

IUS ET ADMINISTRATIO

ISSN 2300-4797

NR 2/2024 (55)

DOI: 10.15584/iuseta.2024.2.1

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Is prevention better than cure? Remarks on product liability in the U.S. and the EU in light of the recent Panera lemonade lawsuits

Zapobiegać czy leczyć? Analiza odpowiedzialności za produkt w USA i UE na przykładzie pozwów przeciwko Panera Bread

Abstract

This article explores the differing approaches to product liability in the United States and the European Union and investigates the regulatory frameworks and consumer protection mechanisms that govern product safety in these regions. It examines the foundational principles and historical evolution of consumer protection laws in both regions, highlighting key differences in their approaches to litigation and enforcement. The inception of the following paper was inspired by a series of lawsuits filed against Panera Bread, a restaurant chain, whose caffeinated lemonade allegedly caused the death of two people.

Keywords: product liability, product safety, consumer protection, Panera Bread Charged Lemonade.

Streszczenie

Artykuł analizuje różne podejścia do odpowiedzialności za produkty w Stanach Zjednoczonych i Unii Europejskiej oraz bada ramy regulacyjne i mechanizmy ochrony konsumentów, które regulują bezpieczeństwo produktów w tych regionach. Analizuje on podstawowe zasady i historyczną ewolucję przepisów dotyczących ochrony konsumentów w obu regionach, podkreślając kluczowe różnice w ich podejściu do sporów sądowych i egzekwowania prawa. Niniejsze opracowanie zostało zainspirowane przez serię pozwów wniesionych przeciwko sieci restauracji Panera Bread, której lemoniada zawierająca kofeinę rzekomo spowodowała śmierć dwóch osób.

Slowa kluczowe: odpowiedzialność za produkt, bezpieczeństwo produktów, ochrona konsumentów, Panera Bread Charged Lemonade.

1. Introduction

In the realm of consumer goods, product liability serves as a crucial mechanism for protecting public health and safety. Additionally, it requires that companies critically examine the possible risks associated with their products or services¹. The concept of product liability varies considerably between the United States and the European Union, two of the world's largest and most influential markets². Those differences reflect their distinct legal traditions, regulatory frameworks, and cultural attitudes toward consumer protection and corporate responsibility.

A recent tragedy prompted a reevaluation of how product liability is managed across different jurisdictions and raised significant questions about the responsibilities of manufacturers, the rights of consumers, and the regulatory frameworks that govern product safety. The Panera Bread lemonade scandal involved concerns over the caffeine content of a beverage called Charged Lemonade sold by the chain. Customers were unaware that the beverage contained high levels of caffeine which could lead to health risks. The issue gained significant attention when the family of a woman, who died after consuming the drink, sued Panera³. They claimed that the company failed to properly disclose the caffeine content, contributing to her death. The scandal highlights a delicate balance needed in regulating product safe-ty. Too little regulation can leave consumers vulnerable to harm, while excessive regulation might stifle innovation and burden businesses with compliance costs. This case prompts us to consider this balance: how much regulation is sufficient, and how much is excessive? It also raises questions about which consumer rights are the most important and whether those rights were violated in this instance.

2. Background on consumer protection in the United States of America

The Progressive Era is widely regarded as the beginning of consumer rights in the U.S., when Americans not only started to purchase more ready-made goods but also began accumulating luxury goods, thereby learning about consumer power

¹ R. Morrow, *Technology Issues and Product Liability* [in:] *Product Liability and Innovation: Managing Risk in an Uncertain Environment*, eds. J. Hunziker, T. Jones, Washington, D.C. 1994, p. 24.

² Households and NPISHs Final consumption expenditure, https://data.worldbank.org/indicator/ NE.CON.PRVT.CD?year_high_desc=true [access: 28.06.2024].

³ E. Chuck, *Family sues Panera Bread after college student who drank Charged Lemonade dies*, https://www.nbcnews.com/news/us-news/panera-lawsuit-charged-lemonade-sarah-katz-death-rcna120785 [access: 28.06.2024].

exercised by supporting certain businesses over others⁴. Initiatives aimed at protecting consumers and providing remedies for unfair practices followed accordingly⁵. The first piece of federal law concerning consumer safety was the Pure Food and Drug Act of 1906, enacted after 27 years of obstructions⁶. The sudden change was brought about by Upton Sinclair's exposé, "The Jungle", detailing the appalling conditions in the meatpacking industry⁷. At that time, workers and consumers enjoyed few rights and the existing production regulations were poorly enforced⁸. Following the Great Depression, several other consumer rights-related bills were passed⁹. In 1962, President John F. Kennedy introduced the Bill of Consumer Rights to Congress, outlining four key consumer rights: the right to safety, the right to be informed, the right to choose, and the right to be heard¹⁰, laying the foundation for modern consumer law. Over the years, many legislative frameworks have been established to protect consumers from unfair practices, ensure product safety, and promote fair trade at both the federal and state levels¹¹.

Currently, consumer protection law encompasses a large web of state and federal acts regulating products and services. On the federal level, there is a wide range of bills, usually tailored to specific regulatory issues¹². Consumer protection laws vary significantly across states, making it challenging to provide a comprehensive overview of regulatory differences due to slight variations in nearly every matter

⁸ R. Currarino, *The Labor Question in America: Economic Democracy in the Gilded Age*, University of Illinois Press 2011, p. 11.

⁹ Most notably: The Securities Act of 1933, The Securities Exchange Act of 1934, The Fair Labor Standards Act of 1938; The Federal Food, Drug and Cosmetic Act of 1938.

⁴ L. Cohen, A Consumers Republic: The Politics of Mass Consumption in Postwar America, New York 2008, pp. 20–21.

⁵ *Ibidem*, p. 21.

⁶ I.D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, "American Journal of Public Health" 1985, Vol. 75, No. 1, p. 18.

⁷ Food and Drug Administration Official Website, Changes In Science, Law And Regulatory Authorities, Part I: The 1906 Food and Drugs Act and Its Enforcement, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement [access: 30.06.2024].

¹⁰ John F. Kenned's Special Message to the Congress on Protecting the Consumer Interest, https://www.presidency.ucsb.edu/documents/special-message-the-congress-protecting-the-consumer-interest, [access: 26.06.2024].

¹¹ Most importantly: The Federal Food, Drug, and Cosmetic Act, Federal Trade Commission Act, The Fair Debt Collection Practices Act, The Fair Credit Reporting Act, The Truth in Lending Act, The Fair Credit Billing Act and The Consumer Product Safety Act which established the Consumer Product Safety Commission.

¹² See for example: The Dodd-Frank Wall Street Reform and Consumer Protection Act, The Gramm-Leach-Bliley Act, The Identity Theft and Assumption Deterrence Act, The Children's Online Privacy Protection Act.

governed by state codes. State governments enforce laws and advocate for consumers but lack an overarching centralized agency¹³. In most states, Attorneys General enforce the law by filing lawsuits, creating trade practice rules, investigating violations and initiating criminal cases¹⁴. The states with the strongest and most comprehensive statutes on unfair acts and practices are Hawaii, Massachusetts, Connecticut, Vermont, and Illinois¹⁵.

On the whole, while U.S. consumer protection mechanisms often operate independently and lack centralization, they benefit from a diverse array of governmental actors, legal rights, and remedies – though access to these protections is unequal¹⁶.

3. Background on consumer protection in the European Union

Initially, consumer protection was barely acknowledged and only mentioned in passing in the Treaty of Rome – nowadays, it is a key policy of the EU¹⁷. The 1975 Preliminary Programme for Consumer Protection¹⁸ set out five fundamental consumer rights: the right to protection of health and safety; the right to protection of economic interests, the right to redress, the right to information and education, and the right to be heard. These rights were inspired by JFK's address to Congress¹⁹. To ensure a high level of consumer protection, Art. 169 of the Treaty on the Functioning of the European Union mandates the EU to safeguard consumers' health, safety, and economic interests, while promoting their rights to information, education, and self-organization²⁰. Furthermore, according to the provisions in Directive 2011/83/EU, full harmonization of crucial regulatory aspects is intended to provide legal certainty and eliminate barriers for consumers

¹³ Consumer Protection in the United States: An Overview, ed. S. Waller, "European Journal of Consumer Law" 2011, p. 21.

¹⁴ Ibidem.

¹⁵ C. Carter, *Consumer Protection in the States – A 50-State Evaluation of Unfair and Deceptive Practices Laws*, National Consumer Law Center Report 2018, pp. 1–3. Note: the latest report available.

¹⁶ Consumer Protection in the United States: An Overview, ed. S. Waller, "European Journal of Consumer Law" 2011, p. 2.

¹⁷ E. Mišćenić, *The Constant Change of EU Consumer Law: The Real Deal or Just an Illusion?*, "Annals Belgrade Law Review" 2022, Vol. 70(3), p. 701.

¹⁸ Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy, Official Journal of the European Communities, C 92, 25 April 1975, C92/2, p. 3.

¹⁹ A. Moskal, *Digital Markets Act: A Consumer Protection Perspective*, "European Papers" 2022, Vol. 7, No. 3; European Forum, Highlight of 31 January 2023, p. 1114.

²⁰ Consolidated version of the Treaty on the Functioning of the European Union, Official Journal of the European Union, 2012/C 326/01.

and traders²¹. Establishing a single, uniform framework across the Union aims to ensure high consumer protection and complete the internal market. Harmonization is however characterised as necessarily partial, meaning it cannot exceed what is essential for the functioning of internal markets and it must aim to improve the markets²². Over the years, EU consumer law has faced challenges due to varied legal solutions, differing definitions, and inconsistent withdrawal periods among Member States²³. EU officials boast of a robust set of laws ensuring a high level of consumer protection anywhere in the Union²⁴ and describe its consumer protection rules as "the strictest in the world". However, according to Ursula Pachl, deputy director general of The European Consumer Organisation, there is still a striking disparity between those regulations and their enforcement, as Member States have too much liberty in their implementation²⁵. Some believe the EU at times enforces legal paternalism, while others argue we aren't doing enough to protect the vulnerable and that consumer protection is too focused on market integration²⁶. To improve access to litigation and enforcement of consumer laws, the EU has recently become more involved in ensuring justice through alternative dispute resolution methods²⁷.

4. Differences in approaches in terms of product liability

The principles of product liability in the United States are similar to those in Europe, but their application and societal context highlight key differences²⁸. American culture values individualism and personal responsibility, often opposing

²¹ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, Official Journal of the European Union L 304/64.

²² M. Hesselink, *The Ideal of Codification and the Dynamics of Europeanisation: The Dutch Experience* [in:] *The Harmonization of European Contract Law Implications for European Private Laws, Business and Legal Practice*, eds. S. Vogenauer, S. Weatherill, Oxford–Portland 2006, p. 49.

²³ E. Mišćenić, *The Constant Change...*, p. 700.

²⁴ A. Gallego Torres, *Europe's Consumer Protection Story* [in:] *The New Consumer, 50th Special Anniversary Edition*, European Commission 2022, p. 3.

²⁵ L. Thompson, *Does the new EU consumer rights directive go far enough?*, https://www. equaltimes.org/does-the-new-eu-consumer-rights?lang=en [access: 30.06.2024].

²⁶ Rethinking EU Consumer Law, ed. G. Howells, Abingdon 2018, pp. 3–5.

²⁷ *Ibidem*, p. 10.

²⁸ B.J. Riordan, Unravelling the Mystery – A Comparative Introduction to Product Liability Law in the US and Europe, "South Carolina Journal of International Law and Business" 2003, Vol. 1, Issue 1, p. 29.

government regulation²⁹. An example of such opposition was the Federal Trade Commission's proposal to limit advertising to children. Television networks, advertising agencies, food and toy companies, and even cigarette manufacturers fought the proposal, filing lawsuits against the FTC and framing it as excessive government interference³⁰.

The U.S. lacks a federal act regulating product liability, which in 1979 led the Department of Commerce to propose the Model Uniform Products Liability Act, promoting standardized procedures for product liability cases³¹. The act, ultimately, wasn't adopted federally but influenced some state laws³². Each state bases product liability claims on a combination of negligence, strict liability, consumer expectation, and/or breach of warranty. For example, the state of Massachusetts bases its liability standard on negligence alone³³, while California includes negligence, strict liability, consumer expectation, warranty, and others. Strict liability in this state can apply to manufacturing defects, design defects, or inadequate warnings³⁴. Plaintiffs can sue almost every business in the distribution chain, with strict liability applying without fault and regardless of a contractual relationship³⁵. Discrepancies also appear in regards to the burden of proof for design defects: in 47 states it is the plaintiff that must prove the defect, meanwhile in Alaska, California and Hawaii, it is the defendant that must prove the product had no such defect 36 . Consequently, the availability of defenses or viability of the claim itself varies state to state, leaving Americans with a lack of a universal framework for product redress.

In the EU product liability was governed by Directive $85/374/EEC^{37}$ until March 2024, when a new directive was agreed upon³⁸ to further harmonize product

33 M.G.L.A. 231 § 85.

³⁴ See: California Civil Jury Instructions (CACI) Series 1200–1207B, https://www.justia.com/ trials-litigation/docs/caci/1200/ [access: 2.07.2024].

³⁵ S.S. Wu, Product Liability Issues in the U.S. and Associated Risk Management [in:] Autonomous Driving, eds. M. Maurer, J. Gerdes, B. Lenz, H. Winner, Berlin–Heidelberg 2016, p. 559.

³⁶ Cornell Law School Legal Information Institute, Wex Legal Encyclopedia, Products Liability Overview, https://www.law.cornell.edu/wex/products_liability [access: 2.07.2024].

³⁷ 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.

³⁸ European Parliament legislative resolution of 12 March 2024 on the proposal for a directive of the European Parliament and of the Council on liability for defective products, P9_TA(2024)0132.

²⁹ M. Browne, K. Clapp, N. Kubasek, L. Biksacky, *Protecting Consumers from Themselves:* Consumer Law and the Vulnerable Consumer, "Duke Law Review" 2015, Vol. 63, p. 162.

³⁰ Ibidem, p. 166.

³¹ V. Schwartz, *The Uniform Product Liability Act – A Brief Overview*, "Vanderbilt Law Review" 1980, Vol. 33, Issue 3, p. 582 *et seq.*

³² B. Bell, Fortieth Anniversary: The Commerce Department's Foray Into Re-Writing Products Liability Law, "Yale Journal on Regulation Notice & Comment" 2019, p. 3.

liability provisions, most importantly, introducing universal, no-fault-based liability³⁹. Under this regime, liability is independent of the manufacturer's fault or negligence – the injured party only needs to prove the product was defective, caused damage, and that there is a causal link between the two⁴⁰. The Directive also significantly broadens the definition of a defect⁴¹, expands the list of potentially liable parties⁴² and mandates evidence disclosure by both parties⁴³. Unlike U.S. laws, the EU Directive does not distinguish between design, manufacturing, and instruction or warning defects, although some Members do⁴⁴.

In the U.S. resolving responsibility and seeking compensation for accidental injuries or deaths often requires lengthy litigation⁴⁵. High-profile lawsuits, like Liebeck v. McDonald's⁴⁶, seem to highlight American litigiousness, though the U.S. is not *de facto* significantly more litigious than other nations⁴⁷. J. Ramseyer and

⁴² Art. 7 in Proposal for a Directive of the European Parliament and of the Council on liability for defective products 2022/0302, COM(2022) 495 Final, https://eur-lex.europa.eu/resource.html? uri=cellar:b9a6a6fe-3ff4-11ed-92ed-01aa75ed71a1.0001.02/DOC_1&format=PDF [access: 2.07.2024].

⁴³ According to a press release of the European Parliament, it is to further help victims of damage with their compensation claim by giving them the ability to request that the court order the business to disclose the "necessary and proportionate" evidence. See: *Defective products: revamped rules to better protect consumers from damages*, European Parliament News, Press Release, https://www.europarl.europa.eu/news/en/press-room/20240308IPR18990/defective-products-revamped-rules-to-better-protect-consumers-from-damages [access: 3.07.2024].

⁴⁴ M. Mirić, *Product Liability Reform in the EU*, "EU and Comparative Law Issues and Challenges Series" 2023, Vol. 7, p. 386.

⁴⁵ R. Morrow, *Technology Issues...*, pp. 23–24.

⁴⁶ Liebeck v. McDonald's Restaurants, No. CV-93-02419, 1995 (N.M. Dist. Aug. 18, 1994). In this lawsuit Stella Liebeck, a 79-year-old woman, sued McDonald's after she suffered thirddegree burns from spilling a cup of their hot coffee in her lap. The jury awarded her \$2.7 million in punitive damages, highlighting the company's knowledge of the burn risk from their coffee being served at dangerously high temperatures.

⁴⁷ For example: in the US 5,806 lawsuits filed per 100,000 residents compared to 3,681 lawsuits in the UK. See: J.M. Ramseyer, E.B. Rasmusen, *Are Americans More Litigious? Some Quantitative Evidence* [in:] *The American Illness: Essays on the Rule of Law*, ed. F.H. Buckley, New Haven, CT 2013, pp. 2–5.

³⁹ EU Legislation in Progress Briefing, New Product Liability Directive, p. 2, https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739341/EPRS_BRI(2023)739341_EN.pdf [access: 2.07.2024].

⁴⁰ European Parliament Legislative Train, New Product Liability Directive – Q4 2020, p. 1, https://www.europarl.europa.eu/legislative-train/carriage/new-product-liability-directive/report?sid =8201 [access: 2.07.2024].

⁴¹ Art. 6(1) in Proposal for a Directive of the European Parliament and of the Council on liability for defective products 2022/0302, COM(2022) 495 Final, https://eur-lex.europa.eu/resource. html?uri=cellar:b9a6a6fe-3ff4-11ed-92ed-01aa75ed71a1.0001.02/DOC_1&format=PDF [access: 2.07.2024]. Compare with: Art. 6(1) of Directive (85/374/EEC), (OJ L 210, 7.8.1985).

E. Rasmusen point out that while American courts are famous for occasional large payouts in specialized cases, their handling of routine disputes is on par with other wealthy countries, and suggest targeting specific problematic areas like class action lawsuits for reform⁴⁸. The reason why American society is seen as overly litigious might be hiding in both legislation "approach to legislation". In the U.S., contingency fees motivate consumers to seek court redress, while in the EU, preventive regulations and a loser-pays system discourage lawsuits, favouring lowcost or free alternative dispute resolution methods⁴⁹. Furthermore, the EU generally focuses on a "precautionary principle" in the event of potential risk to achieve high protection through preventative measures⁵⁰. This principle is stated *verbatim* in Art. 7 of Regulation (EC) No 178/2002 of food law⁵¹ and echoed in rulings like C-157/96⁵² and C-180/96⁵³, where the Court held that when the existence or extent of risks to human health is uncertain, institutions can implement protective measures without waiting for the full extent or seriousness of those risks to become clear. This opinion was quoted further in case T-199/96⁵⁴ regarding the presence of a carcinogenic compound in cosmetics.

EU consumer law is ever-evolving, with the Omnibus Directive⁵⁵ (part of the New Deal for Consumers), modernising consumer law enforcement and transparency⁵⁶, and the General Data Protection Regulation⁵⁷ setting a milestone in data

⁵¹ 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.

⁵² C-157/96 – The Queen v Ministry of Agriculture, Fisheries and Food and Commissioners of Customs & Excise, ex parte National Farmers' Union and Others.

 53 C-180/96 – United Kingdom of Great Britain and Northern Ireland v. Commission of the European Communities.

⁵⁴ T-199/96 – Laboratoires Pharmaceutiques Bergaderm and Goupil v. Commission.

⁵⁵ Directive (EU) 2019/2161 of the European Parliament and of the Council of 27 November 2019 amending Council Directive 93/13/EEC and Directives 98/6/EC, 2005/29/EC and 2011/83/EU of the European Parliament and of the Council as regards the better enforcement and modernisation of Union consumer protection rules.

⁵⁶ European Commission, What is the New Deal for Consumers? https://ec.europa.eu/commission/ presscorner/detail/es/MEMO_18_2821 [access: 5.07.2024].

⁵⁷ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

⁴⁸ *Ibidem*, p. 25.

⁴⁹ J. Fischer, *Consumer Protection in the United States and European Union: Are Protections Most Effective Before or After a Sale?*, "Wisconsin International Law Journal" 2014, Vol. XX, No. X, p. 117.

⁵⁰ Communication from the Commission on the precautionary principle COM(2000), p. 63, https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/ language-en [access: 1.07.2024].

protection. Historically, the U.S. has lacked comprehensive data protection, focusing instead on preventing harm in specific cases and largely ignoring how consumer data is collected⁵⁸. Following the GDPR, U.S. states like California implemented "GDPR-inspired" provisions⁵⁹. However, as of March 2024, still only 18 states have comprehensive data protection laws⁶⁰.

Another notable difference exists in the right to withdrawal. EU law grants consumers a fourteen-day right to withdraw from most contracts made remotely or off-premises, as per Directive $2011/83/E^{61}$ – a right not universally available in the U.S., where withdrawal rights are a mix of contract, state, and federal statutes. Generally, U.S. sellers are not required to honor return requests unless specified⁶², with states like Connecticut allowing businesses to set their own return policy, provided it is posted conspicuously for customers and defaulting to a 7-day return for new, unused items if no policy is posted⁶³.

While both the EU and the U.S. have highly developed and sophisticated consumer law branches, there is a discernible difference in approaches stemming from their separate history as well as their judicial roots – one common, one continental. American law relies on market power, pre-contractual disclosures, and the *caveat emptor* doctrine⁶⁴, which is still generally followed with some exemptions and requires buyers to inspect goods before purchase, barring recovery for defects they could have discovered⁶⁵.

5. The Panera Bread Lemonade Lawsuits

The new incident that sparked interest in the realm of product liability involves the death of 21-year-old Sarah Katz, who, having a heart condition, died

⁵⁸ F.D. Bellamy, *U.S. data privacy laws to enter new era in 2023*, Attorney Analysis from Westlaw Today, for Thomson Reuters, https://www.reuters.com/legal/legalindustry/us-data-privacy-laws-enter-new-era-2023-2023-01-12/ [access: 5.07.2024].

⁵⁹ Ibidem.

⁶⁰ Bloomberg Law, *Which States Have Consumer Data Privacy Law*?, https://pro.bloomberglaw. com/insights/privacy/state-privacy-legislation-tracker/ [access: 5.07.2024].

⁶¹ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights.

⁶² P. Abril, F. Blázquez, J. Evora, *The Right of Withdrawal in Consumer Contracts: a Comparative Analysis of American and European Law*, "InDret" 2018, p. 5.

⁶³ Connecticut State Department of Consumer Protection, Returns and Exchanges https://portal. ct.gov/dcp/common-elements/consumer-facts-and-contacts/returns-and-exchanges [access: 5.07.2024].

⁶⁴ P. Abril, F. Blázquez, J. Evora, *The Right of Withdrawal...*, p. 5.

⁶⁵ Cornell Law School Legal Information Institute, Wex Legal Encyclopedia, Caveat Emptor, https://www.law.cornell.edu/wex/caveat_emptor [access: 3.07.2024].

after drinking Charged Lemonade at Panera Bread in Philadelphia⁶⁶. Her family filed a wrongful death lawsuit⁶⁷ against the restaurant, calling it a "dangerous energy drink", with 390 milligrams of caffeine and the equivalent of nearly 30 teaspoons of sugar in 30 ounces⁶⁸. This caffeine content exceeds that of standard cans of Red Bull (77.4 mg) and Monster (160 mg) combined⁶⁹. The lawsuit claims Panera failed to inform consumers about the high caffeine levels, leading Katz to believe it was a safe, traditional lemonade or sports drink⁷⁰. Following her death, Panera added a warning on the drink about its caffeine content and advised moderation⁷¹. Sarah Katz's case was not isolated – another lawsuit involves a 46-year-old man who died of cardiac arrest after drinking two lemonades at Panera⁷². The chain argues their products didn't cause his death and views the lawsuits as meritless⁷³. The third lawsuit was filed by a 28-year-old woman who claims permanent cardiac injuries from the lemonade⁷⁴. The fourth lawsuit involves an 18-year-old who allegedly suffered a cardiac arrest and seizures after consuming the drink⁷⁵. Facing these lawsuits, Panera removed the Charged Lemonade from its menu⁷⁶,

⁶⁹ Ibidem.

⁷¹ E. Chuck, *Panera now displaying warning about its caffeinated lemonade in all stores after lawsuit over customer's death*, https://www.nbcnews.com/news/us-news/panera-adds-warning-caffeinated-lemonade-stores-lawsuit-customers-deat-rcna122628 [access: 28.06.2024].

⁷² G. Dean, *Panera is facing a 2nd wrongful death lawsuit after a man had a cardiac arrest following drinking its caffeinated 'charged' lemonade*, https://www.businessinsider.com/panera-bread-charged-lemonade-man-died-after-drinking-caffeinated-beverage-2023-12?IR=T [access: 28.06.2024].

⁷³ S. Price, *Florida man dies after drinking Panera Bread's caffeinated 'Charged Lemonade', according to lawsuit*, https://www.fox35orlando.com/news/florida-man-dies-from-after-drinking-panera-breads-caffeinated-charged-lemonade-according-to-lawsuit# [access: 28.06.2024].

⁷⁴ E. Chuck, A woman alleges Panera's highly caffeinated Charged Lemonade caused her to develop permanent heart problems, https://www.today.com/food/news/woman-alleges-paneras-highly-caffeinated-charged-lemonade-caused-devel-rcna134401 [access: 28.06.2024].

⁷⁵ M. Holohan, *Teen's heart stops after drinking Panera Charged Lemonade: These were his 1st symptoms, lawsuit alleges*, https://www.today.com/health/news/panera-charged-lemonade-cardiac-arrest-teen-rcna153285 [access: 2.07.2024].

⁷⁶ J. Valinsky, *Panera is dropping Charged Lemonade, the subject of multiple wrongful death lawsuits*, https://edition.cnn.com/2024/05/07/food/panera-charged-lemonade-discontinued/index.html [access: 2.07.2024].

⁶⁶ E. Chuck, *Family sues Panera Bread..., supra* note 3.

⁶⁷ Katz *et al.* v. Panera Bread Company *et al.*, 2:2023cv04135. Note: nature of suit listed as personal injury, product liability.

⁶⁸ K. Mannie, *Panera sued over 'Charged Lemonade' energy drink after college student dies*, https://globalnews.ca/news/10045411/panera-bread-charged-lemonade-lawsuit-sarah-katz/ [access: 28.06.2024].

⁷⁰ G. Martinez, *FDA* "gathering information" on woman who allegedly died after drinking Panera Bread lemonade, https://www.cbsnews.com/news/fda-panera-bread-charged-lemonade-penn-student-death/ [access: 28.06.2024].

and the FDA began investigating the matter⁷⁷. U.S. District Judge Timothy J. Savage rejected Panera's argument that there was no causal link between Katz's death and the lemonade⁷⁸.

Questions arise about consumer rights and information disclosure as U.S. regulations limit caffeine only in "cola-like" drinks to 71 mg per 12-oz can⁷⁹, leaving other beverages unregulated, which by some is seen as failure to protect consumer' interest and health⁸⁰. Panera did not violate any regulations as caffeine is considered "Generally Recognized as Safe" (GRAS)⁸¹, exempting it from FDA premarket approval under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act. Moreover, caffeine levels, as explained above, are not regulated in lemonades. In the EU, beverages with high caffeine content (exceeding 150 mg per 1 or 150 mg/33.8 oz) must carry the warning "High caffeine content. Not recommended for children or pregnant or breastfeeding women" followed by the caffeine content expressed in mg per 100 ml, per Regulation (EU) No 1169/2011⁸². Contrastively, in the U.S. there is no requirement for foods or beverages to list caffeine content or warnings⁸³.

Ingredients are regulated in general by Title 21 of the Code of Federal Regulations. However, if an ingredient is absent in 21 CFR, it does not automatically mean it is not permitted. Self-GRAS determinations by manufacturers allow use without FDA notification if companies deem them safe⁸⁴. The EU on the other hand does not have a path similar to GRAS, maintaining databases of approved additives⁸⁵

⁷⁹ U.S. Code of Federal Regulations, Title 21 – Food and Drugs, § 182.1180.

⁷⁷ Supra note 68.

⁷⁸ C. Dolmetsch, *Panera Charged Lemonade deaths puts renewed focus on energy drink safety*, https://www.sentinelsource.com/news/national_world/panera-charged-lemonade-deaths-puts-renewed-focus-on-energy-drink-safety/article_5cecffe8-d9d6-5840-bc31-c85a95a26b02.html [access: 28.06.2024].

⁸⁰ J. Kole, A. Barnhill, *Caffeine Content Labeling: A Missed Opportunity for Promoting Personal and Public Health*, "Journal of Caffeine Research" 2013, Vol. 3 No. 3, pp. 109–110.

⁸¹ GRAS database available at: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SCOGS [access: 5.07.2024].

⁸² Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

⁸³ J. Kole, A. Barnhill, *Caffeine Content Labeling*..., p. 110.

⁸⁴ A. Mozingo, Unlocking Product Innovation Potential on Both Sides of the Atlantic, "Food & Beverage Insider" 2021, Vol. 2, No. 5, p. 30.

⁸⁵ EU compliant additives database available at: https://food.ec.europa.eu/safety/food-improvement-agents/additives/database_en [access: 5.07.2024].

and novel foods⁸⁶. In compliance with Regulation (EU) 2015/2283⁸⁷, a novel food's pre-market authorization is required before it can be placed on the EU market. Member States are also able to impose higher standards for their internal markets.

Another contentious issue in regard to ingredient regulation is their use in cosmetics. The Federal Food, Drug and Cosmetic Act does not require FDA approval for cosmetic products and ingredients before they enter the market – they must, however, be safe for consumers under labeled or customary conditions of use⁸⁸. Currently, many hazardous or carcinogenic substances used in the US, such as potassium bromate (which the FDA has been petitioned to ban for over 20 years), are banned in the EU⁸⁹. The Union bans or restricts over 1,300 chemicals in cosmetics, whereas the U.S. only bans or restricts 11⁹⁰.

6. Conclusions

It is generally accepted that there has always been a trade-off between new machinery, or new technologies and the personal risks they pose⁹¹. The same applies to every product available on the market. In product liability, incentives to put out safe products are crucial. In the U.S. producers adhere to best practices to reduce litigation, while in Europe they focus on satisfying regulatory standards – both leading to fewer defects and injuries⁹². The U.S. legal system, characterized by its reliance on market-driven solutions, contrasts with the EU's precautionary principle and preventive regulations. It is indeed difficult to definitively draw a line between legal pragmatism and paternalism. While opinions on the impact of product liability on innovation are polarised, it is widely agreed that much is at stake, whether it be the future of companies and products or the safety of consumers⁹³.

⁸⁶ EU novel foods catalogue available at: https://food.ec.europa.eu/safety/novel-food/novel-food-status-catalogue_en [access: 5.07.2024].

⁸⁷ Regulation (EU) 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.

⁸⁸ U.S. Food and Drug Administration Official Website, Cosmetic Ingredients, https://www.fda.gov/cosmetics/cosmetic-products-ingredients/cosmetic-ingredients [access: 5.07.2024].

⁸⁹ R. Rabin, *What Foods Are Banned in Europe but Not Banned in the U.S.*?, https://www.nytimes.com/2018/12/28/well/eat/food-additives-banned-europe-united-states.html [access: 5.07.2024].

⁹⁰ O. Milman, US cosmetics are full of chemicals banned by Europe – why?, https://www. theguardian.com/us-news/2019/may/22/chemicals-in-cosmetics-us-restricted-eu [access: 5.07.2024].

⁹¹ R. Morrow, *Technology Issues...*, p. 23.

⁹² B.J. Riordan, Unravelling the Mystery..., p. 39.

⁹³ R.M. Morrow, Product Liability..., p. 28.

American judicial reporter, Mark J. Stern, commented that instead of ensuring that products are safe before reaching consumers, the American system relies on lawsuits, which do not always reflect their validity - in this instance, the lemonade cases have garnered much media attention not because the inherent danger of the beverage, but because of their absurdity⁹⁴. Despite the shock value of this case, most experts believe it will not lead to changes in the law. Elizabeth Burch, a law professor at the University of Georgia, indicated that the health problems of Brown and Katz might limit the number of lawsuits, and stated that these cases were extreme, when opening the floodgates would require a broader theory of liability suitable for class action scenarios – which is not yet the case in this instance⁹⁵. The Panera Bread lemonade scandal underscores the need for a balanced approach to regulation and the critical importance of upholding consumer rights, especially the right to be informed. Adequate regulation ensures product safety without stifling personal freedom and product innovation, while the right to be informed is essential for protecting consumers from harm. In this case, the failure to clearly disclose the caffeine content in the lemonade and a lack of warnings represent a potential breach of consumer rights, emphasizing the need for better regulatory practices and more transparent communication from businesses.

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⁹⁵ C. Dolmetsch, *Panera Charged..., supra* note 79.

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