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The Regulation of Trans Fats in Food Products in the US and the EU

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The regulation of trans fats sets an interesting precedent for the regulation of other legal but harmful food ingredients, such as salt, sugar and saturated fat. In this paper, we distinguish three regulatory measures to reduce such ingredients in food and population intakes: the labelling of an ingredient, a limit on the amount of the ingredient in food products and a ban on the production technology that creates the ingredient. We will compare the regulations promulgated in the US and in the EU to reduce trans fats in food and population intakes. This comparison will identify a common focus on scientific risk assessment and precautionary action but a different orientation towards regulating the internal market and towards producer interests. The comparison also lays bare differences in the regulatory systems of the US and the EU that may inspire US and EU regulators to reflect on possible improvements for future fights against legal but harmful food ingredients.

Keywords: Trans fat; labelling; legislative limits; US; EU; economic consumerism; producerism

1. Introduction

A Dutch slice of cheese, a French croissant, an Italian pizza or an American burger, each of these tasty food products contain high levels of trans fatty acids (trans fats). Trans fats are a type of unsaturated fatty acids that may be naturally present in dairy and meat or can be industrially produced in order to enhance the shelf-life and texture of food products. Even though unsaturated fatty acids are in general not known to be harmful for human health, trans fats pose significant health risks. Nowadays, there is broad scientific consensus that high intakes of trans fats increase the risk of coronary heart disease,¹ which can eventually cause heart attacks and death. Figures even show that the risk of dying from heart disease is between 20 to 32% higher when 2% of the daily energy intake is consumed as trans fats as compared to different other fats or carbohydrates. Furthermore, high intakes of trans fats are associated with cardiovascular disease, obesity and type 2 diabetes.²

On 14 May 2018, the World Health Organisation (WHO) called for the elimination of industrially-produced trans fats from the global food supply by 2023.³ It released the REPLACE action package, which provides

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¹ Coronary heart disease refers to a group of diseases that is caused by a narrowing or anomaly in the arteries of the heart due to a build-up of fatty substances. See the Netherlands National Institute for Public Health and the Environment (*Rijksinstituut voor Volksgezondheid en Milieu (RIVM)*), 'Coronaire hartziekten', <<https://www.volksgezondheidenzorg.info/onderwerp/coronaire-hartziekten/cijfers-context/huidige-situatie#definitie--node-coronaire-hartziekten>> (last visited 5 November 2017); NHS, 'Coronary Heart Disease', <<https://www.nhs.uk/conditions/coronary-heart-disease/>> (last visited 11 July 2019).

² European Commission, 'Trans fats in Foods and in the Overall Diet of the Union Population', (Factsheet, 2015), p. 1; European Commission, *Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population*, COM(2015) 619 final, p. 5; European Parliament, *Trans fats – Overview of recent developments. Briefing*, (March 2016), p. 2; European Food and Safety Authority, Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids', (2004) 81 *EFSA Journal* No. 1, p. 2.

³ WHO, 'WHO plan to eliminate industrially-produced trans fatty acids from the global food supply chain', <<https://www.who.int/news-room/detail/14-05-2018-who-plan-to-eliminate-industrially-produced-trans-fatty-acids-from-global-food-supply>> (last visited 22 July 2019).

a step-by-step guide for governments to eliminate trans fats from their food supply chain.⁴ A year later, the International Food and Beverage Alliance (IFBA), which include the food giants Unilever, Nestlé and McDonalds, pledged to align to the WHO's standard of a maximum of 2% trans fats in the fat and oil content of food products by 2023.⁵

The campaign of the WHO and the commitment of several food giants to reformulate their products sets an interesting precedent for how other legal but harmful food ingredients – such as salt, sugar and saturated fats – may be tackled in the future. As the reformulation of products is costly and time-consuming, businesses tend to opt for less drastic health-promoting initiatives such as portion control, clear nutritional information and responsible marketing. But the fight against trans fats shows that health organisations, governments and consumers may not have to settle with less.⁶

Regulators have also taken actions to reduce trans fats in food and population intakes. On 24 April 2019, the EU adopted a regulation to limit the amount of trans fats in food products, in line with the WHO recommendations. This regulation was preceded by trans fat limits in several European Member States. By setting a legislative limit on the trans fat content in food products in 2003, Denmark was the first European Member State and the first country in the world to introduce a policy in the fight against trans fats.

Another jurisdictional area at the forefront of the fight against trans fats is the US. The fight against trans fats in the US dates back to 1993, when a citizen petition was filed to require trans fat labelling on pre-packed food products. Ten years after this citizen petition and only two months after the Danish had published their trans fat limit, the US set precedent as the first country with mandatory trans fat labelling legislation.⁷

In this paper, we will compare the regulatory approaches of the US and the EU in the fight against trans fats. Our comparison will identify several principles and orientations that are guiding in both regulatory systems and that can explain similarities and differences in the regulatory approaches of the US and the EU. An understanding of the similarities and differences between the regulatory approaches of the US and the EU on the basis of these principles and orientations can inform future decision-making about the regulation of other legal but harmful food ingredients.

The paper will be structured as follows: first, a brief introduction into the fight against trans fats will be given and we will identify several regulatory measures that have been proposed in this fight. Second, we will discuss the trans fat regulations that are taken in the US and in the EU. The focus will mainly be on the regulations that are taken at the federal level in the US and at the European level in the EU, because the regulatory framework at these levels covers the largest jurisdictional area. But we will also discuss some regulatory measures at sub-federal level in the US and at the level of the Member States in the EU that have either set precedent for other local or state regulations or have triggered regulations at the federal or EU-level. Third, four policy principles and orientations will be identified in a comparison of the regulatory approaches of the US and the EU. We will conclude this paper with some comments and recommendations for future decision-making on legal but harmful food ingredients.

2. The regulation of trans fats

When regulating harmful trans fats in food products, the main concern is industrially-produced trans fats. These can be distinguished from naturally occurring trans fats, which are produced by the gut bacteria of ruminant animals, such as cattle sheep and goats, and are found in small amounts in the fatty parts of meat- and milk-based products from these animals.

The proportions of industrially-produced trans fats are generally much higher than the proportions of naturally occurring trans fats in food products. Industrially-produced trans fats are formed when fats or oils are modified by partial hydrogenation and, hence, occur in partially hydrogenated fats or oils (PHOs). PHOs are used by manufacturers to enhance the texture and to increase the shelf life of processed foods in an

⁴ WHO/NMH/NHD, 'Replace Trans Fat', 18.4, May 2018.

⁵ IFBA, 'Press Release: International Food & Beverage Companies Align with WHO Standard in Global Commitment on Industrially Produced Trans Fat', 7 May 2019, <https://ifballiance.org/uploads/press/pdf/5cd16e6620f34_IFBA_Press%20Release_%20iTFA_%2007.05.2019.pdf> (last accessed 23 July 2019).

⁶ K. Askwe, Food Navigator, 'Food 'powerhouses' to phase out industrially produced trans fats by 2023', 10 May 2019, <<https://www.foodnavigator.com/Article/2019/05/10/Food-powerhouses-to-phase-out-industrial-trans-fats-by-2023>> (last visited 23 July 2019).

⁷ The Danish trans fat limit was published in March 2003 (Executive Order No 160 of 11 March 2003 on the Content of Trans Fatty Acids in Oils and Fats – see the Danish Nutrition Council, *The influence of trans fatty acids on health* (2003)). The trans fat labelling legislation of the US was published in July 2003 (FDA, Final Rule, Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 133, 41434 (11 July 2003)).

inexpensive way. During the process of partial hydrogenation, hydrogen is added to the liquid oils to make it solid or semi-solid at room temperature. The amount of trans fats formed by partial hydrogenation depends on the production technology used and can vary from small amounts to more than 50%. Repeatedly heating oils that initially contain low contents of trans fats can also generate additional amounts.⁸

Trans fat regulations focus on industrially-produced trans fats, as the proportions of industrially-produced trans fats are in general much higher than the proportions of naturally occurring trans fats in food products and the amounts of industrially-produced trans fats can be reduced by changing the production process and by reformulating food products in order to use less PHOs.⁹

The fight for regulating trans fats in food products started in 1993 in the US when the Centre for Science in the Public Interest (CSPI) pressured the responsible federal organisation to introduce mandatory labelling of trans fats on food packages. Since then, different regulatory measures to reduce the amount of trans fats in food products have been introduced across the globe. The felt need to implement trans fat reducing measures in order to protect the public health was triggered by changes in the food supply and the purchasing behaviour of consumers. Processed and packaged food constitutes a growing part of the consumed food products globally and is already a significant part of the consumed food products in Western societies.¹⁰ Because processed and packaged food products contain relatively high proportions of trans fats compared to other food products, the need and urgency for taking regulatory measures to reduce trans fat intakes among consumers is now widely supported.

Broadly, three regulatory measures can be distinguished: (1) trans fat labelling that requires the amount of trans fats to be indicated on the food package, (2) limits on trans fat content in a food product and (3) a complete ban on PHOs. These measures can be formulated either as legislative actions that ask for mandatory changes from manufacturers or as voluntary measures. Voluntary measures can be initiated by governments in agreement with the cooperating food manufacturers or by the manufacturers themselves when they feel the need to take measures because of public awareness and pressure. An example is the Dutch-British cooperation Unilever that decided voluntarily to ban trans fats from its products. This decision was dictated by public pressure due to media coverage and was, according to Unilever, in line with its policy to 'know their products' and also 'apply that knowledge'.¹¹

Mandatory or voluntary **labelling** requires that the amount of trans fat content is indicated on the food package in the ingredient list and/or the nutrition declaration. Thereby, it aims to inform the consumer about their trans fat intake when eating or drinking the food. Labelling can be criticised for unfairly targeting producers of packaged foods as opposed to producers of unpackaged or restaurant foods because it does not have a direct impact on the latter category of foods.¹² With regard to voluntary labelling, it depends on the existing labelling legislation in a jurisdiction whether voluntary labelling is allowed. Some labelling regulations do not allow that other information is displayed than the required information.

The measure of a voluntary or legislative **limit** on trans fats requires the manufacturer to reformulate its products or adapt its production technology to reduce the trans fat levels in the food.¹³ The restriction can either concern the proportion of trans fats in the ingredients or in the final product. When the restriction is put on the ingredients, the limit sets a maximum percentage of trans fats allowed in the oils and fats in the product. This usually leads to a lower amount of trans fats in the final product than in the case that the percentage of trans fats in the final product is restricted.¹⁴

⁸ See European Parliament, *supra* note 2, p. 2; Centre for Disease Control, 'Trans Fat: The Facts', (2014); World Health Organization (WHO), *Eliminating trans fats in Europe. A policy brief* (2015), p. 2.

⁹ For example, the European Commission states that the proportion of trans fats in industrially-produced fats and oils can be modified whereas the proportion of trans fats in ruminant fats is relatively stable. See European Commission, COM(2015) 619 final, *supra* note 2, p. 4.

¹⁰ According to the Netherlands Scientific Council for Government Policy (*Wetenschappelijke Raad voor Regeringsbeleid, WRR*), pre-packaged food products, including processed foods and drinks, make up around half of the consumed food products in Western societies. An increase in welfare, single-person households and number of working women and the related growing preference for convenient food have led to an increase in supply and consumption of composite food products and ready-made meals. This development is facilitated by the introduction of the fridge, oven and microwave in developed countries, but also in other parts of the world. See WRR, 'Naar een voedselbeleid', (WRR report number 93, 2014), p. 11.

¹¹ European Parliament. Policy Department Economic and Scientific Policy, *Trans Fatty Acids and Health: A Review of Health Hazards and Existing Legislation* (November 2008), p. 15.

¹² See WHO, *supra* note 8, pp. 4–6.

¹³ The amount of trans fats formed can vary according to the production technology used for partial hydrogenation. Adapting the production technology can, thus, significantly reduce the level of trans fats in PHOs.

¹⁴ See European Parliament, *supra* note 11, p. 13.

The last measure, the voluntary or legislative **ban** on PHOs, does not ban trans fats directly, but bans the production process by which trans fats are formed. The ban requires the food manufacturer to find new and mostly more expensive ways to produce its foods with the right texture and a sufficient shelf life.

3. Regulations in the US

As we have identified different regulatory measures to decrease trans fat intakes, we will discuss in this section the regulatory measures that are taken in the US. First, a brief introduction will be given into the regulatory system of the US in terms of the supervisory and legislative authorities that deal with food law. This provides the background knowledge that is needed for our subsequent discussion of the federal trans fat regulations and some state and local trans fat regulations in the US.

3.1. Supervisory and legislative authorities in the US

Legislation and regulation of the food market can take place at the federal, state or local level in the US. The division of competence between the federal and state level, to which the term *federalism* refers, has its legal basis in the Supremacy Clause of the American Constitution. The clause provides that the Constitution and federal laws have supremacy over state legislation, meaning that federal laws pre-empt state and local laws if they come in conflict. However, federal law can only pre-empt state law when the Constitution has explicitly transferred legislative authority to federal authorities, for otherwise the authority is reserved to the states or to the people.¹⁵

The competence to take regulatory measures relating to health and welfare of the citizenry is an exclusive state power, with the possibility of delegating to local authorities. This exclusive state power is denoted by the term *police power* and is exercised by states in order to protect health, safety, welfare and the general wellbeing of the citizens.¹⁶

Even though there is an exclusive state power to make food inspection laws and health laws, federal authorities may also take health protecting regulatory measures on the food market because it falls under federal authority via another power. The American Constitution grants federal authorities the power to regulate commerce. Commerce is given a very expansive interpretation as it does not only cover interstate trade but also any activity that indirectly affects interstate trade. Since the food market crosses state boundaries, the regulation of food products is often interpreted as falling within the scope of this federal authority to regulate interstate trade.¹⁷

The result of the different federal and state powers is a patchwork of different laws. Besides regional difference in areas that do not fall within the scope of federal authority, states can also take more stringent measures than the federal legislation prescribes as long as these state laws do not place an unreasonable burden on interstate commerce. There is a risk that the different state laws are inconsistent with federal laws in the sense that there is a direct or indirect conflict between state and federal laws. To prevent inconsistencies from occurring, the federal government issues model laws. An example is the model Food, Drugs and Cosmetics Act. 'When the models or the federal laws are perceived as adequate by state governments, usually the states will adopt the model or federal regulations essentially word for word into state law'.¹⁸

The federal legislative authority is vested in the US Congress. In areas that require technical expertise, such as health and science related topics, the Congress often delegates legislative authority to administrative authorities. 'The laws promulgated by administrative authorities are called regulations or administrative rules.'¹⁹

The federal responsibility for food regulations in the US is primarily delegated to two federal agencies: the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA). The FDA is the main actor for the regulation of industrially-produced trans fats, as this agency is responsible for all food products except meat. Meats, poultry and egg products are inspected by the Food Safety Inspection Service of the USDA.²⁰

The fight against trans fats in the US, however, is not initiated by either of these two administrative authorities. The fight dates back to 1993 when the CSPI urged the FDA to require labelling of trans fats.

¹⁵ N.D. Fortman, *Food Regulation. Law, Science and Policy* (2017), p. 8.

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ *Ibid.*, p. 9.

¹⁹ *Ibid.*, p. 7.

²⁰ *Ibid.*, p. 14.

Since this did not trigger the FDA to take any regulatory measures, the CSPI filed an official petition to the FDA in 1994 to require trans fats to be listed on nutrition labels. When the labelling requirement was finally promulgated by the FDA in 2003, the CSPI went a step further by petitioning the FDA for prohibiting the use of PHOs.²¹

The petitions of the CSPI have been an important trigger for the FDA to enact trans fat regulations. In 2003 the FDA finalised its ruling requiring trans fat labelling and in 2015 the FDA has ruled that PHOs are no longer generally recognised as safe, resulting in a ban of PHOs in all food products unless the FDA approves for specific use.

3.2. Federal regulations in the US

The FDA has promulgated two regulations to reduce trans fat intakes: the federal labelling legislation of 2003 and the ban of PHOs in food products of 2015. We will discuss these regulations in their respective order.

3.2.1. Federal labelling legislation in the US

It took many years before the FDA enacted legislation that required trans fats to be labelled on food products. Even though the CSPI had already petitioned the FDA to require trans fats to be listed on Nutrition Fact Labels in 1994, the FDA only brought a legislative proposal forward in 1999²² and it took the FDA until 2003 to finalise a labelling rule.²³

The labelling rule requires that the amount of trans fat content is listed on a separate line under saturated fat on nutrition facts labels.²⁴ This requirement concerns only food products that contain more than 0.5 gram of trans fats per serving. A common criticism is that food products with less than 0.5 grams of trans fats are misleadingly labelled as trans fat free.²⁵ The legislation gave manufacturers until 2006 to comply with the requirements.

The labelling legislation 'triggered reformulation of many foods to eliminate or decrease the amount of trans fat'.²⁶ It also led to several private legal actions against food manufacturers that did not comply with the labelling legislation or did not comply with their widely advertised decrease of trans fats in their food products. Following the labelling legislation, the US organisation BanTransFat.com, led by California lawyer Steven Joseph, sued McDonalds in 2003 for quietly reversing its widely publicised switch from PHOs to safer oils. McDonalds settled this lawsuit by paying \$7 million to the American Heart Association for an education campaign about trans fat intake. At the same time, BanTransFat.com also threatened to sue Kraft for failing to label the presence of trans fats in Oreo cookies.²⁷ Moreover, after the 2006 compliance deadline of the labelling legislation, the CSPI sued KFC and Burger King for failing to disclose the use of PHOs. This encouraged both companies to change to trans fat free oils.²⁸

3.2.2. Federal ban on PHOs in the US

The 2015 ban on PHOs in food products, the second federal legislation, entails that PHOs are no longer *generally recognised as safe* (GRAS) by the FDA. Until 2015, PHOs had a so-called GRAS status.

²¹ Centre for Science in the Public Interest (CSPI), 'Artificial Trans Fat: A Timeline', (27 July 2016). On the basis of Title 21 of the U.S. Code §348(b) 'any person may, with respect to the intended use of a food additive, file (...) a petition proposing the conditions under which such additive may be safely used'. See M.R. Grossman, 'FDA Issues Order to Ban Artificial Trans Fat by 2018', (2015) 4 *European Food and Feed Law* No. 317, p. 319.

²² FDA, Proposal, *Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 64 Fed. Reg. 221, 62746 (17 November 1999).

²³ FDA, Final Rule, *Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 68 Fed. Reg. 133, 41434 (11 July 2003).

²⁴ See Fortman, *supra* note 15, p. 70.

²⁵ See Grossman, *supra* note 21, p. 317.

²⁶ *Ibid.*

²⁷ BanTransFat.com, 'The McDonalds Settlement', (February 2005) <<http://www.bantransfats.com/mcdonalds.html>> (last visited 23 July 2019); BanTransFat.com, 'The Oreo Case', (June 2003) <<http://www.bantransfats.com/theorecase.html>> (last visited 23 July 2019).

²⁸ See CSPI, *supra* note 21; CSPI, 'KFC sued KFC Sued for Fouling Chicken with Partially Hydrogenated Oil: Lawsuit Aimed at Eliminating, or Disclosing Use of Artery-Clogging Frying Oil', (June 2006) <<https://cspinet.org/news/kfc-sued-fouling-chicken-partially-hydrogenated-oil-20060612>> (last visited 5 July 2017); CSPI, 'Burger King Hit with Trans Fat Lawsuit: CSPI Says Burger King is Biggest Chain Without Firm Plans to Convert to Safer Alternatives to Partially Hydrogenated Oils', (May 2007) <<https://cspinet.org/news/burger-king-hit-trans-fat-lawsuit-20070516>> (last visited 5 July 2017).

An additive is given a GRAS status, when there is scientific consensus about the safeness of the substance under its intended use.²⁹ The scientific consensus specifically concerns the use of a substance and not the substance itself. For example, the use of caffeine in cola up to 0.02% is considered to be GRAS, but caffeine itself is not a GRAS substance.³⁰ The GRAS status also depends on the food in which the substance is used. From the court case of *Coco Rico, Inc.*,³¹ it followed that 'the general acceptance of a substance in one food does not make the use of a substance GRAS for another food or use'.³² *Coco Rico, Inc.* used a coconut concentrate containing potassium nitrate in soft drinks and claimed that potassium nitrate was GRAS because it was approved for use in meats. However, the court ruled that 'the sanction permitting very limited use of potassium nitrate in meats cannot be construed to sanction use of the same substance for an altogether different purpose in beverages'.³³

The decision of the FDA in 2015³⁴ to revoke the GRAS status of PHOs has the consequence that PHOs will be regarded as food additives in the definition of the Federal Food, Drug and Cosmetics Act (FD&C Act). The FD&C Act defines a food additive as:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (...), if such substance is not generally recognized (...) to be safe under the conditions of its intended use.³⁵

Hence, by definition, a substance is a food additive if (1) it affects the characteristics of any food and (2) it does not have a GRAS status. As PHOs affect the texture and shelf life of food and the 2015 decision revokes the GRAS status, PHOs fall under the definition of food additives of the FD&C Act.³⁶

Consequently, the use of PHOs has to comply with the requirements of the FD&C Act. The FD&C Act requires that all new food additives are approved for use by the FDA before its use in food, as it presumes that new food additives are unsafe unless proven otherwise. In order to get approval, the food manufacturer has to submit a food additive petition.³⁷ This petition should, inter alia, include full reports of all safety investigations with respect to the intended use of the additive. If the additive is approved, the FDA issues a federal regulation specifying 'the approved function, the types of foods in which the additive can be used, the maximum amounts to be used, and how the additive must be identified on food labels'.³⁸

Similar to the GRAS status, a food additive is not approved as a substance in general, but only for its intended use. The manufacturer bears the full burden of proof and a permanent approval is never given. 'FDA continually reviews safety of approved additives based on the latest scientific knowledge to determine if approvals should be modified or withdrawn'.³⁹

The burden of proof for food additive approval is lower than for the GRAS status. The GRAS status requires 'either a strong consensus or near unanimity'⁴⁰ among experts, while for the food additive approval 'reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use'⁴¹ is enough.

Despite the heavier burden of proof, the GRAS status offers significant benefit over food additive approval for manufacturers. The GRAS status of an additive allows firms to immediately market a food product without an official approval of the safety of the use of the additive by the FDA. The FDA will verify the safety of the use of the additive, that was self-determined by the manufacturer, when the substance is already

²⁹ Federal Food, Drug & Cosmetics Act (FD&C Act), §201(s).

³⁰ See Fortman, supra note 15, pp. 221–222.

³¹ *United States v An Article of Food, Coco Rico, Inc.* 752 F.2d 11 (1985).

³² See Fortman, supra note 15, p. 222.

³³ *Ibid.*, p. 224; *United States v An Article of Food, Coco Rico, Inc.*, supra note 31.

³⁴ FDA, Notice & Declaratory Order, *Final Determination Regarding Partially Hydrogenated Oils*, 80 Fed. Reg. 116, 34650 (17 June 2015).

³⁵ FD&C Act, §201(s).

³⁶ The FD&C Act also exclude prior-sanctioned substances and several ingredients, such as colour additives, dietary supplements and pesticides and drugs in animal feed, from the definition of 'food additive'. Prior-sanctioned substances encompass substances 'that were sanctioned or approved by the FDA or USDA before the 1985 Food Additives Amendment'. This amendment established the regulation of food additives as it is currently prescribed by the FD&C Act. PHOs are not prior-sanctioned substances or among the list of excluded ingredients. Hence, they will fall under the food additives regulations of the FD&C Act. See Fortman, supra note 15, p. 222.

³⁷ The requirements for a food additive petition are listed in section 409(b) (2) of the FD&C Act, and 21 Code of Federal Regulations § 171.1 (c) describes the requirements in greater detail. See Fortman, *ibid.*, p. 207.

³⁸ See Fortman, *ibid.*, p. 208.

³⁹ *Ibid.*, p. 208.

⁴⁰ *Ibid.*, p. 221.

⁴¹ *Ibid.*, p. 207.

marketed. By contrast, the food additive approval process does not permit the marketing of the additive before it has gained approval by the FDA. The consequence is that manufacturers face the costs of having to wait with marketing until they have passed the costly and protracted food additive approval process.⁴²

In the decision of 2015 to revoke the GRAS status of PHOs, the FDA has set a compliance date of 18 June 2018. This means that manufactures either had to remove PHOs from their products or go through the timely process of food additive approval before that date. The Grocery Manufacturers Association hoped to prevent regular food additive approvals for PHOs in the future by filing a food additive petition to allow the use of small amounts of PHOs. However, the FDA denied the petition, because it did not consider the provided information sufficient to conclude that the requested uses of PHOs are safe.⁴³ This denial is in line with the FDA's previous conclusions that only totally eliminating trans fats from food would be enough. It based these conclusions on its own scientific evidence showing that the levels of trans fat intake proportionally effect the risk of coronary heart disease.

3.3. State and local regulations in the US

State and local authorities play a prominent role in food safety regulations in the US, as state and local food regulations determine to a large extent food safety and food quality. A reason for this is the allocation of resources: the combined food-related budget of the federal agencies is only a small amount of the total federal government budget and the combined total of state and local officials far outnumbers the federal food regulatory staff.⁴⁴

Several local governments have enacted trans fat limits.⁴⁵ The City of New York was the first big city to promulgate trans fat legislation. The New York Board of Health of New York City approved in December 2006 the so-called 'New York City Ban': an amendment to the New York City Health Code⁴⁶ restricting the use of artificial trans fats in all New York City restaurants and other food service establishments. The legal restriction was implemented in two stages:

The initial stage, which began July 1, 2007, prohibited food service establishments from using artificial trans fats containing oils, shortening or margarine with 0.5 grams or more of trans fat per serving for frying or as a spread. The second stage, which began July 1, 2008, required all products to have less than 0.5 grams of trans fat per serving. Foods served in the manufacturer's originally sealed packaging were exempt. Enforcement of the restriction relied on the existing restaurant sanitary inspection system, which included a new check for the presence of trans fat in products used by the restaurant, separate from the food safety score.⁴⁷

The regulation in New York City was preceded by the project of BanTransFats.com in the smaller city of Tiburon in California. The project encouraged restaurants to voluntarily choose to cook their dishes in trans fat free oils.

These two examples triggered other local and state authorities to impose a similar limit on trans fats in restaurants. For example, in 2007 the local government of Montgomery County in Maryland approved a ban on storing, distributing, holding for service, using in preparation of any menu item or serving in any food service facility of food containing more than 0.5 grams of trans fats per serving. Foods sold or served in a manufacturer's original package were exempted from this restriction.⁴⁸ Similar to the New York City and Montgomery bans, the state of California promulgated in 2008 that no food may be stored, distributed, served by, or used in the preparation of any food within a food facility if it contains more than 0.5 grams of trans fats per serving.⁴⁹ Thereby, the state of California became the first US state to impose a ban on trans fats in restaurants.

⁴² Ibid., p. 221.

⁴³ FDA, Notice, *Grocery Manufacturer Association; Denial of Food Additive Petition*, 83 Fed. Reg. 98, 3663 (21 May 2018).

⁴⁴ See Fortman, *supra* note 15, p. 17.

⁴⁵ National Restaurant Association, 'Enacted State and Local Trans Fat Bans', (2013) <https://www.restaurant.org/downloads/pdfs/advocacy/maps/map_transfat.pdf> (last visited 12 October 2018).

⁴⁶ Section 81.08 of the New York City Health Code.

⁴⁷ New York City Global Partners, 'Best Practice: Restriction of Trans Fat in Restaurant Food', (15 January 2014) <http://www.nyc.gov/html/ia/gprb/downloads/pdf/NYC_Health_TransFat.pdf> (last visited 12 October 2018).

⁴⁸ County Council Resolution No. 16-134, Montgomery (2007).

⁴⁹ Assembly Bill 97 (AB 97) of the State of California, section 1, chapter 12.6 (2008); Section 114377 of the California Health and Safety Code.

The state and local trans fat legislations have been criticised for causing unfair competition among restaurants, since large fast food restaurants are better able to handle the regulation than small independent restaurant owners. Also, the legislations have been criticised for having a limited scope of application, as it would be unfair to target only restaurants and other food service establishments, and not grocery stores or food producers.⁵⁰ However, if the scope of application of the state and local legislations is broadened, the legislations may affect interstate trade and may, thereby, come in conflict with federal legislation that has supremacy over state and local legislations.

4. Regulations in the EU

In this section, we will discuss the regulatory measures that are taken in the EU. We will start with a brief introduction into EU food law. Subsequently, we will discuss the EU food labelling legislation and the trans fat limit that the EU adopted in April 2019. We will conclude with a discussion of some trans fat regulations that are taken in EU Member States and that have triggered the EU to introduce the 2019 trans fat limit.

4.1. Supervisory and legislative authorities in the EU

While the vertical division of competence in the US is based on the principle of federalism, the EU is not a federal state but a union of independent sovereign states. The precise character of the EU is heavily contested, as it is neither a federal state nor, simply, an intergovernmental organisation in which sovereign states cooperate on the basis of international treaties. The transfer of sovereign powers to the EU level has caused communalisation. The EU is often described as an international community with intergovernmental characteristics. The Netherlands Scientific Council for Government Policy (*Wetenschappelijke Raad voor Regeringsbeleid, WRR*) describes the EU as a multilevel *sui generis* political system with a European, national and regional level in which unique forms of governance coexist, such as governance in horizontal networks, and hierarchical and intergovernmental forms of governance and politics.⁵¹

The division of competence in the EU is based on the Treaty on the Functioning of the European Union (TFEU). The Treaty can confer on the EU an exclusive competence (whereby Member States may not legislate),⁵² a competence shared with the Member States (whereby Member States may legislate as long as the EU has not done so)⁵³ or a supporting and coordinating competence (whereby the EU may legislate to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas).⁵⁴

The type of competence of the EU depends on the policy area that is chosen as the legal basis for legislation. The legal basis for legislation concerning trans fat intakes can be found in the following areas: the protection and improvement of public health (Article 168 of the TFEU), the protection of consumers (Article 169 of the TFEU) and the harmonisation of the internal market (Article 114 of the TFEU).

With regard to *the protection and improvement of public health*, the EU has the competence to support, coordinate or supplement the actions of the Member States. This is the least far-reaching competence, as the EU is only authorised to define guidelines and pass laws to establish incentive measures but not to adopt legislation in order to harmonise national laws.⁵⁵

With regard to *the protection of consumers* and *the functioning of the internal market*, the EU has a shared competence with the Member States.⁵⁶ The EU can adopt legally binding acts and Member States lose their power to the extent that the EU has exercised its competence.⁵⁷ Article 114 of the TFEU confers upon the EU the competence to *harmonise* the internal market. This harmonisation can take the form of full harmonisation (maximum harmonisation) or partial harmonisation (minimum harmonisation). In the case of full harmonisation, Member States must implement the EU measures, may not enact or retain any rules which depart from them, but are allowed to implement and use other regulatory options.⁵⁸ In the case of partial

⁵⁰ European Parliament, *supra* note 11, p. 16.

⁵¹ WRR, 'Europa in Nederland', (WRR-rapportnummer 78, 2007), p. 32.

⁵² See Art. 2(1) of the Treaty on the Functioning of the European Union (TFEU).

⁵³ See Art. 2(2) of the TFEU.

⁵⁴ See Art. 2(5) of the TFEU.

⁵⁵ See Art. 6 in combination with Art. 168 of the TFEU; P. Craig & G. De Búrca, *EU Law: Text, Cases and Materials* (2015).

⁵⁶ See Art. 4(2)(a) and Art. 4(2)(f).

⁵⁷ See Art. 2(2) of the TFEU.

⁵⁸ For example, the Directive on commercial agents (85/653) provides for options regarding a commercial agent's remedies towards the principal. See European Parliamentary Research Service, *EU competence in private law – The Treaty framework for a European private law and challenges for coherence* (2015), p. 6.

harmonisation, Member States are obliged to implement the minimum EU standards, but are allowed to retain or introduce higher national standards.⁵⁹

The legislative and executive responsibility for food regulation at the EU level lies with the European executive and legislative institutions: the European Commission (EC), the European Parliament and the European Council. In the ordinary legislative procedure of the EU, the EC is responsible for initiating food regulations and the European Parliament and the European Council are responsible for adopting legislative measures.⁶⁰ Within the EC, the Directorate-General for Health and Food Safety (DG SANTE) is responsible for EU food law. Through its Health and Food Audits and Analysis Directorate (previously called 'Food and Veterinary Office' – FVO), DG SANTE also 'carries out inspections in the EU countries and in non-EU countries exporting to the EU to evaluate compliance with EU standards'.⁶¹

When the EC is authorised to adopt implementing acts, which set conditions to ensure that a given law is implemented uniformly across the EU, the so-called *comitology* procedures⁶² apply in order to compensate for the absence of the European Council. The comitology procedures 'require that a committee composed of representatives from all EU countries provide a formal opinion, usually in the form of a vote, on the Commission's proposed measures'.⁶³ In food law, the EC needs the approval of the Standing Committee on the Food Chain and Animal Health (SCFCAH).⁶⁴

The General Food Law (GFL)⁶⁵ of the EU forms the basis of food law both at the EU and national levels. Its main objective is to secure a high level of protection of public health and consumer interests with regard to food products.⁶⁶ It does so by laying down general principles, requirements and procedures that form an overarching framework for the development of food legislation and covers all stages of food and feed production and distribution.⁶⁷ Also, the GFL creates procedures to deal with emergencies as well as the Rapid Alert System for Food and Feed (RASFF).⁶⁸

On the basis of the GFL, the European Food and Safety Authority (EFSA) has been established.⁶⁹ This European food agency is funded by the EU but operates independently from the European legislative and executive institutions and the EU Member States. It is responsible for assessing existing and emerging risks related to the food chain, provides independent scientific advice and has a duty to communicate its scientific findings to the public.⁷⁰

4.2. Regulations at the EU level

On 24 April 2019, the EC adopted a regulation to limit the content of trans fats in food in the EU. This trans fat limit is the first EU-level regulation to reduce trans fat intakes in food products in general. Before the 2019 trans fat regulation, there only existed an EU-level trans fat legislation for a specific category of food: Commission Directive 2006/141/EC of 22 December 2006, which sets a limit of 3% on the trans fat content that may be in the total fat content of infant and follow-on formulae.⁷¹ In this subsection, we will discuss the

⁵⁹ Ibid.

⁶⁰ See Art. 294 of the TFEU.

⁶¹ European Commission, 'Food: Official controls and enforcement', <https://ec.europa.eu/food/safety/official_controls_en> (last visited 11 July 2019).

⁶² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, [2011] OJ L 55/13.

⁶³ European Commission, 'Comitology', <https://ec.europa.eu/info/implementing-and-delegated-acts/comitology_en> (last visited 16 July 2019).

⁶⁴ B.M.J. van der Meulen, 'The Structure of European Food Law', (2013) 2 *Laws*, p. 96.

⁶⁵ 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, General Food Law (GFL), [2002] OJ L 31/1.

⁶⁶ Van der Meulen, *supra* note 64, p. 78.

⁶⁷ European Commission, 'General Food Law', <https://ec.europa.eu/food/safety/general_food_law_en> (last visited 16 July 2019).

⁶⁸ See Art. 50 of the GFL.

⁶⁹ See Chapter III of the GFL.

⁷⁰ EFSA, 'About EFSA', <<https://www.efsa.europa.eu/en/aboutefsa>> (last visited 15 November 2017).

⁷¹ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, [2006] OJ L 401/1. This directive will be replaced as of 2020 by Commission delegated Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, which sets the same legislative limit on the amount of trans fats in the fat content of infant and follow-on formulae.

arguments that led to the 2019 trans fat limit on the basis of policy documents of the EC and the European Parliament that were published prior to adopting the legislative limit.

But before analysing the 2019 EU trans fat limit, we will discuss the 2011 EU labelling legislation (also called the FIC regulation).⁷² This discussion will make clear that the labelling legislation of the EU neither requires nor allows the indication of trans fat content on pre-packed food products and that the EC is not likely to propose changes to the legislation in order to allow trans fat labelling.

4.2.1. EU labelling legislation

The EU labelling legislation is enshrined in the regulation on the provision of food information to consumers (the FIC regulation), which 'establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling'.⁷³ Article 3 of the FIC regulation explicates that the EU system of food information aims at protecting the health and interests of consumers, but also tries to strike a balance with the aim of maintaining a free market. Thereby, the FIC regulation adheres to principles such as the protection of consumers' health, the protection of consumers' interests and the free movement of goods. These principles can also be found in, respectively, Articles 5, 8 and 6 of the GFL. Bremmers⁷⁴ notes that the general principles to which the FIC regulation adheres are complementary and in cases similar to the ones in the GFL. He, furthermore, distinguishes a supply chain orientation (Article 4 of the GFL), a focus on risk analysis ('science-based food law'; Article 6 of the GFL) and precautionary action (Article 7 of the GFL).

The FIC regulation was adopted on 25 October 2011, entered into force on 13 December 2014 and is legally binding in all European Member States. It vests the primary responsibility for providing food information in business operators (Article 8 of the FIC regulation), but national enforcement authorities have to assure that business operators comply with the regulation.⁷⁵

The FIC regulation defines trans fats as 'fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration'.⁷⁶ The regulation specifies the mandatory food information on ingredient lists and the mandatory and voluntary food information on nutrition declarations, but includes trans fats neither in the food information in ingredient lists nor in the food information in nutrition declarations, as we will discuss below.

Trans fats are not included in the mandatory food information in ingredient lists. The mandatory food information in ingredient lists is also the exclusive information. That is, no other food information is allowed to be mentioned in the ingredient list. Hence, the FIC regulation neither requires nor allows the display of trans fat content in the ingredient list of food packages. Instead of trans fats, the FIC regulation requires that 'fully' or 'partially' hydrogenated oils or fats (PHOs), together with the specific vegetable origin, are listed in the ingredient list. However, since the regulation does not require that the proportion of trans fats present in PHOs is listed and the amount of trans fats present in PHOs varies significantly, consumers cannot extract from the ingredient list what amount of trans fat is present in the food product.⁷⁷

Trans fats are also not included in the ingredients that have to be mentioned and those that can be included voluntarily in the nutrition declaration. Article 30(1) of the FIC regulation lists the mandatory nutrient information, which includes the energy value and, inter alia, the amount of fats. Thereby, the nutrition declaration provides consumers with information on 'the presence of energy and certain nutrients in foods',⁷⁸ which should enable consumers to make healthier food and dietary choices. This may be supplemented by the voluntary nutrient information listed in Article 30(2) of the FIC regulation. Since trans fats are neither among the mandatory nor among the voluntary nutrient information, it is neither legally required nor allowed to indicate trans fat content on the nutrition declaration.⁷⁹

⁷² Council 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 (FIC) [2011] OJ L304/18.

⁷³ Art. 1(2) of the FIC Regulation (EU) No 1169/2011.

⁷⁴ H. Bremmers, 'Substance Over Form: A Principle for European Food Information Regulation?', in H. Bremmers & K. Purnhagen (eds.), *Regulating and Managing Food Safety in the EU* (2018), pp. 195–216, at p. 200.

⁷⁵ *Ibid.*, p. 198.

⁷⁶ Annex I of the FIC Regulation (EU) No 1169/2011.

⁷⁷ Annex VII, Part A, points 8 and 9 of the FIC Regulation (EU) No 1169/2011; See WHO, *supra* note 8, p. 4; European Parliament, *supra* note 2, p. 4; European Commission, COM(2015) 619 final, *supra* note 2, p. 9.

⁷⁸ Para. 34 of the FIC Regulation (EU) No 1169/2011.

⁷⁹ European Commission, COM(2015) 619 final, *supra* note 2, p. 6, footnote 14.

On the basis of Article 30(7) of the FIC Regulation, the EC has assessed the effectiveness of requiring mandatory trans fat labelling. In its report on 'the presence of trans fat in foods and in the overall diet of the Union population'⁸⁰ of 3 December 2015, the EC concluded that mandatory labelling is a measure with important limitations. The EC discerned the following limitations: first, labelling has little impact without consumer education programmes, since there is low consumer awareness about the harmfulness of trans fats. Second, labelling only targets pre-packed foods and not food that is sold loose or consumed in restaurants, which leads to unfairly targeting a specific group of producers. Third, labelling legislation could widen health inequalities, because not all products will be reformulated and low income populations will be more likely to consume products that still contain high trans fat levels as they are mostly cheaper. Fourth, since Member States would still be allowed to set national legal limits, the risk of increasing internal market fragmentation remains.⁸¹ Hence, the EC is not likely to propose changes to the FIC regulation in order to require or allow the labelling of trans fats on pre-packed food products.

4.2.2. EU limit on trans fats

On 24 April 2019, the EC adopted a regulation to limit the trans fat content in food products.⁸² The regulation defines trans fats in accordance with the definition set out in the FIC regulation and sets a limit of 2 grams per 100 gram of fat (or 2% of the overall fat content) to 'the content of trans fat, other than trans fat naturally occurring in fat of animal origin, in food intended for the final consumer and food intended for supply to retail'.⁸³ It should be noted that this legislative limit of 2% concerns the amount of trans fats in the overall fat content of a food product and is, thereby, more restrictive than a limit on the amount of trans fats in the product as a whole. Furthermore, this limit applies only to food intended for the final consumer and food intended for supply to retail. For other food, the 2019 regulation requires that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2% of the fat content.⁸⁴ Food which does not comply with the regulation may be placed on the market until 1 April 2021.

The legal basis for taking this EU action is found within the framework of Article 114 of the TFEU, which confers upon the EU the legislative power to harmonise the internal market. The adoption of a legal measure to limit trans fats is considered through existing regulation on the addition of vitamins and minerals and of certain other substances to foods.⁸⁵ This regulation empowers the EC to take measures that restrict the addition of certain substances to foods or the use of such substances in the manufacture of foods in view of harmful effects. The 2019 trans fat limit is an amendment to this regulation and is supported by scientific evidence of the EFSA that showed the harmful effects of trans fats.⁸⁶

The 2019 trans fat limit is a result of ten years of policy research and scientific consultations that were set in motion by the EFSA. On 4 December 2009, the EFSA adopted a scientific opinion on dietary reference values for fats, including trans fats. The opinion concluded that the intake of trans fats should be as low as possible within the context of a nutritionally adequate diet.⁸⁷

Following this scientific opinion, Article 30(7) of the FIC regulation called on the EC to submit a report on the presence of trans fats in foods and in the overall diet of the EU population, with the aim of assessing the impact of appropriate means, such as the provision of information on trans fats to consumers or restrictions on their use, that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers. If appropriate, the EC had to accompany this assessment with a legislative proposal.

⁸⁰ Art. 30(7) of the FIC Regulation (EU) No 1169/2011.

⁸¹ See European Commission, COM(2015) 619 final, *supra* note 2, p. 12.

⁸² Commission regulation (EU) 2019/649 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin [2019] OJ L110/17.

⁸³ Art. 1 of Commission regulation (EU) 2019/649, *ibid*.

⁸⁴ Art. 2 of Commission regulation (EU) 2019/649, *ibid*.

⁸⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods [2006] OJ L404/06.

⁸⁶ COM(2019) 2902 final, p. 23.

⁸⁷ See EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), 'Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol,' (2010) 8 *EFSA Journal* no. 3, p. 1461. See also para. 2 of Commission regulation (EU) 2019/649, *supra* n. 82.

On 3 December 2015, the EC published this report.⁸⁸ The report recalled that 'heart disease is the leading cause of death in the Union and a high intake of TFA [*trans fatty acids*] seriously increases the risk for heart disease – more than any other nutrient on a per calorie basis'.⁸⁹ It also acknowledged the need:

to continue and expedite work in this area by collecting more information and by developing a fuller analysis of the magnitude of the problem to be addressed and the different possible solutions, in particular the option of legal limits for industrial TFA [*trans fatty acids*].⁹⁰

The report suggested that establishing a legal limit appeared to be the most effective measure in terms of protecting consumers' health and interests and compatibility with the internal market, but this had to be underpinned with a comprehensive comparative assessment of the different regulatory options. To that end, the EC published an inception impact assessment on 11 October 2016, held consultations with stakeholders and asked the EFSA on 30 April 2018:

to compile the outcomes of scientific advice already provided by the Authority on the health effects of trans fats, in particular on nutrition and health claims, dietary reference values and food additives; and to inform the Commission on how such scientific advice relates to current goals and recommendations on the intake of trans fats to maintain health.⁹¹

These stakeholder consultations in combination with the scientific opinion led to the publication of the impact assessment by the EC on 24 April 2019, accompanying the legislative proposal to set a limit of 2% to the content of trans fats in the overall fat content of food products intended for the final consumer or for supply to retail.

In the impact assessment, the EC identifies three general policy objectives of EU action on industrial trans fats: to ensure a high level of protection of consumer health, to reduce health inequalities and to contribute to an effective functioning of the Internal Market. These policy objectives reflect the challenge of EU food law to balance ensuring a free market with protecting consumers' health and interests.⁹²

On the basis of these policy objectives, the EC assesses different policy options against the baseline scenario in which no initiative would be taken on trans fats at the EU level. The EC considers the following policy options: (1) establishing a legal limit, (1a) through a voluntary agreement or (1b) through a legally-binding measure, (2) introducing the legal obligation to indicate trans fats in the nutrition declaration and (3) prohibiting the use of PHOs, (3a) through a voluntary measure or (3b) through a legally binding measure. The EC also considers combining mandatory labelling with legislation or voluntary agreements.⁹³

There are several policy options that the EC does not consider in its impact assessment. As to labelling legislation, the EC does not consider trans fat labelling in the ingredient list instead of labelling in the nutrition declaration. Also, the EC does not consider voluntary labelling legislation, whereas the 2011 EU labelling legislation provides the option of including trans fats in a list of ingredients that can voluntarily be mentioned in nutrition declarations. As to a trans fat limit, the EC focusses on a 2% limit of trans fats in fat. It considers this limit to be in line with EFSA and WHO recommendations, achievable in practice and generally accepted by both consumer organisations as well as health NGOs on the one hand, and industry on the other hand. Whereas four of the seven Member States with national legal limits apply different limits for lower fat products, the EC notes that such exceptions risk leading to trans fat intakes above the recommended 1% of the daily energy intake.⁹⁴

The EC concludes that the mandatory trans fat limit and the mandatory ban on PHOs perform better than the alternatives in terms of consumers' health benefits, reduction in health inequalities, improvements in the functioning of the Internal Market, efficiency and proportionality. In particular, the alternative regulatory options, i.e. voluntary measures and trans fat labelling, are not likely to improve the functioning of the Internal Market as existing difference in national legal standards will remain with these measures. The EC

⁸⁸ European Commission, COM(2015) 619 final, *supra* note 2.

⁸⁹ *Ibid.*, p. 14.

⁹⁰ *Ibid.*, p. 15.

⁹¹ Commission regulation (EU) 2019/649, *supra* note 82, para. 5.

⁹² COM(2019) 2902 final, *supra* note 86, p. 26.

⁹³ *Ibid.*, p. 28.

⁹⁴ *Ibid.*, p. 39.

does not see the social benefit of combining either the mandatory trans fat limit or the mandatory ban on PHOs with mandatory trans fat labelling, as mandatory labelling would increase overall costs significantly.

The EC expresses a preference for a trans fat limit over a ban on PHOs for two reasons. The first reason is that a trans fat limit performs better in terms of efficiency and coherence with existing Member State laws on industrial trans fats than a ban on PHOs, in that equivalent social benefits are delivered at a lower cost to the industry and the measure is consistent with the measures already adopted by a number of Member States (and actions planned in others). The second reason is that industry in the EU has expressed a preference for a trans fat limit, whereas a ban on PHOs is expected to meet opposition from industry and potentially also from Member States that already have legal limits in place. In order to protect small and micro enterprises, which constitute the majority of food business operators in the EU and are expected to face relatively greater costs and challenges compared to larger firms, the EC suggests providing sufficient transition periods.⁹⁵

As the two reasons make clear, the EC puts more weight on internal market arguments than on the impact on international trade. The EC notes that elimination of industrial trans fats from the EU food chain will help EU producers in selling to markets such as Canada and the US, but only as far as these markets are accessible.⁹⁶ Given the ban on PHOs, the US and Canadian market will remain inaccessible to many EU producers, also after the EU limit has been applied.

4.3. Regulations at the national level

Seven European Member States have adopted legislative actions to limit trans fat in population intakes. Denmark was the first Member State in the EU and the first country in the world to introduce a policy on trans fats by setting a legislative limit on industrial trans fats in 2003.⁹⁷ The Danish trans fat limit inspired Austria (2009), Hungary (2013), Latvia (2015), Slovenia (2017), Romania (2017) and Lithuania (2017). All seven Member States set a legal limit on industrial trans fats of 2% of the total fat content in food. The limit applies to food sold to the final consumer and ruminant trans fats are exempt in all cases. But some Member States (Austria, Hungary, Latvia and Lithuania) have applied derogations. Austria and Hungary allow industrial trans fat up to 10% in processed food with less than 3% total fat content and up to 4% in processed food where the total fat content is between 3% and 20% of the product. Latvia and Lithuania only allow industrial trans fats up to 4% in processed food with less than 20% of total fat content.⁹⁸

The national trans fat limits in the seven EU Member States are similar to the 2019 EU trans fat limit. However, the Danish trans fat limit was not immediately appreciated by the EC:

In 2004, the European Commission requested that Denmark suspend its regulation, arguing that the restrictions can have adverse effects on trade within the EU. The case was dropped in 2007, when the Commission accepted the Danish argument that the measure was justified in the interest of public health.⁹⁹

There are also several European Member States that have adopted voluntary measures, through either industry self-regulation (Belgium, Germany, Greece, the Netherlands, Poland and the UK), voluntary dietary recommendations (Bulgaria, Finland, Malta, Slovakia and the UK) or voluntary composition criteria for specific products (Estonia).¹⁰⁰

In the Netherlands, the food industry voluntarily reduced trans fat content in its products in response to the raised public awareness of the negative health impacts of trans fats. The Anglo-Dutch company Unilever decided in the early 1990s to eliminate trans fats from its products and other producers followed this decision. 'By 1996 it was reported that Dutch margarines contained only trace amounts'¹⁰¹ of trans fats and according to the Netherlands National Institute for Public Health and the Environment (*Rijksinstituut voor Volksgezondheid, RIVM*), the consumption of trans fats between 1988 and 1998 decrease with 60% as a consequence of the reduction of trans fats in margarines and cooking fats and oils.¹⁰²

⁹⁵ Ibid., pp. 68–71.

⁹⁶ Ibid., p. 50.

⁹⁷ See Executive Order No 160 of 11 March 2003 on the Content of Trans Fatty Acids in Oils and Fats, and also the Danish Nutrition Council, *The influence of trans fatty acids on health* (2003).

⁹⁸ COM(2019) 2902 final, supra note 86, Annex 8, pp. 118–119.

⁹⁹ See European Parliament, supra note 2, p. 8.

¹⁰⁰ COM(2019) 2902 final, supra note 86, Annex 8, pp. 118–119.

¹⁰¹ European Parliament, supra note 11, p. 15.

¹⁰² RIVM, 'Ons eten gemeten: Gezonde voeding en veilig voedsel in Nederland', (RIVM-report number 270555007, 2004), p. 23.

The EC writes that ‘the case of the Netherlands is often cited as a success in voluntary and self-regulated TFA reduction by food business operators’.¹⁰³ It adds that the success of this approach, however, ‘appears to depend on the country and the degree of public engagement and corporate social responsibility of food business operators’.¹⁰⁴

Although the EC praised the progress of the Netherlands in the trans fat reduction in the 1990s, the amount of trans fats in food still remained above the recommended 1% of the daily energy intake. Dutch health institutions have drawn attention to the desirability of a further reduction of trans fat intakes. In 2002, the Dutch Health Council urged the government to encourage the food industry to reduce trans fat content to the level found in nature.¹⁰⁵ In 2004, the RIVM made several policy recommendations to raise awareness of consumers about the negative health effects of trans fats and to further reduce the amount of trans fats in food products.¹⁰⁶ And in 2015, the Dutch Health Council published guidelines for a good diet¹⁰⁷ with a background paper on the health risks of trans fat intake and the relation between the amount of trans fats in a diet and the increase in health risks.¹⁰⁸

The culture towards trans fat regulation, determined partly by the public engagement, is crucial for the success of and interest in voluntary measures, as the lack of a sequel to the recommendations by the RIVM and the Dutch Health Council shows. Despite the clear recommendations, neither the food industry nor the Dutch government has felt the need to take regulatory measures to further reduce the trans fat intake of consumers. Without public interest and pressure, food producers have little interest in going through the costs and risks of reducing the trans fat content in their products. The Dutch government similarly seems to simply ignore the recommendations when there is no political need to make new commitments.

5. Similarities and differences between the US and the EU regulatory systems

Comparing the regulatory approaches of the US and the EU towards reducing trans fats in food and population intakes, we can identify several principles and orientations that point at similarities or differences between the regulatory approaches of the US and the EU. The US and the EU share a focus on scientific risk assessment (see subsection 5.1.). Also, the use of the precautionary principle can be identified in both systems (see subsection 5.2.). However, the US and the EU differ in their approach to the functioning of the internal market (see subsection 5.3.) and their socioeconomic orientation (see subsection 5.4.).

5.1. Scientific risk assessment

A major commonality in the approach to the regulation of trans fats in the US and the EU is the reliance on scientific risk assessment conducted by expert scientists. Both the US and the EU use the framework of risk analysis fostered by the WHO and the Food and Agriculture Organization of the United Nations (FAO).¹⁰⁹ Risk analysis is a science-based decision procedure that is made up of three components: risk assessment, risk management and risk communication. According to the WHO, ‘risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards’.¹¹⁰ ‘Risk management is the process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options’.¹¹¹ And ‘risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties’.¹¹²

¹⁰³ See COM(2015) 619 final, p. 14.

¹⁰⁴ Ibid.

¹⁰⁵ See European Parliament, *supra* note 11, p. 15; Health Council of the Netherlands (*Gezondheidsraad*), Committee on Trends in food consumption, ‘Significant trends in food consumption in the Netherlands,’ (publication no. 12, 2002).

¹⁰⁶ RIVM, *supra* note 102.

¹⁰⁷ Health Council of the Netherlands, ‘Richtlijnen goede voeding’, <<https://www.gezondheidsraad.nl/nl/taak-werkwijze/werkterrein/gezonde-voeding/richtlijnen-goede-voeding-2015>> (last visited 6 November 2017).

¹⁰⁸ Health Council of the Netherlands, ‘Transvetzuren: Achtergronddocument bij Richtlijnen goede voeding 2015’, (report number A15/20, 2015).

¹⁰⁹ WHO, ‘Food Safety: About risk analysis in food’, <<https://www.who.int/foodsafety/risk-analysis/en/>> (last visited 19 July 2019).

¹¹⁰ WHO, ‘Food Safety: Risk Assessment’, <<https://www.who.int/foodsafety/risk-analysis/riskassessment/en/>> (last accessed 19 July 2019).

¹¹¹ WHO, ‘Food Safety: Risk Management’, <<https://www.who.int/foodsafety/risk-analysis/risk-management/en/>> (last accessed 19 July 2019).

¹¹² WHO, ‘Food Safety: Risk Communication’, <<https://www.who.int/foodsafety/risk-analysis/riskcommunication/en/>> (last accessed 19 July 2019).

In the EU, the principle of risk analysis is laid down in Article 6 of the GFL.¹¹³ The regulatory decision, i.e., the risk management, is made by the EC. The EC bases this decision on a scientific risk assessment that can either be done by the EFSA, which was instituted by the GFL to ensure the science basis of risk analysis in EU food law,¹¹⁴ or by the businesses. Whether the EFSA or the industry is responsible for the scientific risk assessment depends on the type of decision under consideration. If the risk analysis concerns the decision whether to take restrictive measures, such as limiting market access of products, then science is asked to identify hazards and risks, i.e., to determine whether the product is *unsafe*. In this situation, the burden of proof is on the authorities and the responsible authority – DG SANCO – will ask the EFSA for a scientific opinion. By contrast, if the risk analysis concerns a decision to lift restrictions, such as granting market access to a product, then science is asked to exclude hazards and risks, i.e., to determine whether the product is safe. In this situation, the burden of proof is on the businesses that want to bring a product to the market.¹¹⁵

The 2019 EU trans fat limit is based on a scientific risk assessment by the EFSA. The regulation includes trans fats in Annex III of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. Annex III lists the substances whose use in foods is prohibited, restricted or under EU scrutiny. According to Article 8(2) of Regulation (EC) No 1925/2006, the EC may, on its own initiative or on the basis of information provided by Member States, take a decision to include a substance in Annex III if that substance is associated with a potential risk to consumers. The EC shall in its decision follow the assessment of available information provided by the EFSA and shall use the comitology procedures in which it will be accompanied by the Standing Committee on the Food Chain and Animal Health (SCFCAH). In the recitals to the 2019 regulation to limit trans fats, the EC also recognises the scientific risk assessments provided by the EFSA in 2009 and 2018 and the call of the WHO in 2019 to eliminate trans fats from the global food supply chain.

In the US, the regulatory decision, i.e., the risk management, is made by the same agency that assesses the risk. In the case of trans fat regulations, the responsible agency is the FDA.

As the risk analysis is science-based, food agencies often rely on committees for scientific advice. The responsibilities and procedures of these advisory committees are laid down in the Federal Advisory Committee Act:

The FDA relies on expert advisory committees heavily for therapeutic products approval. To a lesser extent they are used for food. The FD&C Act §721 (b) (5) (D) & (D) mandates an advisory committee for color additives, but that is an exception and most advisory committees are established at FDA's discretion.¹¹⁶

The decisions to introduce the 2003 trans fat labelling legislation and the 2015 ban on PHOs reflect the FDA's heavy reliance on scientific risk assessment. In the 2003 trans fat labelling legislation, the FDA writes that 'given the current state of scientific knowledge, the FDA is requiring the mandatory declaration in the nutrition label of the amount of trans fatty acids present in foods, including dietary supplements'.¹¹⁷ And in the 2015 decision to ban PHOs, the FDA writes that it bases its determination on the available scientific evidence and the findings of expert scientific panels.¹¹⁸ To make this scientific risk assessment, the FDA uses the expertise of expert groups and advisory committees, such as the Institute of Medicine/National Academy of Science (IOM/NAS), the American Heart Association, the American Dietetic Association, the WHO, the Dietary Guidelines Advisory Committee and the FDA Food Advisory Committee Nutrition Subcommittee.¹¹⁹

There is a difference between the FDA's scientific risk assessment for the 2003 labelling legislation and for the 2015 ban on PHOs in terms of the burden of proof. The risk assessment for the 2003 labelling legislation concerns the decision to take a restrictive measure and, therefore, science has to identify whether trans fats are unsafe. Given the new scientific evidence about the health risks of trans fat intake, the FDA revisited its

¹¹³ See Art. 6 of the GFL, and also Van der Meulen, *supra* note 64, p. 88.

¹¹⁴ See Art. 22 of the GFL.

¹¹⁵ See Van der Meulen, *supra* note 64, p. 89.

¹¹⁶ See Fortman, *supra* note 15, p. 11.

¹¹⁷ FDA, 68 Fed. Reg. 133, 41434 (11 July 2003), *supra* note 23, p. 41436.

¹¹⁸ FDA, 80 Fed. Reg. 116, 34650 (17 June 2015), *supra* note 34, p. 34650.

¹¹⁹ *Ibid.*, p. 34654. See also FDA, 68 Fed. Reg. 133, 41434 (11 July 2003), *supra* note 23, pp. 41436–41437.

decision during the 1990 amendments to the nutrition labelling legislation that it was premature to include trans fats in nutrition labelling because of a lack of agreement on the dietary implications of trans fat intake. Hence, the burden of proof to show that trans fat intake is unsafe in order to require trans fat labelling was on the FDA.

By contrast, the 2015 ban on PHOs concerns the decision to lift a measure, because science can no longer show that trans fats are safe. Specifically, the FDA's ban on PHOs entails that the FDA revokes the GRAS status of PHOs as 'there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced trans fatty acids (IP-TFA) are generally recognized as safe (GRAS) for any use in human food'.¹²⁰ The burden of proof is on the industry to show that their use of PHOs is safe enough to deserve a GRAS status or food additive approval.

To conclude, we can identify a reliance on scientific risk assessment in the approach of both the EU and the US towards trans fat regulation. In general, the burden of proof for showing the *unsafety* of products is on the authorities, whereas the burden of proof for showing the safety of products is on the industry. When the burden of proof is on the authorities, both the EU and the US authorities involve independent scientific experts in making a risk assessment.

5.2. Precautionary principle

Another commonality between the approach of the US and the EU to trans fat regulations is the reliance on the precautionary principle. The precautionary principle 'states that in the case of serious or irreversible threats to the health of humans or the ecosystem, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures'.¹²¹ The principle should be distinguished from the principle of prevention. Prevention is a response to the scientific identification and proof of health hazards and risks. By contrast, precautionary action addresses uncertain and potential risks. It 'seeks to shift the ways in which science informs policy from a strategy of "reaction" to a strategy of "precaution"'.¹²²

The precautionary principle plays a prominent role in food law in the EU. Article 7 of the GFL makes clear that the EC should be guided by the precautionary principle in its risk assessment, as it states that:

in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted.

The principle has been shaped by an influential policy paper of the EC¹²³ and court decisions.¹²⁴

The precautionary principle is especially important for the EU's challenge to strike a balance between protecting the health and interests of consumers and maintaining a free market. Purnhagen frames this as the balance between the 'social' of fundamental rights and the 'economy' of fundamental freedoms in the internal market.¹²⁵ 'In this balancing test, there are generally no priorities assigned for either favouring fundamental freedoms or fundamental rights in internal market regulation.'¹²⁶ However, the precautionary principle provides a condition under which it is allowed to strike the balance in favour of the 'social' of fundamental rights, i.e., public health, environmental protection or consumer protection. The principle requires or at least legitimises the regulator to trump the requirement of de-regulation resulting from the fundamental freedoms when there is still uncertainty about the possible harmful effects of a product, i.e.,

¹²⁰ FDA, 80 Fed. Reg. 116, 34650 (17 June 2015), *supra* note 34, p. 34650.

¹²¹ M. Martuzzi & J.A. Tickner (eds.), *The precautionary principle: protecting public health, the environment and the future of our children* (WHO Europe, 2004), p. 1.

¹²² *Ibid.*, p. 3.

¹²³ COM(2000) 1 final.

¹²⁴ See K. Purnhagen, 'The EU's Precautionary Principle in Food Law is an Information Tool!', (2015) 11 *Wageningen Working Papers in Law and Governance*, p. 3. Purnhagen mentions the following court cases: Case C-157/96 of 5 the Court of May 1998, *National Farmers' Union and Others*, [1998] ECR I-2211, para. 63; Case C-180/96, Judgment of the Court of 12 July 1996, *United Kingdom v Commission*, [1998] ECR I-2265, para. 99; Case C-236/01, Judgment of the Court of 9 September 2003, *Monsanto Agricoltura Italia v Presidenza del Consiglio dei Ministri*, [2003] ECR I-8105, para. 111; Case T-13/99, Judgment of the Court of 11 September 2002, *Pfizer Animal Health v Council*, [2002] ECR II-3305, para. 139.

¹²⁵ Purnhagen, *ibid.*, pp. 14–16.

¹²⁶ *Ibid.*, p. 14.

when data points at a possible risk but is inconclusive. Thereby, the principle 'eases the proof of causation between action and harm which authorities or operators regularly have to bring forward'.¹²⁷

This balancing test provided by the precautionary principle is recognised in recital 20 of the GFL, which states that the precautionary principle gives 'rise to barriers to the free movement of food or feed' in order to 'ensure health protection in the Community'. Before its formal recognition, the balancing test was also already used in the case law of the Court of Justice of the European Union (CJEU): in *Sandoz*,¹²⁸ the CJEU held that the refusal to market a muesli bar with added vitamins, which was lawfully sold in Germany, was justified as there was uncertainty in science about the negative effects of vitamins.

Contrary to the EU, the US has not formally adopted the precautionary principle in food law but the risk analysis in food safety in the US nevertheless reflects the use of the precautionary principle.¹²⁹ For example, the FDA applies the precautionary principle when it requires prior approval of food additives before entering the market. This application of the precautionary principle shifts the burden of proof to the industry by maintaining that substances are deemed hazardous until proven otherwise.¹³⁰

5.3. Internal market

Regulating the internal market forms a legal basis for EU-level legislation in the EU and for federal legislation in the US. In the EU, this EU competence follows from Article 114 of the TFEU that confers upon the EU the power to harmonise the internal market. In the US, this federal authority follows from the federal power to regulate commerce, granted by the American Constitution.

However, there is an important difference between the EU and the US in the application of this legal basis. In the EU, the legal basis concerns the *harmonisation* of the internal market. It is, therefore, used in *response* to legislation of the Member States. National legislation stimulates the EU to introduce EU-level legislation and the EU competence does not restrict EU Member States in taking measures with cross-border effects as long as the EU has not enacted any legislation.

By contrast, the regulation of interstate trade forms a legal basis for federal authorities in the US independent of whether state or local authorities have adopted different regulations. That is, a difference in trans fat regulations between some states or districts does not necessarily stimulate federal trans fat regulations. Rather, the state and local authorities are restricted in taking trans fat regulations, before federal legislation is even made, as they are not allowed to take measures which place an unreasonable burden on interstate commerce. Since legislation concerning all packaged and unpackaged food products would reach beyond state borders, we see that state and local trans fat regulations concern only food from restaurants and other food service establishments.

This difference is exemplary for the difference between the institutional set-up of the US and of the EU. Whereas the US is a federal system, the EU is a multilevel political system with intergovernmental characteristics. The federal government in the US has relatively more legislative power in the US than the EU legislator has in the EU as the EU is a community of independent, sovereign states. Also, there is public debate and pressure groups at the federal level in the US in order to stimulate trans fat regulations, while this public debate mainly takes place at the national level in the EU and the pressure to adopt EU-level regulations mainly comes from the Member States and not from citizens directly.

5.4. Socio-economic orientation

The differences between the US and the EU in regulating trans fats in food products should be understood in the context of the socio-economic orientations that underlie the regulation of the food industry. Food policy extends to a large number of policy areas, such as health care, the economy and the environment. Because of the connection of food policy to a wide range of policy areas, food policy involves different interests that have to be weighed. These interests include economic interests as well as interests relating to health, the quality and availability of food products and the environmental impact. The different interests do not have to exclude each other, but the chosen policies and resulting regulatory measures always have a political dimension that requires prioritisation among the different interests. The way public, societal and economic interests are weighed is determinative for the chosen food policies and, more specifically, for the regulation of trans fats in food products. In other words, the socio-economic orientation towards the regulation of the food industry plays an important role in the chosen regulations of trans fats in food products.

¹²⁷ Ibid., p. 16.

¹²⁸ Case C-174/82, *Officier van Justitie v Sandoz*, [1983] ECR 2445, para. 84.

¹²⁹ See Grossman, *supra* note 21, p. 361.

¹³⁰ See COM(2000) 1 final, p. 20.

The recognition and acknowledgement of basic and persistent differences in socio-economic orientations is also advocated by J. Whitman, who is a leading scholar in comparative law. Whitman proposes to revive an analytical distinction that was common in the 1930s: a distinction between 'consumerism' and 'producerism'. According to Whitman, this distinction can enhance an understanding of basic and persistent differences between the regulatory systems of the US and the EU.¹³¹

Consumer-oriented and producer-oriented legal systems tend to focus on different kinds of constructed legal-economic identities: consumers and producers. Whereas consumers and producers are two kinds of constructed legal-economic identities, they are not two different classes of persons: people can be both consumers and producers. According to Whitman, the focus of a legal order on either the consumer or the producer is 'a value choice about which of these two possible identities deserve priority in a modern market'.¹³² It is a value choice about prioritising either the rights and interests on the demand-side of the market or the rights and interests on the supply-side of the market.¹³³

Two types of consumerism can be distinguished: *economic* consumerism and *protection-oriented* consumerism. Economic consumerism tends to focus on the consumer economic interests, such as the availability and price of products. Protection-oriented consumerism tends to focus on consumer protection interests, such as legal guarantees of the quality and safety of goods and services.¹³⁴

Producerism is also a broad notion as the term 'producer' is a broad, diffuse and conflict-ridden category. It 'refers to every actor providing some factor in the production and delivery of goods and services'.¹³⁵ It is almost never possible to speak of any single, monolithic 'producer' interest and, consequently, any given piece of legislation may favour one group of 'producers' over another. However, the leading idea behind producerism is protection. This includes, for example, the protection of small, specialised businesses in the market and the rights of workers and suppliers.¹³⁶

Law favouring consumer *economic* interests often comes into conflict with producer-oriented law. For example, while economic consumerism would favour long opening hours of shops, producerism would limit opening hours to protect small shop owners and workers. Similarly, the merger of big firms would not pose a problem from an economic consumerist perspective as long as 'the dominance exercised by a given firm or firms provides consumers with competitive prices',¹³⁷ but a producer oriented legal system would be more reluctant to accept big competitors because of the risk for small businesses to lose their competitive position and the risk of diminished rights for workers and suppliers.

By contrast, consumer protection legislation and producer-oriented law may often go hand in glove:

Legislation intended to guarantee the quality and safety of consumer goods can easily have the effect, intended or unintended, of protecting existing producer interests. This has to do largely with the dynamic of competition. High quality and safety standards may tend to protect the position of existing competitors in a given industry. If there are such consumer protection standards in place, new entrants cannot break in by offering relatively low-quality goods.¹³⁸

Whitman argues that continental Europe remains far more oriented towards producer interests than the US, 'even in this high age of consumerism'.¹³⁹ As he writes:

European policymakers often claim that Europe has made 'the political discovery of the consumer,' but this statement is only true if we qualify it carefully. Continental law is indeed putting a growing emphasis on the consumer protection interest, developing many paternalistic guarantees of the safety and quality of goods and services. But the consumer economic interest is making slower

¹³¹ See J. Whitman, 'Consumerism Versus Producerism: A Study in Comparative Law', (Faculty Scholarship Series, Paper 644, 2007), <http://digitalcommons.law.yale.edu/fss_papers/644> (last visited 16 November 2017). The article is a leading article on this topic. It is referred to by many comparative legal researchers for laying down an important framework. For example, see E.J. Eberle, 'The Method and Role of Comparative Law', (2009) 8 *Washington University Global Studies Law Review* no. 451; I. Ramsey, 'Regulation and the Constitution of the EU Single Market: the Contribution of Consumer Law', (2011) 50 *Can. Bus. L.J.* no. 322.

¹³² Whitman, *ibid.*, pp. 366, 370.

¹³³ *Ibid.*, p. 370.

¹³⁴ *Ibid.*, p. 347.

¹³⁵ *Ibid.*, p. 368.

¹³⁶ *Ibid.*

¹³⁷ *Ibid.*, p. 373.

¹³⁸ *Ibid.*, p. 369.

¹³⁹ *Ibid.*, p. 348.

headway. The result (...) is that contemporary continental law can leave many producer protections on the books. This reflects a fundamental fact about continental cultures: countries like France and Germany remain both far more paternalistic and far more producerist in their deep cultural orientation than America.¹⁴⁰

This orientation in the EU towards producer interests is, first of all, reflected in the choice of the EU to adopt a trans fat limit instead of a ban on PHOs. In its assessment of the relative impact of various policy options to reduce trans fats in food and population intakes, the EC draws the conclusion that a mandatory trans fat limit and a mandatory ban on PHOs 'perform better than the alternatives in relation to health benefits (measured in disability-adjusted life years), reduction in health inequalities, improvements in the functioning of the Internal Market, efficiency and proportionality'.¹⁴¹ Even though both policy options achieve the same health benefits, the EC expresses a preference for a trans fat limit over a ban on PHOs. A major reason for this preference is the interests of producers. Producers have clearly expressed a preference for a trans fat limit over a ban on PHOs. And according to the EC, the higher costs to industry with a ban on PHOs do not outweigh the social benefits, as a mandatory trans fat limit can deliver social benefits equivalent to those delivered by a ban on PHOs.¹⁴²

Secondly, the orientation towards producer interests in the EU is also reflected in the choice of the EU to refrain from implementing mandatory trans fat labelling. The EC argues that combining a trans fat limit with mandatory trans fat labelling would raise overall costs for industry significantly, whereas it is unlikely to deliver added social benefits.¹⁴³ Furthermore, the EC notes that 'firms that have already removed industrial trans fats from their products and firms whose products will never contain industrial trans fats by virtue of their composition will still need to change the nutrient declaration'.¹⁴⁴

In the US, producer interests are also considered but have less effect on the final decision to adopt a certain trans fat regulation. In its decision to impose trans fat labelling and its decision to ban PHOs, the FDA is mainly focussed on the interests of consumers in food information and the protection of the health of consumers. The FDA does not compare regulatory measures on the basis of producer interests.

The producer interests only play a decisive role in the US in setting the compliance date for the trans fat labelling legislation and for the ban on PHOs. Just like the EU, FDA applied a relatively long compliance period to provide regulatory relief for small businesses.¹⁴⁵ Apart from that, the FDA considers the costs of producers in order to determine the effects of the labelling legislation on the quality of food and not in order to determine whether labelling legislation is the most preferred policy option. The FDA anticipates that labelling legislation leads to changes in food purchases by consumers and, thereby, incentivises producers to reformulate their products.¹⁴⁶ Furthermore, the FDA argues that an exemption of small businesses from the labelling legislation is not desirable. On the one hand, because the potential benefits from the final rule would not be realised with such an exemption as so many of the businesses in the food processing industry are classified as small by the Small Business Administration. On the other hand, because exempt businesses may be forced by market pressures to adopt the final label in any case.¹⁴⁷

As a result, the US ends up with a combination of trans fat legislation (trans fat labelling and a ban on PHOs) that is more costly for the industry than the legislation in the EU, whereas the protection of the health of consumers may be equivalent to the protection of the health of consumers under the EU legislation.

To conclude, the regulation of trans fats in the EU is more producer-friendly than the regulation of trans fats in the US. Also, the decision-making process of the EU seems to be more oriented towards producer interests than the decision-making process in the US. The EC bases its determination of a trans fat regulation on a comprehensive assessment of various regulatory options. Thereby, it has the possibility to compare different regulations in terms of the protection of consumer health and interests, but also in terms of producer

¹⁴⁰ Ibid.

¹⁴¹ Com(2019) 2902 final., supra note 86, p. 68.

¹⁴² Ibid., p. 70.

¹⁴³ Ibid., p. 69.

¹⁴⁴ Ibid., p. 64.

¹⁴⁵ FDA, 68 Fed. Reg. 133, 41434 (11 July 2003), supra note 23, p. 41495; FDA, 80 Fed. Reg. 116, 34650 (17 June 2015), supra note 34, p. 34668.

¹⁴⁶ FDA, 68 Fed. Reg. 133, 41434 (11 July 2003), *ibid.*, p. 41468.

¹⁴⁷ Ibid., p. 41495.

interests. By contrast, the FDA does not make such a comprehensive assessment of policy options. Rather, the FDA's trans fat regulations have been adopted in response to citizen petitions for those specific regulations.

The Danish Nutrition Council identified the decision of the FDA to adopt trans fat labelling instead of a trans fat limit or a ban on PHOs as a cautious approach towards restrictive intervention by authorities:

The American position is that the population is entitled to information on the conditions to which it is exposed, including the composition of food. A cautious approach is, on the other hand, adopted on restrictive intervention by the authorities. The Danish position is the opposite, namely that the authorities should, via statutory instruments, ensure for example the safety of food at the production stage so that the safety of the chosen diet is not based on the individual consumer's ability to interpret any information on the content of the food that may be difficult to understand.¹⁴⁸

Whereas this appraisal of the Danish trans fat limit should be taken with a pinch of salt, as the EU labelling legislation prohibited Denmark to take the less restrictive measure of trans fat labelling, the Danish Nutrition Council makes an interesting point about the caution that the FDA seems to show with respect to taking restrictive measures. The concern for the health and interests of consumers did not encourage the FDA to consider more restrictive measures in 2003, such as a trans fat limit or a ban on PHOs, that are certainly more effective in protecting the health of consumers. But as time passed and scientific evidence about the health risks of trans fat intake strengthened, the FDA could no longer avoid taking more restrictive measures and has ended up with a package of interventions (trans fat labelling and a ban on PHOs) instead of a single intervention (as in the EU).

6. Concluding remarks

The fight against industrially-produced trans fats started in 1993 with a citizen petition in the US and reached global prominence in 2018 when the WHO called for the elimination of industrially-produced trans fats from the global food supply chain by 2023. The fight has encouraged industry to reformulate their products and inspired regulators across the globe to adopt trans fat reducing measures, such as mandatory trans fat labelling, a limit on the maximum amount of industrially-produced trans fats in food products and a ban on the production process that generates trans fats.¹⁴⁹ Thereby, the fight against industrially-produced trans fats may set an example for future fights against legal but harmful food ingredients, such as salt, sugar and saturated fat.

A comparison of the trans fat regulations in the US and the EU shows that despite a common focus on scientific risk assessment and precautionary action, regulators may come to different regulations in the fight against legal but harmful food ingredients. In fact, the regulations in the US and the EU cover all three regulatory options – labelling of the ingredient, a limit on the maximum amount of the ingredient and a ban on production technology that produces the ingredient. In the EU, a limit of 2% has been imposed on the maximum content of trans fats in the fat content of food products, both at the EU-level and in some EU Member States. In the US, federal authorities have introduced both trans fat labelling legislation and a ban on PHOs. Furthermore, state and local authorities in the US have restricted the use of trans fats in restaurant food.

The comparison may stimulate regulators to reflect on their approach towards regulating legal but harmful food ingredients for future fights. In particular, the US and the EU could learn from each other's approaches towards the regulation of legal but harmful food ingredients. On the one hand, the US could learn from the comprehensive assessment of regulatory options that was done in the EU before introducing trans fat regulations. The US seems to have introduced trans fat regulations on a step-by-step basis, in response to citizen's petitions. The result is a package of trans fat regulations that may turn out to be more restrictive than initially intended and may not provide the best balance of consumer interests and producer interests according to US standards. On the other hand, the EU could use the US as an example for lifting food regulation from the Member State level to the EU-level by creating a legal basis for introducing EU-wide food regulations that is independent of the measures taken in EU Member States and by stimulating engagement and participation of citizens in EU food law.

Competing Interests

The author has no competing interests to declare.

¹⁴⁸ See the Danish Nutrition Council, *supra* note 97, p. 53.

¹⁴⁹ See WHO/NMH/NHD, *supra* note 4.

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