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CIVIL LIABILITY FOR DAMAGE CAUSED BY A DIETARY SUPPLEMENT

Abstract

This paper is an attempt to answer a question concerning the existing legal framework and whether or not it is sufficient to ensure civil liability for damages caused by the consumption of a defective dietary supplement.

The issue of proper regulation of liability for the defects of unsafe food products will become increasingly important in view of the rapid development of food production and consumption. It is assumed that normative sanctioning of that type of liability should primarily contribute to ensuring better protection of the consumer. However, the example of liability of damage caused by consuming dietary supplements illustrates that we are dealing with a multi-dimensional issue that may go beyond the applicable regime.

The existing legal framework is insufficient to ensure civil liability for damages caused by the consumption of a defective dietary supplement. It is a direct consequence of the specific nature of dietary supplements and the lack of an adequate risk analysis when adding a definition of that product to EU law. *De lege ferenda,* it is imperative that the term of a product 'defect' be expanded and that additional disclosure duties are imposed on manufacturers, among others.

KEYWORDS

dietary supplement, civil liability, defective product, unsafe product

SŁOWA KLUCZOWE

suplement diety, odpowiedzialność cywilna, produkt wadliwy, produkt niebezpieczny

INTRODUCTION

Given the need to ensure food safety, humankind currently faces the need to search for alternative sources of food that will be manufactured in a manner that is primarily neutral to the climate. That, in turn, implies the development of ways to manufacture and consume food products that have been produced using new technologies – foods that frequently do not resemble 'traditional' foods at all.[1] Dietary supplements are an example of such foods. It is extremely difficult to predict the health effects of bringing such food products to the market. With modern production technologies and innovative raw materials used for the manufacturing of products that are intended to be placed on the market, the products have become more and more complex. The same is true for food products. As a result, ensuring control of their safety has become increasingly difficult, and thus it has become more likely that products will have defects that have not been seen before.[2] That leads to all types of risks and creates new threats unknown before.[3]

Therefore, legal regulations that cover genetically modified foods, new foods or dietary supplements now have to face a very significant challenge which "comes down to major difficulties (if not downright impossibility of) determining the safety of using such food already when the product is put on the market".[4] That is because in each case there is 'created' a kind of a 'legislative safety standard' which is a response to the lack of an actual safety standard; the actual safety

[1] See: P. Wojciechowski, *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny żywnościowy pierwotny i przetworzony. Wybrane problemy*, "Studia Iuridica Agraria" 2011, Vol. IX, p. 329.

[2] E. Łętowska, *Ustawa o ochronie niektórych praw konsumentów, komentarz*, Warsaw 2000, p. 111.

[3] E. Kremer, *Odpowiedzialność za zobowiązania związane z prowadzeniem gospodarstwa rolnego*, Kraków 2004, p. 113.

[4] M. Korzycka-Iwanow, *Kilka uwag o „ryzyku rozwoju" w regulacjach żywności zmodyfikowanej genetycznie (GMO), nowej żywności i suplementu diety, "*Forum Prawnicze" February 2012, p. 18.

standard is missing due to a serious gap in scientific knowledge or uncertainty as to the product qualification which arose in relation to the defectiveness of law.[5]

It is of key importance to regulate liability for the defects of such products properly. Failure to adapt the traditional liability regimes – *ex delicto* and *ex contractu* – to the needs arising from the intense development of production and commerce provided the main impetus for introducing a legal regulation governing product liability.[6] It is assumed that normative sanctioning of that type of liability should primarily contribute to ensuring better protection of the consumer as an economically weaker party. However, the example of liability of damages caused by consuming dietary supplements shows that we deal with a multi-dimensional issue that may go beyond the regime of liability for a defective product. Thus, it is reasonable to pose a question whether or not the existing legal framework is sufficient to ensure civil liability for damages caused by the consumption of a defective dietary supplement.

The issue of liability for unsafe food has already been subject to a dissection in the legal literature.[7] Therefore, this paper only tackles selected legal issues concerning dietary supplements and it is only limited to issues relating to proving the defectiveness of dietary supplements as a criterion of liability for an unsafe product.

1. THE ISSUE OF RISK WHEN USING DIETARY SUPPLEMENTS

The variety of legal solutions that function in the individual Member States of the European Union made the free movement of dietary supplements on the single market more difficult. It was found that the issue would be solved by adopting community regulations concerning those products that are sold as foodstuffs. On 10 June 2002, the European Parliament and the Council passed Directive 2002/46/EC on the approximation of the laws of the Member States

[5] *Ibidem*.

[6] P. Wojciechowski, *Odpowiedzialność...,* p. 330.

[7] See for example: P. Wojciechowski, *Odpowiedzialność...;* M. Korzycka-Iwanow, *Kilka uwag...;* M. Jagielska, *Odpowiedzialność za produkt,* Warsaw 2009; M. Jagielska, *Podstawy odpowiedzialności za produkt,* Warsaw 2004; M. Stańko, *Odpowiedzialność za produkt żywnościowy w polskim systemie prawnym, "*Studia Iuridica Agraria" 2009, Vol. 7; I. Trapè, *Odpowiedzialność za produkt niebezpieczny podmiotów dystrybuujących żywność,* "Przegląd Prawa Rolnego" 2008, No. 2; Ł. Sokołowski, *Cywilna odpowiedzialność za szkodę wyrządzoną przez niebezpieczny środek spożywczy,* LEX/el. 2017; K. Leśkiewicz, *The legal concept of unsafe (dangerous) food*, "Studia Iuridica" 2023, No. 95; etc.

relating to food supplements.[8] Before it was issued, there were discussions based on the Green Book and White Book which highlighted the need for implementing the duty to analyse risk when creating food law. Introducing into law a definition of a new product that is consumed due to human physiological needs should be accompanied by presenting a reliable scientific foundation that would justify its free circulation in the EU market, and in this case such foundation was missing.[9]

As for the language of Directive 2002/46/EC, readers are struck by a vague diagnosis of the social situation.[10] Pursuant to Article 1, the Directive concerns food supplements marketed as foodstuffs and presented as such. While reading it, one may conclude that even though dietary supplements are governed by food law, they are not strictly food.[11] However, the next article of Directive 2002/46/EC reads that dietary supplements are in fact qualified as foods in normative terms; however, due to their specific nature they are not only subject to special provisions, but they are also in a certain position vis-a-vis foods that make up 'normal' diet[12] as they are products whose purpose is only to supplement that diet.

The nature of the risk relating to the consumption of dietary supplements is multi-dimensional. It should be considered not only from the perspective of 'typical' defects that one may come across in the case of such products but also from the perspective of specific health risks they generate. The literature on the topic recommends taking dietary supplements when identifying specific symptoms that indicate a deficiency of specific minerals and getting medical advice in case of any concerns.[13] That is because vitamins and minerals and certain plant-based preparations also appear on the list of ingredients of the over-the-counter (OTC) medicines. Consequently, dietary supplements may lead to pharmacotherapy complications when they are taken along with certain medicines due to interactions between the ingredients of the supplements (vitamins, minerals, herbs and others) and commonly used medicines.[14] Taking dietary supplements lowers

[8] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, OJ L 183 of 12 July 2002, p. 51 as amended – hereinafter: "Directive 2002/46/EC".

[9] M. Korzycka (in:) M. Korzycka, P. Wojciechowski, *System prawa żywnościowego*, Warsaw 2017, p. 179; see: M. Korzycka-Iwanow, M. Zboralska, *Never-Ending Debate on Food Supplements: Harmonisation or Dishar-monisation of the Law, "*European Food and Feed Law Review" 2010, No. 124, pp. 124-125.

[10] See: Recital 3 to Preamble to Directive 2002/46/EC.

[11] M. Korzycka (in:) M. Korzycka, P. Wojciechowski, *System...,* pp. 179-180.

[12] See Article 2 letter a) of Directive 2002/46/EC.

[13] E. Laye, *Top 10 suplementów diety. Najskuteczniejsze środki odżywcze o naukowo udowodnionym działaniu,* Białystok 2018, pp. 13-135.

[14] M. Jarosz, K. Wolnicka, *Interakcje pomiędzy lekami a suplementami diety* (in:) *Uważaj, co jesz, gdy zażywasz leki. Interakcje między żywnością, suplementami diety i lekami. Porady lekarzy i dietetyków*, (eds.) M. Jarosz, K. Wolnicka, Warsaw 2007, pp. 94-95.

the absorption of certain drugs, for example, antibiotics or cardiological drugs; it may also increase their excretion from the body or disrupt the metabolism. Furthermore, it has been demonstrated that large doses of dietary supplements may be harmful to human health and excessive use of supplements increases the risk of malicious cancer (among other things).

According to the Polish Sanitary Inspectorate data, dietary supplements have for years been listed at the top of incorrectly labelled products, primarily because they claim to have therapeutic effect.[15] The same problem applies to their presentation and advertisement. Inspections carried out by the Commercial Inspection in 2018 revealed that some 20% of dietary supplement batches subject to inspection contained irregularities, mainly concerning the labelling, as well as inadequate commercial quality, presentation and shelf life.[16] In the majority of cases, there was no question about their impact on the safety of dietary supplement use; "the irregularities included but were not limited to the following: (...) failure to indicate the portion recommended for daily consumption; failure to state "Not recommended for use in children and pregnant women" in case of products containing caffeine; (...) listing the colouring agent Tartrazine without making an additional statement reading "Tartrazine may have an adverse impact on activity and attention in children"; failure to give a statement to the effect that the products should be stored out of the reach of young children; lack of a statement to the effect that food supplements should not be used as a substitute for a varied diet; lack of a warning not to exceed the stated recommended daily dose (...)".

It is worth noting that the Commercial Inspection did not deal with the issue of labelling, presentation or advertising dietary supplements which suggested characteristics that the products do not possess because, by the very definition, they cannot possess such properties (for example, reducing body mass, 'rejuvenating' skin or hair, etc.). Meanwhile, the EU legislator resolved that issue and highlighted its importance while expressly banning, in Article 7(1)(b) of Regulation (EU) No. 1169/2011, misleading food information that attributes to the food product (including a dietary supplement) effects or properties which it does not have. It, therefore, needs to be considered whether or not the liability for damage arising from the above circumstances may be enforced under the regime of liability for an unsafe product.

[15] *Reports as part of the cycle on Poland's sanitary condition (Stan sanitarny kraju), 2007- 2013. Chief Sanitary Inspectorate in Poland*; www.gis.gov.pl (accessed 30 April 2023).

[16] *Informacja z kontroli jakości handlowej suplementów diety w zakresie oznakowania, w tym zgodności składu faktycznego ze składem deklarowanym na opakowaniu.* Commercial Inspection, Office of Competition and Consumer Protection; https://uokik.gov.pl/download.php?plik=21043 (accessed 30 April 2023).

2. BASES OF CIVIL LIABILITY FOR DEFECTS OF DIETARY SUPPLEMENTS

There is one common liability regime for unsafe products 'in general' in the entire European Union. Like other EU member states, Poland has implemented Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products as part of its legal system.[17] While there were certain difficulties implementing Directive 85/374/EEC and the process was not fully successful,[18] the Polish regulation which is set out in Articles 449^{1}–449^{11} of the Civil Code Act of 23 April 1964[19] does not demonstrate any significant defects and does not depart from the 'spirit' of the directive adopted by the majority of the EU member states.[20] That is because most member states took advantage of the possibility of excluding liability for 'development risk' (except for Sweden, Finland and Luxembourg); Spain, on the other hand, excluded the possibility of invoking that reason in the case of foods and medicines.[21]

Civil liability for defective food (including dietary supplements) is a special risk-based liability regime that does not necessitate proving the perpetrator's fault. Broadly speaking, marketing a defective product is a tort that is decisive for assigning such liability. The manufacturer is typically the liable party, and any person who suffered a loss as a result of the product defect is the party afforded protection. Such liability applies to consequential damages; it cannot be excluded or limited. Furthermore, it is not an absolute liability; the manufacturer may release itself from that liability by taking advantage of specific statutory defences.

3. UNSAFE, DEFECTIVE OR DANGEROUSLY DEFECTIVE DIETARY SUPPLEMENT

Directive 85/374/EEC uses the term "liability for damage caused by a defect in a product" (Article 1); meanwhile, Title VI^{1} of the CC implementing its provi-

[17] OJ L 210 of 7 August 1985, pp. 29-33, as amended; hereinafter: "Directive 85/374/EEC".

[18] See: M. Jagielska, *Rozdział 2 Dyrektywa o odpowiedzialności za produkt wadliwy* (in:) *idem*, *Odpowiedzialność za produkt,* Warsaw 2009.

[19] hereinafter: "CC".

[20] See: B. Gnela (in:) *Kodeks cywilny. Komentarz. Tom III. Zobowiązania. Część ogólna (Article 353-534),* (eds.) M. Fras, M. Habdas, Warsaw 2018, Article 449(1); https://sip.lex.pl/#/commentary/587770159/567599/fras-mariusz-red-habdas-magdalena-red-kodeks-cywilny-komentarz-tom-iii-zobowiazania-czesc-ogolna...?pit=2023-04-29&cm=URELATIONS (accessed 30 April 2023).

[21] M. Korzycka-Iwanow, *Kilka uwag*..., p. 7.

sions in Article 449[1]ff employs the term "damage caused by an unsafe product". As a result, the literature on the topic includes concepts as to why use such a distinction[22] and whether it is right.[23] It seems reasonable to concede to a view that "the Polish regulations on product liability actually concern a product which does not ensure safety as a result of its defects, or a dangerously defective product"[24] (or, in other words, unsafe product defects).

The difference between the terms 'defect' [*wada*] and 'unsafety/danger' [*niebezpieczeństwo*] must be emphasised. In essence, a product that is proper, fit for the intended use and fully operational (i.e. not defective) can also be a source of danger that will result in a damage as it may be unsafe to others due to its other qualities, for example, due to the use of inappropriate (e.g. toxic) substances for its production.[25] Therefore, a product defect may be, but does not necessarily have to be, the reason behind its unsafe qualities. As a consequence, it is assumed that the term 'unsafe' product [*produkt niebezpieczny*] is broader than the term 'defective' product [*produkt wadliwy*].[26]

That issue is of special importance in terms of food products such as dietary supplements. No marketing authorisation needs to be obtained for dietary supplements that would require carrying out several tests (which is the case with medicinal products), and the danger relating to their use does not necessarily have to result from defects existing in such products. Both deficiency and excess of nutrients in diet may cause certain side effects and medical conditions.[27] According to M. Korzycka, a defect ('defectiveness') of a product is otherwise a failure to ensure a product's safety to a degree that a consumer has the right to expect.[28] Dietary supplements may be a good example of when

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[22] See: E. Łętowska, *Ochrona niektórych praw konsumentów. Komentarz*, Warsaw 2001, p. 121; C. Żuławska (in:) G. Bieniek, H. Ciepła, S. Dmowski, J. Gudowski, K. Kołakowski, M. Sychowicz, T. Wiśniewski, C. Żuławska, *Komentarz do kodeksu cywilnego. Księga trzecia. Zobowiązania, Vol. 1,* Warsaw 2011, p. 707.

[23] B. Gnela (in:) *Kodeks*..., Article 449(1), item 31; https://sip.lex.pl/#/... (accessed 30 April 2023).

[24] *Ibidem*; see: B. Gnela, *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny (tzw. odpowiedzialność za produkt),* Kraków 2000, p. 277; B. Gnela, *Odpowiedzialność za produkt (uwagi o polskiej regulacji),* "Państwo i Prawo" 2009, Book 9, p. 36; cf M. Stańko, *Odpowiedzialność*..., p. 254.

[25] J. Kuźmicka-Sulikowska, *Pojęcie produktu niebezpiecznego na gruncie przepisów kodeksu cywilnego dotyczących odpowiedzialności za szkodę wyrządzoną przez ten produkt* (in:) *Księga dla naszych kolegów: prace prawnicze poświęcone pamięci doktora Andrzeja Ciska, doktora Zygmunta Masternaka i doktora Marka Zagrosika (praca zbiorowa),* Wrocław 2013, p. 248.

[26] S. Sikorski, *O odpowiedzialności za szkodę wyrządzoną przez produkt niebezpieczny,* "Prawo Spółek" 2003, No. 12, pp. 35-36.

[27] I. Ozimek, N. Przeździecka-Czyżewska, *Reklama suplementów diety* (in:) *Ochrona prawna konsumenta na rynku mediów elektronicznych,* (ed.) M. Królikowska-Olczak, B. Pachuca-Smulska, Warsaw 2015, p. 73.

[28] M. Korzycka-Iwanow, *Prawo żywnościowe. Zarys prawa polskiego i wspólnotowego*, Warsaw 2005, p. 160.

defectiveness should be understood so broadly for the purpose of food law and the special protection of food consumers.

For the sake of clarification, it is worth noting the two colloquially distinguished types of products that are unsafe.[29] On the one hand, there are the so-called '*per se* unsafe products', where the risk of damage is an immanent consequence of their nature – alcoholic beverages may be given as an existing example (however, we cannot rule out a future situation where certain dietary supplements are also considered to be such products). On the other hand, some products are unsafe because their quality is inadequate. Inadequate quality includes both direct defects in a product (e.g. manufacturing defects, instruction defects, for example, when the suggested daily dosage of a dietary supplement is too high), as well as products that are fully operational and fit for the intended use but that give rise to a threat due to the use of some inappropriate substances in their production,[30] such as allergens.[31]

The most simplistic view assumes *a priori* that any damage caused by *per se* unsafe products will be automatically excluded from the scope of application of liability for an unsafe product.[32] There are, however, several cases where the assumption that a product is unsafe should not exclude liability for the damage caused by such a product (for example, when the product contains harmful contaminants in addition to typical ingredients[33]). Furthermore, it is worth noting situations where the manufacturers fail to put the relevant information or warnings on the product (for example, information on the content of specific substances, such as "contains fibre", "contains vitamin D" or information about the absence of certain substances, such as: "no preservatives", "no added sugar", "no phosphates", "no gluten", or "no antibiotics"), or where manufacturers provide wrong or incomplete information and such information is indispensable for the correct and safe use of a given product.[34] Those issues must be taken into consideration when assessing the defects in the dietary supplements.

[29] J. Kuźmicka-Sulikowska, *Pojęcie produktu…,* p. 261.

[30] M. Jagielska, *Podstawy...*, pp. 59-63.

[31] See: P. Wojciechowski, *Informacja o braku zawartości określonych substancji w żywności w regulacjach prawa żywnościowego,* "Przegląd Prawa Rolnego" 2018, No. 1 (22).

[32] E. Bagińska, *Nowe unormowanie odpowiedzialności cywilnej za produkt,* "Przegląd Sądowy" 2000, No. 9, p. 53.

[33] Z. Banaszczyk, P. Granecki, *Produkt niebezpieczny per se i niebezpiecznie wadliwy a odpowiedzialność producenta z art. 449[1] i nast. KC, "*Monitor Prawniczy" 2002, No. 17, p. 781.

[34] See: P. Wojciechowski, *Informacja…,* pp. 103-121.

4. CRITERIA OF DIETARY SUPPLEMENTS DEFECTIVENESS

The fact that there is no definition of an 'unsafe product defect' [*niebezpieczna wada produktu*] in the Civil Code (Article 6(1) of Directive 85/374/EEC) implies interpretation issues under Article 449[1] § 3 of the CC. Under Article 449[1] § 3 of the CC, the criterion of product safety is examined upon considering its 'normal' use. Meanwhile, the provisions of Directive 85/374/EEC disregard only those cases of incorrect product use that need to be considered unreasonable under specific circumstances which means that the criterion adopted in the CC is much narrower.[35] It is, therefore, proposed that the term 'normal' use of a product, as used in the CC, be understood as the foreseeable use of a given product resulting from its intended use or the uses of a given product known in practice. In addition, it should be assumed that by exercising due diligence, a manufacturer should know frequent situations in which its products are used incorrectly and should counteract such a phenomenon by eliminating the related threat.[36]

Consumption is a normal use of food. Any food that does not ensure safety during and after consumption will therefore be unsafe,[37] regardless of the processing degree.[38] Objectification of the definition of 'food' in Article 2 of Regulation (EC) No. 178/2002[39] (by accounting only for its technical aspect related to consumption rather than issues relating to the nourishment of the body[40]) gives rise to the following question – what should be the extent of liability for damages caused by the consumption of a dietary supplement? One should bear in mind that it is highly probable that such a product may be consumed by accident, for example, by children; on the other hand, an 'adult' consumer may exceed the recommended daily dose of the supplement (also by accident) while yet another consumer will not achieve the intended effects that the dietary supplement manufacturer declared and will thus suffer damage.

In the case of specific products, such as medicinal products, doctor's recommendations and the text of the product leaflet attached to the packaging, among

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[35] M. Stańko, *Odpowiedzialność...,* p. 257.

[36] B. Gnela, *Odpowiedzialność za szkodę...,* p. 289; M. Stańko, *Odpowiedzialność...,* p. 257.

[37] See: Ł. Bobeł, K. Leśkiewicz, *Odpowiedzialność cywilna za szkodę wyrządzoną przez niebezpieczny środek spożywczy,* "Przemysł Spożywczy" 2007, No. 3, pp. 39-42.

[38] See: I. Trapè, *Odpowiedzialność...*, pp. 104-109; M. Korzycka-Iwanow, *„Żywność" w kontekście odpowiedzialności cywilnej za szkodę wyrządzoną przez produkt niebezpieczny* (in:) *Współczesne problemy prawa prywatnego. Księga pamiątkowa ku czci Profesora Edwarda Gniewka,* (eds.) J. Gołaczyński, P. Machnikowski, Warsaw 2010, pp. 289-291 and p. 296.

[39] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 of 1 February 2002, pp.1-24 as amended, hereinafter: "Regulation (EC) No. 178/2002").

[40] K. Leśkiewicz, *Wokół prawnego pojęcia żywności, "*Przegląd Prawa Rolnego" 2015, No. 1, p. 182.

other things, have an important role in defining 'normal use'. Liability for medicinal products does not include situations where a product was (for example) used improperly or contrary to information given by the manufacturer or the doctor's recommendations.[41] However, transposing the above to the dietary supplements gives rise to multiple concerns. 'Normal use' in the case of foods may not be perceived in the same way as in the case of medicinal products.

Circumstances existing when a product is put on the market (Article 449[1] § 3 sentence 2 of the CC) are decisive for the evaluation of product safety; those circumstances include, amongst others, the manner of a product presentation on the market and the information on product features communicated to the consumers. It is pointed out that the said provision does not implement Directive 85/374/EEC properly; under the Directive, all circumstances should be taken into account.[42] Regulation (EC) No. 178/2002 follows the same spirit as it employs the term 'unsafe' (rather than 'defective') food,[43] and according to Article 14 of that act of law:

I. food shall not be placed on the market if it is unsafe;
II. food shall be deemed to be unsafe if it is considered to be: injurious to health or unfit for human consumption;
III. In determining whether any food is unsafe, regard shall be had: (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods;
IV. In determining whether any food is injurious to health, regard shall be had: (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations; (b) to the probable cumulative toxic effects; (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

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[41] H. Tuchołka, *Odpowiedzialność za szkody wyrządzone przez wytwarzane, importowane i wprowadzane na Polski rynek środki farmaceutyczne*, PiM 2001, No. 9, p. 86.

[42] B. Gnela, *Odpowiedzialność przedsiębiorców za szkody wyrządzone przez produkt niebezpieczny* (in:) *Odpowiedzialność cywilna w obrocie gospodarczym*, Prace Naukowe UE we Wrocławiu No. 203, (ed.) A. Śmieja, Wrocław 2011, pp. 39-58.

[43] See: M. Korzycka (in:) *Komentarz do rozporządzenia nr 178/2002 ustanawiającego ogólne zasady i wymagania prawa żywnościowego, powołującego Europejski Urząd ds. Bezpieczeństwa Żywności oraz ustanawiającego procedury w zakresie bezpieczeństwa żywności,* (eds.) M. Korzycka, P. Wojciechowski, LEX/el. 2018, Art. 14; https://sip.lex.pl/#/commentary/587771221/568661/korzycka-malgorzata-red-wojciechowski-pawel-red-komentarz-do-rozporzadzenia-nr-178-2002...?pit=2023-04-29&cm=URELATIONS (accessed 30 April 2023).

V. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

It is only through a comparison of the criteria adopted in Article 14 of Regulation (EC) No. 178/2002 with the solutions presented in Article 449^1 § 3 of the CC that the term "liability for damage caused by consumption of a dietary supplement" is put in perspective. Even though it is not the purpose of this paper to analyse all components of Article 14 of Regulation (EC) 178/2002, it should be noted that – in line with the Regulation – in determining whether any food is unsafe, regard should be had not only to the "normal conditions of use of the food by the consumer" but also to its use at each stage of production, processing and distribution, and information provided to the consumer, including information concerning the avoidance of specific adverse health effects from a particular food or category of foods.

Thus, the legislator voices the need for the manufacturer to anticipate frequent cases of improper product use and to eliminate dangers related to such use. The scope of information intended for the consumer, and concerning, among other things, the avoidance of specific adverse health effects from a particular food (dietary supplement) or category of foods will also be crucial while assessing the due diligence on the part of the manufacturer.[44] It is interesting, however, whether we can actually discuss any room for the manufacturer to anticipate cases of incorrect product use and eliminate the threat related to such use, given that there is absolutely no scientific background to determine the impact of most ingredients of dietary supplements on human health and that there are no relevant clinical trials relating to the interaction between dietary supplements and medicines, for example.

Apart from the above, certain 'other' circumstances may affect food safety and can be of importance for the assessment of product defectiveness. As regards dietary supplements, we distinguish the following 'other' circumstances, among others: the manner and the form of their consumption (there are different threats relating to dietary supplements which must be combined with another substance, mixed or diluted); acceptable (unacceptable) combinations of dietary supplements, also with medicinal products (a cumulation of certain ingredients may be a threat to health), the average frequency of consuming certain ingredients of dietary supplements and a portion size that is safe to health, and also the target group for a given product.[45]

[44] M. Stańko, *Odpowiedzialność...,* p. 260.

[45] P. Wojciechowski, *Odpowiedzialność...,* pp. 336-337; see: E. Łętowska, *Uwaga na niebezpieczne produkty,* "Rzeczpospolita" 18 February 1998.

Next, attention should be paid to the special importance given by the EU legislator to the presentation (in a broad sense of the term) of dietary supplements on the market and the clarifications, information and instructions that accompany it.[46] Given multiple breaches pointed out in regard to the labelling, presentation and advertising of dietary supplements, it is worth considering whether or not any dietary supplement that does not fulfil legal requirements or that is not labelled properly should be found unsafe. *A contrario*, will the manufacturer be released from liability for damages caused by a dietary supplement in other situations, that is when the dietary supplement has met all the requirements under food law and has been properly labelled?

The answer to the second question includes the presumption made in Article 14(7) of Regulation (EC) No. 178/2002, which reads "Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned". Naturally, the presumption applies to Community provisions, and in the event of their absence, also to national provisions (Article 14(9)). Therefore, in practice, compliance does not exclude the manufacturer's liability; however, it does lead to certain evidentiary difficulties for the aggrieved party who must prove that a given dietary supplement was unsafe even though it complied with laws.[47]

The importance of the first question is primarily related to the fact that it tackles issues relating to a ban on giving misleading details in any information concerning food, which includes but is not limited to: a ban on attributing qualities or medical properties to a dietary supplement that it does not possess; a ban on suggesting that the product possesses special characteristics that it does not actually possess, and a ban on the unauthorised use of nutrition claims, health claims or reduction of disease risk claims. The rules of labelling, presentation and advertisement of dietary supplements have been specifically regulated by law, for example, in Regulation 1169/2011, in the Polish Food and Nutrition Safety Act of 25 August 2006[48] and in the executive regulation,[49] as an elaboration on and clarification of the general ban on misleading consumers which is set out in Articles 8 and 16 of Regulation 178/2002.

As indicated above, legal requirements as to the level of food safety relate to the food harmlessness and whether it is fit for human consumption. Thus, it is pointed out in the literature that, even though the information given to the consumer is taken into consideration when assessing the product, it does not mean in practice that an incorrect labelling of the product will automatically change the

[46] P. Wojciechowski, *Odpowiedzialność...,* p. 337.

[47] See: *Ibidem*, p. 338.

[48] Journal of Laws of 2022, item 2132 as amended.

[49] Regulation of the Minister of Health of 9 October 2007 on the composition and labelling of dietary supplements, Polish Journal of Laws of 2023, item 79.

product qualification to an unsafe product and that it will involve the liability of the entity operating on the food market as part of the analysed regime.[50] However, that thesis seems questionable, given the fact that, for example, the failure to possess characteristics declared by the manufacturer can make a dietary supplement worthless, and consequently, it may give rise to a question as to whether or not the dietary supplement is 'fit for human consumption'.

Therefore, it seems that, while assessing the (un)safety of a food product, i.e. a dietary supplement, and the related liability, one should always consider the compliance of its labelling, presentation and advertisement with the legal requirements. Failure to include information on an ingredient with allergenic properties, as required by law, might even lead to a consumer's death. The manner of posting the required information on the product is equally important as whether or not a given message contains all of the required details. Such information should be coherent and clear.[51] In practice, it will therefore be easy to demonstrate a breach of food law requirements concerning mandatory information on food, a catalogue of which is presented in Chapter IV of Regulation (EU) No. 1169/2011. There is, however, a problem with voluntary information – in reality, this is the information that consumers come across most frequently in the presentation and advertisement of dietary supplements and the one that is most frequently misleading.[52] It is indicated at the same time that both product presentation and its advertisement influence the consumer's opinion on the product and its safety; as such, it has also an information function, in addition to the promotional one.[53] All those factors may shape the consumer's opinion about the quality, while determining the safety level of a given dietary supplement.[54]

5. SUMMARY

Supplements need to be considered as a special type of defective products in case of which it is currently impossible to define the safety of their use when they are actually put on the market. As there is no actual safety standard, the broadest catalogue of possible cases must be covered by civil liability for damage caused by the consumption of a defective dietary supplement. This will fill a serious gap

[50] Ł. Sokołowski, *Cywilna*..., p. 3.

[51] P. Wojciechowski, *Odpowiedzialność*…, p. 337.

[52] See: K. Leśkiewicz, *Zakaz wprowadzania w błąd konsumenta w prezentacji suplementów diety (aspekty prawne),* "Przegląd Prawa Rolnego" 2011, No. 1.

[53] E. Łętowska, *Ustawa o ochronie...,* p. 124.

[54] P. Wojciechowski, *Odpowiedzialność*…, p. 338.

in scientific knowledge or uncertainty as to the qualification of dietary supplements which arose in relation to the defectiveness of law.

The existing legal framework is insufficient to ensure civil liability for damages caused by the consumption of a defective dietary supplement. It is a direct consequence of the specific nature of dietary supplements and the lack of an adequate risk analysis when adding a definition of that product to EU law. Enforcement of regulations in that area has become even more difficult due to interpretation ambiguities that arose at the intersection of Polish law and EU law that regulates the issue of liability for a defective (unsafe) product. In addition, transposing the said issue to food law makes the situation even more difficult.

As the law stands, in the case of dietary supplements it is worth postulating that a defect ('defectiveness') of a product should be understood broadly – as a failure to ensure product safety to a degree that a consumer has the right to expect. Due to a problem delineating the lines within which liability for damage caused by the consumption of a dietary supplement should be enforced, it is also worth considering imposing additional disclosure duties on the manufacturer and implementing a mechanism for the authorisation of such information. Currently, (other than the catalogue of mandatory information referred to in Regulation (EU) 1169/2011) the manufacturers decide which information is to be disclosed to consumers when the product is put on the market; thus, the manufacturers shape the safety standard for a group of products that exist on the market without any requirement for clinical trials concerning their safety.

It also seems that, while assessing the (un)safety of a dietary supplement, and the related liability, one should always consider the compliance of its labelling, presentation and advertisement with the legal requirements, both in terms of mandatory information and voluntary information (e.g. in terms of misleading consumers) as referred to in Regulation (EU) 1169/2011. Finally, it is worth mentioning a concept existing under the French legal doctrine which finds it acceptable to demand legal redress for damage in the form of 'fear/concern' relating to a threat to health or life when there is no actual damage.[55] In such a case, consumers may hold the manufacturer liable for the so-called 'loss of happiness' since it is possible to demand legal redress for damage in the form of 'fear/concern'.

REFERENCES

Bagińska E., *Nowe unormowanie odpowiedzialności cywilnej za produkt*, "Przegląd Sądowy" 2000, No. 9

[55] See: P. Modrzejewski, *Zakończenie (in:) Odpowiedzialność cywilna za szkody wyrządzone przez niebezpieczny produkt medyczny,* Warsaw 2023, https://sip.lex.pl/#/monograph/369532508/100?keyword=modrzejewski&tocHit=1&cm=STOP (accessed: 3 May 2023).

Banaszczyk Z., Granecki P., *Produkt niebezpieczny per se i niebezpiecznie wadliwy a odpowiedzialność producenta* z art. 4491 i nast. KC, "Monitor Prawniczy" 2002, No. 17

Bobeł Ł., Leśkiewicz K., *Odpowiedzialność cywilna za szkodę wyrządzoną przez niebezpieczny środek spożywczy*, "Przemysł Spożywczy" 2007, No. 3

Gnela B. (in:) Kodeks cywilny. Komentarz. Tom III. Zobowiązania. Część ogólna (Article 353-534), (eds.) M. Fras, M. Habdas, Warsaw 2018, Article 449(1); https://sip.lex.pl/#/commentary/587770159/567599/fras-mariusz-red-habdas-magdalena-red-kodeks-cywilny-komentarz-tom-iii-zobowiazania-czesc-ogolna...?pit=2023-04-29&cm=URELATIONS

Gnela B., *Odpowiedzialność przedsiębiorców za szkody wyrządzone przez produkt niebezpieczny* (in:) Odpowiedzialność cywilna w obrocie gospodarczym, Prace Naukowe UE we Wrocławiu No. 203, (ed.) A. Śmieja, Wrocław 2011

Gnela B., *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny (tzw. odpowiedzialność za produkt),* Kraków 2000

Gnela B., *Odpowiedzialność za produkt (uwagi o polskiej regulacji)*, "Państwo i Prawo" 2009, Book 9

Jagielska M., *Odpowiedzialność za produkt*, Warsaw 2009

Jagielska M., *Podstawy odpowiedzialności za produkt*, Warsaw 2004

Jagielska M., Rozdział 2 Dyrektywa o odpowiedzialności za produkt wadliwy (in:) *Idem*, *Odpowiedzialność za produkt*, Warsaw 2009

Jarosz M., Wolnicka K., *Interakcje pomiędzy lekami a suplementami diety* (in:) Uważaj, co jesz, gdy zażywasz leki. Interakcje między żywnością, suplementami diety i lekami. Porady lekarzy i dietetyków, eds. M. Jarosz, K. Wolnicka, Warsaw 2007

Korzycka M. (in:) Komentarz do rozporządzenia nr 178/2002 ustanawiającego ogólne zasady i wymagania prawa żywnościowego, powołującego Europejski Urząd ds. Bezpieczeństwa Żywności oraz ustanawiającego procedury w zakresie bezpieczeństwa żywności, (eds.) M. Korzycka, P. Wojciechowski, LEX/el. 2018, Art. 14; https://sip.lex.pl/#/commentary/587771221/568661/korzycka-malgorzata-red-wojciechowski-pawel-red-komentarz-do-rozporzadzenia-nr-178-2002...?pit=2023-04-29&cm=URELATIONS

Korzycka-Iwanow M., Zboralska M., *Never-Ending Debate on Food Supplements: Harmonisation or Dishar-monisation of the Law*, "European Food and Feed Law Review" 2010, No. 124

Korzycka-Iwanow M., *Prawo żywnościowe. Zarys prawa polskiego i wspólnotowego*, Warsaw 2005

Korzycka M., Wojciechowski P., *System prawa żywnościowego*, Warsaw 2017

Korzycka-Iwanow M., *„Żywność" w kontekście odpowiedzialności cywilnej za szkodę wyrządzoną przez produkt niebezpieczny* (in:) Współczesne problemy prawa prywatnego. Księga pamiątkowa ku czci Profesora Edwarda Gniewka, (eds.) J. Gołaczyński, P. Machnikowski, Warsaw 2010

Kremer E., *Odpowiedzialność za zobowiązania związane z prowadzeniem gospodarstwa rolnego*, Kraków 2004

Kuźmicka-Sulikowska J., *Pojęcie produktu niebezpiecznego na gruncie przepisów kodeksu cywilnego dotyczących odpowiedzialności za szkodę wyrządzoną przez ten produkt* (in:) Księga dla naszych kolegów: prace prawnicze poświęcone pamięci

doktora Andrzeja Ciska, doktora Zygmunta Masternaka i doktora Marka Zagrosika (praca zbiorowa), Wrocław 2013

Laye E., *Top 10 suplementów diety. Najskuteczniejsze środki odżywcze o naukowo udowodnionym działaniu*, Białystok 2018

Leśkiewicz K., *The legal concept of unsafe (dangerous) food*, "Studia Iuridica" 2023, No. 95

Leśkiewicz K., *Wokół prawnego pojęcia żywności*, "Przegląd Prawa Rolnego" 2015, No. 1

Leśkiewicz K., *Zakaz wprowadzania w błąd konsumenta w prezentacji suplementów diety (aspekty prawne)*, "Przegląd Prawa Rolnego" 2011, No. 1

Łętowska E., *Ochrona niektórych praw konsumentów. Komentarz*, Warsaw 2001

Łętowska E., *Ustawa o ochronie niektórych praw konsumentów, komentarz*, Warsaw 2000

Ozimek I., Przeździecka-Czyżewska N., *Reklama suplementów diety (in:) Ochrona prawna konsumenta na rynku mediów elektronicznych*, (ed.) M. Królikowska-Olczak, B. Pachuca-Smulska, Warsaw 2015

Sikorski S., *O odpowiedzialności za szkodę wyrządzoną przez produkt niebezpieczny*, "Prawo Spółek" 2003, No. 12

Sokołowski Ł., *Cywilna odpowiedzialność za szkodę wyrządzoną przez niebezpieczny środek spożywczy*, LEX/el. 2017

Stańko M., *Odpowiedzialność za produkt żywnościowy w polskim systemie prawnym*, "Studia Iuridica Agraria" 2009, Vol. 7

Trapè I., *Odpowiedzialność za produkt niebezpieczny podmiotów dystrybuujących żywność*, "Przegląd Prawa Rolnego" 2008, No. 2

Tuchołka H., *Odpowiedzialność za szkody wyrządzone przez wytwarzane, importowane i wprowadzane na Polski rynek środki farmaceutyczne*, PiM 2001, No. 9

Wojciechowski P., *Informacja o braku zawartości określonych substancji w żywności w regulacjach prawa żywnościowego,* "Przegląd Prawa Rolnego" 2018

Wojciechowski P., *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny żywnościowy pierwotny i przetworzony. Wybrane problemy*, "Studia Iuridica Agraria" 2011, Vol. IX

Żuławska C. (in:) G. Bieniek, H. Ciepła, S. Dmowski, J. Gudowski, K. Kołakowski, M. Sychowicz, T. Wiśniewski, C. Żuławska, Komentarz do kodeksu cywilnego. Księga trzecia. Zobowiązania, Vol. 1, Warsaw 2011