Executive Summary of the 4th Summer Academy on Global Food Law and Policy

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At the beginning of a pleasant summer week towards the end of July, Food Law professionals from all over the world travelled to the village of Cadenabbia on Lake Como in Italy in order to participate in the fourth edition of the Summer Academy on Global Food Law and Policy. The Academy, which has established its reputation as a high-level training and networking opportunity within the world of food law and policy, was presided by Associate Professor of Law at HEC Paris, Alberto Alemanno, and organised in cooperation with Lexxion, publisher of the European Journal of Risk Regulation (EJRR) and the European Food and Feed Law Review (EFFL).

For five days, presentations, panel discussions and moot court simulations on a wide selection of topics stimulated participants and speakers to enter into a lively dialogue, which continued throughout lunch and leisure activities in the beautiful surroundings of Lake Como. Among the topics discussed were global food governance, nutrition policy, health claims, geographical indications, food innovations and global vs. private standards.

Alberto Alemanno kicked off by confronting the Academy with the observation that European Food Law requires a scientific approach to substance-related risks, while this is not the case where behavioural risks are concerned.

This observation led Alemanno to the subject of his presentation, which also introduced the overall theme of the Academy: past, present and future challenges of Global Food Law.

Historically, EU law has focused on the liberalisation of trade in foodstuffs rather than on food safety, food quality and nutrition. However, following the food crises at the beginning of the Nineties, it became clear that the free trade objective could not stand alone, and that food safety was a *conditio sine qua non* for the well-functioning of the internal market for food.

This realisation resulted in the adoption of a set of general EU rules and the harmonisation of the most important food safety rules. At the same time, science emerged as a leading concept within food regulation, and risk-analysis detached itself from risk-management.

At the international level, science began to resolve food safety disputes. Within the WTO system, science enables panels and appellate bodies to distinguish between legitimate and illegitimate national protective measures.

One of today's main challenges for the global food market is how to deal with risk *before* there is scientific certainty as to its scope and seriousness. A solution may be found in the application of the precautionary principle, which both the EU and WTO have accepted for food law. This principle allows countries to implement temporary measures against third country products, the safety of which is subject to scientific dispute. A restricted focus on ruling out safety hazards may, however, provoke the negligence of benefits versus risks and even of risk trade-offs, which can pose a serious threat to innovation.

Although trade liberalisation delivered significant benefits to the global food market, it is also perceived as one of the main contributors to another major challenge, with which the world faces today: the obesity epidemic. Obesity is one of the main causes of non-communicable diseases such as stroke, cancer, diabetes, etc., which currently account for 63 % of the global deaths. Some of the risk factors that precipitate the growing prevalence of obesity are the increased availability of food in combination with the lack of physical exercise and an unhealthy diet.

Due to their complexity and multifactorial nature, it is difficult to identify an effective strategy to fight obesity and non-communicable diseases. So far, the EU has shown reluctance to adopt stringent legislation for fear of being accused of 'nannying'. Hence, EU policy has mainly focused on self-regulation,

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with overall disappointing results. New initiatives in this area concentrate on, inter alia, taxation and regulation. Interest is also growing in 'nudging' people towards making positive – i.e. healthy – decisions while preserving individual choice, by applying behavioural insight to health.

Although it is undisputed that nudging can create some positive effects, it is not clear how effective it is in the long run. It is clear, however, that for nudges to be at all beneficial, their implementation needs to be secured through traditional regulation, while, at the same time, the counter-effective impact of behavioural marketing has to be ruled out.

The Academy continued with a presentation by Emmanuel Saurat, associate at Sidley Austin LLP in Brussels, who looked into yet another regulatory challenge: food innovation.

Innovation confronts us with unknown risk factors. In order to deal with unknown risks, the precautionary principle can be applied.

The precautionary principle currently appears in global food law in article 7 of the SPS-Agreement, and in EU food law in article 6 of Regulation 2002/178. The principle originates from the "Vorsorgeprinzip" of German environmental law, from where it found its way into the EU Treaty with the adoption of the Maastricht Treaty in 1993 – in which its application was restricted to environmental law, as well.

When, during the BSE-crisis, the UK brought the EU-ban of UK bovine meat before the Court of Justice of the European Union (CJEU), the Court applied the precautionary principle to the area of food law – without, however, expressly referring to the principle as such.

The CJEU's current application of the precautionary principle bestows a heavy burden of proof on the Member State that wishes to protect its population against an unknown risk, while EU institutions enjoy broad discretion when adopting precautionary measures. Also, within WTO-law, it is difficult for a Member State to satisfy the burden of proof required to legitimately ban a product it regards as dangerous from its market.

Food innovation presupposes confidentiality of food science in order to secure the competitive position of the innovator. However, it may be clear that exceptions automatically apply to information that is relevant for the protection of human or animal health or the environment. In case of a negative decision as to the confidentiality of an application for approval of, e.g. a novel food, the applicant may withdraw its application in order to avoid disclosing sensitive information.

In some cases, public authorisations replace individual approval. This is so for health claims, whereas the approval of additives requires individual authorisation.

This does not mean, however, that third parties cannot interfere in decisions that can be of importance to them. In Case T-262/10, "Microban vs. Commission", the Court decided that a third party may challenge a denial of approval if its direct and individual concerns are at stake.

The second day of the Academy commenced with Lee Ann Jackson from the Agriculture and Commodities Division of the World Trade Organisation, who shed her light on the past, present and future of the SPS-Agreement.

The SPS-Agreement resulted from weighing, on the one hand, the free trade objective and, on the other, the right of WTO Member States to protect human, animal and plant life and health from any risks that may occur when (food) products cross borders.

In accordance with the SPS-Agreement, Member States' regulatory interventions can only be justified if they are based on science. Such scientific basis can either originate from internationally accepted standards or from a risk assessment initiated by the Member State in question.

The SPS-Agreement allows for the adoption of provisional measures in cases where the scientific information at hand is insufficient to rule out safety concerns. Such measures must be reviewed regularly.

If a Member State adopts a measure that is not based on an international standard and that will be likely to have a significant effect on international trade, the Member must notify the other Members of the adopted measure.

In recent years, private standards have developed at a rapid pace. UNCTAD has estimated that there are currently about 400 private schemes on a global basis, which are driven by private companies' will to eliminate potential liability and damage to their reputations caused by food safety issues.

While private standards can create new trade potential, they can also raise new barriers. Where private schemes go beyond official requirements, they can become *de facto* decisive for market access. Moreover, individual schemes create different requirements, which can lead to overlaps or even contradictions. Finally, private standards typically generate costs for the companies complying with them.

This may have a disadvantageous effect on smaller- and medium-sized companies.

While the use of private standards may thus sometimes result in trade distortions, they can pave the way for the eventual adoption of international standards. The SPS-Committee, therefore, takes great interest in the development of new private schemes.

The Tuesday afternoon session introduced the Academy to the legal challenges posed by the obesity epidemic. A panel of three food law specialists presented their diverging views on the regulatory solution to the epidemic: Amandine Garde, Senior Lecturer and Director of the Durham European Law Institute at Durham University; Catherine Adams Hutt, President of RdR Solutions in Texas and Former Chief Quality, Food Safety and Nutrition Officer at McDonald's; and, lastly, Susanne Kettler, Director Regulatory Affairs at Coca-Cola Europe.

According to Garde, obesity is caused by, on the one hand, excess energy intake and, on the other, lack of exercise. Because of its multi-factorial nature, obesity prevention presupposes a multi-sector approach.

Public authorities have developed different strategies in their battle against obesity, ranging from financing research and (international) collaboration to state intervention in the form of regulation and "nudge" – the policy approach of guiding people towards certain behaviours by influencing their environment.

At the EU level, discussions on how to tackle the obesity epidemic have led to the establishment of the EU Platform for Action on Diet, Physical Activity and Health (2005) through which stakeholders within the food sector can work together on the development of *best practices*. The Platform is based on the presumption that a voluntary approach can result in cheap, flexible and effective solutions, such as the limitation of advertising and product reformulation. However, there is a risk that the industry's willingness to commit to change is limited, since its interests do not necessarily coincide with those of consumers.

It is here that Garde sees an important role for state intervention. Regulatory proposals have been developed with regard to the regulation of consumer information, the imposition of food taxes and the regulation of food marketing to children. Apart from traditional regulation, nudging is an increasingly popular tool in fighting obesity.

State intervention, however, leads to complications of another kind. If society wants to adopt regulatory measures that specifically attack less-healthy food products, such as fat taxes, it needs to develop nutrient profiles in order to be able to distinguish between foods on the basis of their nutritional qualities. However, it is not always simple to draw a line between what is healthy and what is not. Moreover, measures directed towards certain products or groups of products can have unexpected side-effects. Therefore, research is necessary to sustain such measures.

Another relevant question that rises in relation to nutrition-regulation is how to approach the consumer. The provision of food information to consumers is based on the presumption that empowered consumers can and, therefore, will make changes to lifestyle and consumption patterns contributing to the improvement of their health. However, in practice, consumers do not always act rationally, and other drivers of consumption, such as taste, price, availability and peer pressure simultaneously guide them.

Catherine Adams Hutt underlined the idea that, indeed, people do not eat for the sake of nutrition, but for pleasure. Therefore, in her opinion, labelling is per definition an inappropriate measure to fight obesity.

According to Adams Hutt, obesity rates in the US continue to register unacceptably high, but appear to have stabilised. This may suggest that Americans have "reached a biological limit for how obese people can get",[1] but it may also be possible that the fight against obesity is actually bearing fruit.

Adams Hutt showed that she strongly advocates for self-regulation as opposed to regulation, pointing out clear signs of self-regulatory successes in the US: High-profile food manufacturers have voluntarily adopted measures that aim to improve consumers' nutrition choices through product reformulation, smaller portion sizes and by funding nutrition awareness initiatives.

Susanne Kettler stressed the importance for consumers to maintain a healthy energy balance by ensuring that they take in no more energy than they will use in the course of a day. In her opinion, nutrient profiling is not a preferred strategy against obesity. Nutrient profiling leads to the demonisation of certain foods that, in principle, can be part of a sensible diet. Therefore, it is important that consumers be guided as how to obtain a healthy lifestyle by practicing moderation, variation and regular physical activity.

1 Citation *Dr. David Ludwig, Children's Hospital Boston*.

According to Kettler, the key to change is activating consumers' choice for the healthy alternative by product reformulation (fewer calories per serving) and reduced portion sizes. Other important elements in fighting obesity are the following: accurate, factual consumer information, including nutrition information; the industry's commitment to avoid marketing to children under 12 years old and the promotion of an active lifestyle.

On the third morning of the Academy, the agenda shifted from a focus on nutrition policy to international standard setting. Raluca Ivanescu, adviser to the Directorate General for Agriculture and Fisheries within the Council of the European Union, introduced the Academy to the work of Codex Alimentarius.

Codex Alimentarius is an intergovernmental organization aiming to improve food safety and ensure fair practices in food trade through the harmonization of food standards.

The first international food standards date back to the early 1900's. Several attempts to establish regional food codes followed during the Forties and Fifties. The first step towards a global standard was the founding of the Codex Alimentarius Commission in 1961.

Nowadays, Codex Alimentarius consists of 185 Members (184 countries and the EU), representing 99 % of the world population. Codex meetings are also attended by so-called observers (currently 49 IGOs, 151 NGOs, 16 UN-bodies), that have the right to speak, but not to vote.

Codex Alimentarius consists, firstly, of the Codex Alimentarius Commission, which functions like a "parliament": Codex's supreme decision-making body. In contrast, the Codex Executive Committee fulfils a government-like function. Furthermore, Codex comprises a secretariat and several subsidiary bodies including general subject committees, commodity committees, regional coordinating committees and ad hoc intergovernmental task forces.

The adoption of global standards occurs through the so-called "step-procedure", according to which a total number of eight steps have to be taken before the final adoption of a standard, guideline or other text.

Commission decisions are taken by consensus. However, no clear rules prescribe when consensus has been reached; it is up to the Chair to decide when this is the case. Only recently, there has been a development towards stricter application and interpretation of what consensus means. Voting is one alternative to consensus, but it is highly controversial since decision-making by vote directly opposes the principle of consensus.

Since 1995, Codex Alimentarius has been working on the basis of risk analysis. The Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius were adopted by the Commission in 2003.

Codex standards cannot as such overrule national laws, but many countries have adopted legislation that implements the standards within their national legal system. Within the context of WTO-law, the SPS-Agreement makes direct reference to Codex standards, which in practice gives countries that implement Codex standards an advantage in WTO conflicts.

This may be illustrated by the case of Ractopamine, a beta-antagonist which is used as a growth-promoting agent in pigs and cattle by countries such as the USA, Canada and Argentina. For years, opposing countries, amongst which EU Member States and China, have blocked the import of pork and beef products that contain residue levels of this drug. Recently, the long-term discussions on the acceptability of ractopamine residues culminated in a vote by the Codex Alimentarius Commission, which resulted in the adoption, by one vote, of maximum residue levels for Ractopamine in pork and beef.

The adoption of the Codex standard will not force the EU and China to lift their bans of Ractopamine bred meat. However, the existence of a global standard implies a presumption of conformity with WTO-law of all measures based on this standard, which will make it more difficult for the opposing countries to maintain their arguments.

This case, along with similar cases that took many years of discussions, clearly shows some of the weaknesses of the Codex Alimentarius system. Codex standard setting is often cumbersome and slow, with power struggles and stakeholder pressure blocking progress. Nevertheless, Codex has developed into a globally recognized standard-setting body, which has successfully and consensually adopted many credible, science-based safety standards, thus uniting 99 % of the world's population in standard setting.

Peter Barton Hutt, lecturer in Food and Drug Law at Harvard Law School and Senior Counsel at Covington & Burling LLP in Washington D.C. nourished the participants with his views on the past, present and future of food law during the Academy's Wednesday afternoon session.

The history of food law – one of Hutt's personal interests – was sketched from the very first attempts to put food safety concerns into writing through to the full-fledged risk-based food safety laws that we know, today.

According to Hutt, modern food law started with the adoption of food adulteration and marked fraud prohibitions, which, in written form, can be traced back as far as the Roman Empire.

Anglo-Saxon legacy commenced with the adoption of a 1212 Statute prohibiting the use of ingredients that were "not wholesome for Man's body" in order to prevent, *inter alia*, the fraudulent blending of charcoal with pepper, which at the time was very valuable. The statute remained in force for the next 578 years, when the first steps towards the adoption of a more elaborate food code were taken.

In the second half of the 19th Century, a major food crisis occurred in Bradford, England. As a result of the accidental use in sweets of arsenic instead of sugar, several people died and many more fell ill. The accident resulted in the adoption of the first modern food safety laws, dealing with food safety and food adultery and prohibiting the use in food of substances that were "injurious to health".

The US had no federal food laws, when, in 1906, the US Chamber of Commerce put on a nationwide contest offering USD 10,000 to the person who would write a national law on food. The result, comprising a copy of the English Food Safety Act, was called the US National Food and Drug Law.

Although the US law has since undergone several changes – the first actual reference to food "safety" did not occur until the adoption of the 1958 Food Additives Amendment – its food safety standard is virtually unchanged.

As for food information, early laws already prohibited fraudulent presentation of foods. The 1906 US law directly forbade labelling that was "false or misleading in any particular". Until recently, to measure this standard, the US authorities applied a consumer benchmark based on a person who was ignorant, uneducated and credulent. In 2007, in light of the freedom of commercial speech protected by the First Amendment, Congress adopted a "reasonable consumer" benchmark.

A major controversy in present US food law is the use of claims.

According to a 1988 federal law, a health claim is permitted if such claim is supported by "significant scientific agreement". However, federal courts ruled that the First Amendment of the US Constitution stood in the way of a strict application, so that the American Food and Drug Administration (FDA) could not simply deny the approval of claims that had "some scientific support", but that failed to meet the statutory standard of "significant scientific agreement". As a result, the FDA has developed a system for the approval of qualified health claims which attempt to describe the strength of the scientific evidence that supports a claim.

Apart from health claims, the US system allows for structure/function claims, which describe the role of a nutrient or dietary ingredient intended to affect normal structure or human function. Structure/function claims do not require pre-approval by the FDA, but they must be truthful and not misleading.

The result, on the one hand, is that it has become very difficult for American consumers to distinguish among the many different types of claims on food labels, including health claims, qualified health claims, and structure/function claims. On the other hand, possibilities for industry are limited, partly because of the limitations set by claims legislation, and partly as a result of of the high costs of scientific research necessary to substantiate a claim.

The difficulties presented in the US claims case are illustrative for what, according to Hutt, can be expected to become one of the main challenges of future food law: how to finance the sector. The collection of fees raises concerns about the independence of government institutions. Moreover increasing fees may simply result in food becoming (too) expensive.

The question that arises is what alternative we have at hand for government-financed food safety. Should we replace regulation with self-regulation? Should we strive for global harmonization? Or, could mutual recognition be the answer? We can identify developments in all of these directions, and only time can tell what the future will bring us.

Sven Bostyn, Senior Lecturer in Intellectual Property Law at the University of Liverpool delivered to the Academy a presentation on Geographical Indications and patent law in relation to, *inter alia*, functional foods and health claims.

EU food law recognizes three geographical designations of origin, which are names that indicate a certain quality of the product linked to their origin in a particular geographic area. Primarily Mediterranean countries have a long history of protecting both geographical and traditional designations, and other legal regimes have gotten used to their effect.

The EU distinguishes between products that carry a Protected Designation of Origin (PDO) or a Protected Geographical Indication (PGI) and products that are labelled Traditional Specialties Guaranteed (TSG).

Clearly, EU legislation protects these designations only within the EU-borders. Outside the EU, they do not have any value. Within the EU territory, however, other rules may also apply. At the WTO-level, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) establishes that all Members shall provide for legal protection against the misleading use of geographical indications and unfair competition.

The possibility to apply for a geographical indication is not open to individuals, but pertains to the (abstract) group of producers of the same product in a specific area that fulfils the criteria for which protection has been given. One of the defining features of the system is that it presupposes an exclusive link between product and place, which yields distinctive or even unique qualities associated with the product's origin. The geographical indication aims to protect the exclusive reputation of the product.

The distinction between the different regimes lies in the strength of the link between the qualities of the product and the region where it is produced. PDO's presuppose the strongest link whereas, for PGI's, the causal link between the place of origin and the quality of the product may be more a matter of reputation rather than verifiable fact. Moreover, for a PDO, production, processing and preparation *all* need to take place in the named geographical area, while, for a PGI, *either* production, processing or preparation need to take place in the named geographical area.

Registration as a TSG presupposes that the registered product has traditional features or characteristics. There is no need to establish a link between the named product and the nominated geographical area to qualify for protection.

Different from geographical indications, which protect tradition and heritage, patents protect novelties. Any new technological invention that involves an original step susceptible to industrial application can be patented if it is sufficiently disclosed. The definition excludes discoveries. However, a discovery can be turned into a patentable invention if a technical application or effect is shown.

A European patent splinters into a bundle of national patents after it has been granted. Hereafter, infringement is a purely national issue.

In correspondence with the provisions of the European Patent Convention (EPC), the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims contained in the application as published. In practice, this means that a balance must be found between, on the one hand, fair protection for the patent proprietor and, on the other, a reasonable degree of legal certainty for third parties.

In principle, the patentability of medical claims is restricted. Any claim for a treatment method aiming at a certain therapeutic effect is excluded. If the claimed effect is merely cosmetic, the treatment method can be patented. Products for use in a medical treatment method are patentable. For such products, two types of claims are at hand. In the first place, the patent may claim, without any further specification, that a certain effect will be achieved (a functional claim). Secondly, the claim may be structural. In order for the latter to be acceptable, at least some data hinting towards the claimed effect must be included.

The Academy ended with a presentation by Alberto Spagnolli, Head of the Executive Office at the European Food Safety Authority (EFSA), on the functioning of EFSA.

EFSA is composed of four bodies: The Management Board, represented by the Executive Director and assisted by staff; an Advisory Forum, composed of representatives from national food safety bodies with a role equivalent to EFSA; the Scientific Committee; and Scientific Panels, each within their own sphere of competence. EFSA's Scientific Committee and Panels are composed of independent scientists selected on the basis of proven excellence.

EFSA's Management Board is divided into five Directorates for, respectively, Science Strategy & Coordination; Scientific Evaluation of Regulated Products; Risk Assessment & Scientific Assistance; Communications; and Resources & Support. Each Directorate is subdivided into separate units.

EFSA's core values are scientific excellence, independence, openness, transparency and responsiveness. In order to assure EFSA's independence, a Policy on Independence and Scientific Decision Making Processes (2011) and Implementing Rules (2012) have been adopted. According to these policies, all people working for EFSA or in any way involved in EFSA's scientific opinions must regularly declare their personal interests, as to timely uncover any potential conflicts.

Public access to scientific documentation at all times and open panel meetings provide transparency. Moreover, EFSA has adopted guidelines on transparency in risk assessment.

EFSA also organizes public consultations, events, scientific colloquia and (network) meetings, and has established a Stakeholders Consultative Platform.