health claim is made, the following information must be provided in the labelling, presenting or advertising the food:

(i) Nutritional information as prescribed by the Regulation (EU) 1169/2011,

(ii) statement indicating the importance of a varied and balanced diet and a healthy lifestyle,

(iii) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect,

(iv) where appropriate, a statement addressed to persons who should avoid using the food and

(v) an appropriate warning for products that are likely to present a health risk if consumed to excess.

Moreover, a trade mark, brand name or fictitious name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the necessary authorisation procedures, provided that it is accompanied by a related nutrition or health claim. Nonetheless, there are still some exceptions to that rule. For instance, food with a trademark or a brand name which existed before 1 January 2005 and does not comply with the health and nutrition claims regulations, can still be placed on the Croatian market (until 19 January 2022), after which changes will have to be implemented or the product shall be withdrawn from the market.

When placing the food containing the approved nutrition and health claims on the market of the Republic of Croatia for the first time, the responsible subjects are obliged to notify the Ministry of Health thereto. The notification must be accompanied by information and documents listed in the Article 7 (2) of the Ordinance on Monitoring, i.e.

(i) product label,

(ii) packaging of the product,

(iii) product specification containing the information on chemical forms of vitamins and minerals (only for the food containing vitamins and minerals) and

(iv) confirmation of payment of the monitoring costs.

Placing the food on the market of the Republic of Croatia, containing the health and nutrition claims which are not approved, shall be allowed only for the products containing the so called "*on hold*" claims (claims which assessment has not yet been finalized by the European Food Safety Agency (the "**EFSA**") and/or which are not yet been considered by the European Commission).

Such products fall into the scope of the specific "notification" procedure in which case an additional documentation is required. Along with the abovementioned documents, a food business operator shall be obliged to provide the competent Ministry of Health with (i) the certificate of origin of the product (ii) certificate of analysis, (iii) evidence on main chemical components, (iv) quantities of active nutrients, (v) statements of interactions, (vi) non-toxicology data and human safety data (vii) EFSA ID for the "on hold" claim (viii) business operator's company information required by the Scientific Committee of the Ministry of Health.

3. Administrative Measures

The sanctions provided by the specific health and nutrition claims legislation are imposed mainly by the Sanitary Inspection in accordance with the procedure for investigating infringements, set forth in the Act on Sanitary Inspection. The sanitary inspector performs inspection without prior notice, but before commencement of the supervision it is obliged to notify the responsible person of the supervised legal entity. During the supervision and in case of the infringement of the respective laws and regulations, the competent inspector may:

(i) order elimination of nonconformities with regard to the product label and give appropriate deadline for their elimination,

(ii) order the infringer to notify the Ministry of Health on placing the food on the market,

(iii) temporarily or permanently prohibit placement of food on the market and/or withdrawal from the market

(iv) prohibit any form of advertisement and informing the consumers about the food which does not comply with conditions set forth in the respective laws and regulations and

(v) order removal of any content and advertisement, to the media space provider, which is contrary to the conditions set forth in the respective laws and regulations.

4. Fines

Food business operators may be imposed with the monetary fines ranging between HRK 50,000 (Approx. EUR 6,700) to HRK 100,000 (Approx. EUR 13,400), depending on severity of the infringement. Authorized persons acting on behalf of such food business operators may also incur fines ranging from HRK 10,000 (Approx. EUR 1,300) and HRK 15,000 (Approx. EUR 2,000). In cases when the competent inspector orders elimination of nonconformities and gives an appropriate deadline for the elimination, fines shall be imposed only if the infringer fails to comply with such order.

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Danish Food authorities practises in the area of health claims

Authors: Martin Dræbye Gantzhorn & Gundula Maria Kjær

1. Introduction:

It is often said that the Danish Veterinary and Food Administration (DVFA), the competent authority responsible for enforcing the food legislation in Denmark, is rather strict compared to other national food control authorities. Especially, we often hear this "accusation" regarding the authorities' enforcement of the nutrition and health claims regulation.

In the following, we are highlighting some of the more controversial or peculiar cases, which could be partly the reason for the abovementioned argument.

2. Administrative practice in the area of health claims

2.1 Ban on the use of the marketing statements "Superfruits" and "Superjuice"

In 2010, the DVFA issued a ban on the statements «*Superfruits*» and «Superjuice» to a food business operator who marketed fruit juices with the mentioned claims. The company made a complaint to the Board of Appeal, which supported the view of the DVFA.

The **reason given for the ban** was that with the use of the mentioned claims, the company gave the consumer a perception of the products containing fruits (blueberry + aronia and pomegranate + raspberry), of having extraordinary characteristics compared to other fruits. Furthermore, it was concluded that the company had failed to document these certain characteristics.

The DVFA was also focused on the fact that the claimed fruits where only present in small amounts in the products.

The Board of Appeal has later clarified that they do not in all situations view the term "Super" as being misleading and that in many cases the specific term will be seen as a clear exaggeration of a product's high quality, which will not be seen as misleading.

2.2 Ban on the use of the marketing statement "Wellness"

In 2009, the DVFA issued a ban on the statement "*Wellness*" to a food business operator who marketed tea with the mentioned claim. The company made a complaint to the Board of Appeal, which supported the view of the DVFA.

The **reason given for the ban** was that "Wellness" was considered an unspecific health claim according to Article 10(3) of Regulation no. 1924/2006. Since the company had not used an approved specific health claim alongside the unspecific statement, this was not in accordance with the Regulation.

The company argued that the term "Wellness" did not indicate a health related effect and that there was a difference between referring to general well-being and health related well-being. Therefore, the statement was in the view of the company not covered by the Health Claims Regulation.

The Board of Appeal argued that the term "Wellness" is **considered a health claim** covered by Regulation no. 1924/2006. The reason for this is that it indicates that the product has a psychological effect in terms of the well-being of the consumer. Therefore, it would not make a difference if the product actually had a health-related effect since the psychological effect was already identified.

2.3 Statements on a company intranet (internal website)

In 2016, we assisted a company canteen in an administrative case against the DVFA. According to the DVFA, the canteen used non-compliant nutrition and health claims on the company intranet. The DVFA issued an injunction for the canteen to comply with the food legislation.

Our translation of the claims in question: "*Seasonal fruit and vegetables ensures optimal vitamin and mineral content" and "Leguminous fruit and vegetables and thereby fibers, secures blood sugar balance*".

On behalf of the company, we made a complaint to the Board of Appeal, which supported the view of the DVFA.

According to the DVFA, the first claim was an unspecific nutrition claim, which indicated that the seasonal fruit and vegetables had a higher content of vitamins and minerals compared to the non-seasonal fruit and vegetables. The second claim was found to be a non-approved and thereby non-documented health claim.

Even though, the claims were made on an **internal website** and with the intention of promoting the employees' intake of fruit and vegetables, the DVFA found that the claims were **part of commercial communication** and therefore covered by the Health Claims Regulation.

The Board of Appeal supported this view and argued that profitability due to healthier employees (having a higher intake of fruit and vegetables) with higher efficiency and less days off sick was a commercial aim and therefore the claims were considered covered by the Regulation.

In Denmark, the result of a food inspection by the DVFA is concluded in a report with smiley faces 1-4, where 1 is a smiley with a big smile and 4 is a smiley with a very sad face. Establishments with four happy smileys on their last four inspection reports – and no remarks during the last 12 months – are awarded an Elite smiley. The smiley reports are made public and are often used as a marketing tool.

The canteen in question had for years obtained the elite smiley. However, with this decision by the DVFA regarding two statements on the internal website, the company lost their elite smiley.

3. Bech-Bruun comments

The three above mentioned administrative decisions indicate the rather strict DVFA approach in terms of interpreting the health claims legislation.

The decisions might legally be accurate. The issue is whether the DVFA in many cases could choose to provide the affected company guidance on the legislation instead of issuing sanctions. This would especially be relevant in cases concerning minor issues.

The present Food Minister Mr Esben Lunde Larsen has as one of his priorities for the food authorities to **provide more guidance instead of sanctioning**. We are yet to see the full effect of this commitment.

This spring the Danish politicians will negotiate a new political agreement covering the area of food. This agreement will among other elements set out the principles for the DVFA food inspections, i.e. determining focus areas and frequency of inspections. The area of health claims is typically covered by the political agreement. The issue of guidance vs. sanctioning is continuously a topic for political discussion.

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European Court of Justice "Dextro Energy" case Nutrient profiles through the back door

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In its judgment from 8. June 2017 (C-296/16 P – unfortunally available in French and Greman only), the European Court of Justice (ECJ) affirmed a European General Court (EGC) decision from 16. March 2016 (T-100/15) rejecting an action for annulment brought by Dextro Energy against the non-approval of Health Claims in accordance with Regulation (EU) Nr. 2016/8.

The "Dextro" judgments of the EGC and the ECJ will have substantial consequences for the advertisement of health claims on food products that are essentially composed of **sugar, fat or salt**, ingredients that are regularly warned against consumption in large amounts, i.e. those which stand in conflict with generally recognised nutritional and health principles or are stigmatised with relation to diseases of civilisation that result from overconsumption.

This relates not only to the approval of such health claims in the context of sugar, fat or salt. Advertisement with health claims that have already been approved for such food products could now be considered (latently) misleading (see Art. 3 Health Claims Regulation (EC) No 1924/2006; cf. recital 12 of Commission Regulation (EU) No 432/2012, discussed further below).

Circumstances

On 21. December 2011, in an individual procedure in accordance with Art. 13 para. 5 and Art. 18 of Regulation (EC) No 1924/2006, Dextro Energy applied to the competent German authority, the Federal Office of Consumer Protection and Food Safety, for approval of the following health-related claims, each with a specific target group:

- "Glucose is metabolised in the normal energy metabolism process"
- "Glucose supports physical activity"
- "Glucose contributes to a normal energy production metabolism"
- "Glucose contributes to a normal energy production metabolism during physical activity"
- "Glucose contributes to normal muscle function during physical activity"

In a letter to the European Food Safety Authority (EFSA) from 26. March 2012, Dextro Energy suggested editing the claim "Glucose supports physical activity" to add the word "normal" before "physical", and in the claim "Glucose contributes to normal muscle function during physical activity", to remove the words "during physical activity".

On 25. April 2012, EFSA submitted five statements of scientific opinion on the proposed health-related claims in accordance with Art. 18 para. 3 in connection with Art. 16 para. 3 of the Health Claims Regulation. In its evaluation of the claim "Glucose is metabolised in the normal energy metabolism process", EFSA came to the conclusion that based on available data, a causal relationship had been established between the intake of glucose and its contribution to the energy production metabolism. In relation to the four other health-related claims, EFSA found that they were also referring to the same effect of glucose as a contributor to energy production metabolism and therefore also could be rated positively.

Despite this positive assessment by EFSA, the European Commission rejected the approval of the claims by means of Regulation (EU) Nr. 2015/8 on 6. January 2015. The Commission founded its non-approval on the assertion that no health-related claims should be made that conflict with generally recognized nutritional and health principles. Purportedly the use of the submitted claims would send a contradictory and confusing signal to consumers, as they were being encouraged to consume sugar whilst the national and international authorities were recommending minimal sugar consumption based on generally recognised scientific evidence. Thus the claims would not align with Article 3, para. 2 lit. a of the Health Claims Regulation, under which no ambiguous or misleading claims are permissible. Furthermore, the misleading effect of a statement could not be avoided by permitting the relevant health-related claim only under particular conditions for use and/or with additional clarifications or warnings.

Decision of the EGC and ECJ

General Court of the European Union

In response to this decision, Dextro Energy filed a claim in the EGC with a request for annulment of Regulation (EU) Nr. 2015/8.

The General Court explained in its judgment that there are three elements that the Commission must weigh in its decision on an application for approval of a health-related claim in accordance with Art. 18 para. 4 of the Health Claims Regulation, namely:

- first, the scientific findings in the EFSA report,
- second, all relative provisions of European Union law, and
- third, other relevant, legitimate factors of the matter at hand.

Thus the court rejected the position of Dextro Energy that a claim recommended for approval by the EFSA should be approved. The court further explained that, as stated in recital 30 of Regulation Nr. 1924/2006, in some cases a scientific risk assessment on its own could not provide all necessary information upon which a risk management decision should be made; therefore other **legitimate factors** relevant in the evaluation of the matter at hand should be considered. As a result, the Commission has broad discretion. Since the legislators of the European Union did not precisely name these factors, such matters should be decided on a case-by-case basis with due consideration to (among other things) the goal of the Health Claims Regulation named in its 34th recital, namely to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection.

In the opinion of the court, the generally recognised **nutritional and health principles** that the Commission took into consideration in Regulation (EU) Nr. 2015/8 present a factor that should be legitimate and relevant to the decision for approval of contentious health-related claims, as the application of these principles should guarantee strong protection for the consumer. Additionally, the legislature expressly stated the relevance of the generally recognised nutritional and health principles in evaluating the approval of a health-related claim in recital 18 of the Health Claims Regulation. Contrary to the position of Dextro Energy, it could also not be concluded that the Commission erred in its determination that the health-related claims referred to in EFSA opinions as scientifically proven should be treated as such where the use of a health-related claim calling for the consumption of sugar contradicts the generally recognised nutritional and health principles. EFSA evaluates only whether the health-related claim is supported by scientific evidence and whether its formulation is in compliance with Regulation Nr. 1924/2006, and not whether it stands in contradiction to general nutrition and health principles.

The judgment of the Commission that the health-related claims at issue stand in opposition to the generally recognised nutritional and health principles, the court found, was also not erroneous because the **nutritional significance** of carbohydrates in the human diet is generally recognised, just as is the particular significance of glucose. Despite this nutritional significance, national and international authorities have recommended that consumers reduce consumption of sugar and thus the use of a health-related claim encouraging the consumption of sugar would contradict the generally recognised nutritional and health principles.

The court also found no error in the Commission's determination that the implementation of the health-related claims at issue would encourage the consumption of sugar. As stated in recital 9 of the Health Claims Regulation, consumers assume that food products advertised with health claims to offer a nutritional, physiological, or other health-related benefit compared to similar or other products. This could influence the consumer to make choices that lead to a total consumption of nutrients or other substances that contradicts the relevant scientific recommendations.

The Commission furthermore correctly assumed that the claims submitted were **ambiguous and misleading** in the sense of Art. 3 para. 2 lit. a of the Health Claims Regulation in that they emphasise only one particular characteristic relating to the improvement of energy production metabolism while failing to mention that regardless of the benefit to the energy production metabolism, dangers associated with the consumption of sugar that are neither eliminated nor reduced. In light of these circumstances, the decision of the Commission was proportionate.

European Court of Justice

In its judgment of 8. June 2017, the ECJ rejected Dextro Energy's appeal of the EGC's decision in its entirety. Thus it became final that Dextro Energy may not advertise its products using the disputed health claims.

In its judgment, the ECJ did not review the EGC's findings of fact nor its standards of proof, rather, it limited its opinion to the evaluation of Dextro Energy's complaints, which referred to the EGC's application of the law. However, the ECJ rejected the totality of these complaints either as obviously inadmissible or in any case unfounded, since the complaints were essentially a renewed appeal of the Commission's decision rather than of the EGC's application of the law.

Practical consequences

The decisions of the EGC and the ECJ will likely have wide-ranging consequences for the advertisement of food products that are substantially composed of sugar, fat or salt – substances that consumers are generally advised not to overconsume as they are contraindicated by generally recognised nutritional and health principles. Advertisement of such foods with health claims in any form are likely all but completely excluded. The fact that the EGC expressly stated that such substances in limited amounts are nutritionally significant does not change anything, because the courts have taken the position that advertising with health claims always leads to the danger that consumers will use more of these foods than is healthy.

The "Dextro Energy" decision also fundamentally aligns with the perspective of the Commission already stated in recital 12 of **Regulation (EU) Nr. 432/2012**, the list of permitted health claims. The provision states as follows:

"Health claims inconsistent with generally accepted nutrition and health principles should not be made. The Authority concluded that for one claim (2) on the effect of fats on the normal absorption of fat soluble vitamins and another claim (3) on the effect of sodium on the maintenance of normal muscle function a cause and effect relationship has been established. However, the use of these health claims would convey a conflicting and confusing message to consumers, because it would encourage consumption of those nutrients for which, on the basis of generally accepted scientific advice, European, national and international authorities inform the consumer that their intake should be reduced."

For the time being, in light of Regulation (EU) Nr. 2015/8 and in its confirmation in the decisions above, health claims based upon facts such as those named in recital 12 of Regulation (EU) 432/2012 will be rejected in individual proceedings.

At the same time, much-discussed **nutrient profiles** are being introduced (Art. 4 Health Claims Regulation). On the subject of nutrient profiles and difficulties in their establishment, see Meyer, EFFL 2/2012, 62, "Nutrient Profiles – Advertising Ban Violates the Law of The EU".

Both of Dextro Energy's remaining application procedures, with regard to two additional health claims about "cognitive function" and "brain function" (EFSA 2015;13(2):4026 + 2015;13(2):4027), are most probably also resolved by the decisions discussed above, i.e., will likely be rejected.

THE "BEKÖMMLICH" CONTROVERSY

Author: Alfred Hagen Meyer

(from Middle High German 'bekom(en)lich' - German-Middle High German Dictionary) once had a meaning along the lines of 'suitable' or 'comfortable' (Wikipedia).
The press release of Germany's Federal Court of Justice (BGH) from 17.5.2018 (Case Nr. I ZR 252/16) explains as follows:

'According to the findings of the appeals court, the term "bekömmlich" is understood in the relevant sector of the public [today] as "healthy", "beneficial" and "easily digestible". In its use with relation to food, it gives the impression that the food is easily absorbed in the digestive system and – also over long-term consumption – is well-tolerated.'

Any other conclusion would have been a surprise in light of the Higher Regional Court of Stuttgart's previous brilliant review of the issue (OLG Stuttgart, 03.11.2016 - 2 U 37/16 – judgment equivalent to a scientific exposition) and the most recent decisions of the BGH on terms such as 'detox' (see Hartmann in meyer.food blog). At the same time, it should be noted that the BGH itself made no reversals. It is possible (but uncertain) that an earlier BGH decision and one of the Federal Administrative Court (BVwG) indicate that 'bekömmlich', when used in connection with a claim about the reduced amount of a particular substance, would be health-related, but without such accompanying claim would not (BGH case 'Gurktaler Kräuterlikör', BVwG – although inconclusive – 'Deutsches Weintor II'). In its resolution of 13.1.2011 (I ZR 22/09 „Gurktaler Kräuterlikör", lexetius.com/2011,90) the BGH additionally found (recital 16 / para. 4) that

'Measured by this standard, the use of the term 'bekömmlich' in relation to the Defendant's herbal liqueur is permissible in the opinion of the Senate. Its use expresses that the liqueur neither burdens nor damages the body or its functions (cf. OVG Koblenz, WRP 2009, 1418, 1419). Thereby no explanation, suggestion or indirect expression indicates that the product promotes health (...).
The inclusion of a declaration of this nature, neutral as such, into the scope of Art. 2, para. 2, no. 5 of Regulation (EC) Nr. 1924/2006 and thus also – for beverages with an alcohol content of over 1.2 percent by volume – the prohibition in Art. 4, para. 3 of Regulation (EC) Nr. 1924/2006 would contradict the Community principle of proportionality by means of interfering with the freedom of expression and communication pursuant to Art. 6, para. 3 TEU in conjunction with Art. 10 ECHR.

The Federal Administrative Court (judgment of 14.02.2013, BVwG 3 C 23.12, recital 12) left open the question of

'whether the indication of the Bekömmlichkeit [wholesomeness, or at least "bekömmlich"-ness] of a wine without relation to a "soft acidity" or without a comparable context – i.e., as a simple expression indicating pleasant flavour or a general wellbeing – would be permissible.'

Additionally, the following question might still remain open:

'whether and, if so, how the category of "health-related claims" (including references to overall good health or health-related well-being, cf. Art. 10, para. 3 Regulation (EC) 1924/2006) should be differentiated from statements about general well-being. Both concerns cannot be answered conclusively based on the judgement of the European Court of Justice (C-544/10), which does not discuss such an issue.'

The definition of the term 'health-related' (Art. 2, para. 2, Nr. 1 Health Claims Regulation 1924/2006), without indications of a direct or indirect correlation nor intensity or duration of an effect, suggests that it should be interpreted broadly, even though under constitutional law a limited interpretation would be more likely appropriate due to the strict right of permission.
The ECJ's suggestion regarding 'implications', also as to effects that are negative or damaging to health (ECJ 6.12.2012, C-544/10 'Deutsches Weintor') requires at least an advertising claim that suggests that the consumption of a food has an effect on health (Meyer in Fezer, Lauterkeitsrecht, p. 4 para. 300/301). A 'Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being' (Art. 10, para. 3 Health Claims Regulation 1924/2006) would suffice for a correlation with health; however, at least the latter must be present, otherwise the criterion (which should differentiate from mere non-health-related 'well-being') would be rendered toothless.
The grounds for such a decision, the need for which has not yet come before the courts, will determine whether the judgment of the BGH of 17.5.2018 acts as the new leading case for 'unspecific' health claims under Art. 10, para. 3 Health Claims Regulation 1924/2006 – most likely, but the BGH can be unpredictable.

In distinguishing specific and unspecific health claims, the BGH has already created some confusion. Under the BGH's guidelines, unspecific health-related claims might be for example those that relate to supported or increased well-being by means of consumption of a substance at issue, such as 'for support of optimal performance' or 'increases endurance and performance'; on the other hand, specific claims should be those that express or suggest an 'enhancement of bodily functions' (BGH, judgment of 17.1.2013, I ZR 5/12 'Vitalpilze'; lexetius.com/2013,2586); a differentiation criterion that would be difficult to apply even to a claim that is expressly permissible under Regulation (EU) Nr. 432/2012, such as 'Carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise' (discussed by Meyer in Fezer, Lauterkeitsrecht, p. 4 para. 323).

So then as the Germans say, '*wohl bekomm's!*' – meaning 'cheers!' or 'to your health!' – or perhaps have a schnapps first.

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Health Claims – Food control in Luxembourg: a permissive system?

Author: Florence d'Ath

In Luxembourg, the Grand Ducal Regulation of 25 August 2015 on food information to consumer, nutrition and health claims and lot numbers is the only legal text which covers the subject of health claims on food products. A closer look, however, reveals that this Regulation does not add anything to the European legislation but simply states that applications for authorization of a new health claim must be submitted to the Luxembourg Directorate of Health.

Luxembourg case law does not provide for more information on the subject either. Luxembourg being a small country with relatively moderate food manufacturing activities, few conflicts on labelling are referred to the Luxembourg courts. Hence, there is a jurisprudential void regarding nutrition and health claims. When writing on the subject, Luxembourg scholars or lawyers therefore usually refer to the European, Belgian or French case law.

Nutrition and health claims having to be based on scientific evidence, Luxembourg created the Food Safety Authority (In French, 'Service de la sécurité alimentaire': 'SECUALIM') on March 19th, 2009. SECUALIM operates under the responsibility of the Directorate for Health. One of its main missions is to perform foodstuff controls, including on nutrition and health claims. Controls are undertaken either through samples or through an inspection. In most of the cases, controls are driven by the existence of potential sanitary risks.

It should however be noted that food labelling legislation in Luxembourg is not subject to an efficient control system in general. As an illustration, the relevant authorities of Luxembourg do not have the power to impose administrative fines in case of infringement on food labelling legislation. For this reason, as well as others, the Luxembourg food control system is currently under scrutiny and about to be re-shaped. Yet, the current draft bill is far from revolutionizing the regulatory landscape on food labelling and control in Luxembourg, as explained below.

The current regime

In Luxembourg, the food control system is currently mainly organized under the Law of 25 September 1953 on the reorganization of the control of food, beverages and usual products (the 'Food control law of 1953').

Despite the existence of controls, one must admit that the current regime is not deterrent for food business operators, mainly because the Luxembourg authorities may not inflict administrative fines in case of infringements. Furthermore, the existing criminal sanctions provided under the Food control law of 1953 (and pronounced by a judge, as the case may be) are really low compared to those of Luxembourg's neighboring countries, such as France, Belgium or Germany.

As of today, in case of infringement to the food legislation (e.g. misleading or erroneous labelling), sanctions are limited to the potential confiscation of the infringing products and/or a fine of 251 to 2.000 euros. Only in the case of food fraud are the sanctions slightly higher, i.e. a fine of maximum 15.000 euros and/or a prison term of 8 days to 1 year.

The reform

To improve the current regime, a bill on a new system of controls and sanctions relating to foodstuffs was presented to the Chamber of Deputies in September 2013. The draft bill provides for the establishment of a new more effective system, as well as for the transparency of control results. It would replace the current Food control law of 1953 to a large extent. Following this draft bill, control modalities would be extended, as agents could enter specific warehouses, installations or sites without notice, in case of serious ground for suspecting a violation to the law (art.9). Agents could also request any communication they see fit on foodstuff (art.10). Sanctions would also be increased, as infringements could be subject to an imprisonment of 8 days to 3 years, and/or to a fine of 251 to 500.000 euros (which represents an increase of more than 3000 %).

A major flaw of the reform, however, is that the material scope of the draft bill is currently limited to food hygiene, traceability and security (equivalent to the EU 'Hygiene Package' legislation). Other regulations – including EU regulations on food information to consumers, additives, novel foods as well as nutrition or health claims – would thus fall outside of the scope of application of the reform. As a consequence, a two-tier control system could exist in Luxembourg, with efficient controls and deterrent sanctions for food hygiene, traceability and security, and a permissive system for the rest.

After its publication, the draft bill was criticized by various consultative bodies. Since then, the reform seems to have come to a standstill. Hopefully, the draft bill will be amended to include a broader range of food regulations under its scope... including nutrition and health claims.

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Health claims: Dutch case law and administrative practices

Authors: Natasja Brusik & Victor van Ahee; Loyens & Loeff

In this contribution we will provide a high level overview of the Dutch landscape on (nutrition and) health claims (NHC) and case law and practices. As such we will elaborate on some 'national' case law relating to health claims and what a food business operator is faced with then it wants to use health claims in the Netherlands.

Case law

In the Netherlands consumers, consumer organisations and companies (and/or competitors) can contest health claims on two levels, with a judicial court (whether or not after enforcement requests with the Dutch Food and Safety Authority) and with a self-regulatory institution. It will follow from the below review that the self-regulatory ecosystem is much more active in NHC-cases than the Dutch courts. This is the reason (and maybe therefore also the problem) that relatively few Dutch food law matters are submitted to the Court of Justice of the European Union (CJEU).

Dutch courts

In the Dutch courts very little cases have been published that relate to the use of health claims. This can be explained with three reasons;

(i) Dutch legal procedures can be costly in time and money where the non judicial self-regulatory court is a faster and cheaper alternative,

(ii) fines of the Dutch Food Safety Authority have been very limited (usually by far not exceeding the legal costs of an appeal); and

(iii) in practice there is not a lot of (financial and reputational) willingness for competitors or consumer organisations to bring forward a claim against a food business operator/ competitor in front of a court (and face a judicial fight) – in the last five years only one case was published where a company (unsuccessfully) sued a competitor for the use of a health claim.

The cases that have been brought to court relating to health claims are therefore usually a case of principle or high stakes. The most recent (and relevant) are included below.

The Rotterdam District Court in 2015 (17 September 2015 - ECLI:NL:2015:6460) ruled on a health claim relating to the reduction of weight possibilities of a particular product (food). On a website some testimonials were made by prior customers who have lost an x amount of weight in x time. The court ruled such information can be considered as a weight reduction health claim, as such claim does not have to be limited to a general indication of weight reduction – as the claimant indicated – but also specific examples of weight reduction also constitute a weight reduction health claim for the product. The claimant further made an interesting, yet unsuccessful, claim that it is obliged to provide this information based on the Dutch (consumer protection) law requiring parties selling a product giving proper information on the relevant product sold. This argument was not successful with the court (as the information provided went much further than the basic material information). The fine (of EUR 525 !) which the claimant appealed to remained in place.

Also there have been a couple of court cases relating to fines for selling and trading food products (which are in effect qualified as medicine). In these cases repetitive arguments that compliance with the NHC-regulations exists were not sufficient to prevent those producers/distributors from receiving fines based on medicine-legislation. These fines are substantially higher in the Netherlands.

As follows from the above, the Dutch courts do not offer a lot of support in the development of the legal interpretation of the NHC-regulation in the Netherlands. This is disappointing from a legal theory perspective, but for the food business operators it may be beneficial, as they are usually not helped with long and expensive court cases.

Taking a look into the future, we expect more administrative court cases in the future relating to the NHC-regulation. The reason for this expectation is that since a year (and in view of the new Official Control Regulation (EU 2017/625)) turnover related fines for violations of NHC-regulation have been introduced and more stringent enforcement can be expected. Such fines can be imposed for violations of the NHC-regulation with a certain degree of health risk and/or intent of the violation. If such fine is imposed (where up to 1% of the turnover can be fined) there will be more reason for a food business operator to contest a fine in court.

Self-regulatory rulings

In the Netherlands, and in contrast to the very quiet food law court-cases, a vibrant ecosystem of self-regulatory labelling case law has developed over the last decades formed by rulings of the Dutch Advertising Code Committee (the '*Reclame Code Commissie*' or RCC). The RCC applies the Dutch Advertising Code (the '*Nederlandse Reclame Code*' or NRC). Part of the NRC is the compliance with the applicable laws, which makes the RCC a private version of a court assessing compliance with food law (including the NHC-regulation).

Although the RCC is not a judicial institution (and is convened by representatives of advertisers, food business operators and consumer organisations), because of the approachability and low costs of the RCC it has become an established institution on the implementation of food law. As such - at least on first glance - parties get a full legal review of their case on the merits.

In 2014 the RCC ruled on a health claim by Dextro (case nr. 2014/00396), which was substantiated by Dextro with the argument that EFSA already ruled positively on the relevant health claim and more subsidiary that the claim only relates to non-specific health claim (art. 10 (3) NHC-regulation. In this case the RCC considers the EU-legislation and EU-case law and even considers German case law (as part of the argument of the advertiser). Based on those sources the RCC individually interprets the authorised claims, the assessment of EFSA and the claim of the advertiser. As such the RCC acts no different than a judicial court.

On one hand the activities of the RCC prevent long and costly procedures for consumers and food business operators, but on the other hand, the interpretation of the NHC-regulation (and CJEU -cases) should be able to be contested in front of a judicial court as well (as the final interpretation should lie with the CJEU). There is no appeal against an RCC judgement (which judgement is not binding in most cases), so the judgements of the RCC are almost never contested in court. This is a downside of the self-regulatory system. Especially if taken into effect that interesting points are put forward in the case law of the RCC.

With respect to claims for health claims 'on hold'(botanicals) the RCC has also developed its own case law . In its ruling of 20 June 2017 (case nr. 2017/00292) and others the RCC indicated that food business operators using an on hold botanical claim have the obligation to substantiate their claims, if such claim is contested (sufficiently substantiated) by a consumer or competitor. The mere referring to the health claim application is not enough. As for food business operators it will be hard to prove a specific effect (based on which the claim is made), as it is still not clear on a EU level what test should apply, the burden to prove a claim is pretty high. This can be prevented – as is indicated by the RCC - if a food business operator makes a statement with or alongside the health claim that that claim is an *'on hold claim*' or '*EFSA review pending*'.

The RCC in 2016 (case nr. 2016/00431) ruled in a case on a candy product named 'Goody Good Stuff' that this name could not be considered to be a (generic) health claim. The average consumer (in the Netherlands) will not consider the name Goody Good Stuff to relate to a specific health benefit of a candy. Even if such would be the case, the RCC is of the opinion that the ingredient declaration would remediate such misunderstanding.
The reasoning of the RCC incorporates the case law on misleading labels and the FIC-regulation to generic health claims (of which can be disputed whether this is the right approach). It is without further substantiation by the RCC not clear how it expects an average consumer to assess the health aspects of a product (that could have a name referring to (health) benefits) based on the ingredient declaration.

The RCC therefore provides an occasional interesting ruling in relation to health claims. The sustainability of such ruling is however never tested in a court, as most matters and at the RCC (either in first instance or in appeal) either because the labelling or advertising is amended or because the advertising is no longer used. This is to some extent disappointing from a food law theory perspective.

As indicated above, a case with the RCC is usually faster and cheaper than going through a civil or administrative court case. This enhances the appeal of the RCC in favour of the courts, not just for consumers but also for consumer organisations and competitors. The last years have shown an increased number of cases where consumer organisations (most prominently Foodwatch with about a dozen cases in the last two years) and competitors have filed complaints relating to health claims with the RCC.

To sum up, although the RCC provides much more case law than the Dutch civil and administrative courts, interesting cases relating to health claims (or other food law matters) usually end at the RCC. With the introduction of more stringent enforcement and higher fines, we are eager to see in the coming years whether more cases will be coming to the administrative courts and less to the RCC.

Self-regulatory rulings

As mentioned before, in the Netherlands the authority that enforces food law is the Dutch Food Safety Authority, the NVWA. The NVWA is authorized to impose fines on food business operators that do not comply with the NHC-regulation.

For its enforcement actions, the NVWA has its own enforcement policy (latest amendment is from early 2017), in which it 'prioritizes' which elements of its scope of authority should get the most attention. Violations of the NHC-regulation (unless when infant or child formulae are involved) are considered rather low in the enforcement priority and are included in the C-category (where the A-category includes the most serious violations and the D-category the least serious). Generally this means a warning will be given before any fine is imposed.

Besides the 'reactive' approach of enforcement of the NVWA, in the Netherlands there is also the Health Advertising Assessment Council, the *Keuringsraad KOAG/KAG*, is active. This is also a self-regulatory institution that provides advice on and assessment of advertising for medical and health products. In relation to health claims the Keuringsraad provides for the possibility to proactively have a health claim assessed on the basis of Dutch and EU legislation (including the NHC-regulation).

The Keuringsraad is a knowledgeable and experienced institution (but remains a self-regulatory and therefore private party). There is some recognition as the RCC incorporates the advice of the Keuringsraad in its rulings on medicinal and health products. Also the Keuringsraad has adopted guidelines on the flexibility on wording for authorised health claims and botanicals that are on hold. These guidelines have been drafted in cooperation with the NVWA, however the guidelines are not sanctioned by the NVWA and as such not legally binding on the NVWA.

A good aspect of the Keuringsraad is that they provide the opportunity to proactively assess a product, which means a food business operator can submit a draft-advertising or label for assessment. Although a positive assessment will not guarantee compliance (as this is up to the court), the assessment of the Keuringsraad will be of significant weight in a judicial matter.

Conclusion

As follows from the above, the Dutch courts have little hand in the development of health claim case law and interpretation. This case law is predominantly coming from the RCC. Current developments might change this on the longer term, which is positive from a legal theory perspective, but might be more of a (legal cost and fines) burden for food business operators.

Although the NVWA is not high-prioritising the enforcement of the NHC-regulation, enforcement is possible (and against more hefty fines in the future). A possibility to prevent this – to some extent – is prior assessment by the Keuringsraad.

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Recent national case law and administrative practices in Poland with regard to health claims

Authors: Grażyna Osęka & Marta Zawadka-Foodie Sp.z o.o. sp. k.

The control of the correct use of nutrition and health claims in Poland is primarily exercised by the State Poviat and Voivodeship Sanitary Inspectors. They have competence to verify all important data and information confirming the compliance of the labelling with Regulation No 1924/2006.

Polish official food control authorities have not developed national guidelines on the flexibility of wording for health claims, as in Finland (EVIRA), or relevant guidance for food businesses, as in the UK (FSA). In its administrative practice, the sanitary inspection considers legislation and the document developed by the European Commission in 2007: "Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods. Conclusions of the Standing Committee on the Food Chain and Animal Health" as well as the recommendations agreed by experts from Member States participating in the work of the European Commission's Working Group on Nutrition and Health Claims: "General principles on flexibility of wording for health claims" of 2012.

Claims are assessed individually by inspectors in the different poviats and voivodeships so interpretations of the same expressions often vary. A constant source of controversy is the word "**probiotic**", which is considered a health claim, according to the above-mentioned Commission guidance of 2007. Despite unambiguous conclusions made in the guidance, the approach followed by control authorities in the different Member States as regards the use of this expression is inconsistent. For instance, Italy adopted national guidelines on probiotics, according to which a claim "It supports the intestinal flora balance" is still allowed. In contrast, the Food Safety Authority of Ireland published an official interpretation of the word "probiotic" as an unauthorized health claim. Polish authorities have not followed Italy or Ireland in adopting an official position on the claim "probiotic", which leads to doubts and diverging interpretations among the different poviats and voivodeships.

The administrative practice of Polish food control authorities shows that flexibility of wording for health claims is strongly limited. Last year, the presentation and advertising of food supplements, including claims used in the labelling of Internet-sold products, were placed under intensified scrutiny. Botanical claims from the pending list and literature supporting the health declarations used were subject to particularly strict assessment.

Control of food supplements on the Internet, medicinal properties and the pending list

In its judgment of 11 October 2017, file No VII SA/Wa 2629/16, the Voivodeship Administrative Court in Warsaw held that a mere indication of a disease entity in food presentation or advertising suggested to the consumer that the product or its ingredients could positively influence health status improvement in a particular disease and implied the benefits of using them when suffering from certain diseases. Claims, displayed on a web portal, that the food "psyllium" helps to tackle the most persistent constipation and limit frequent diarrhea, and the food supplement "Alkaline powder" contributes to heartburn alleviation, thus suggest to the consumer health status improvement in specific diseases, listed in the International Statistical Classification of Diseases and Related Health Problems ICD 10.

Authorities also contested the presentation of the food supplement „Alkaline powder 300 g acidification" with regard to the following health claim: "Oligofructose is a natural ballast substance partially digested, with a prebiotic effect. It stimulates the digestive system to work, stimulates bifidobacterium development in the large intestine", which is neither listed in Annex to Regulation No 432/2012 nor in the so-called pending list.

The Court found that the act had a substantially harmful effect. Infringement of a provision aimed at protecting the consumer is among the more serious offences against food law. By attributing to products medicinal properties which they do not possess, one can exert a significant influence on human health and life, because consumers, believing that information included in presentation and advertising is true, may use these products for treatment, as a result of which their health may not only not improve but also deteriorate due to lack of medicinal properties. The degree of the harmful effect of the act was also influenced by wide coverage of published information – 523 consumers had bought incorrectly presented and advertised foods.

Scientific evidence substantiating claims from the pending list

The judgment of the Supreme Administrative Court of 4 April 2017, file No II OSK 1987/15, confirmed that the label with a description concerning zinc, selenium and vitamin E complied with Regulation No 432/2012. However, the validity of health claims from the pending list was questioned in the opinion by the Food and Nutrition Institute (Instytut Żywności i Żywienia – IŻŻ) attached to the case file. It contested the effect of the different food supplement ingredients at doses used in the product. They were assessed as too low to produce the claimed effect on humans (Tribulus terrestris). According to IŻŻ opinion, with regard to maca, its positive impact on sexual function was observed in clinical trials after a minimum of 4 weeks of treatment at doses of 1500-3000 mg. As regards L-arginine, the beneficial effect was demonstrated also at significantly higher doses. The Institute clearly concluded that there was no scientific basis to claim that an ad hoc, one-time use of the product [...] has any effect on sexual function.

Claims in press advertising indicating, inter alia, "a high content of L-arginine" as a "key substance to tackle problems with sexual performance", combined with a statement that "the after-effect is as if on cue" makes consumers hope that the desired effect will be quickly achieved, whereas, according to IŻŻ opinion, the beneficial effect of L-arginine was demonstrated at doses much higher than the one used in the controlled product.

Flexibility of wording for health claims

is subject matter of the judgment of the Voivodeship Administrative Court in Warsaw of 21 March 2017, file No VII SA/Wa 712/16. Pursuant to Article 10 (3) of Regulation No 1924/2006, reference to general, non-specific benefits of the nutrient may only be made if accompanied by an authorized health claim as referred to in Article 13 (health claims other than those referring to the reduction of disease risk and to children's development and health) or Article 14 (reduction of disease risk claims and claims referring to children's development and health), and Article 13 clearly relates only to health claims describing or referring to the role of a nutrient or other substance (and not the entire product).

The document of 19 June 2012 "GENERAL PRINCIPLES ON FLEXIBILITY OF WORDING FOR HEALTH CLAIMS", points out that the terms and conditions of the EU Register of nutrition and health claims made on foods state that health claims should only be made for the nutrient, substance, food or food category for which they have been authorized and not for the product that contains them. This is because the authorized claim describes the particular health relationship that EFSA said is substantiated by scientific evidence.

The document instructs that it is unacceptable to use such claims as: "Y contributes to the normal function of the immune system" or "Y contributes to the normal function of the immune system. Y contains X", as there is no clear link made between X and the claimed effect. The above-mentioned principle is reflected in the case law of Polish administrative courts.

The court held that the control authority had rightly concluded that the expressions used in a TV advert of the food supplement "T", claiming that: "The effect results from product ingredients. Prostrate knotweed extract has a positive influence on bacterial flora of the urinary tract. Dandelion root extract contributes to maintaining normal flow of urine", and not stating to which ingredient a given health claim relates constituted infringement of Regulation No 1924/2006.

It is worth pointing out that application of law in the Polish system is primarily based on deduction, which consists in examining each case for correctness in the light of a previously adopted abstract and general standard/pattern. What can be observed is casuistry, randomness and excessive length of the proceedings resulting from the 2 + 2 model (administrative authorities of the first and second instance and judicial-administrative authorities of the first and second instance).

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Marta Zawadka – translator, certified HACCP system auditor Marta Zawadka is responsible for reports concerning the marketing of foods abroad and cooperation with translation companies. She also participates in counselling projects from other domains of food law. Previously, she worked at the Association of Sugar Producers in Poland, performing tasks related to the organization's activity in the area of food law and product quality, inter alia, as part of cooperation with the European Association of Sugar Manufacturers. She is a graduate of MA studies in Applied Linguistics at the University of Warsaw and post-graduate studies: Systems of Food Safety and Quality Management at the Warsaw University of Life Sciences. She is currently doing undergraduate studies in Human Nutrition and Evaluation at the Warsaw University of Life Sciences.

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The consulting company Foodie sp. z o.o. sp. k. is celebrating the 10th anniversary of its activity this year. On this occasion, the Anniversary Conference "FOOD LAW: LABELLING, ADVERTISING, CLAIMS – KEY DEVELOPMENTS AND NEW INTERPRETATIONS" was organized on 22 May 2018 in Warsaw. As a guest speaker Bärbel Ines Hintermeier, LL.M. attended the conference in Warsaw.

Spanish reduction strategy on salt, sugar and saturated fat

Authors: Mónica Weimann & Cristina Sánchez Weickgenann

In February of this year, the Spanish Ministry of Health, Social Services and Equality together with the Spanish Food and Beverages Federation ('FIAB') launched a voluntary commitment campaign to significantly reduce salt, sugar and saturated fat levels in more than 3,500 products by 2020, to which more than 500 food and beverage companies have already signed up. The so-called "Collaboration Plan for the Improvement of Food and Beverages and Other Measures (2017-2020)" covers 44.5% of the products with added sugars in the shopping basket of the average Spanish family. As part of the plan, catering companies will improve the quality of meals offered in school canteens and hospital cafeterias: processed and fried products will be reduced, and more lean meat, fish, vegetables and fruit will be offered. Vending machines will offer between 30% and 50% more "balanced foods" and the maximum amount of added sugar in hot drinks machines will be reduced by 15%. The changes are intended to tackle diabetes, cardiovascular diseases, cancer, and obesity, in particular that of children. In addition, it is worth noting that the Catalan region of Spain introduced last year a tax on sugary soft drinks in a bid to improve public health by reducing sugar consumption on the advice of the World Health Organisation, aiming to change not only consumers' lifestyle habits, but also the producers' practices. Although Spanish trade associations and companies urged the Spanish government to repeal the aforementioned tax, contending that the sector feels discriminated against other products containing added sugars but not yet affected by the tax, the tax is still in force pending appeal before the Spanish Constitutional Court.

Botanicals

To date, no health claims have been authorised regarding botanicals, but a high number of health claims relating to them are in an "on-hold" status, subject to the transitional measure of art. 27(5) Reg. 1924/2006. Thus, health claims not included in the annex of Reg. 432/2012 and which are on hold, may still be made under the responsibility of food business operators, provided they comply with Reg. 1924/2006 and with existing national, in this case Spanish, provisions, until the appropriate decision has been taken by the European Food and Safety Authority (EFSA).

The legal landscape in Spain regarding botanicals is not unified in one single law, but spread out over various legal regulations, where the different herbs and plants that may be added to (specific) foodstuffs can be found:

1.- Royal Decree 3176/1983 of 16 November approving the technical health regulations for the production, circulation and trade of plant species for infusions for use in foodstuffs ("RD 3176/1983").

Article 3 of RD 3176/1983 lists a number of plant species that are authorised to be used in infusions, defined as "*the liquid product obtained after pouring boiling water over the plant species with the aim of extracting soluble components*".

2.- Royal Decree 1354/1983 of 27 April approving the technical health regulations for the production, circulation and trade of tea and derivatives ("RD 1354/1983").

RD 1354/1983 defines Tea as *"the young leaves and the healthy and clean buds, of the different species of the botanical genus "Thea", in good condition, conveniently prepared for human consumption, and possessing the aroma and taste characteristic of its variety and area of production*".

Furthermore, Article 3 of RD 1354/1983 establishes a classification of teas, including Green Tea, Black tea or tea, Semi-fermented tea or oolong tea, Decaffeinated tea, Soluble extract of tea and Flavoured tea.

3.- Medicinal Products and Medical Devices (Guaranteed Standards and Rational Use) Act 29/2006 of 26 July provides that "*plants which are traditionally regarded as medicinal and which are offered for sale without reference to therapeutic, diagnostic or preventive properties may be freely sold to the public, but street vending thereof is prohibited*".

Order of 3 October 1973, creating a special register for preparations based on medicinal plant species ("**ORD 3/10/1973**"), includes an annex listing 109 plant species that were regarded as "medicinal plants" and to which Act 29/2006 referred.

However, ORD 3/10/1973 (and thus its annex) was repealed in 2007 by Royal Decree 1345/2007 of 11 October, regulating the procedure of authorization, registration and conditions of dispensation of medicinal products for human use manufactured industrially, which establishes that "*plants traditionally regarded as medicinal regardless of their form of presentation, provided that they do not have the status of medicinal product and are offered without reference to therapeutic, diagnostic or preventive properties, can be sold freely, in the terms of Act 29/2006*".

In addition, Order SCO/190/2004, of 28 January, setting out the list of plants whose sale to the public is prohibited or restricted because of their toxicity ("**ORD 190/2004**") is worth mentioning, although it is not longer in force after being quashed by a judgement of the *Audiencia Nacional*, dated 29 June 2005, on the grounds of lacking legal formalities in its adoption.

Notwithstanding the above, following a Questions and Answers Document on RD 1345/2007, published on 24 July 2008 by the Spanish Medicines and Healthcare Products Regulatory Agency ('AEMPS'), the plants traditionally considered as medicinal may be freely sold to the public, as long as they do not refer to therapeutic, diagnostic or preventive properties and provided that they are not included in –quashed– ORD 190/2004. Thus, it may be concluded that the lists of both ORD 3/10/1973 and ORD 190/2004, despite being, respectively, repealed and quashed, are still applicable in practice.

4.- Royal Decree 2242/1984 of 26 September on technical-health regulations for the preparation, circulation and trade of seasonings and spices ("RD 2242/1984").

RD 2242/1984 defines spices or aromatic seasonings as "*the plants or parts thereof, fresh or dried, whole, chopped or ground, which by their characteristic colour, aroma or flavour are intended for the preparation of food and beverages, in order to incorporate these characteristics into making such food and beverages more appetizing and tasty and, consequently, achieving a better use for them*". Article 5 of RD 2242/1984 lists the 49 different seasonings and spices which may be used in food products and beverages.

5.- As can be inferred from the above, **in practice a high uncertainty exists** for food operators when marketing in Spain foodstuffs containing botanicals. This applies in particular to the issue of health-related claims made regarding botanicals, since none of the above referred regulations address this matter.

In order to gain an insight into the position of Spanish authorities and bodies on this, it is helpful to consult

(i) the FAQ of AECOSAN (the Spanish Consumer, Health and Nutrition Authority), which do not have any legal binding effect but are issued for information purposes only and

(ii) the adjudications made by AUTOCONTROL's (the Spanish Advertising Standards Association) Jury. The latter's adjudications only bind its members, although their moral authority is also accepted by non-members in the vast majority of cases. The acceptance of said moral authority is not only based on the result of the jurors' high awareness level, but also on the high regard that the self-regulatory organisation has achieved at a national and European level.

In particular, AUTOCONTROL's adjudications may serve as an indication on the legal situation of health-related claims in foodstuff containing botanicals. In this sense, **AUTOCONTROL has actually allowed the use of health claims regarding botanicals on certain products**, which matched on-hold claims in connection to these specific botanicals, stressing with it

(i) the prohibition that the specific health claim is made stronger than the on-hold claim, and

(ii) the need for a clear link between the botanical and the claim.

When advising on health claims in Spain, besides applicable EU regulations, reference has to be made to Royal Decree 1907/1996 of 2 August, regarding the advertising and commercial promotion of products, activities and services with alleged health-related effects ("RD 1907/1996"). This **regulation is a peculiarity of Spanish law** and although in force for over 20 years, it is still frequently applied by Spanish authorities and bodies in connection to health-related claims on foodstuffs, in particular food supplements.

Its scope refers to "*products, activities and services with alleged health-related effects*", which are to be understood as products, materials, methods or substances that do not fall under the category of medicinal o pharmaceutical products and that are promoted as useful for the diagnosis, prevention or treatment of diseases, as well as for the enhancement of the physical and mental health condition. Usually these products, materials, substances or methods are intentionally misrepresented and portrayed to the customer through the use of messages, illustrations or suggestions pointing to a state of health, a medical, pharmaceutical or therapeutic state, that neither reflect reality, nor have any scientific backing. The results are false information and abusive advertisement that may often harm the consumer, as the product poses an actual threat or as the due care and attention when using the product is being neglected. Especially since the marketing of these products via the internet, radio or television is virtually uncontrolled, it is imperative that the control by the State is reinforced in order to guarantee public health and avoid future risks for the consumer.

For such purpose RD 1907/1996 lays down a number of prohibitions for the advertising and promotion - be it direct or indirect, massive or individualised - of products that:

- Have as an aim preventing, treating or curing communicable diseases, cancer and other tumorous diseases, insomnia, diabetes and other metabolic disorders.
- Suggest specific slimming or anti-obesity properties.
- Claim a therapeutic utility for one or more diseases, without complying with the requirements provided in Law 29/2006.
- Provide assurances of relief or certain healing.
- Rely on being backed by any type of authorizations, approvals or controls from health authorities of any country.
- Refer to their use in health centres or to their distribution through pharmacies.
- Intend to provide testimonies of health professionals, celebrities or people known by the public or of real or supposed patients, as a means of inducing consumption.
- Intend to replace the common diet or nutrition, especially in cases of maternity, breastfeeding, childhood or old age.
- Attribute to certain forms, presentations or brands of food products for ordinary consumption, concrete and specific preventive, therapeutic or curative properties.
- Attribute to food products, for use in dietary or special regimes, preventive, curative or other properties different from those recognized according to their special regulations.
- Attribute to cosmetic products properties other than those recognized in accordance with their special regulations.
- Suggest or indicate that their use or consumption enhances physical, mental, sports or sexual performance.
- Use the term "natural" as a characteristic linked to therapeutic claims or effects.
- Attribute a superfluous nature or intend to substitute the utility of legally recognized medicines or healthcare products.
- Attribute a superfluous nature or intend to substitute the consultation or the intervention of healthcare professionals.
- Attribute specific preventive or therapeutic effects that are not backed by sufficient technical or scientific evidence expressly recognized by the Spanish health authorities.

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The Swedish Consumer ombudsman foraging for botanicals

Author: Magnus Friedberg; Gulliksson

The Swedish Consumer ombudsman – "the CO", has brought a lawsuit against Mezina AB a daughter company to Mezina A/S for violation of Regulation 1924/2006. The more interesting part of the suit concerns botanicals and the CO's interpretation of the transitional rule in article 28.5.

Incidentally, the supervision of the food legislation with regard to claims, e.g. the Information Regulation 1169/2011 and the Regulation on nutritional claims and health claims for food 1924/2006, falls primarily on the National Food Agency and the local food agencies in the various municipals; but the Swedish Consumer Agency and the CO also have a stake in this. Simply put; the food agencies take care of labelling and what goes on "on-pack" and the Consumer Agency and the CO take care of claims made in other forms of advertising and marketing activities. Hence the CO's place in this matter.

The more interesting part of this case as already stated concerns **botanicals**. The products in question contains ginger, boswellia, rose hip, artichoke, dandelion and blueberry all for which health claims are made.

Both parties agree that all the claims made correspond with the claims subject to pending applications. So, that is not a problem. Some of the claims made have been assessed by EFSA with negative results, but that is not really an issue either. The CO's **main complaint is that the claims have not been substantiated by Mezzina, based on generally accepted scientific evidence.** Therefore, the claims are in violation of the Regulation articles 3 a, 5 and 6 of the Regulation, and in addition the claims are in violation of the Swedish Marketing Act, sections 5 and 10. Thus, the claims are not in compliance with the Regulation or national applicable provisions.

As Mezina has argued, this can only be understood as meaning that the operator has to present its own evidence in support of the claims to uphold its responsibilities according to the Regulation. It apparently cannot rely on the evidence filed with the application for approval. This would in turn mean that stricter requirements would apply on operators use health claims based on article 28.5 than other operators using health claims approved by the EU-Commission. The latter can rely on the scientific basis for the claims on which they have been approved. This would also mean relying on evidence they cannot rely on once the claim has been assessed – approved or not as an operator according to the Regulation cannot refer to other evidence than that which has been the basis for the approval. Why should this category of operators be treated differently than others?

The question is what does the operators "responsibilities" include in the cases of claims concerning botanicals on hold – assessed by EFSA or not? Which claims are to be considered to be on hold? The ones where EFSA has not yet made an assessment of the application or all pending applications regardless? In the meantime, should the responsibilities mean that the operator has to provide its own scientific evidence in support of the claims made? If so what happens if national courts come to different conclusions concerning the evidence provided by the operator or if we subsequently have an approval or for that matter rejection on the EU-level; are these operators rely on their own evidence in violation of the law? Another question is of course, what about the application of Swedish national legislation? In the Mezina-case the CO claims that the claims are unsubstantiated and therefore misleading and in violation of good practice according to the Marketing Act. Can a member state invoke national legislation in this way to, so to say, not just put claims on hold but effective put stop to them?

Mezina finds support for its position in the Swedish National Food Agency's guidelines. The guidelines support to claim that "generally accepted scientific evidence" means the evidence on which the application is based on as well as on other points. The Swedish food supplement industry organization "Svensk Egenvård" also supports Mezinas position as well as Food Drink Europe. But it is unclear what the operator's "responsibility" in article 28.5 and what "generally accepted scientific evidence" really means in these cases.

The parties agree that there is no case law from the European Court of Justice on point and therefore support the CO's motion for a request for a preliminary ruling by the Court of Justice of the EU (CJEU). Maybe by that time the issue of botanicals has been resolved – who knows.

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The French authorities strengthening position on food control: an overview of their 2017 activity report and 2018 controls perspectives

Author: Antoine de Brosse

The activity report and control perspectives of French official services was released in early February.

For food regulated matters, companies are controlled at a local level by the Department Directorate of Populations Protection ("DDPP") and the Department Directorate for Social Cohesion and Populations Protection ("DDCSPP"). They both bring together the former Departmental Directorate for Competition Policy, Consumer Affairs and Fraud Control ("DDCCRF") and Veterinary services ("DSV").

These two former Departmental Directorates remain linked to their respective national administrations, the General Directorate for Competition Policy, Consumer Affairs and Fraud Control ("DGCCRF") and the General Directorate of Food ("DGAL"), according to competence assignments provided by the Rural Code and the Consumer Code.

The "DGCCRF" and the "DGAL" have published their activity reports for 2017, which give interesting information on the past year and the year to come.

As concerns, the former fraud and competition services, these latter proceeded to more than 500000 controls, observed around 125000 breaches and infringements in 2017, which resulted in more than 100000 informative follow-ups or correctives measures to comply with the regulation requirements, and about 5000 criminal or administrative transactions or trials.

A focus was made on e-commerce activities; indeed, more than 10,000 websites were controlled, especially those dedicated to the sale of food supplements.

The report of the DGCCRF also indicates that its official laboratories (common laboratory service or "SCL") have developed new methods of analysis, especially for the detection of fipronil in eggs and nanomaterials in food. These methods allowed the implementation of numerous labelling controls for such substances.

It remains to be seen whether these new methods of analysis comply with the requirements of the European rules in this area.

The priorities of the French authorities for 2018 will include, in addition to the recommendations of the national food program, the control of websites and emerging risks, such as endocrine disruptors or nanomaterials also present in food packaging.

As concerns former Veterinary services, the statistics of the "DGAL" clearly indicate an **increase of the controls**. The measures regarding imported foodstuffs, phytosanitary products, food hygiene, animal health and protection were mostly taken through the administrative procedure rather than criminal one. Such administrative procedure allows the administration to order companies to correct, stop or modify their practice to comply with regulation in a very fast manner.

"DGCCRF" priorities for 2018 will focus on **better integration of fraud risk** in national inspections plans. A focus on animal protection in slaughterhouse, chemical risks or risks linked to the use of critical antibiotics in veterinary medicine is also planned.

The European Commission's missions include audits of the official services of the Member States to ensure that they properly monitor companies' compliance with European Union rules. The Commission indicated the actions of the French services (e.g. "DDPP", "DGCCRF", "DGAL" ...) will be monitored in 2018. The Commission will verify in particular the action of the French services in terms of labelling, nutrition and health claims, seafood products, sustainable use of pesticides, animal proteins, import procedures.

French authorities will necessarily strengthen their control on all the above-mentioned aspects of the regulation, in order to justify their action towards the Commission. Companies can therefore expect to be controlled in these areas.

Lastly, in December 2017, the French "Court of Accounts" (a financial jurisdiction controlling the public accounts) formulated several recommendations to the French Ministry of the Economy and Finance to reinforce the sanctions on food law in the context of the on-going discussion in France **to improve access to quality food and the scandal of infant milk**.

It proposed that **fines for infringements** (e.g. misleading labelling) should no longer be strictly fixed but calculated based on a percentage of the turnover generated by the infringement practice. It also proposed that consumers could be compensated when a transaction is settled between the Prosecutor and a company. At last, the Court of account proposed to systematically publish the pronounced sanctions and that the EU increases help cooperation between national official services for the recovery of pronounced sanctions, knowing that cooperation in terms of information between national official services already exists, particularly with regards to fraud.

Even if they are merely recommendations, it is quite possible that a part of them will be adopted by the French Parliament in the future; the trend is to reinforce the sanctions.

Advice

Due to a reinforcement of controls and sanctions, it will be wise to check the legal compliance of the company's website and the presence of endocrine disruptors and nanomaterials in products, materials and objects in contact with food (e.g. packaging) especially if they are operating in France.

The text

Link to the "DGCCRF"'s 2017 annual report:
https://www.economie.gouv.fr/files/files/directions_services/dgccrf/dgccrf/rapports_activite/2017/resultats-dgccrf-2017.pdf

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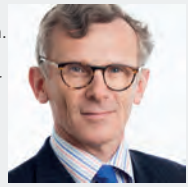

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Recent developments in Lithuania regarding national particularities. Reduction of acrylamide levels in food

Author: Tadas Vilčinskas; Lextal

Acrylamide is a carcinogenic substance produced from free asparagine (amino acid), naturally present in products and sugars when potato, cereal products, coffee and coffee substitutes are treated in high temperatures (roasted, fried or baked).

As from 11 April 2018, a regulation laying down that food producers have to substantially reduce the levels of the substance, which develops in food and is hazardous to human health, i. e. acrylamide, came into force all over the EU. Such regulation was established after the European Food Safety Authority (EFSA) had confirmed the previous considerations that the presence of acrylamide in food may increase the risk of oncological diseases in consumers in all age groups. Establishments producing baked, roasted, fried foodstuffs or establishments producing dishes for catering as well as farmers growing certain kinds of food plants (potatoes, cereals) will have to adapt to the new regulation.

The most frequently consumed products with potential presence of acrylamide are: roasted or fried potatoes, potato chips, coffee (acrylamide is produced in the process of roasting coffee beans), cookies, crackers, wafers, gingerbreads, cakes, crisp or soft bread, etc.

Producers of risky products will have to continuously monitor the levels of acrylamide in their production, select samples and analyse the testing results. In case of detection of increased levels of acrylamide, they will have to apply the acrylamide reduction measures specified in the regulation. For example, the good manufacturing practice for bread and other fine bakery products shows that the acrylamide levels in final products can be substantially reduced by increasing the duration of the yeast fermentation process, regulating the baking temperature and time, visual assessment of the colour (browning) of products. The monitoring process will be carried out by State Food and Veterinary Service.

Catering establishments will have to apply colour palettes / manuals in Lithuania in order to reduce the acrylamide levels in roasted or fried dishes among other measures taken by State Food and Veterinary Service. For ready-to-eat products future monitoring developments and regulation will follow.

Author

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Slovenia becomes next country to introduce restrictions on trans-fatty acids in foodstuffs

Author: Nives Slemenjak

Among the constantly evolving measures aimed at consumer protection and health is the introduction of maximum permitted levels of trans-fatty acids ("TFA") in foodstuffs. Slovenia has joined certain other (EU) countries, which already restricted the content of TFA in food, by adopting new rules laying down maximum permitted levels of TFA in foodstuffs (*Pravilnik o največji dovoljeni vsebnosti transmaščobnih kislin v živilih*, "TFA Rules").

Following the notification procedure at the European Commission in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015, the TFA Rules were adopted on 19 March 2018 and published a day later.

The TFA Rules shall apply as of 4 April 2018 with a one-year transition period.

Maximum levels and scope of application

The maximum permitted TFA level in foodstuffs is 2 g per 100 g of total fat content in the foodstuff applying to the following products (prepackaged and non-prepackaged):

- vegetable oils, fats and fat emulsions; and
- foodstuffs containing such oils, fats and fat emulsions.

Animal oils and fats as well as foodstuffs in which the content of TFA is the result of their natural presence in animal oils and fats forming an integral part of these foods are explicitly excluded from the application of the TFA Rules.

Who will have to observe the TFA Rules?

The TFA Rules apply to all relevant foodstuffs marketed in Slovenia, regardless of their country of origin.

That said, all manufacturers of products containing TFA, either based in another EU Member State or a third country, who market or intend to market their products in Slovenia, are obliged to follow the TFA Rules.

Non-compliant products on the market prior to the TFA Rules

The entry into force of the TFA Rules on 4 April 2018 does not mean that all products already placed on the Slovenian market that do not comply with the TFA Rules need to be removed.

A one-year transition period, under which non-compliant foodstuffs placed on the market prior to the enforcement of the TFA Rules may be sold until stock depletion and until 4 April 2019 at the latest, will apply.

From 4 April 2019 onwards, all foodstuffs containing TFA and marketed in Slovenia must comply with the TFA Rules requirements.

Increased inspection procedures

A recent national research project revealed an increase in the use of TFA as well as the presence of high levels of TFA in certain products in the past years, particularly baked goods. Increased inspection procedures and regular compliance checks are thus expected.

Demonstrable non-compliance with TFA Rules can result in fines of up to EUR 10,000 per breach. If food safety is concerned, non-compliance may also trigger fines under other regulations. In certain cases, inspectors also have the authority to prohibit the marketing of non-compliant products.

Author

Nives Slemenjak joined Schoenherr in 2012, where she predominantly engages in employment law matters and is also frequently active in the area of regulatory. As a member of Schoenherr's regulatory team, Nives has been advising numerous clients regarding diverse legal requirements in relation to marketing of food products in Slovenia (particularly labelling and advertising compliance) and has fine-tuned her strong expertise in the field of food law. Amongst other regulatory-specific areas, she also holds knowledge in field of pharmaceutical law, including regulation of medicinal and chemical products (such as cosmetics etc.).

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