

ŁUKASZ MIKOŁAJ SOKOŁOWSKI\*

ORCID: 0000-0001-7391-7205

# Liability for damage caused by unsafe innovative food – a legal perspective

## 1. Introduction

The subject of this article concerns liability for unsafe food. There have been several publications published so far<sup>1</sup> which have taken into account the specificity of the product such as food, and its impact on the civil liability regime for unsafe products. However, given the dynamic development of technology and innovation in the whole economy, and in the agri-food sector in particular and basing on the current state of research, it may be worthwhile to look at the regulations on liability for unsafe products from the perspective of a particular type of food, which is innovative food. These considerations will enable to answer the question whether the existing liability regime meets the requirements of the modern agri-food sector and protects adequately consumers' health and life from the risks that may result from product innovation.

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\* Wydział Prawa i Administracji, Uniwersytet im. Adama Mickiewicza w Poznaniu.

<sup>1</sup> See in particular: Ł. Bobeł, K. Leśkiewicz, *Odpowiedzialność cywilna za szkodę wyrządzoną przez niebezpieczny środek spożywczy*, "Przemysł Spożywczy" 2007, No. 3, p. 39 et seq.; J. Kuźmicka-Sulikowska, *Pojęcie produktu niebezpiecznego na gruncie przepisów kodeksu cywilnego dotyczących odpowiedzialności za szkodę wyrządzoną przez ten produkt*, in: J. Mazurkiewicz (ed.), *Księga dla naszych kolegów. Prace prawnicze poświęcone pamięci doktora Andrzeja Ciska, doktora Zygmunta Masternaka, doktora Marka Zagrosika*, Wrocław 2013, p. 245 et seq.; P. Wojciechowski, *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny żywnościowy pierwotny i przetworzony. Wybrane problemy*, "Studia Iuridica Agraria" 2011, Vol. 9, p. 328 et seq.

## 2. Innovative food

Recent years have seen a growing variety of food innovations. As the literature shows, this is an apparent reaction to expanding consumer needs who are looking for food with particular properties, a new trend currently observed in consumer behaviour.<sup>2</sup> Customers today are increasingly frequently seeking certain types of foods with particular properties. Innovation is also an important factor influencing the efficiency and competitive advantage of food business operators in the agri-food processing industry.<sup>3</sup> It allows them to outperform competitors on a given market, acquire new customers and keep interest of the existing ones in their products, ensuring them a stable position in a given segment.<sup>4</sup> What is also worth noting is a growing number of “the most innovative food product” competitions,<sup>5</sup> and even voluntary food quality certificates increasingly frequently take product innovation into account.<sup>6</sup>

However, what needs to be stressed as well is that neither EU nor Polish legislation has distinguished a separate catalogue of innovative food. What is more, despite the fact that there is no legal definition of the concept of innovative food, this term is frequently used in practice to categorise products. It is necessary therefore to define the scope of foodstuffs which can be classified as innovative and to define the term “innovation” itself.

Today, innovation is understood very broadly.<sup>7</sup> Joseph Schumpeter, who is regarded to be the pioneer of the theory of innovation, understood it as a means of introducing new products or improving the existing ones, creating new or improving the existing production processes, using a new way of selling or buying, opening new markets, using new raw materials or semi-finished products and introducing a new organisation of production.<sup>8</sup> His understanding of the concept allows to distinguish three basic types of

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<sup>2</sup> T. Olejniczak, *Zakupy innowacji produktowych na rynku żywności – w świetle badań konsumenckich*, “Zeszyty Naukowe Wyższej Szkoły Bankowej we Wrocławiu” 2011, No. 25, p. 87 et seq.

<sup>3</sup> A. Barska, *Innowacje na rynku produktów żywnościowych z perspektywy polskich i czeskich konsumentów generacji Y*, “Zeszyty Naukowe Szkoły Głównej Gospodarstwa Wiejskiego w Warszawie. Problemy Rolnictwa Światowego” 2017, Vol. 17, issue 1, p. 8.

<sup>4</sup> Ibidem, p. 9.

<sup>5</sup> See for instance the competition “Złote Innowacje FMCG & Retail 2019;” <http://zloteinnowacje.pl/> [accessed on 30 April 2020].

<sup>6</sup> See for instance the certificate “Dobry Produkt;” <https://www.portalspozywczy.pl/dobryprodukt/> [accessed on 30 April 2020].

<sup>7</sup> K. Kozłowska, *Ocena wybranych aspektów innowacyjności polskich przedsiębiorstw*, in: P. Urbanek, E. Walińska (eds.), *Ekonomia i zarządzanie w teorii i praktyce. Ekonomia i nauki o zarządzaniu w warunkach integracji gospodarczej*, Łódź 2016, p. 170.

<sup>8</sup> J.A. Schumpeter, *Teoria wzrostu gospodarczego*, Warszawa 1960, p. 104.

innovation: the product-, process- and service-related ones.<sup>9</sup> In this article, only product innovation, i.e. changes related to the introduction of new products or the improvement of the existing ones, will be discussed.<sup>10</sup>

In the light of the above, new conventional foods with specific characteristics, commonly referred to as functional foods, as well as and perhaps most importantly, foods falling into specific legal categories such as novel foods, genetically modified foods, food supplements whose placing on the EU market is subject to specific legal requirements (e.g. authorisation or notification of their placing on the market) may constitute innovative foods. Although the general principle of food law is that everything that is not prohibited by law is allowed, these products are subject to the prohibition principle.<sup>11</sup>

Innovative food may certainly be the answer to the greatest challenge of modern times, which is to ensure food safety.<sup>12</sup> On the other hand, the consumption of new, unknown products carries the risk of negative effects on health and life. From this perspective, the research objective set out above appears to be necessary and the conclusions of the research undertaken may serve to ensure food safety being the fundamental and unconditional objective of food law.<sup>13</sup>

### 3. Strict liability

As Paweł Wojciechowski has pointed out, there are two regimes of liability for damage in civil law systems: the *ex delicto* regime and the *ex contractu* regime. The latter also indicates general liability and a specific contractual liability (warranty, guarantee).<sup>14</sup>

<sup>9</sup> K. Kozłowska, *Ocena wybranych aspektów...*, p. 171.

<sup>10</sup> Ibidem.

<sup>11</sup> R. Büscher, *Was sind "Novel Food?" Zum Anwendungsbereich der "Novel Food"-Verordnung*, in: R. Streinz (ed.), *"Novel Food". Rechtliche und wirtschaftliche Aspekte der Anwendung neuer biotechnologischer Verfahren bei der Lebensmittelherstellung*, vol. 2, Bayreuth 1995, p. 21; T.M. Spranger, *WTO-rechtliche Probleme der Genehmigungspflicht für neuartige Lebensmittel im Hinblick auf das SPS-Übereinkommen*, "ZLR – Zeitschrift für das gesamte Lebensmittelrecht" 2000, No. 1, p. 111.

<sup>12</sup> For more see: R. Budzinowski, *Współczesne wyzwania związane z żywnością i ich rola w kształtowaniu polityki rolnej i prawa rolnego*, "Przegląd Prawa Rolnego" 2015, No. 2, p. 17.

<sup>13</sup> Article 5 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 31.01.2002, as amended (hereinafter Regulation No. 178/2002).

<sup>14</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 328 and the literature cited there. The author points out that this classification is not undisputable, since, on the one hand, there is a regime with

When the innovative food purchased by a consumer turns out to be unsafe or lacking compliance with food law<sup>15</sup> this may constitute improper performance of the obligation on the part of the seller and give rise to liability.<sup>16</sup> However, the contractual regime is restricted by the *privity of contract* principle, according to which it does not apply where the injured person is not a party to the contract but a third person.<sup>17</sup> Given the relatively low prices of food and the risk that food can pose predominantly to human health and life, the contractual liability regime is of little practical importance.

Contractual liability under general rules involves proving a fault<sup>18</sup> of the offender, but with regard to innovative food, due to the novel nature of the products and the complexity of the technological processes, to do so is practically or entails very high costs.<sup>19</sup> This is because in case of innovative food effective security controls are harder to implement and as a result there is a greater likelihood that new defects will occur.<sup>20</sup> The development of technology may also involve various types of hazards and create new, previously unknown threats.<sup>21</sup>

The rapid development of production and trade and the associated with it risk that human life or health may be at stake have led to a situation that traditional legal solutions governing liability for damages have become ineffective.<sup>22</sup> In response to the challenges posed by the development of technology and the application of innovation, a specific regime of liability for a hazardous product based on the principle of risk was established, thus contributing to the elimination of asymmetries in knowledge and information in the entrepreneur (business)-consumer relationship<sup>23</sup> known as B2C. At

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a uniform scope, strictly defined as an ex-contractual regime, and, on the other hand, there are many different types, the only common and negative feature of which is that it is not a responsibility *ex contractu*.

<sup>15</sup> For example, non-compliant with food law on labelling.

<sup>16</sup> Pursuant to article 471 of the Civil Code or to the provisions on guarantees or warranties.

<sup>17</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 329.

<sup>18</sup> Ibidem, p. 330 and the literature cited there. The author indicates that the efforts of the case-law were aimed at alleviating these difficulties. This was achieved through various forms of objectification of guilt. The measure of due diligence was raised, the concept of anonymous guilt was created, presumptions were made about the producer's guilt, it was considered that in case of doubt it should be decided in favour of the injured party.

<sup>19</sup> M. Kraus, *Novel Food: Risikominimierung neuartiger Lebensmittel durch Zulassungsrestriktionen?*, Bayreuth 2001, p. 42.

<sup>20</sup> P. Wojciechowski, *Odpowiedzialność...*, pp. 328–329.

<sup>21</sup> E. Kremer, *Odpowiedzialność za zobowiązania związane z prowadzeniem gospodarstwa rolnego*, Kraków 2004, p. 113.

<sup>22</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 329.

<sup>23</sup> M. Kraus, *Novel Food...*, p. 42.

the same time it provides a more effective protection of the party who is economically weaker in this relationship.

The clear reference in EU law provisions on food law<sup>24</sup> to the regime of liability for a damage caused by a hazardous product suggests that this regime should be of key significance in the event of harm (damage) caused by unsafe food.<sup>25</sup> Although the regulations on liability for unsafe products do not explicitly take into account the specificity of food, the specific features of innovative food have an impact on the application of the solutions adopted.

One of the prerequisites for civil liability for a prohibited act is the fault on the part of the offender. However, the law provides that in some cases, due to the protective objectives of the regulation, certain entities will be held liable on the principle of risk arising from strict liability, even if they were without fault. This special regime is also applicable to liability for an unsafe product as well as to liability for a damage caused by an innovative foodstuff that is considered to be hazardous to the health and life of the consumer.

The approximation of the laws of the Member States on the producer's liability for damage caused by a defective product is essential because the existing disparities may distort competition, affect the movement of goods within the common market and entail different levels of consumer protection in respect of damage to health or property caused by a defective product.<sup>26</sup> The aim of the regulation is therefore to harmonise legislation across the EU. In Poland these instruments have been implemented in the Civil Code.<sup>27</sup>

#### 4. Unsafe food

The provisions governing product liability relate to a product understood as a movable thing whether or not combined with another thing, to animals and to electricity.<sup>28</sup> There is therefore no doubt that these products include also

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<sup>24</sup> Article 95 of the Act of 25 August 2006 on food and nutrition safety (Journal of Laws No. 136, item 914 as amended).

<sup>25</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 352. Also compare M. Syska in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności i żywienia. Komentarz*, Warszawa 2013, p. 1057. The author notes that the position on the primacy of the rules on liability for unsafe products over other liability regimes has no normative justification, but it should be pointed out that it is of particular practical importance with regard to food products.

<sup>26</sup> Preamble to 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, OJ L 1985, No. 210, p. 29 (hereinafter Directive 85/374/EEC).

<sup>27</sup> They are contained in articles 449<sup>1</sup>–449<sup>10</sup> of the Civil Code.

<sup>28</sup> Pursuant to article 449<sup>1</sup> § 2 of the Civil Code this definition corresponds to the definition set out in article 2 of Directive 85/374/EEC, which is the basis for regulation in all EU Member States.

foodstuffs.<sup>29</sup> Due to its specificity and the characteristics of food law, food is a special type of product. Thus the issue of liability for unsafe foodstuffs, particularly for innovative ones, is of a specific nature when compared to the liability for a defective product.<sup>30</sup>

A product is unsafe if it does not provide the safety that may be expected from its normal use. Whether a product is safe is determined by the circumstances existing at the time it was placed on the market, particularly in what manner it was presented on the market and what information about its properties was given to the consumer.<sup>31</sup>

The standard of food health quality, i.e. its safety, has been defined in relevant norms. A food is considered unsafe if it is harmful to health or unfit for human consumption.<sup>32</sup> In determining whether any food is unsafe, regard should be taken of the normal use of the food by the consumer, its use at each stage of production, processing and distribution, information provided to the consumer, including information on the label or other information generally available to the consumer and concerning the avoidance of specific adverse health effects associated with a particular food or category of foods.<sup>33</sup>

In determining whether any food is injurious to health, regard must be had to the probable immediate and/or short-term and long-term effects of the food on the health of a person consuming it, but also on subsequent generations, to the probable cumulative toxic effects, as well as the particular health sensitiveness of a specific category of consumers if the food is intended for that category of consumers.<sup>34</sup>

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.<sup>35</sup>

Therefore, the safety assessment of a food is made taking into account its purpose which is human consumption, the circumstances in which food is prepared and consumed, the cumulative effect of undesirable ingredients, the average frequency and volume of consumption of a particular product and whether it is intended for a specific group of consumers.

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<sup>29</sup> J. Kuźmicka-Sulikowska, *Pojęcie produktu niebezpiecznego...*, p. 250.

<sup>30</sup> Set out in Directive 85/374/EEC.

<sup>31</sup> Article 449<sup>1</sup> clause 3 sentence 1 and 2 of the Civil Code and article 6(1) of Directive 85/374/EEC.

<sup>32</sup> Article 14(2) of Regulation No. 178/2002.

<sup>33</sup> Article 14(3) of Regulation No. 178/2002.

<sup>34</sup> Article 14(4) of Regulation No. 178/2002.

<sup>35</sup> Article 14(5) of Regulation No. 178/2002.

Of particular importance for the assessment of the safety of a product is also the manner in which it is presented and information about its properties provided to the consumer who should be reasonably well informed, attentive and circumspect, and who may be expected to have some degree of knowledge and orientation in reality, although this knowledge may not be complete and professional. Food labelling, including the labelling of certain legal categories that can be classified as innovative food, such as novel food, is regulated in detail by law.<sup>36</sup> Not only the scope of the information to be provided has been specified, but also the manner and form of its presentation. It should be noted, however, that not every failure to mark a product will result in it being considered unsafe.<sup>37</sup> As indicated above, the legal requirements as to the level of food safety address its harmlessness and suitability for human consumption. Although the information provided to the consumer is taken into account when testing the product, this does not mean that incorrect labelling automatically reclassifies the product as unsafe and entails liability of the food business operator under the regime discussed here.<sup>38</sup>

In view of the prescriptive determination of the criteria of food safety and the general prohibition of the placing of unsafe food on the market, the regulation that a product cannot be considered unsafe for the sole reason that a better product has subsequently been put in circulation will be of lesser importance for innovative food.<sup>39</sup> After all, one cannot talk about more or less safe food or better food. If it turns out that a particular food does not meet the safety requirements, the food business operator is obliged to withdraw the food from the market and notify the competent public authorities and consumers about the fact if there is a reason to believe that the hazardous product has reached them.<sup>40</sup>

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<sup>36</sup> E.g. labelling requirements for novel foods may be clarified in the decision approving their putting into circulation and included in the EU list of novel foods – article 6(2) of Regulation (EU) No. 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001, OJ L 2015, 327, p. 1 as amended.

<sup>37</sup> For example, incorrect information on the presence in a novel food or food ingredient of a substance which is not present in existing food equivalents and which is a source of ethical problems.

<sup>38</sup> Compare P. Wojciechowski, *Odpowiedzialność...*, p. 338. The author indicates that where a food product meets all the requirements of food law and is properly labelled, other circumstances, including the characteristics and properties of the product as they occur at the time it is placed on the market, which have resulted in the product failing to ensure the safety that can be expected from its normal use, will have to be invoked to demonstrate its hazard.

<sup>39</sup> Article 449<sup>1</sup> clause 3 sentence 3 of the Civil Code and article 6(2) of Directive 85/374/EEC.

<sup>40</sup> Pursuant to article 19 of Regulation No. 178/2002.

## 5. The food operator liable for putting unsafe innovative food in circulation

In the event of damage caused by foodstuffs, the food business operator shall be liable pursuant to the provisions of the Civil Code concerning liability for damage caused by an unsafe product.<sup>41</sup> Thus, the person who manufactures an unsafe product within the scope of the business activity, i.e. the producer, is liable for damage caused to anyone by the unsafe product.<sup>42</sup> As provided for in the definition of business activity<sup>43</sup> civil liability is borne by those who produce food for profit in a professional, organized and continuous manner. Thus, civil liability for unsafe food applies also to agricultural producers, and among them farmers who are producers of primary food products.

Farmers and other producers of the raw material or of a component part of a product are jointly and severally liable with the producer of the unsafe product, unless the sole cause of the damage case by that product was its defective design or a defect in the producer's instructions.<sup>44</sup> As can be seen, there are two categories of product defects: (i) defects in the design of the product, where the use of a particular component as well as defects in the information provided by the producer are taken into account, and for which therefore the operators are not responsible, and (ii) defects in the production process, independent of the design or the food recipe, arising from the use of unsafe components, for which the manufacturers of raw materials or components of the product are also held liable.

The liability for unsafe food is also borne by quasi-producers, i.e. entities that claim to be the producer by putting their names, trademarks or other distinctive feature on the product, as well as by importers.<sup>45</sup> Also operators who place novel foods on the European Union market, but are not food producers, may be held liable.

It should be stressed that the regulations under consideration do not equal the liability of the producer with that of the distributor. The latter will only be liable if the producer, quasi-producer or importer of the food

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<sup>41</sup> As also indicated in article 95 of the Act on food and nutrition safety.

<sup>42</sup> Article 449<sup>1</sup> clause 1 of the Civil Code and article 1 of Directive 85/374/EEC.

<sup>43</sup> Definition of business activity contained in article 2 of the Act of 6 March 2018 – Entrepreneurs' Law (Journal of Laws item 646 as amended).

<sup>44</sup> Article 449<sup>5</sup> clause 1 and 3 of the Civil Code and article 3(1) in connection with article 5 of Directive 85/374/EEC.

<sup>45</sup> Article 449<sup>5</sup> clause 2 and 3 of the Civil Code and article 3(1 and 2) in connection with article 5 of Directive 85/374/EEC.

is not known and the distributor has disposed of the unsafe product within the scope of its business activities and has not, within one month from the date of notification of the damage, disclosed the name and address of the producer, quasi-producer or importer to the person affected. Where the producer, quasi-manufacturer or importer cannot be identified by the seller of the product, the latter is exempted from liability if he identifies the person from whom the product was purchased.<sup>46</sup>

The case-law of the CJEU<sup>47</sup> excludes the possibility of extending liability to the food supplier. The Court challenged the compatibility with EU legislation of Danish national rules providing for direct liability of the supplier for damage caused by the defective product to the injured parties and to other suppliers in the distribution chain to whom the product was passed on. In the Court's view, the national legislation of the Member States may impose liability on the supplier, but solely on the basis of fault. Strict liability is subsidiary, while it is the responsibility of the supplier to identify the producer.

Not only the producer but also any other operator that carries out production in the course of a business activity may be the operator liable for unsafe food. Consequently, an operator providing catering and related services may be held liable for unsafe food. Here, however, a distinction should be made between situations in which the effect of the services provided will be the preparation of a new product, for which this entity is liable, and situations in which the entity serves, divides or portions, without affecting its safety, a ready-made product<sup>48</sup> for which its producer is liable.

Determining the party that is liable for an unsafe product is not easy and therefore cannot be done automatically. It is not uncommon for operators to operate on the food market on the basis of a licence. In such a case the licensor will not be the party to be held liable even if the defect concerned the licensed process, because it is not the licensor but the licensee who will have produced the specific foodstuff.

In the light of the above considerations, it appears that the liability for an unsafe product to be borne by an operator who has placed an innovative food on the EU market depends on the role of that operator in the food chain. This liability will vary depending on whether the operator is a pro-

<sup>46</sup> Article 449<sup>5</sup> clause 4 and 5 of the Civil Code and article 3(3) of Directive 85/374/EEC.

<sup>47</sup> Compare judgment of the EJC of 10 January 2006 case C-402/03 *Skov Æg* against *Bilka Lavprisvarehus A/S* and *Bilka Lavprisvarehus A/S v Jette Mikkelsen and Michael Due Nielsen*, ECLI:EU:C:2006:6.

<sup>48</sup> Compare case-law of German courts, among others OLG in Düsseldorf, "NJW-RR Neue Juristische Wochenschrift Rechtsprechungs-Report Zivilrecht" 2001, p. 458.

ducer or not and whether the product is marketed under the operator's own brand, claiming to be the producer. This will also be the case where the operator is only an importer or distributor, but where that role is not limited to logistical activities but extends to the supervision of the production and marketing stages as well.<sup>49</sup>

## 6. Damage, the injured party, burden of proof

Liability for an unsafe product includes damage to the person and property, but is limited in scope. The food business operator is liable for damage to property only if the thing destroyed or damaged belongs to items normally intended for personal use and has primarily been used by the injured party in that way. Compensation for the damage does not cover damage to the product itself or the benefits which the injured party could derive from its use. Nor does it apply where the damage to property is less than an amount equivalent to five hundred euros.<sup>50</sup>

Personal injury, on the other hand, includes both damage to property and non-proprietary damage, which are harm and infringement of personal rights. The compensation for the damage may also include reimbursement of medical and funeral expenses, payment of a pension to persons for whom the deceased was under a statutory maintenance obligation and to relatives to whom the deceased voluntarily and continuously provided means of subsistence, or payment of compensation or indemnification to the members of the family of the deceased, if the death of the deceased resulted in a significant deterioration of their life situation. Personal injuries include the losses suffered and the benefits lost.

Liability for unsafe food is tortious in nature. Therefore, the entity entitled to receive compensation will be anyone who has suffered damage, regardless of whether that person purchased the unsafe food himself and whether he holds any legal title to the goods.

It should also be stressed that the burden of proof of the defect, damage and the causal link between the defect and the damage lies with the injured person.<sup>51</sup> The issue of imposing an obligation on the injured person to demonstrate the hazardous properties of the product raises doubts. The protective

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<sup>49</sup> I. Trapé, *Odpowiedzialność za produkt niebezpieczny podmiotów dystrybuujących żywność*, "Przegląd Prawa Rolnego" 2008, No. 2, p. 111.

<sup>50</sup> Articles 449<sup>2</sup> and 449<sup>7</sup> of the Civil Code and article 9 of Directive 85/374/EEC.

<sup>51</sup> Article 6 of the Civil Code and article 4 of Directive 85/374/EEC.

purpose of the regulations on liability for an unsafe product requires that the injured person is not responsible for proving the hazard of the product, but is required to demonstrate an adequate causal link between the normal use of the product and the damage suffered.<sup>52</sup> The entity liable for the damage will be able to discharge itself from liability if it demonstrates that the product was not unsafe or that the damage does not result from the hazardous properties of the product.<sup>53</sup> Polish regulations<sup>54</sup> provide for a presumption that a product which has caused injury is deemed to have been produced and placed on the market within the scope of the producer's business.

## 7. Exonerative grounds

The food business operator will be able to exonerate himself in certain cases. However, he will bear the burden of proving that there have been exonerating circumstances allowing him to do so.<sup>55</sup>

First of all, it needs to be pointed out that an exemption of strict liability is possible if the operator has not placed the product on the market.<sup>56</sup> And this is not a question of placing an innovative food on the market legally on the basis of an authorisation or a complex notification, but of actual placing it on the market, in the sense of the holding of food or feed for the purpose of sale, including offering them for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of their transfer.

In order to release oneself from liability for unsafe products, it is not enough to prove that the food has not been sold or given away free of charge, i.e. that there has been no transfer of title to the thing. The mere offering for sale or any other form of disposition is a sign that the product has been placed on the market. The European Court of Justice held that, for example, article 11 of Directive 85/374/EEC must be interpreted as meaning that a product is placed on the market when it has left the production process conducted by

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<sup>52</sup> C. Żuławska, Comments to article 449<sup>1</sup> in: G. Bieniek et al., *Komentarz do Kodeksu cywilnego. Księga trzecia: Zobowiązania*, vol. 1, Warszawa 2011, p. 716 et seq.

<sup>53</sup> M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, p. 1056.

<sup>54</sup> Article 449<sup>4</sup> of the Civil Code.

<sup>55</sup> They have been regulated in articles 449<sup>3</sup> and 449<sup>5</sup> clause 1 of the Civil Code and article 7 of Directive 85/374/EEC.

<sup>56</sup> The placing on the market of food, in accordance with article 3(8) of Regulation No. 178/2002 is to be understood as holding food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and sale, distribution and other forms of transfer.

the producer and entered the commercial process in which it is offered to the public for use or consumption.<sup>57</sup>

It should be noted that as long as the foodstuff is in the producer's possession and is not released, the liability regime for damage caused by an unsafe product does not apply.<sup>58</sup> However, if a foodstuff is unsafe already while in possession of the food operator and offered for purchase, it will be all the more unsafe when passed on to the next actor in the food chain.<sup>59</sup>

The exemption from liability will also be possible where the operator has not produced the foodstuff for sale or another form of distribution for business purposes or has not produced or distributed the product in the course of his business. Therefore, an operator who introduces a product in the course of his business in return for payment and, at the same time, free of charge, or an operator who offers a foodstuff for promotional, advertising or marketing purposes, are not exempted from liability.<sup>60</sup>

An exonerative ground is also the absence of a defect when the product is placed on the market or in the event of a subsequent emergence of a defect causing the damage. This is of particular practical importance due to the specificity of the food production process and the need to ensure that the requirements of food law are met throughout the whole chain "from field to table." Another reason is also the fact that food may acquire the characteristics of a hazardous product at any stage of the food chain, even it was not an unsafe product at the time it was launched by the producer.<sup>61</sup> The hazardous property may also arise after food has been purchased by the consumer. The producer will therefore be able to relieve himself of liability on proving that the food was not unsafe at the time of placing it on the market and that the defect occurred during transportation, distribution or improper storage by the consumer. However, it may be quite difficult to provide effective evidence of such circumstances, particularly the last one.

The impossibility of detecting the existence of a defect at the time of placing food on the market due to the state of scientific and technical knowledge (known as development risk) may also be grounds for exemption from liability for an unsafe product. This premise may be of paramount significance in the case of innovative foods. However, because of the lack of experience

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<sup>57</sup> Compare the judgment of the ECJ of 9 February 2006, case C-127/04 – *Declan O'Byrne v Sanofi Pasteur MSD Ltd and Sanofi Pasteur SA*, ECLI:EU:C:2006:93.

<sup>58</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 345.

<sup>59</sup> *Ibidem*, p. 346.

<sup>60</sup> More on this: M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, p. 1044.

<sup>61</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 344.

with a long-term consumption of certain substances, it cannot be ruled out that in the future there may arise negative consequences resulting from the consumption of a particular type of food, such as for example the accumulation of harmful ingredients.

In the light of the ECJ's case law,<sup>62</sup> keeping in mind the development risk, when a product is placed on the market, account must be taken of the most advanced level of scientific and technical knowledge. This means that it is not industry practices and safety standards, but the state of the art at expert level that comes to the fore.<sup>63</sup> It ought to be objective in nature and not be the knowledge that the subject concerned had or could have possessed.<sup>64</sup> The producer must meet demanding requirements in terms of both product knowledge and general knowledge.<sup>65</sup> However, this knowledge should be available when the product is placed on the market,<sup>66</sup> which will not be the case if it had been released in an unpublished document or an unpublished research results report.<sup>67</sup> The literature states that such availability should be understood as the objective possibility for an expert to reach such information and not as the actual possession of such information by the producer.<sup>68</sup>

Demonstrating the existence of an exonerative ground in the form of development risk is a complicated procedure that raises many doubts. When verifying the state of knowledge, it is not always necessary to take into account the prevailing opinions generally available, but rather the most advanced ones, which allows taking into account even the most separate views.<sup>69</sup> Where product safety concerns are backed up by scientific expertise and have the merit of credibility, the producer may no longer invoke development risk.<sup>70</sup> As far as innovative foods are concerned, the results of a pre-market research into product safety are of great importance.

<sup>62</sup> Compare the judgment of the ECJ of 29 May 1997, case C-300/95, *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*, ECLI:EU:C:1997:255.

<sup>63</sup> M. Jagielska, in: A. Olejniczak (ed.), *System Prawa Prywatnego*, vol. 6: *Prawo zobowiązań – część ogólna*, Warszawa 2014, p. 992 et seq.

<sup>64</sup> Compare the judgment of the ECJ of 29 May 1997, case C-300/95, *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*, ECLI:EU:C:1997:255.

<sup>65</sup> M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, p. 1047 and the literature quoted there.

<sup>66</sup> Compare the judgment of the ECJ of 29 May 1997, case C-300/95, *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*, ECLI:EU:C:1997:255.

<sup>67</sup> M. Jagielska, in: A. Olejniczak (ed.), *System Prawa Prywatnego*, vol. 6, p. 994.

<sup>68</sup> M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, p. 1047.

<sup>69</sup> M. Jagielska, in: A. Olejniczak (ed.), *System Prawa Prywatnego*, vol. 6, p. 993.

<sup>70</sup> M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, p. 1048.

In retrospect, it may also be difficult to assess whether the state of the art that existed at the time the product was marketed allowed to predict its hazardous properties. Awareness of certain scientific data that subsequently led to the detection of hazardous properties of a product does not necessarily mean that such conclusions could already have been drawn when the product was placed on the market.<sup>71</sup>

For certain categories of foods, their placing on the market may require authorisation, registration or notification following the assessment of scientific data supporting food safety. This however, is not a one-off procedure. The authorisation of certain innovative foods is necessary each time a specific product is offered for sale, not only when it is first put on the market. Therefore, neither the approval process, nor the authorisation or notification of an innovative food has any influence on the obligations of a food business operator to ensure food safety.<sup>72</sup> It cannot be conclusively stated either that the granting of a permit or the issuing of a notification implies the existence of the exonerative ground considered. The safety of a foodstuff should be a matter of concern for food business operators at every stage of the food chain, even after its safety has been officially established. What is more, a long time may pass between obtaining a permit or notification and placing a product on the market. Hence such an importance of the monitoring of the consumption of food, and of innovative food in particular. As may be seen from the above there are only limited possibilities of reliance by operators placing innovative food on the EU market on the development risk defence.

The food business operator will not be held liable either if he can prove that the defect causing damage results from the compliance of the product with mandatory provisions. In this situation it will be ineffective to rely on industry standards as they are not absolutely mandatory. However, the production of a foodstuff with the observance of legal regulations is not in itself sufficient to exempt the producer from liability for damages.<sup>73</sup> It must also be demonstrated that the hazardous properties of a product result precisely from the compliance with mandatory legal provisions in force.<sup>74</sup>

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<sup>71</sup> P. Wojciechowski, *Odpowiedzialność...*, p. 347.

<sup>72</sup> A.H. Meyer, *Gen Food Novel Food. Recht neuartiger Lebensmittel*, München 2002, p. 109.

<sup>73</sup> For more on this see: M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, pp. 1048–1049.

<sup>74</sup> Ł. Bobeł, K. Leśkiewicz, *Odpowiedzialność cywilna...*, p. 42.

## 8. The limitation period of consumer claims

A claim for damages caused by an unsafe product is time-barred after a period of three years from the date on which the injured party learned or could reasonably be expected to have learned of the damage and of the person obliged to redress it.<sup>75</sup> In any event, the limitation period for a claim expires ten years after the product has been placed on the market.<sup>76</sup> There were doubts in the doctrine regarding the 10-year limitation period running irrespective of the disclosure or occurrence of the damage.<sup>77</sup> They derived from the judgment of the Constitutional Court (Trybunał Konstytucyjny) which found the second sentence of article 442(1) of the Civil Code to be inconsistent with article 2 and article 77(1) of the Constitution of the Republic of Poland in that it deprives the injured party of the right to claim compensation for damage inflicted to a person that was revealed ten years after the occurrence of the event causing the damage.<sup>78</sup>

According to Wojciechowski, the adoption of a rigid 10-year limitation period represents the division of risk between producers making profits from the sale of products and consumers who benefit from the new solutions.<sup>79</sup> This view should be fully shared. Liability on a strict liability basis is an especially strict liability regime constituting a greater burden than liability based on the fault principle.<sup>80</sup> The reasons for setting a time limit for relying on the fault-free liability principle was to ensure that all producers have a fixed and uniform end-date for their liability throughout the European Union not to hamper technical progress, to reduce the additional burden on producers bringing it down to certain limits and to involve insurers in covering the risk-based liability.<sup>81</sup> At the same time, the solutions that have been adopted do not exclude the tort liability of the producer for a prohibited act on general principles, under which in the event of personal injury, the limitation period cannot be shorter than three

<sup>75</sup> Article 449<sup>8</sup> of the Civil Code.

<sup>76</sup> *Ibidem*.

<sup>77</sup> M. Syska, in: A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności...*, pp. 1048–1049; P. Wojciechowski, in: M. Korzycka, P. Wojciechowski, *System prawa żywnościowego*, Warszawa 2017, p. 315.

<sup>78</sup> Compare the judgment of the Constitutional Court of 1 September 2006, file No. SK 14/05, LEX No. 208351.

<sup>79</sup> P. Wojciechowski, in: M. Korzycka, P. Wojciechowski, *System prawa...*, p. 317.

<sup>80</sup> Opinion of Advocate General Verica Trstenjak delivered on 8 September 2009 in case C-358/08 *Aventis Pasteur SA v OB*, ECLI:EU:C:2009:524.

<sup>81</sup> *Ibidem*.

years from the date on which the injured party learned about the injury and about the person obliged to redress it.<sup>82</sup>

## 9. Conclusions

The introduction of a strict liability regime based on the risk principle should be welcomed. It facilitates seeking redress for a damage caused by an unsafe product. No fault on the part of the producer is required to be proved. Moreover, the regime is independent of producers' contractual liability for improper performance of the contract.

This strict liability regime is socially justified. It forces food producers to take measures that serve the primary purpose of food law and the regulation of novel foods, which is ensuring the safety of novel foods. Furthermore, strict liability prevents damage at the lowest possible cost to operators. The cost of preventing damage caused by unsafe innovative food on the part of an operator is certainly lower than the cost of redressing that damage, which is usually a loss of health or life.

Unfortunately, the existing regulations do not take fully into account the specific nature of food, especially innovative food, and limit the possibility of redressing damage caused by this type of food. The burden of proof remains largely on the affected consumer. Where a producer may be identified, other entities operating on the food market including the distributor whose actions may have an exclusive impact on the quality and safety of the product are generally exempt from liability under this regime. This entails negative consequences for the consumer because a producer, invoking exonerative grounds, may relieve himself of liability for food defects occurring after the production process is completed.

With regard to innovative foods whose placing on the market is subject to authorisation, it should also be stressed that the authorisation obtained does not eliminate liability for a hazardous product, especially if there was a time lapse between the moment when authorisation was granted and the actual marketing of the product. Hence the limited possibility of operators placing an innovative foodstuff on the EU market to rely on the development risk defence.

A strict regime, on the one hand, and the limited possibilities of applying this liability regime on the other hand, reflect the distribution of innovative risks between businesses (operators) and consumers. And yet, the regulations

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<sup>82</sup> Article 442 § 3 of the Civil Code.

currently in place do not exclude the reliance on a less rigorous tort liability of the producer on general terms. They strengthen, although in the case of innovative food only to a narrow extent, the legal protection of the consumer of innovative food.

## **LIABILITY FOR DAMAGE CAUSED BY UNSAFE INNOVATIVE FOOD – A LEGAL PERSPECTIVE**

### Summary

The subject of the considerations presented in the article are issues related to the liability for placing unsafe innovative food on the market. They are aimed at answering the question of whether the tort liability regime based on the risk principle meets the requirements of the modern agri-food sector and provides effective protection of consumer's health and life against threats that may result from product innovations. The adoption of legal solutions providing for producer's strict liability for an unsafe product must be assessed positively. They facilitate the consumer's ability to seek redress for damage caused by an unsafe product. Unfortunately, these regulations do not take into account fully the specific nature of food, especially innovative food, limiting the possibility of redressing damage caused by this type of food.

## **DELLE QUESTIONI GIURIDICHE RELATIVE ALLA RESPONSABILITÀ PER DANNI CAUSATI DA ALIMENTI INNOVATIVI PERICOLOSI**

### Riassunto

L'articolo si propone di dibattere il problema di responsabilità per aver introdotto sul mercato alimenti innovativi pericolosi. L'obiettivo è quello di stabilire se il regime di responsabilità delittuosa, basato sul principio di rischio, soddisfa i requisiti richiesti dal settore agroalimentare odierno e protegga con efficacia la salute e la vita dei consumatori di fronte alle minacce che possono derivare dall'applicare innovazioni nei prodotti. La definizione di soluzioni giuridiche che prevedano la responsabilità del produttore in termini di rischio per un prodotto pericoloso va valutata positivamente in quanto, per il consumatore, diventa più facile richiedere i danni causati da questo tipo di prodotto. Purtroppo, però, le regolazioni in questione non tengono pienamente conto della specificità degli alimenti, soprattutto degli alimenti innovativi, limitando così la possibilità di riparare i danni causati.