



Comparative Analysis of Certain Requirements of Food Legislation in the European Union and the Customs Union of Russia, Belarus, and Kazakhstan

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Foreword

This report presents a comparative analysis of the food legislation requirements of the European Union and the Customs Union. Its purpose is to guide food business operators and public authorities engaged in reforming national food safety systems in the peculiarities of EU and Customs Union legal requirements and help them evaluate their capabilities in meeting those requirements. This report supports the International Finance Corporation's efforts to facilitate the opening of new markets for the producers in emerging markets.

Public authorities will find this report useful for aligning their national food safety policies and frameworks with the EU and Customs Union. Similarly, food producers looking to export their products to these markets will be able to align their food safety control systems with target markets.

This report compares the most critical aspects of food legislation of the EU and the Customs Union, such as:

- Requirements and Arrangements of Food Control;
- Requirements to Food Quality;
- Requirements to Food Labeling;
- Food and Food-related Articles and Materials that Require Special Authorization;
- Laboratory Control and Food Safety Criteria.

Food safety standards are a major driver of food production and trade. Consumers want safe food which is sustainably produced and can be traced back to individual producers. Ensuring food safety and consumer protection increasingly occupy the agendas of governments, which are looking to expand their trade networks. Likewise, food businesses interested in widening their export range need to understand quality and safety requirements in their target markets. This report offers unique, up-to-date information on the similarities and differences of the food safety requirements of the EU and Customs Union, with detailed assessments of the regulations that govern food safety.

Lisa Kaestner,

Practice Manager,
Trade and Competitiveness
Global Practice, Europe and
Central Asia
World Bank Group

Rufat Alimardanov,

Country Manager,
IFC in Ukraine and
Belarus

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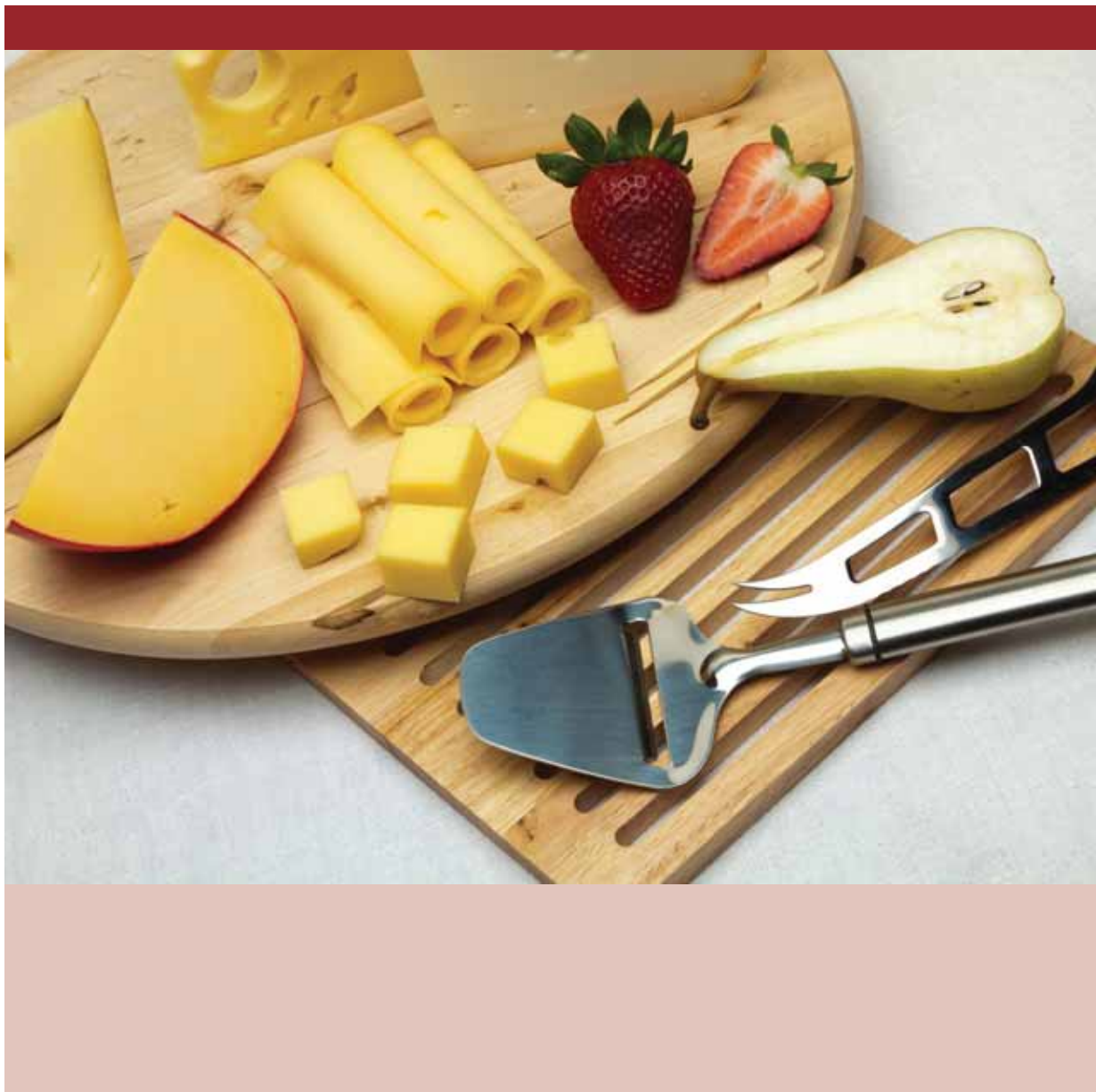
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Important Note

This analytical report had been prepared in April-November 2014. While the publication was in the process of preparation, the Customs Union underwent a number of important changes: on January 1st, 2015, an agreement on establishing the Eurasian Economic Union (EEU) entered into force; it is planned that from January 1, 2016 the Single Economic Space will become fully functioning. Further, Armenia and Kyrgyzstan joined Belarus, Kazakhstan and Russia as the Customs Union member states.

Still, all those changes have not impacted approaches to food safety policy. All legal documents of the Customs Union used for this analysis remain in full force.



Comparative Analysis of Requirements and Arrangements of Food Control between the Customs Union of Russia, Belarus, and Kazakhstan and the European Union

Executive Summary

Ensuring food safety is a key shared responsibility of both governments and industry. Failure to deliver on this commitment has led to illness and death. It impacts a country's ability to trade and therefore the economic well-being of the country. For these reasons globally governments and industry expend significant efforts and resources to ensure that food is safe and governments have established systems for food control. These food control systems have 5 common elements: food laws and regulations that provide the legal basis and regulatory requirements of the system; food control management systems that establish the roles and responsibilities of government and industry; inspection services that monitor and enforce the regulations and ensure that the proper activities are taking place; laboratory services for monitoring through testing compliance with the regulations; and information, education and training for industry, government and consumers.

While each food control system has these elements, the approach and specifics differ. In each country and union of countries, the food control system reflects their specific needs, historical context, and culture. The Customs Union food control system is based on ensuring the safety of food through compliance with final product specifications. In this system, responsibility for food safety mainly resides with food control bodies, and they accomplish this task by verifying that the end-product meets the required technical specification established by the government. Even when a producer is required to

declare safety and conformity of the product, it is still the government who authorizes the declaration. The government sets the specifications which typically include many attributes related to food quality as well as safety and then verifies compliance through inspection and testing. Industry is only required to provide a final product that complies with the technical specification. In comparison, the European Union food control system is based on risk control and mitigation. Within the risk-based approach, food business operators are responsible for identifying food safety hazards and related risks from farm-to-fork and developing and implementing practices that prevent, minimize or eliminate those hazards (HACCP)¹, while the government is responsible for monitoring and verifying the effectiveness of the risk control measures. In the European Union risk-based system, food quality attributes such as size, color, shape, smell and taste are not generally a part of the food control system. Instead, they are left to the market place to judge if they are acceptable. These two approaches to food control are fundamentally different. The Customs Union is based on end-product compliance to a specific technical regulation or standard, whereas the European Union is based on preventive measures and minimizing risks associated with each process throughout the complete food chain. These differences have significant implications for content and organization of the laws and regulations, monitoring and control, inspection, testing, labeling, approaches to food quality, and the responsibilities of government, industry and consumers in ensuring that the food is safe. Both systems are effective, but the differences in philosophy, organization, implementation and enforcement have significant impact on both business operators wishing to export to either or both of the Unions and countries wishing to harmonize with either Union. For industry, these differences require extensive working knowledge of the specifics of each system, and the ability to adjust their processes and products accordingly.

¹ HACCP – Hazard Analysis and Critical Control Points – A science-based system that identifies, evaluates and controls hazards that are significant for food safety. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. HACCP is based on seven principles: (1) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels (hazard analysis); (2) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; (3) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (4) establishing and implementing effective monitoring procedures at critical control points; (5) establishing corrective actions when monitoring indicates that a critical control point is not under control; (6) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in paragraphs 1 to 5 are working effectively; (7) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in paragraphs 1 to 6. See Codex Alimentarius document . *Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application, Annex to CAC/RCP 1-1969. Recommended international code of practice general principles of food hygiene, and EU Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses*, European Commission Health & Consumer Protection Directorate-General Brussels, 16 November 2005;

The differences can be better elucidated through the following. In general, the Customs Union has adopted an approach to technical regulation that is very similar to the one used in the European Union (the so called “new EU approach to technical harmonization and standards”)² for a wide range of consumer goods and industrial items (toys, cosmetics, electric equipment, elevators, high-pressure vessels, and many others) with one significant exception, in the European Union this “new approach” *does not* cover foodstuffs. The main features of technical regulation and harmonization common to both Unions for non-food items include:

- legislative harmonization is limited to essential safety requirements; essential safety requirements are outlined in mandatory sectorial directives (EU), or in technical regulations (CU);
- products for which essential safety requirements are developed may be placed on the market only if they do not endanger the safety of persons, goods, etc.;
- drawing up technical production specifications (standards) is acceptable and is entrusted to organizations competent in industrial standardization;
- technical specifications (standards) are not mandatory;
- the public authorities must ensure the protection of safety (or other requirements envisaged) on their territory;
- the public authorities are obliged to recognize that products manufactured in conformity with harmonized standards are presumed to conform to the essential requirements; in the absence of harmonized standards, public authorities accept conformity with national standards;
- member states presume conformity for products which are accompanied by a means of attestation, and these products are allowed to freely circulate on the market;
- means of attestation are:
 - certificates and marks of conformity,
 - test results,
 - a declaration of conformity issued by the manufacturer, which may be coupled with a surveillance system;
- member states designate bodies authorized to issue marks or certificates of conformity;
- as a visual sign of conformity, a mark is placed on the label (“EAC” mark in the Customs Union, and “CE” mark in the European Union).

The significant difference between the Customs Union and the European Union is that in the European Union,

food is NOT covered by technical harmonization within the “New Approach”, and all of the above features are not applicable to foodstuffs. In the European Union this “New Approach” has not been extended to food control as there has been significant reluctance to allow food safety to be determined by standards bodies (usually representing a third party) that operate outside the governmental framework and who have little tradition or experience in defining, controlling, or managing food safety. Food Safety is deemed too important for governments, industry and consumers to relinquish control. In the Customs Union, the use of technical regulations as an approach to control safety has been extended to foodstuffs. The extension of the technical regulations to food by the Customs Union is the fundamental reason for the significant divergence of the Customs Union and European Union food control systems.

The differences start with the mandate, general organization, and application of food control within each Union. The European Union and the Customs Union have their own mandates, scopes and degrees of integration that influence the entire regulatory framework in general, and the food control system in particular at the all-union level and at the level of member states. The Customs Union focuses primarily on internal trade between member states and therefore issues customs policy and rules for allowing commodities into circulation. In this system there are a number of general and product-specific technical regulations that provide a framework for food control within the Customs Union. The common framework is then supported by member states national laws, regulations, and standards. Also, within the Customs Union, for food categories where product-specific technical regulations have not been developed yet, the national law of member states applies. Figure 1 provides a graphical representation of the Customs Union food-related legal instruments.

In order to be compliant with the Customs Union, one has to take into consideration compliance with the Union’s technical regulations as well as the laws and standards of the member states. Further, for business operators it is important to note that the Customs Union system does not address such aspects as enforcement, fines, penalties, incident management, recalls and withdrawals, and authorization/approval of new substance (pesticides or veterinary medicines), leaving those to be under the mandate of the national law of the member

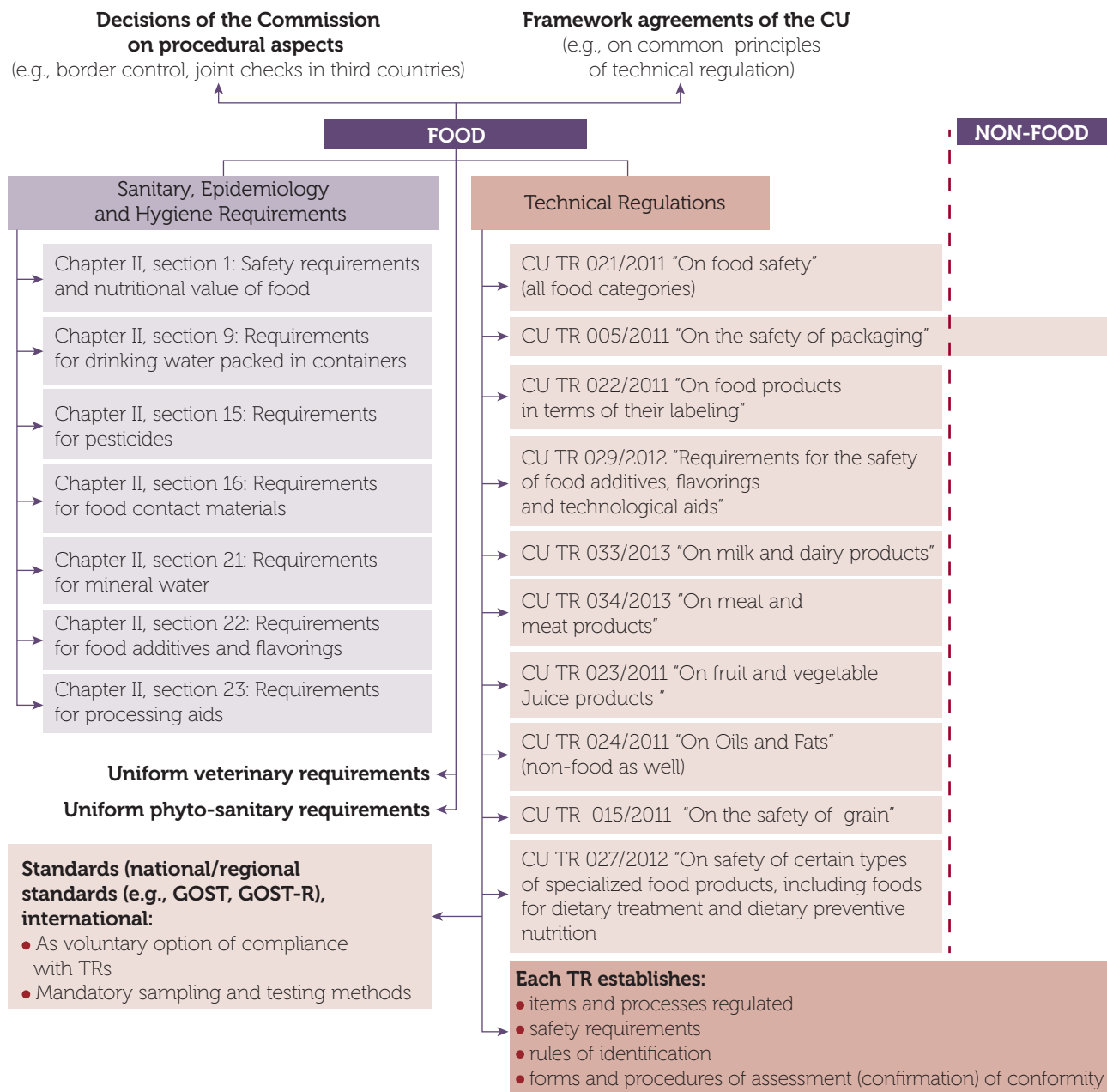
² Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

states. This increases the complexity of the regulatory environment and compliance for industry wishing to export to the Union and for governments wishing to model or harmonize with the Customs Union.

The European Union has taken a different approach and has a much broader agenda, covering economic,

financial, monetary, political, social, scientific, security and many other areas. Because the mandate and focus of the European Union is much broader, the food control system takes into account a greater range of issues which are reflected in the regulatory framework. Further, the European Union regulations³ supersede those of the member states, which creates a harmonized and

Figure 1 Organization of Customs Union Technical Regulations



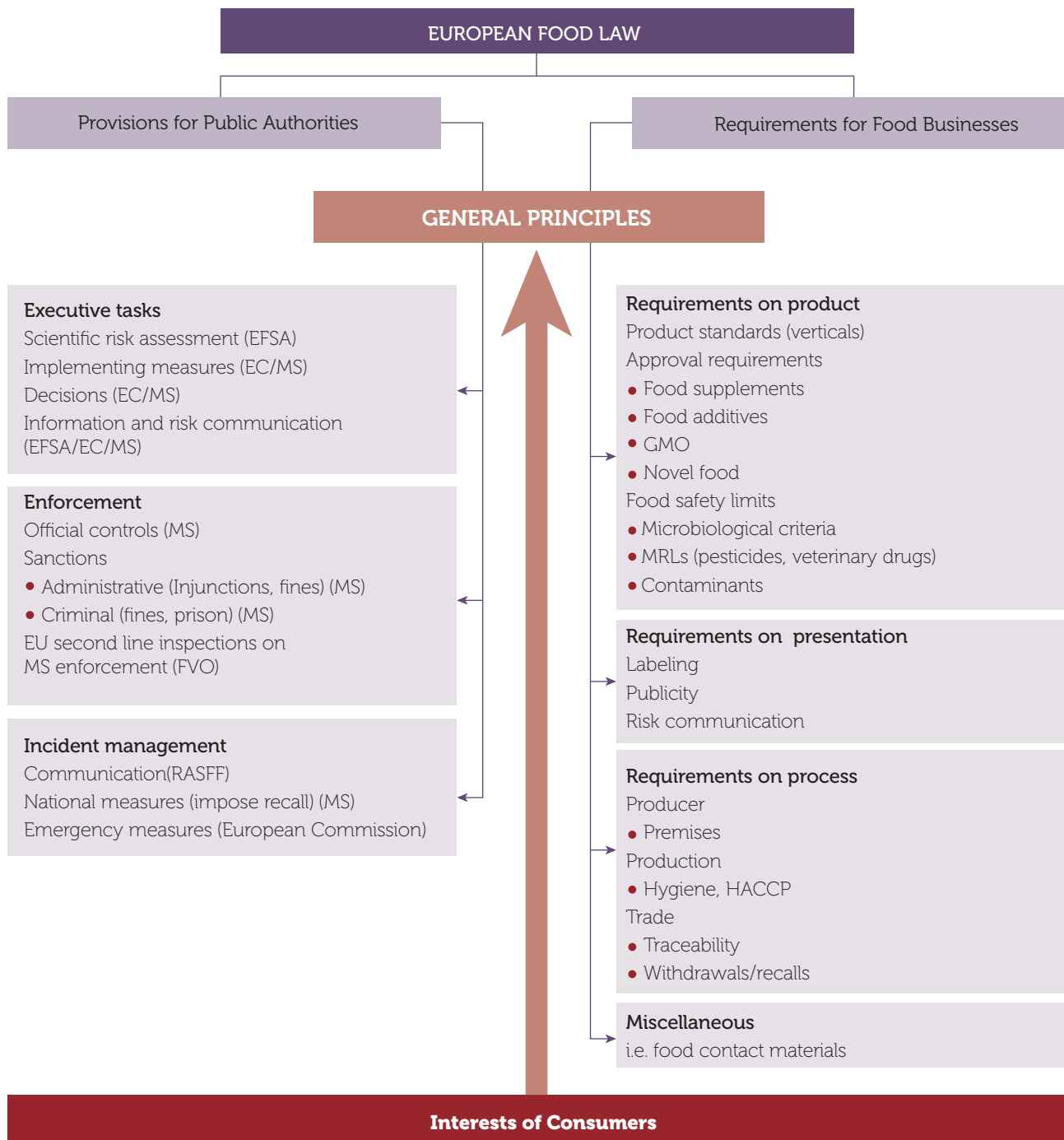
In case of several TRs, when they entered into force, relevant sections of the Uniform sanitary, epidemiology and hygiene requirements stopped being effective with regard to the objects of regulation covered by the TRs

³ There are three main types of legal instruments in the European Union: regulations, directives and decisions. Regulations are addressed to member states, have direct effect, supersede national law and do not require transposition; regulations by their nature are similar to laws. Directives are addressed to member states but do not establish directly applicable requirements; they set objectives that need to be transposed into national laws by national legal instruments. Decisions can be addressed both to member states and/or specific entities; they have direct effect but are usually focused on specific narrow issues.

unified set of horizontal legal acts across all member states. This simplifies compliance for industry in that one system is uniformly applied across all Member States. This uniform system defines and clearly establishes the European Union requirements for compliance, enforcement, incident management, recalls and withdrawals, and authorization/approval of new substances (pesticides, veterinary medicines, food additives, etc.). Finally, since the focus of the European Union is on risk control

and management, it covers a much more comprehensive range of the food chain steps, from production and processing to sale to the final consumers. Therefore, a much wider range of food business operators (virtually all of them) are included under the regulations. The European Union food law is a combination of horizontal and a limited number of vertical legal instruments. Figure 2 is a graphical depiction of the food laws within the European Union.

Figure 2 Graphical Depiction of the Food Laws in the European Union⁴



⁴ This chart is adapted from *The System of Food Law in the European Union*, by Bernd M J Van Der Meulen// Deakin Law Review, Volume 14 No. 2, 2009.

It is important to note that even the definition of food varies between the two Unions. Again this can be traced back to the differences in approach. Because the Customs Union focuses on the compliance of the final food product to a specific technical regulation or standard, the definition of food is limited to “*products that are of animal, plant, microbiological, mineral, artificial, or biotechnological origin and includes natural, processed or reprocessed products intended for human consumption including drinks, chewing gum, specialized food products, packaged potable water, potable mineral water, alcoholic products (including beer and beer-based drinks), non-alcoholic beverages, biologically active supplements (BAS), chewing gum, enzymes and starter cultures of microorganisms, yeast, food additives and flavorings as well as food raw material*”⁵. The European Union takes a wider definition of food: “*food (or ‘food-stuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment*”⁶. This definition by design allows for a broader interpretation of food giving it greater control over the products and substance humans may ingest. Further, it allows for adaptation in that as science and technology advance, such as developments in nano-technology, the incorporation of new substances and products into the scope of food becomes easy. The European Union establishes a general set of exclusions in the definition of food that further refine what food is and what food is not. These are mostly consistent with the Customs Union⁷ and the

exclusions include for instance, cosmetics, tobacco and tobacco products, narcotic or psychotropic substances and residues and contaminants^{8,9}.

The Customs Union and the European Union have both established basic requirements relative to food. Food shall be safe, meet food safety criteria, be hygienically produced and handled, registered as needed, properly packaged, labeled, and be traceable¹⁰. This is further elaborated on by the European Union that unsafe food takes into account the intended use of food and recognizes that food is unsafe when it presents danger to health and is unfit for human consumption. The Customs Union technical regulations include a number of requirements that relate to its circulation on the market¹¹ that are not found in the European Union, the most important of which is that food must pass conformity assessment procedures and bear a special Customs Union mark as a proof of conformity. Further, since the Customs Union is based on conformity assessments, many food products have to meet compositional standards, as well as requirements for chemical and physical properties, nutritional properties, organoleptic (appearance, taste, odor) and, in some cases, size. Within the European Union such aspects are generally, with a few limited exceptions, regulated by the market place and by the rules of providing adequate information to consumers. Finally it must be noted in the European Union it is recognized that food can be unsafe even when it conforms to specific provisions of food law. These requirements and elaborations are important as they play a key role in the food control system and specifically as they emphasize the role of the food business operator.

⁵ Customs Union TR 021/2011 “On Food Safety”.

⁶ Article 2 of Regulation (EC) No. 178/2002, also commonly referred to as General Food Law.

⁷ Note the Customs Union does not specifically exclude these items from food but as they are not defined as food they are also excluded.

⁸ See the companion document for a more exhaustive list of what is excluded from the definition of food.

⁹ There are two additional differences that should be mentioned. In the European Union medicinal products are specifically excluded. In the Customs Union they are not specifically excluded but maybe interpreted as excluded based on terminology and use within the overall framework. In the Customs Union, biologically active additives (BAA) such as probiotic microorganisms, intended for consumption together with food or mixing into food products are specifically defined as food and while not specifically outlined in the European definition it does fall under substances and therefore is included as food.

¹⁰ Even though food safety is a main objective of the food law, European legal acts do not give a definition of food safety. However, Regulation (EU) No. 178/2002, Article 14, provides for a ban on unsafe food and explains when, for the purposes of the food law; food is deemed to be unsafe: “Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is considered to be: injurious to health and/or unfit for human consumption”. Article 5, CU TR 021/2011 “On Food Safety”.

¹¹ The term “circulation on the market” is common within the Customs Union and one that means to sell into the market place. We have chosen to use the common term so that the readers become familiar with the terms used in translation of Customs Union documents into English.

The Customs Union¹² and the European Union¹³ have a well-defined and established system of food control. At a high level, the intent of the Customs Union and the European Union food control systems are similar: to ensure the safety of food for consumers, to allow for free movement of goods within the Union, to protect consumers from fraud and adulteration. The Customs Union further elaborates the intent of food control and establishes that technical regulation and conformity assessment is the framework by which food control is established.¹⁴ In the European Union the intent is further elaborated to preventing or eliminating risks which may arise, either directly or via the environment, for human beings and animals, or reduce these risks to an acceptable level¹⁵.

In the Customs Union the food control system incorporates two levels: food control through all-Union conformity assessment and individual member state controls (supervision) of sanitary, veterinary, phytosanitary aspects.¹⁶ Implementation of routine food control on a daily basis to a significant extent relies on the laws, regulations and standards of its member states. While the technical regulations set specifics of conformity and

requirements (for manufacturers and importers) to the processes of production, processing, transportation, storage, sale, disposal for foodstuffs in general as well as for several categories (meat and meat products, milk and dairy, juices, oils and fats, grains), the implementation and enforcement procedures are mostly those of the individual member states. Therefore for companies wishing to export to the Customs Union this means that they have to comply with and understand both the Customs Union technical regulations as well as those of the member states to which they will export product. In addition, the role of industry is generally limited within the Customs Union to ensuring that the products which are produced and/or imported meet the specific technical requirements as set by the Customs Union or the Member States. Contrary to the European Union approach, industry in the Customs Union does not bear responsibility to define other additional self-control measures to ensure food safety. Even hazards within HACCP systems are limited to those specified in the technical regulations as criteria for finished products. The Customs Union institutional framework and the scope of the official food control system are represented in Figure 3.

¹² Agreement of the Customs Union on sanitary measures (approved by Decision of the Interstate Council of the Eurasian Economic Community No. 28 of December 11, 2009); Agreement of the Customs Union on Veterinary and Sanitary Measures of December 11, 2011, Agreement of the Customs Union on plant quarantine (approved by Decision of the Interstate Council of the Eurasian Economic Community No. 30 of December 11, 2009); Regulations on the procedure for the state sanitary and epidemiological supervision (control) of persons and vehicles crossing the customs border of the Customs Union, of controlled goods moved across the customs border of the Customs Union and the customs territory of the Customs Union (Approved by the Decision of the Customs Union Commission on May 28, 2010 No. 299); Uniform list of goods subject to sanitary and epidemiological supervision (control) at the customs border and in the customs territory of the Customs Union (Approved by Decision No. 299 of the Customs Union Commission dated May 28, 2010); Common list of goods, subjected to veterinary control (supervision), approved by the Decision of the Customs Union Commission No. 317 of June 18, 2010, List of regulated products (goods, materials and commodities under quarantine), subject to quarantine and phytosanitary control (surveillance) at the customs boundary of the Customs Union and in the customs territory of the Customs Union; Approved by Decision No 318 of the Customs Union Commission of June 18, 2010, Agreement on common principles and rules of technical regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation; Agreement on circulation of products subject to mandatory assessment (confirmation) of conformity within the customs area of the Customs Union (December 11, 2009).

¹³ 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; Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. These two documents are over-arching; further, Regulation (EC) No. 882/2004 together with a number of other regulations, establish specific food control procedures.

¹⁴ The intent is to ensure the protection of the customs territory of the Customs Union from the delivery and spread of infectious and mass noninfectious diseases (poisonings) among the population, by products (goods) not conforming to sanitary and epidemiological and hygienic requirements. To establish the procedures for import into the Customs Union area and the movement between the member states of products which are subject to the obligatory assessment (confirmation) of compliance. Finally, the intent is to protect the Customs Union from the importation and spreading of agents of infectious animal diseases, including those common to humans and animals, and goods (products) non-compliant with veterinary (veterinary and sanitary) requirements.

¹⁵ In addition food safety control is intended to guarantee fair practices as regards trade in food and feed and the protection of consumers' interests, including labeling of food and feed and any other form of information intended for consumers.

¹⁶ Other than the Council and the Commission of the Customs Union (currently Eurasian Economic Union Commission), there are no supra-national bodies that are part of the control system.

Enforcement is carried out by national bodies designated as competent authorities for specific areas of state control (supervision), and also competent authorities in the area of technical regulation. Conformity assessment is carried out by authorized certification (conformity assessment) bodies that are listed in a single Customs Union List; testing needed for the purposes of enforcement is carried out by authorized testing laboratories as well, and there is a separate Customs Union list of such laboratories. Because for several groups of products (e.g., specialized products, GMOs) state registration is required (as one of the forms of assessment (confirmation) of conformity), for registration of such products specially designated bodies are responsible.

As mentioned, within the Customs Union foodstuffs are subject to conformity assessment. The process of conformity assessment is carried out in the form of issuing

and registering declarations of conformity by manufacturers or importers. Schemes of declaring conformity vary depending on the product, type of production (serial production of a single lot), the establishment that produces the product and if the product is imported. While each of the schemes for conformity assessment is different they all contain several similar elements: creation and analysis of technical documentation; in some cases carrying out of production control, testing of samples of food products, issuance and registration of a declaration of conformity, and application of the unified mark of circulation on the market of the Customs Union. For some products, such as meat, one of the schemes also requires that the documentation submitted by the manufacturer as evidences of conformity includes a certificate for the quality and safety management system (HACCP-based) issued by the agency for certification of management systems¹⁷.

Figure 3 Food Control System of the Customs Union



¹⁷ This is specifically scheme 6 D as outlined in Customs Union technical regulation CU TR 034/2013 "On meat and meat products".

In addition to conformity assessment, food products are subject to state control (supervision)¹⁸ which combines border controls (people, vehicles, goods) and internal controls in the member states. Food products are divided into three groups that subject to respectively sanitary (epidemiological, hygiene), veterinary, and phyto-sanitary control (supervision). The purpose of , for instance, state sanitary (epidemiological, hygiene) control (supervision) is to prevent the introduction and spread of, and to ensure the elimination of infectious and massive poisonings that are hazardous to human health, to prevent occurrence of emergencies, as well as to prevent acts of terrorism with the use of biological agents, chemical and radioactive substances¹⁹.

Certain specific products when first imported or produced in the Customs Union are subject to state registration including: mineral, therapeutic, and bottled water; beverages such as tonics and beer; food for special purposes, including food for babies and older children, food for pregnant and nursing women; food additives, food-stuffs derived from genetically engineered or modified (transgenic) organisms, and some food contact materials²⁰. The fact whether such products have been registered is verified during state control (supervision).

Certain production/processing facilities have to be registered as well.²¹ This requirement extends to the facilities engaged in production and processing of meat and meat products, milk and dairy products, poultry and poultry products, and fish and fishery products. State registration of production/processing facilities is conducted by the agencies authorized for this purpose by the Customs Union member-states. This procedure begins with the application by the processor and is followed by an inspection of the facility to determine its conformity to the requirements on processes (production, processing, storage, transportation, sale, disposal) established by relevant technical regulations. Details of the procedure are established by the legislation of the Customs Union member-states. Upon satisfactory completion of the inspection and review of the findings, the designated agency assigns an identification (record) number to the facility and adds the production facility in the Register of Food Facilities Subject to State Registration. The state registration of a production/processing facility has no expiration date; however it can be suspended or cancelled in case of serious breach of the requirements of technical regulations.

Table 1 provides a summary of the state control (supervision) framework within the Customs Union.

¹⁸ State sanitary control (supervision) is carried out against requirements to products and processes outlined in the Uniform Sanitary, Epidemiological and Hygiene Requirements over Products Subject to State Control (Supervision); State veterinary control is carried out according to Uniform Veterinary (Veterinary and Sanitary) Requirements for Goods Subject to Veterinary Inspection (Supervision).

¹⁹ Based on item 2-1 of Decision of the Customs Union Commission No. 299 of May 28, 2010 (with amendments to item 2-1 introduced by Decision No. 101 of the Eurasian Economic Council of July 7, 2014, the food products and items that are covered by the scope of certain technical regulations are exempt from the scope of Uniform Sanitary, Epidemiological and Hygiene Requirements. These include for example materials and articles produced of polymer and other materials intended for contact with food and food media, labeling requirements, food additives and flavorings, and technological aids, as well as meat and meat products, and milk and dairy products.

²⁰ The goods from the list, manufactured for the first time on the Customs Union customs territory, as well as imported for the first time to the Customs Union customs territory, are subject to state registration (Part II, Single List of Goods Subject to Sanitary-and-Epidemiologic Supervision (control) at the Customs Border and on the Customs Territory of the Customs Union, as amended by Decision of the Customs Union Commission No 341 of 17.08.2010).

²¹ CU TR 021/2011 "On Safety of Food Products", Article 31.

Table 1 General Framework of the State Control (Supervision) in the Customs Union

State Control (Supervision) ²²			
	Sanitary	Veterinary	Phytosanitary
Key legal act	Customs Union Agreement on Sanitary Measures ²³	Agreement of the Customs Union on Veterinary and Sanitary Measures ²⁴	Customs Union Agreement on Plant Quarantine ²⁵
Competent authority	Competent Authorities in the area of state sanitary control (supervision) in member states		
Scope	Common list of goods subject to sanitary and epidemiological control (supervision)	Common list of goods subject to veterinary control	List of goods subject to quarantine and phytosanitary control (supervision)
	<ul style="list-style-type: none"> Foodstuffs (products in natural or processed form used for human food) including those derived from genetically engineered or modified (transgenic) organisms; Materials, products and equipment contacting with foodstuffs; Pesticides and agrochemicals 	<ul style="list-style-type: none"> Live animals; All food of animal origin, fresh and processed; Food that has ingredients of animal origin; Yeasts, enzymes, starter cultures; Grains and other plant origin items when they are intended for manufacture of feed 	<ul style="list-style-type: none"> Vegetables, fresh or chilled; Dried leguminous vegetables; Fruits, fresh, dried; Nuts, fresh or dried, whether or not shelled or peeled; Coffee, not roasted, whether or not decaffeinated; Cocoa beans; Grains; Cereal flours; Seeds, whether or not broken;
Point of control	At the border and within the customs territory of the Customs Union		
Documents that establish compliance criteria	Uniform sanitary, epidemiology and hygiene requirements for goods subject to veterinary control (supervision)	Uniform veterinary requirements for goods subject to veterinary control (supervision)	—
Procedural documents	<p>Procedure of state sanitary and epidemiological control (supervision) over persons crossing the CU customs border, goods subject to control that are being moved through the customs border and customs territory of the CU</p> <p>Common templates of product (goods) safety documentation</p>	<p>Procedure of carrying out veterinary control at the customs border and on the customs territory of the CU</p> <p>Procedure of carrying out joint inspections and sampling of goods (products) subject to veterinary control (supervision) on the territory of the CU member states and third countries</p> <p>Consolidated list of highly dangerous and quarantine diseases of animals</p> <p>Common templates of veterinary certificates (movement, import)</p>	<p>List of Quarantine Products subject to quarantine and phytosanitary control (supervision) while being imported to the common customs territory of the CU</p> <p>Procedure of carrying out the quarantine and phytosanitary control (supervision) at the external border of the CU</p> <p>Procedure of carrying out the quarantine and phytosanitary control in respect of quarantine products that are moved within the common customs territory of the CU</p>
Registers	Common register of state registration certificates for certain products	Register of food production objects (facilities) that are subject to state registration	—

²² English translations as well as links to the specific documents referenced in the table can be found at http://ec.europa.eu/food/international/trade/sps_requirements_en.print.htm.

²³ Decision No. 28 of 11 December 2009 of the Customs Union Commission, Decision No. 299 of 28 May 2010 of the Customs Union Commission.

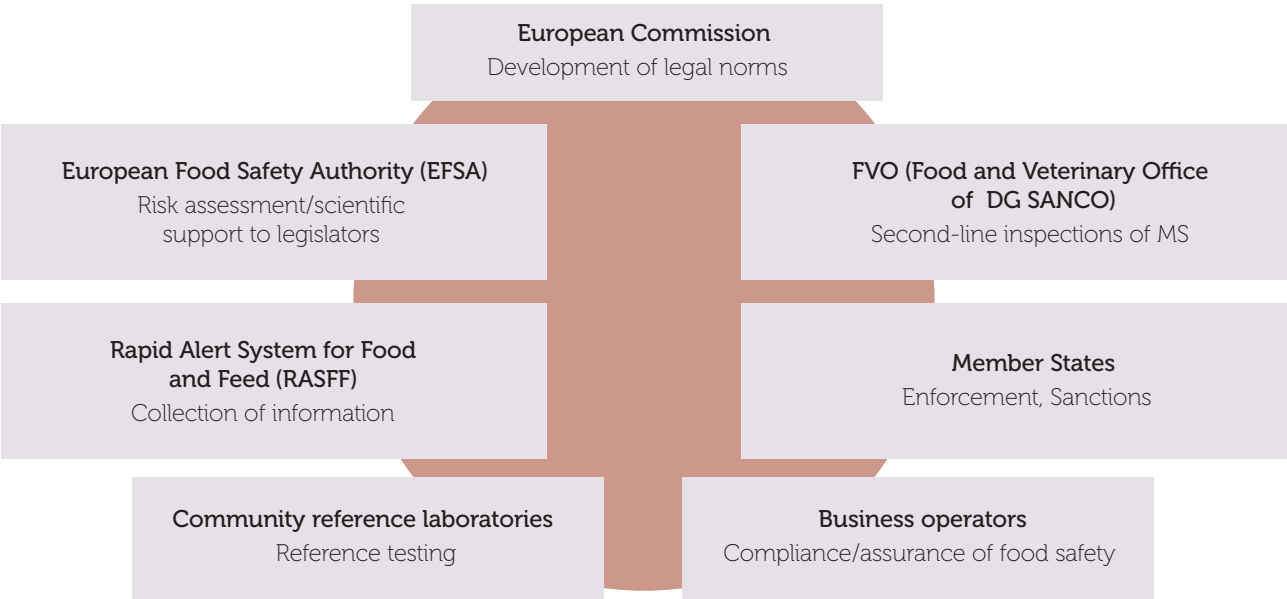
²⁴ Customs Union Agreement on veterinary and sanitary measures, Decision No. 317 of 18 June 2010 of the Customs Union Commission, as amended by Decision No. 342 of 17 August 2010, No. 455 of 18 November 2010, No. 569 and No. 570 of 2 March 2011, No. 623 of 7 April 2011, No. 724 of 22 June 2011 and No. 726 of 15 July 2011.

²⁵ Decision of the Interstate Council of the Eurasian Economic Community No. 30 of 11 December 2009.

The organizational framework for the European Union is quite different from that of the Customs Union in that at the foundational level the European Union provides for uniform, consistent food control procedures across all of its member states. In contrast to the Customs Union, the European Union does not rely on the laws, regulations or standards of member states to execute food control inside the member states. Even in the case of directives as one of the key legal instruments that require transposition into national laws, the level of uniformity is high because directives set uniform objectives at a detailed level. Further, within the European Union the responsibility for food safety at all levels from primary production, transport, processing, storage and delivery to the consumer, including retail, catering, and restaurants is clearly placed on food business operators. In this way the businesses are responsible to ensure, through HACCP and HACCP-like systems, the safety of the products they produce, and the role of the government is to ensure through monitoring and enforcement that the systems and practices are effective and in compliance with the regulations. Figure 4 is a graphical representation of the food control system within the European Union.

In the European Union, food control is organized in a fashion that the uniform laws and regulations including those establishing procedures of routine control are applied throughout all member states. At the same time, because this system is risk-based, member states have a significant amount of independence in planning their control activities. Verification of whether each member state properly applies the European Union food law is conducted through the Food and Veterinary office of DG SANCO²⁶. FVO conducts audits in member states for compliance with requirements for competent authorities to ensure that each member state has the capacity and capability to perform their role effectively and impartially in accordance with the European Union requirements.²⁷ The European Union establishes a uniform code of accreditation for laboratories²⁸ including testing and sampling that is designed to ensure equivalency and consistency of test results across the Member States. In contrast the Customs Union relies on the member states to accredit laboratories, and testing and sampling is conducted in accordance with the member states laws, rules and standards.

Figure 4 A Graphical Representation of the Food Control System in the European Union.



²⁶ The EU Commission contributes to development of legal norms through adoption of implementing legal acts, and enforces feed and food law by checking that legislation has been properly incorporated into national law and implemented by all EU countries. This is done through on-the-spot inspections in the EU and is carried out by the Food & Veterinary Office (FVO) based at Grange in Ireland. The FVO may check individual food production plants, but its main task is to check that EU governments procedures in place for checking that their own food producers are compliant to the EU's high food safety standards. The FVO also plays a key role in the development of EU policy in the food safety, veterinary and plant health sectors.

²⁷ Criteria for National Competent Authorities, Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The criteria include: legal/enforcement powers, management structure, independence, resources, personnel, recruitment and training.

²⁸ Regulation (EC) No. 882/2004.

The European Union does not establish procedures for registration of any foodstuffs similar to the Customs Union. However, it does establish procedures for authorization of certain new substances (e.g., food additives and flavorings, dietary supplements), products (novel food) and materials (food contact materials) when those are developed and planned to be commercialized. Authorization is done once for the product or substance, and individual manufacturers do not have to register the product or substance again.

As for individual food establishments, procedures of approval and registration apply. Establishments that operate in a sector of animal origin food must be approved. Approval procedures include application by the food business operator, and documentary check and on-site inspection by an official inspector. As a result the facility receives approval for operation and is assigned an approval number that is added to a list of approved establishments. Facilities that operate in the non-animal food sector are required to register. This procedure does not involve on-site inspection, and means that a food business operator must only submit information about the establishment to a competent authority. In fact, the European Union establishment *approval* procedure corresponds to the Customs Union procedure of *registration* of facilities.

As the European Union is a risk-based food control system, it includes two additional areas that do not exist in the Customs Union. First, the European Union established the European Food Safety Authority (EFSA) which provides scientific advice and scientific and technical support (including substance and product risk assessments) for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. This creates a uniform risk assessment process and advisory support to governments across the member states of the European Union. Second, the European Union has established Rapid Alert System on Food and Feed (RASFF), for the notification of a direct

or indirect risk to human health deriving from food or feed. This network involves the Member States, the Commission and EFSA. When a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, the Commission under RASFF is immediately notified, and the Commission then transmits this information immediately to the members of the network. Legal acts of the Customs Union provide for establishment of a common Information System between the member states that would perform a similar function, but this system has not been implemented so far.

It is important for governments and industry wishing to export to either Union to understand the systems of border control. Both the European Union and the Customs Union have rigorous systems for border control which have some similarities but also differences. In both cases, a prior notice of the shipment must be submitted to the customs authorities²⁹, border control of foodstuffs consists of documentary checks, identity checks and physical checks. Both Unions are guided by the requirements and rules established by the OIE³⁰ and IPPC³¹ when it comes to veterinary and phytosanitary issues at the border.

Both the Customs Union and the European Union have requirements related to pre-export approvals of the establishments, in the exporting country for animal products. According to the Customs Union procedures, food business operators in third countries who produce, process and/or store food products under veterinary control (supervision) are subject to joint checks (inspections) by competent veterinary authorities of the Customs Union member states³². Establishments that passed the joint checks are added to the List of Establishments in Third Countries. In some cases, such checks (inspections) can be carried out by a competent veterinary authority of only one member state; in other cases no checks are carried out, and an establishment can be added to the list without inspection. In the European Union, the scope of

²⁹ Commission Regulation (EC) No. 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (establishes a form of a Common Veterinary Entry Document (CVED)); Commission Regulation (EC) No. 669/2009 of 24 July 2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC. (establishes the form of Common Entry Document)/CED Decision of the Customs Union Commission No. 899 of December 9, 2011 "On introduction of compulsory prior notice on goods that enter the customs territory of the Customs Union by automobile vehicles" (establishes requirements to prior notice).

³⁰ World Organization of Animal Health (Office International des Epizooties).

³¹ International Plant Protection Convention.

³² Procedure on Carrying-out Joint Checks of Objects and Sampling of Products that Subject to Veterinary Control (Supervision). Approved by Decision of the Customs Union Commission No. 317 of June 18, 2010.

pre-approval procedure is more extensive and it covers pre-approval of establishments and also approval of the countries. The pre-approvals of the countries are done by sector and the relevant lists of approved countries and establishments are maintained by the Commission. All inspections in the third countries are done by one body – Food and Veterinary Office of DG SANCO. The procedure of approval of third countries is very detailed and timely, and it includes a wide variety of requirements to organization of food control system in a third country, as well as on-site inspections of third country establishments. At the same time, as soon as a third country is approved in general, the competent authority in this country has the authority to approve establishments for export into the European Union. This means that for a food business operator wishing to export food of animal origin to European Union it may not become possible until the country is approved.

The purpose of border control is to ensure that imported products meet regulatory requirements of the target market. Thus, border control procedures in the Customs Union and in the European Union reflect the specifics of their general food control systems. In the European Union, all foodstuffs for the purposes of all types of control including border control are divided into products of animal origin and products of plant origin; along with this, in many EU countries products of both types are controlled by single authorities. Respectively, the first group is subject to veterinary checks (including aspects of hygiene and safety), and the other group is subject to phytosanitary checks (primary products) and aspects of hygiene and safety. Since in European Union all member states have designated a competent authority for the control of food safety³³, in most cases it is a responsibility of one body to ensure proper execution of control of the imported food at the border. Obviously, this body closely cooperates with the customs authority. Generally, animal origin foodstuffs are considered of higher risk to human health, and are controlled more closely in comparison to plant origin products. While this approach is quite simple, special attention needs to be paid by potential importers to composite products

(those consisting of processed product of animal origin combined with plant material). As a general rule all food that contains a product of animal origin is covered by veterinary checks unless it is specifically excluded³⁴. In practice it means that all animal origin ingredients in a composite foodstuff entering the European Union shall come from approved countries and approved establishments.

As mentioned, in the Customs Union, all foodstuffs are divided into 3 groups: products that are subject to sanitary control (supervision), veterinary control (supervision) and phytosanitary control (supervision). In none of the Customs Union member states is the food control system a single agency or has a clearly defined body that would perform a coordination function; therefore, each member state designates competent authorities in each of the three areas, and they have shared responsibilities and roles in border control. Obviously, they cooperate with the Customs bodies in their respective countries as well. For a potential exporter it means that they need to clearly define to which of the three categories the product belongs to (whether it is an object of veterinary, sanitary or phyto-sanitary control), and become familiar with details of each particular border control procedure. There are no specific requirements to composite products or detailed rules of attributing foodstuffs to composite products; all foodstuffs with ingredients of animal origin are subject to veterinary checks³⁵.

Another important difference is that both Unions require that all consignments of food products be accompanied by a number of documents including a health certificate or its analogue. However, because foodstuffs that are to be put into circulation at the customs territory of the Customs Union have to pass conformity assessment (confirmation) procedures, in particular, by means of issuance and registration of declaration of conformity with technical regulations, a copy of such declaration or information about it³⁶ shall be presented at the border as well. It should be noted that there is a certain disconnect in the terminology used: technical regulations establish that conformity declaration is required for products that are

³³ It does not mean though that all EU countries have a single agency food control system; in many cases, one agency performs only a coordination function.

³⁴ Commission Regulation (EU) No. 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No. 1162/2009.

³⁵ Common List of Goods Subject to Veterinary Control (Supervision). Approved by the Decision of the Customs Union Commission No. 317 on June 18, 2010.

³⁶ Information about declarations of conformity means that it is sufficient to present identification data (e.g., registration number), and then the fact it has been issued can be confirmed by checking the Customs Union list (e-based data-base) of registered declarations of conformity.

to be “put into circulation”, while all customs regulations and procedures say that presenting a copy of declaration of conformity or information about it is required when product are “released for internal consumption”. There is no definition for “putting into circulation,” and whether it is equivalent to “releasing for internal consumption” is unclear from the legal standpoint. At the same time, in practice the two terms are interpreted as the same by the Customs Union, customs officials, and importers must present their duly registered declarations of conformity at the border. Declaration of conformity can be issued and registered only if a product meets the requirements of all applicable technical regulations. It means that, for example, in case of the fruit juice, it shall meet requirements of CU TR 005/2011 (safety of packaging), CU TR 021/2011 (general food safety), CU TR 022/2011 (labeling, entered into force in February 2015), CU TR 023/2011 (fruit and vegetable juice products); and none can be omitted.

As mentioned, in the Customs Union as well as in the European Union three types of controls are performed at the border: documentary checks, identity checks, and physical checks; the former means taking samples and performing laboratory control. In the Customs Union while the customs procedures are risk-based, the frequency of physical checks is not defined at the all-union level (or is not made public), and in fact falls under the national law of the member states. In the European Union, frequency of physical checks is risk-based and depends upon several factors, including the history of country of origin, the producer and the product. Commission Decision 94/360/EC³⁷ prescribes the level of physical checks for certain products. In general the minimum number of consignments to be subjected to a physical check are 20% for meat, meat products, fish, fishery products, 50% for poultry meat, honey, dairy products and shellfish, and at between 1% and 10% for most products of animal origin that are not intended for human consumption. For certain products where there is a known health risk the European Commission may prescribe a higher level of checking which may include compulsory sampling. Regulation (EC) No. 669/2006 establishes a list of foodstuffs of non-animal origin (e.g., frozen strawberries, peanuts, dried apricots, tea, etc.) from specific countries and frequencies for identity and physical checks that vary from 10% to 50%³⁸.

In summary, the main differences between the Customs Union and the European Union with regard to border control procedures are in the following:

- Scope of requirements to preliminary approvals: the European Union approves third countries for foodstuffs of specific animal food sectors and individual food establishments; for this purpose, inspections in third countries are carried out by DG SANCO Food and Veterinary Office (FVO). Unless a country is approved for certain sector, an establishment from this country cannot be approved to export to the European Union. On the other hand, as soon as a country is approved, approval of establishments can be done by national competent authority without FVO inspections. The Customs Union does not approve third countries; it only approves food establishments; in most cases, this is done through joint inspections of competent veterinary authorities of the Customs Union member states.
- The Customs Union requires that duly registered declaration of conformity (or information about it) is presented together with other documents at the customs; no such requirement exists in the European Union.
- The Customs Union does not define the frequencies of physical checks (or at least does not make it public) whereas in the European Union, frequencies are well defined and uniform throughout the Community.

Within any food control system, the business operators play a crucial role in ensuring the safety of the food that is produced and consumed. From production and post-harvest handling, transportation and storage, to food processing operations and distribution, to retail, catering, and restaurants all business operators have a role in ensuring the safety of food. The role the food industry plays in food control and the way governments apply food control to food business operators within the food supply chain varies dramatically between the Customs Union and the European Union. For governments wishing to model or harmonize with one or the other Union’s food control system, it is important to understand the overall approach and the details of the requirements to food operators/businesses across the supply chain.

³⁷ Commission Decision 94/360/EC of 20 May 1994 on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries, under Council Directive 90/675/EEC.

³⁸ Commission Regulation (EC) No. 669/2009 of 24 July 2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

To explain the differences in requirements to food business operators, we need to go back to the intent and the scope of food legislation in both Unions as those have a material impact on the requirements to food business operators. The intent of food control at a high level is the same within both Unions: to ensure the health and well-being of consumers, prevention of practices misleading consumers (adulteration or fraud) and environmental protection. The European Union extends the intent of the food laws to include an integrated risk based approach “from farm-to-fork” related to food and feed products and establishes primary legal liability and responsibility of food business operators for food safety³⁹.

This extension of the intent is significant to understanding of differences between the Customs Union and European Union with regard to requirements on food business operators. **First**, the European Union recognizes that risks need to be mitigated and controlled throughout the food chain from farm-to-fork. For the European Union this establishes the integrated role of the food chain and the fact that hazards can come from all levels in the supply chain and therefore must be controlled across the entire food chain. **Second** (which derives from the previous statement), the food law applies to *all food business operators* (those carrying out activities related to any stage of production, processing or distribution of food from primary production through sale of the good to the consumer)⁴⁰. **Third**, food business operators have the primary responsibility for food safety. This is not meant to imply there is not a role for government: the government has a major role in food control including setting laws, monitoring compliance and determining the effectiveness of food control measures and enforcement activities. Putting the prime responsibility on the food business operators is the recognition that food safety can best be controlled first and foremost by the food business operators who produce, transport, process, distribute and sell the food products intended for consumers. The only difference between the food business operators in terms of the scope of requirements is made between those involved in production of primary products, and those who operate non-primary products: food business operators in primary production

do not have to implement HACCP, instead they shall observe good hygiene practices; all the rest of the food business operators, whether they are manufacturers or not, must put in place, implement and maintain procedures based on HACCP principles. The **fourth** important aspect is that in many cases due to the limitations of segregation within the food supply chain it is impossible to separate food from feed (for example grains) and therefore both must be controlled.

In the Customs Union conformity assessment and therefore food control is limited to a narrower group of entities and persons: manufacturers, sellers and persons (entities) who represent foreign food manufacturers⁴¹. Their main responsibility is to ensure that their products meet the requirements of the technical regulations, and only food manufacturers are required to implement procedures based on HACCP principles. Therefore, it is assumed that conformity to technical regulations means that the food is safe. This places a much higher responsibility in ensuring food safety on the developers of the technical regulations and on food control bodies who must, by establishing specifications, providing laboratory services, registering declarations of conformity and carrying out control (supervision) confirm that during the period of validity of the declarations the product is safe and complies with specifications. No doubt the manufacturer has a significant role in ensuring the safety of food, but it is not as large and clearly defined as in the European Union. Obviously, the model of declarations of conformity place a larger responsibility on manufacturers compared to the certification model, but still it does not have the same level of responsibility as in the European Union. Finally, in the Customs Union the technical regulations only apply to food, not feed.

Within the scopes of the regulatory framework of the Customs Union and the European Union there are two other topics related to food operators that need to be considered. The first is **flexibility** as an approach to implementation of the legal requirements, and the second is the **breadth** of the requirements. In the Customs Union the technical regulations and rules are applied equally to all operators regardless of size or the volumes of

³⁹ Regulation (EC) No. 853/2004 on the hygiene of foodstuffs.

⁴⁰ According to the EU law, “food business operator” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control; “food business” means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food (Article 3, Regulation (EU) 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).

⁴¹ CU TR 021/2011 “On safety of food products”, Article 10.

products produced, and irrespective to production using traditional methods (e.g., traditional cheeses). Because of the breadth and coverage of the European Union regulatory framework as well as the intent to allow for the production of traditional products as a means to increase incomes especially in rural areas, the European Union incorporates flexibility within its food control system. While the application of systems based on HACCP principles is required at all levels of the food chain (with exception of primary production), the European Union recognizes that it is possible to give smaller enterprises flexibility on how the HACCP principles are applied. The European Union ensures that controls are effective but does not place undue burden on smaller food business operators or eliminate the use of traditional food processing methods. In addition, the European Union recognizes that with respect to food hygiene, at some food chain levels not all of the requirements can be applied in full or can only be applied with certain limitations⁴².

The Customs Union technical regulations include a significant number of specific provisions and requirements with respect to processes of production, processing, transportation and so on. In many cases, they are quite detailed and prescriptive. As a reflection of the overall legal framework, they are a combination of general requirements (applicable to all foodstuffs) and product-specific requirements (where those exist, including food of both plant origin (oils, juice products) and animal origin (fats, meat, milk and dairy), plus specialized foodstuffs that can be both plant and animal origin. In addition, in the near future when relevant new technical regulations will be adopted, there will be product-specific requirements to processes related to poultry products, fishery products and mineral waters. These requirements do not always relate to safety or hygiene; for example, some are on sizes. In the European Union a different approach is applied: the requirements to processes of production, processing, transportation, retail are related only to food hygiene; they include general and product-specific hygiene practices, and the product-specific ones are focused on all sectors of animal origin. At this level of requirements, there are many similarities between the two Unions, but also the differences are quite numerous (e.g., with regard to physical structures, temperature regimes, timing of certain operations).

With regards to HACCP, both Unions use this term and have the 7 principles of HACCP outlined in the respective legal acts,⁴³ but the interpretations are different. This has an impact on how HACCP is used as a tool to ensure the safety of food stuffs with respect to business operators. These differences include:

- In the Customs Union, HACCP requirements are only applied to manufacturers whereas in the European Union HACCP requirements are applied to all levels of the food supply chain after the primary production (including, but not limiting to, processing, warehousing, transportation, retail, catering, cafes and restaurants).
- The Customs Union limits the identification of hazards (HACCP Principle 1) to those during the process of production (manufacture) that can lead to the release into circulation of non-conforming products (non-conforming with the requirements of technical regulations (including those unrelated to hygiene such as organoleptic)). In the European Union food business operators are required to only identify any significant food safety hazards, including those that are not specified in the regulations.
- In the identification of critical control points (CCPs, HACCP Principle 2) the Customs Union focuses on the identification of specific *parameters* which are to be controlled in order to prevent or eliminate hazards. In the European Union CCPs are not parameters but rather *process steps* at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels. The European Union recognizes that it is not possible to eliminate all hazards but instead control these to such a level that they no longer pose a threat to human health whereas the Customs Union specifically states to eliminate hazards.
- With respect to verifying the effectiveness of the controls (HACCP Principle 6), the Customs Union establishes that verification must be done in the form of testing the final product against requirements of relevant technical regulations, and this is the only verification activity mentioned. In the European Union the food business operator is required to establish procedures, which shall be carried out regularly, to verify that the control measures are working effectively. This implies various verification activities, like validation of critical limits, review of records, revision of the HACCP plan as needed, testing against process

⁴² EU Guidelines on implementation of certain provisions of Regulation (EC) No 852/2004.

⁴³ In the EU – Article 5 of Regulation (EC) No. 852/2004 ; in the Customs Union – Articles 10 and 11 of CU TR 021/2011 “On safety of food products”.

hygiene criteria, and, as one of many activities, testing of the final product against the legal criteria.

- With respect to documentation (HACCP Principle 7) the Customs Union focuses on maintaining documents that prove that specific activities *were performed*, whereas in the European Union documents and records must be established and maintained to demonstrate the *effectiveness* of the HACCP system.
- Within the Customs Union there is no requirement for the training of the personnel of food establishments on issues of food hygiene and implementation of HACCP principles which is a requirement in the European Union.⁴⁴

Traceability is a way of responding to potential risks that can arise in food and feed. It is vital that when national authorities or food businesses identify a risk they can trace the cause of the risk back to its source in order to swiftly isolate the problem and prevent contaminated products from reaching consumers. In addition, traceability is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken, appropriate information can be given to consumers and food business operators. Traceability also enables the government to perform a risk assessment to prevent unnecessary wider disruption of trade. As such, traceability does not itself make food safe. It is a risk management tool to be used in order to assist in mitigating through containment a food safety problem. While both Unions⁴⁵ require to some extent traceability there are some differences between the requirements that impact food operators as well as the overall function of a traceability system. The traceability requirements in the Customs Union are limited to food products and raw food materials. This can create a significant gap in the traceability system as this does not include feed, food-producing animals or substances intended to be or expected to be incorporated into a food or feed product. The Customs Union limits traceability requirements to food products and requires only the manufacturer and subsequent proprietors to maintain the records and have a system of identification of products for the purpose of traceability with the help of marking. This excludes tracing back from the manufacturer and limits the ability of the government to understand the source of the problem and ensure the timely withdrawal and notification of consumers as to

⁴⁴Regulation (EC) No. 852/2004, Chapter XII "Training".

⁴⁵In the European Union – Regulation (EC) No. 178/2002; in the Customs Union – technical regulation CU TR 021/2011.



Traceability in Action

In autumn 2004, during standard random monitoring of dioxin levels in milk at a Dutch farm, national competent authorities found a high level of dioxin. They immediately barred the farm from trade, and initiated the tracing of the product through the food chain. This revealed that the source of contamination was clay, used in food processing to separate high quality potatoes from lower quality ones. Potato peels from a restaurant chain were supplied to the farm and used to feed animals. The hazard several times moved from food chain to feed chain and back. It was quickly established that the clay had also been supplied to several food processing companies located in the Netherlands, Belgium, France and Germany. Appropriate actions were swiftly taken.



the risk posed by the event, as the complete food chain is not included. The European Union requires that food business operators at all levels of the food chain have a traceability system, that they maintain the records allowing to trace back and track forward incoming materials

and outgoing products, and that they have a system of identification of products for the purpose of traceability with the help of marking. By having a system that encompasses the complete food chain the European Union has the ability to trace the source of the problem.

Important Notes for Governments, Policy Makers and Businesses

While the intent of food control at a high level is the same for the European Union and the Customs Union of Russia, Belarus and Kazakhstan, which is to ensure the health and well-being of consumers, prevention of practices misleading consumers and environmental protection, there are significant differences between the two Unions. The dissimilarities include:

- the fundamentals of the regulatory instruments and fundamental approaches to food safety and types and power of legal instruments that regulate it;
- organizational arrangements;
- the specifics concerning the scope of legal acts, the implementation and methods of execution; and
- the role of food business operators and the requirements for food business operators within the food control system.

In fact the two systems are so divergent that simultaneous harmonization with the two Unions becomes impossible. Further, from a legal perspective, the differences between the Unions are great enough that if a country or a business harmonizes with either of the Unions, they will be able to meet the requirements of the food control system of the other only by creating two parallel or dual control mechanisms. In real life, because many of the Customs Union provisions on food have not yet been fully implemented, it is difficult to judge about how they will work in practice.

Fundamental approaches: To start with, the mandates of the Customs Union and the European Union as unions of states differ as the European Union covers a much broader range of areas of common policies. The level of integration is much higher in the European Union as well. Both Unions have their own historical and cultural backgrounds with the Customs Union being adapted from the Soviet control and standardization

system, and the European Union as an outgrowth of a consumer driven economy. All this is reflected in the manner of how the regulatory environment is arranged in each Union, including in the area of food control. The Customs Union food control system is based on establishing food safety through conformity assessment of the final product. In this system the final food product is deemed safe when it conforms to specific Customs Union technical regulations, or recognized voluntary standards, and/or member state laws and regulations. The European Union's approach is to have a preventive food control program across all member states founded on the principle of risk assessment and mitigation from farm-to-fork. This is not to imply that one system is better or worse in providing safe food to consumers. Instead this statement is designed to explain why there are differences between the two Unions with respect to food control.

In general, the Customs Union adopted an approach to technical regulation that is very similar to the one used in the European Union (the so called "new European Union approach to technical harmonization and standards"⁴⁶) for a wide range of consumer goods and industrial items (toys, cosmetics, electric equipment, elevators, high-pressure vessels, and many others). However, there is a significant difference: in the European Union, *food* is *NOT* an area covered by technical harmonization within the "new approach", and all the features of this approach are not applicable to control of food safety. In the Customs Union, technical regulation as an approach to control of safety has been extended to foodstuffs as well, and this is at a foundational level why the two systems diverge significantly.

Types and power of legal instruments: The European Union uses three main types of legal instruments – regulations, directives and decisions. Regulations are legal acts that are directly applicable in member states, have

⁴⁶ Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

the power of laws and supersede national laws; they incorporate implementation mechanisms. Directives establish objectives that are compulsory to member states, but require transposition into national law as they do not include implementation mechanisms. Decisions can be addressed to both member states and specific entities; they are directly applicable but usually cover a narrow topic or issue. In recent years, the European Union has moved to the control of food safety through regulations (not directives, as earlier); all the most important aspects of food control are regulated through regulations thus creating a high level of harmonization and uniformity in the member states. In the Customs Union, the main legal instrument used is technical regulations; there also are standards (voluntary, but de-facto mandatory when they establish methods of sampling and testing), procedures (established by decisions), and requirements. They all are directly applicable in the member states (activities in the area of technical regulation and conformity assessment), but with some exceptions they do not incorporate implementation mechanisms – those can only be found in the Customs Union member-states national laws and regulations. Technical regulations while directly applicable are focused mostly on technical aspects of products and establish specifications, not policies. It is important to understand the differences between the legal acts as they help to identify the areas where possible differences may exist between the member states of each Union.

Organizational arrangements: The legal framework of the Customs Union combines horizontal legal acts and vertical legal acts. There are several technical regulations (on general food safety, labeling, packaging, food additives and flavorings) that cover cross-cutting aspects for all food products (it should be noted though that the technical regulation on packaging also covers packaging for non-food items). There are plans to develop a technical regulation on food contact materials that would have a horizontal nature as well. There are also a growing number of vertical technical regulations that are specific to certain product groups, in particular grain, oils and fats, fruit and vegetable juices, meat and meat products, milk and dairy products; several more are being drafted (on alcoholic products, poultry and poultry products, fish and fishery products, and mineral water). In contrast the current legal framework of the European Union in the food area is mainly based on horizontal legal acts, and is moving to even stronger horizontal organization. For governments and businesses in third countries it means that while in the European Union all

key legal aspects are covered by all-union provisions and are uniform in their objectives and implementation procedures, in the Customs Union there is always a need to also identify a range of applicable national laws and regulations of member states, as procedural details are covered by those and may vary from member state to a member state.

From the institutional perspective, there are substantial differences between the two Unions as well: in the European Union there are several supra-national bodies and agencies that actively participate in shaping, implementing and supervising policies in the food safety area, for example, European Union Commission and its Directorate General SANCO and the Food and Veterinary Office (FVO), as well as the European Food Safety Agency (EFSA). Further, there is a competent authority in each member state that is responsible for food safety control; even in countries where institutional framework is more complicated than a single agency model, there is one agency that bears a single responsibility in the food safety area for the purposes of the European Union policies (a “single window” to be contacted by other governments and businesses). In the Customs Union, while the Commission of the Customs Union sets policies, there are no bodies that would execute implementation or provide supervisory roles. The institutional framework is based on a system of national bodies each designated as responsible for a particular role (e.g., responsible for sanitary control, veterinary control, phyto-sanitary control, technical regulation, certification and conformity assessment, registration of specialized food, registration of novel food, and so on). This supports a “specialization” within the Customs Union of the existing food control bodies in the member states, and does not burden the member states with the need of institutional reform, even though one body can be designed for more than one role. Therefore governments and businesses need to remember that in the Customs Union member states there is no “single window” on food control issues. The best approach would be to first check on the official Customs Union website (<http://www.eurasiancommission.org/>) to determine which body in the target country of export is designated responsible for a specific activity.

Specifics concerning the scope of legal acts, specific provisions and implementation: In most cases the corresponding legal acts or their parts in force in the European Union and the Customs Union have differences in scope; sometimes this is due to differences in key definitions, in other cases there are differences in

subject areas and/or activities covered. In general, the European Union legal acts encompass a greater number of areas and specific issues relative to the Customs Union's. However, businesses should keep in mind that it does not necessarily mean that when there is no requirement in the Customs Union technical regulations, the area or specific issue is not regulated at all. In most cases it is likely that there are applicable national norms of the Customs Union member states, and it is important to identify these and comply. Further with reference to legal acts, there is another important feature that is different: the European Union legal acts are addressed to member states (and, first of all, their competent authorities) and food business operators in a broad meaning of this term, while the Customs Union technical regulations either do not clearly identify addressees of some provisions, or identify manufacturers, sellers and importers as the addressees.

There are multiple differences on specific legal provisions related to organization of food control. For governments and businesses in a third country the most noteworthy are the following four:

- In the European Union it is required by law that member states develop national annual and multi-annual control plans that are submitted to the Commission. This, as well as the Rapid Alert System for Food and Feed allows for implementation of the risk-based approach. There are no similar provisions in the Customs Union, and its legal acts do not provide for any mechanism for sharing control plans and results between the member states, or for developing a common short-term or mid-term policy.
- It is a common practice within the European Union to conduct audits by VFO of competent authorities in member states to determine the capability and capacity to implement the European Union regulatory requirements. There are no similar arrangements that exist in the Customs Union.
- With regard to imported food for all groups of animal origin, the European Union requires two-level approvals: approval of a third country (by animal food sectors) and approval of each individual establishment from which food is exported to the European Union. The Customs Union does

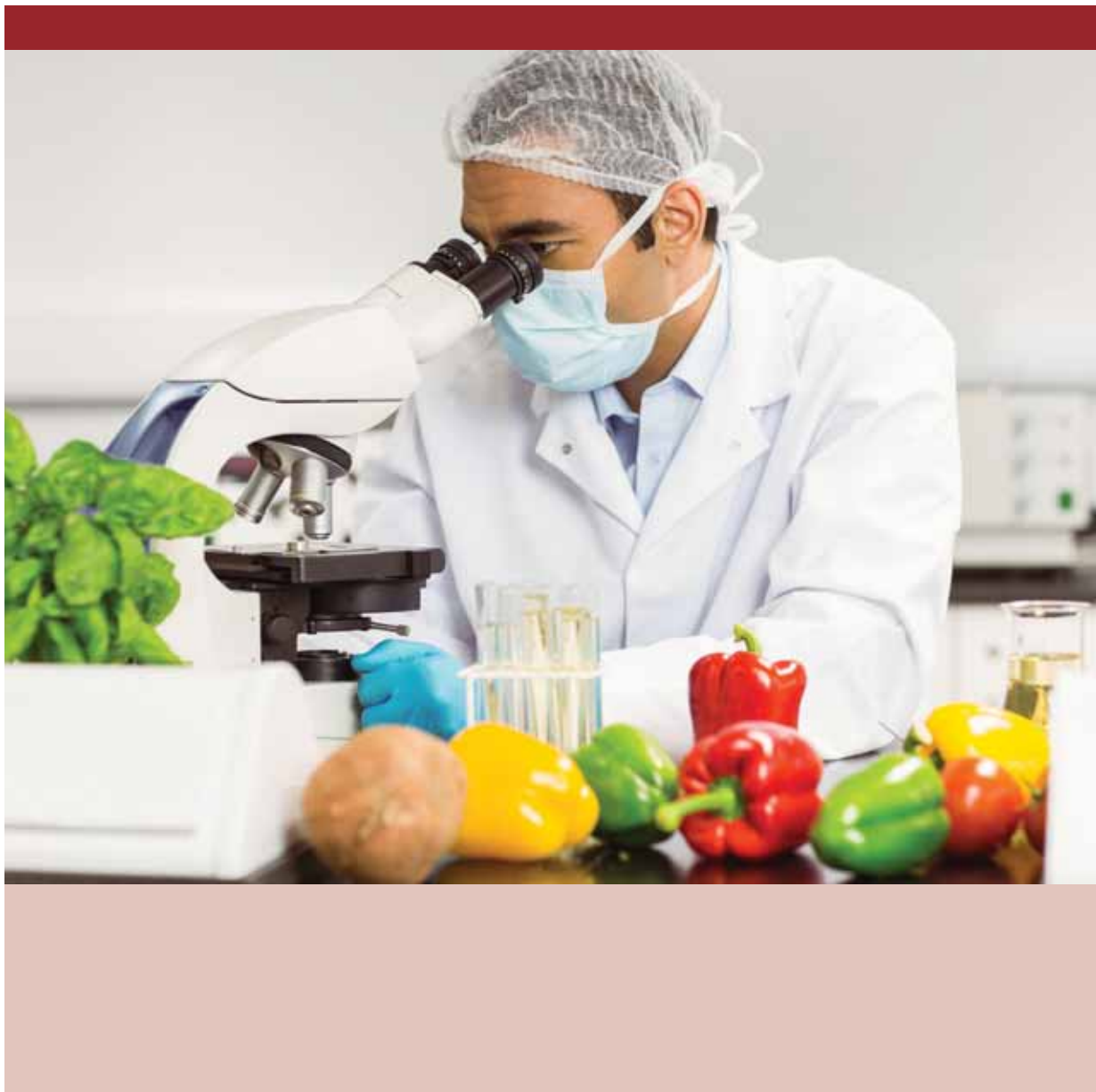
not require country approvals: instead, approvals are required only for individual establishments that produce/process several types of food of animal origin. The approvals are granted after a joint inspection by representatives of veterinary competent authorities of the Customs Union member states, or without on-site inspections.

- At the border, control procedures of foodstuffs are similar in many respects, however differences still exist. With regard to physical checks of consignments (testing of samples) in the European Union the percentage to be sampled is well defined and published in the European Union. In the Customs Union it is unclear as to when and how often a product will undergo checks and therefore for exporters the chances that specific products or shipments will undergo a physical check is not defined.

Role and requirements of food business operators:

Like with other areas, there are similarities and differences between the requirements and procedures that a food business operator shall conduct to ensure that his food is safe. The differences range from procedures of registration of approval, hygiene requirements, temperature control and duration of processes, to provisions of the HACCP system. While both the European Union and the Customs Union require development and implementation of procedures based on HACCP principles, in the European Union this requirement is addressed to all food business operators throughout the food chain, and in the Customs Union only manufacturers are required to comply.

There are differences in interpretation of several HACCP principles: on hazard analysis, critical control points, verification and record-keeping, and the Customs Union interpretation is narrower than that of the European Union. Importantly, HACCP systems at third country establishments are checked as part of the company approval audits. This is a significant difference for food businesses operators as HACCP systems cannot be built or re-built overnight. Therefore food business operators wishing to export to either market must be aware of the specific HACCP requirements in each Union and be ready to address them.



Requirements to Food Quality in the European Union and the Customs Union

Executive Summary

Quality is a term that is used frequently by governments, policy makers, industry, and consumers to describe products and services. It is a descriptor whose definition is influenced by culture, attitudes, expectations, and stated and unstated needs. Historically, quality has been primarily understood as the absence of defect, fraud and adulteration¹. More recently with the global acceptance of the private standard ISO 9000, quality is defined within the business community and by governments as the totality of characteristics of an entity (product, service, process, activity, system, organization, and person) that bear on its ability to satisfy stated and implied needs². Within the definition of quality as it relates to goods including food there are two key points that need to be emphasized: quality is a combination of product characteristics, and these characteristics must meet consumer needs, both states and implied.

Product characteristics include physical attributes such as shape, size, and weight. For food additional attributes of appearance, colour, smell, taste, packaging, and even freshness further define quality. Quality attributes are designed to satisfy the needs of consumers. Yet consumers have stated and implied needs that make defining quality challenging. Consumer needs and preferences are influenced by culture, media, personal taste and habits, and economic background and therefore are not homogeneous nor are they static. Consumer needs change overtime and therefore in order to meet consumer stated and implied needs product characteristics or attributes change as well.

In order to satisfy the consumers' ever changing needs and therefore changing definition of quality, two common paths are followed by governments and industry. One path is where industry and governments study consumers and create new products to meet consumer needs. Alternatively, the other path is where industry and government set consumer preferences and therefore

product quality attributes are static, constant and almost never changing. These options are not mutually exclusive and are found intertwined between government policy, laws and regulations and industry standards globally across many industries including food and agricultural products.

In order to try to satisfy the implied and evolving consumer needs governments and industry expend enormous efforts into studying consumer preferences and change their products accordingly. This increases competition and the number of product variations offered to consumers, and the market grows quickly. For example in the food industry thousands of new products are offered annually ranging from new varieties of tomatoes, different production methods, organic/bio, to new products designed to meet the growing variation in buyers. As the number and variety of food products grow, it becomes unrealistic for governments and policy makers to regulate all their quality attributes through laws, specific standards, and enforcement actions. Therefore, governments attempt only to regulate the key characteristics – those that relate to health (safety), leaving the remainder of the attributes to be defined and set by the market place.

An alternative is where the industry and governments dictate consumer needs through regulation and technical standards. In this situation governments and industry influence the consumer in such a way that the products become static and therefore predictable. The outcome of this is a relatively small number of products offered to the consumer. The products that are offered are independent of manufacturer as they have same uniform characteristics and are always the same everywhere. This strategy does not promote competition but instead facilitates a high level of standardization and allows for long-term planning by governments and industry. The products do not evolve and over time their uniformity becomes an attribute that consumers expect and therefore define the products attributes. Further, since there is no market influence and all product characteristics are firmly established, it becomes possible for the government to set laws and technical specifications that define the uniform quality of a product.

While quite different in outcomes both models and hybrids of such models exist today across the world and

¹ Food and health in Europe. WHO publication, 2004.

² ISO 9000:2000. Quality Management Systems. Fundamentals and Vocabulary. Since we look at the term "quality" in a historical context, we use an old version of ISO 9000 (of 2002); currently the version ISO 9000:2005 is in force.

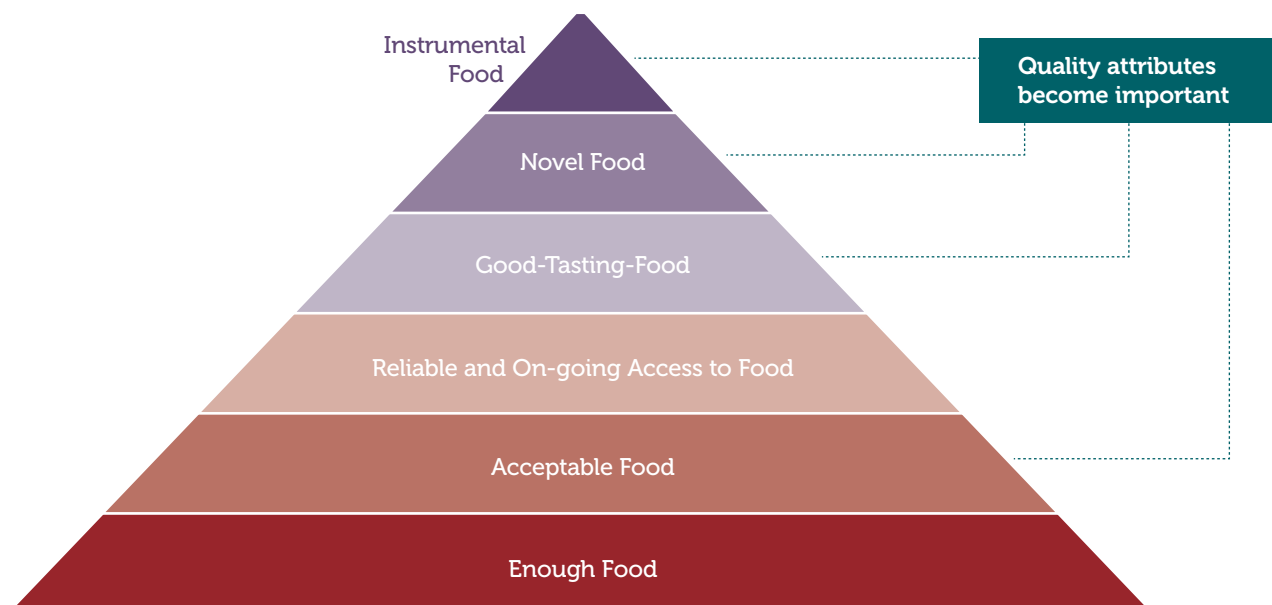
incorporate many consumer products, as well as agricultural products and foodstuffs.

At the foundational level, differentiation of products is determined by consumer needs and purchasing power. Trade-offs are made by consumers based on income, and these trade-offs define product size, quantity and attributes including quality. What may be acceptable to one economic group may not be affordable, acceptable or desired by another.

The food needs of consumers in relation to each other exist in a hierarchy. According to hierarchy of food needs developed by Ellyn Satter³ based on the famous Maslows hierarchy of needs, most common food needs are as follows (from basic to highest):

- The basic need is **getting enough to eat**; at the starvation level quality does not matter; what matters is whether the food is available, and whether it is filling and sustaining;
- The next level of food needs is the ability to acquire **acceptable foods** in socially acceptable ways. "Acceptability" is highly subjective and may relate to certain quality factors, e.g. nutritional quality, acceptable appearance, as well as social norms about food selection and manner of food acquisition. People usually identify the so called core food items that they eat most often and call them regular or common.
- The next level need is **reliable, on-going access to food**. People who feel reasonably assured that an adequate amount of familiar and acceptable food is currently available can plan for subsequent meals, accumulate food, and budget for food purchases. At this level, food shelf-life becomes important.
- **Good tasting food** – once food security and the consistent availability of food are adequately addressed, appetite again becomes salient, and food choices are influenced by aesthetic and gastronomic considerations. People select food that tastes better to their individual taste. New quality attributes are added, like palatability and improved organoleptics and in general, availability of different taste options of core food.
- **Novel food** – at this level on the hierarchy, the prospect of wasting unappealing food is less risky, and experimenting with novel food becomes a possibility. Novel food is not just a new food; it is food that is produced using technologies or ingredients that have never been used before, so tasting becomes an adventure in a way. Preferences change based on new experiences, and consumers seek for new quality attributes.
- **Instrumental food** – the person functioning at the apex of the hierarchy is in a position to consider choosing food for self-actualization and for instrumental reasons, like to achieve a desired physical, cognitive, or spiritual outcome, or to

Figure 1 Satter's Hierarchy of Food Needs



³ GEM NO. 447 Hierarchy of Food Needs, Ellyn Satter, Ellyn Satter Associates, Madison, Wisconsin (J Nutr Educ. Behav. 2007;39:S187-S188.

demonstrate their attitude to certain events or phenomena. These instrumental reasons may or may not be rational or supported by scientific inquiry. An example would be eating - or avoiding - certain food items to resist disease, prolong life, or enhance mental and emotional functioning. At this point people are looking for totally new quality attributes related, for example, to increased convenience, specific nutritional properties, forms of production, production areas, specific production methods or techniques.

This range of food needs present challenges and opportunities for industry and governments. For governments and industry where food quality attributes are primarily determined by industry and market place each company will have a unique strategy for attracting consumers focused on meeting their specific and implied needs. This leads to competition and creativity in the market place creating new food products for consumers at all buying levels. Governments wishing to define and set specific standards will have to develop hundreds if not thousands of standards and technical regulations across a range of products. While this may create a degree of stability within the market place it increases the burden for the government.

A key food attribute is food safety. Food safety is a primary attribute of all food as unsafe food is unacceptable at all levels of food needs and economic purchasing power. Globally two different approaches to food safety have been taken. Where food safety is determined to be the most important food attribute, governments have developed specific regulatory frameworks establishing food safety as a primary regulatory regime. This regulatory regime establishes a finite set of horizontal laws and regulations that cover all products. Alternatively, where food safety is included as just one of the product specific attributes and is regulated as such, a significant number of product specific technical regulations are

developed where a limited set of attributes regulate food safety. Across the world it is common to find a mixture of both regulatory approaches that combine horizontal and product specific (vertical) regulatory environments related to food safety and food quality. This hybridization arises from historical context, cultural differences, as well as governments and industry needs to provide consumer protection especially in high risk areas such as baby food, and food for special medical purposes.

In the case of the Customs Union and the European Union both groups use a combination of broad regulations and product specific regulations to ensure the safety of food within their economic blocks. Having said this, the Customs Union member states predominantly control food safety and quality attributes through a significant set of Union and National product specific technical regulations. The focus of these regulations is to ensure food safety and to clearly define, regulate and enforce a harmonised set of technical specifications for every food product introduced to the Customs Union. In contrast, the European Union has taken a different approach where quality attributes are defined by industry to meet consumers' needs and only regulates and enforces food safety primarily through a series of horizontal regulations. Therefore in the European Union food safety is separated from food quality and specifically regulated.

In order to understand the food quality and safety regulatory frameworks of the Customs Union and the European Union it is important to understand the historical basis from which these two different mechanisms originated. The Customs Union and the European Union evolved differently and were developed to meet very different policy, industry and consumer needs. Both evolved through many decades and while both met the needs of society both approached meeting these needs quite differently.

Historical Context

Customs Union

When the devastating consequences of the WWII were overcome, the three basic food needs (sufficiency of food, acceptability and ongoing access) were satisfied in the Soviet Union. A cornerstone of the Soviet economy was central planning which was designed to provide sufficient products across all 15 republics that comprised

the Soviet Union. The economy was based on 5-year planning cycles, and under a 5-year planning system it was unrealistic and impossible to quickly change the foodstuffs production to adjust it to potentially changing consumer preferences. Further the central planning system dictated a high level of standardization and uniformity across all 15 republics. To balance the needs of

a centralized economy and that of the consumers the Soviet system influenced and specified consumer needs through a set of unified products based on harmonized central standards (GOST). The high degree of uniformity helped to satisfy another food need – the need for good taste (and other organoleptics), because consumers acquired a habit to certain uniform tastes of core products. Also, because of rather high social standards, standardization helped to satisfy partially the highest need of the hierarchy of food needs – the need in instrumental food, in particular, where it concerned such quality attributes as special nutritive properties for specific health conditions (medical purposes, special diets, vulnerable groups of population, e.g. children).

As standardization was a cornerstone of the Soviet economy therefore spending significant resources on developing and enforcing standards was justified and applied to all products including the standardization of food. For each group of products, a separate GOST Standard existed that established a system of quality criteria and a nomenclature of specific parameters used to evaluate quality, including, but not limited to, such quality attributes as organoleptic, presence of chemicals, microbiological condition, shelf-life, storage conditions, solid/liquid phase ratio, moisture content, fat, protein, sugar, salt, starch and other similar characteristics as applicable to different types of foodstuffs. Many other GOST standards supported each ingredient and each production step.

With the independence of the 15 republics the concept of food quality and safety control did not change much in that food quality and safety are defined through new laws and a series of product specific technical regulations and state standards. The economies of the Customs Union have the basic philosophy that food and food safety are best controlled through a body of several horizontal and multiple vertical legal acts for groups of foodstuffs. The principles of technical regulation in the Customs Union require that common legal acts for each food category sold in the Customs Union shall be developed. This will include all products attributes including those related to food safety and food quality.

European Union

With the development of the European economy post WWII, the three basic food needs (sufficiency, acceptability and on-going access to food) were satisfied as



GOST 4.29-71 “Quality rating system. Canned meats, meats-vegetable. Quality characteristics nomenclature”.

Establishes the following quality characteristics:

a) General (applicable to all canned meat/vegetables):

- Appearance,
- Presence of connecting tissues
- Odor and taste
- Color
- Texture
- Ratio of meat phase, bones and liquid phase
- Physical and chemical properties: salt, tint, plumbum, shelf life and storage conditions, microbiological parameters.

b) Additional (applicable to certain product groups): % fat, % moisture, % starch, sodium nitrite, copper, jelly melting T, pH.



well. In the early stage of existence of the European Economic Community (late 1950's - early 1960's), member states had thousands of national product standards. Those standards regulated such aspects of quality as, for example, food composition. To ensure real free movement of goods through national boundaries, European Community legislators at first attempted to harmonize the food standards. However, since all European Union norms have to be approved by unanimous vote on one hand, and thousands of foodstuffs throughout the Community were already offered, creating a harmonized document for each of them was soon recognized as impossible. Through case law and decisions of the European Court of Justice, a general rule was introduced: products that have been lawfully produced and marketed in one of the member states may not be kept out of other member states on the grounds that they do not comply with the national rules. Therefore the

emphasis shifted from product-specific, vertical (product composition) legislation, to horizontal legislation, meaning general rules addressing common aspects for all foodstuffs, or at least for as many products as possible⁴. Over time the focus of the legal enforcement moved to food safety and most of the quality characteristics of food were left, with certain exceptions, to the free market to regulate. Therefore in the European Union with the development of demand-driven food sector, the European food control system does not attempt to regulate those product characteristics (quality) that are supposed to be flexible to meet consumer preferences. Instead the European Union regulators and policy makers focus only on two areas: food safety where there is a health concern and where specific consumer interests must be specially protected because otherwise either a high potential of fraud is possible, or an informed choice by consumers cannot be made.

Determining the Criteria and Scope of the Comparative Analysis of the EU and CU Requirements Related to Food Quality

For the purposes of this legal analysis the scope of food quality is limited to a range of food attributes and characteristics other than those related to food safety, and that are expected to be found in the product by consumers⁵. While the European Union does not regulate food quality in general there is a small number of selected foodstuffs for which legal acts regulate specific product characteristics that can be attributed to food quality. To enable the comparison we call such product characteristics "food quality characteristics" even though they are not called as such in the European Union legal acts. In the Customs Union, requirements on certain quality characteristics extend to wide categories of food products. Within the Customs Union and European Union there are three common areas related to quality that are regulated; along with this, each market has its own specific areas. The common areas include nutritional properties of some foodstuffs, product composition, and physical properties

(organoleptics/size and shape). While three areas are common, the range of products covered is wide in the Customs Union, and narrow in the European Union.

In addition to these "common" quality characteristics each Union has other specific areas that are covered. In particular, the Customs Union member states through their technical regulations and state standards regulate product stability (shelf-life and packaging)⁶. There are no similar regulations within the European Union, and food business operators establish shelf-life through risk-based research for each product, with account to properties of the product and packaging. In the European Union the other specific requirements related to quality include regulations concerning quality associated with a specific territory⁷ or production method⁸. These regulations are quite specific and there are a limited number of corresponding requirements in technical regulations of the Customs Union⁹.

⁴ For more details, see European Food Law handbook, Chapter 7. Bernd van der Meulen, Menno van der Velde, Wageningen, 2008.

⁵ While food safety is an important element of food attributes this topic is covered under a separate review and therefore these attributes are not a part of this document.

⁶ Manufacturer is responsible for establishing shelf life and storage conditions (CU TR 021/2011) based on multiple normative documents.

⁷ Those associated with a specific territory in the European Union fall under the area of protected designation of origin or protected geographical indication.

⁸ This includes quality associated with a production method such as organic/bio or traditional specialty guaranteed.

⁹ Similar specifications can be found under the TR CU 033/2013 (milk and dairy products) and in draft CU TR 201_/00 (alcoholic products). There is no corresponding technical regulation for organic/bio.

In the Customs Union quality specifics are usually defined in product definitions where the definitions include minimum composition requirements in the section of vertical (product-specific) technical regulations that is usually called "Safety of.../name of the product group/" (e.g., Article 5, "*Safety requirements for fruit and/or vegetable juice products*" of CU TR 023/2011 "on Fruit and Vegetable Juice Products"), and in annexes on microbiology, physical and chemical properties and organoleptic characteristics. The intent in the Customs Union technical regulations is to ensure that products entered into the market place conform to the specific technical regulations in all attributes. Quality characteristics outlined in the Technical Regulations are used to ensure uniformity of food products offered to consumers, satisfy the needs of vulnerable groups of consumers, and for the purposes of product identification to establish whether they are subject to conformity assessment under the relevant Technical Regulation.

Under the European Union, within relevant regulations and vertical directives related to quality characteristics certain quality characteristics usually can be found as definitions establishing minimum composition requirements of certain single foodstuffs, and in the Annexes

detailing the definitions. The intent of quality characteristics is to either ensure specific properties of foodstuffs for vulnerable consumers (food for special diets), or to authenticate foodstuffs for consumers and establish additional labelling requirements, or, in case of fresh fruit and vegetables, establish if they are subject to compensation mechanism (though this of course has additional benefits for market development and consumer satisfaction).

In most cases, the scopes (in terms of the foodstuffs covered) of the corresponding Customs Union and European Union legal acts match only partially, which makes the comparison of specific indicators impossible. Further, in the case of the Customs Union technical regulations, quality-related indicators are usually combined with food safety indicators (in particular, chemical food safety hazards) under a general name "physical-chemical properties"; in other cases specific indicators relevant to quality characteristics are combined with other indicators. This combination of indicators can lead to difficulties in understanding them, as identification and compliance require an in-depth review of each specific technical regulation, state standards of member states (e.g., GOSTs) or regional standard.

Characteristics of requirements to food quality		Customs Union	European Union
Primary purpose of requirements on quality-related attributes		<ul style="list-style-type: none"> ● Satisfy the needs of vulnerable groups of consumers; ● Ensure uniformity of food products; ● Enable product identification to establish whether products are subject to conformity assessment. 	<ul style="list-style-type: none"> ● Satisfy the needs of vulnerable groups of consumers; ● Authenticate a small number of foodstuffs for consumers and establish additional labeling requirements; ● In case of fresh fruit and vegetables, establish if they are subject to compensation mechanism.
List of quality-related characteristics covered		<ul style="list-style-type: none"> ● Nutritional properties; ● Composition; ● Physical properties (organoleptics, size, shape); ● Product stability (shelf-life, packaging) 	<ul style="list-style-type: none"> ● Nutritional properties; ● Composition; ● Physical properties (organoleptics, size, shape); ● Quality associated with certain production method or production territory (Organic, PDI, GI, TSI, MP)*
Range of products covered		Wide (see below)	Narrow (see below)
Scope of products covered by common quality related characteristics	Nutritional properties	Foodstuffs for special diets	Foodstuffs for special diets
	Product composition	Most foodstuffs covered by technical regulations (most of milk and dairy, meat and meat products, juices and juice products, oils and fats; in draft technical regulations – poultry products, fish and fishery products, mineral water; potentially – confectionery)	A small number of foodstuffs (coffee extracts and chicory extracts, honey, sugars, fruit and vegetable juices and products, fruit jams, jellies, marmalades, dehydrated milk, cocoa and chocolate, spreadable fats)
	Physical properties (organoleptic, size and shape)	Certain combinations of physical properties - all foodstuffs (see above; water)	Water and a small number of agricultural products (apples, citrus, kiwi fruit, lettuce, peaches and nectarines, pears, strawberries, sweet peppers, green bananas, table grapes and tomatoes)
Quality-related characteristics separated from safety		Not strictly separated	Strictly separated

*PDI – Protected Designation of Origin, GI – Geographical Indicators, TSG – Traditional Specialty Guaranteed; MP – Mountain Products

Comparison of the Specific Quality Characteristics between the Customs Union and European Union

A one-to-one comparison of quality characteristics or attributes between the Customs Union and the European Union is not possible as both Unions have very different organizational methods for product quality attributes. In general the European Union uses a small number of vertical requirements for specific product groups and single products, whereas the Customs Union uses horizontal and vertical technical regulations and numerous regional and national standards (GOSTs and the like) by

which quality attributes are regulated for broad food categories and products. The comparison of attributes at a high level is conducted below and includes relevant references. When in the table below the term “No” is used for the Customs Union, it is not to imply that no standard or requirement exists but instead is used to communicate that the Customs Union technical regulations do not include this area yet, but it is covered by national law of member states.

Attribute	Products	Customs Union Technical Regulations	European Union Regulations and Directives
Nutritional Properties	Specialized for Infants and Children	Yes ¹⁰	Yes ¹¹
	Food for Special Dietary Needs	Yes ¹²	Yes ¹³
	Substances added for Specific Nutritional Properties	Yes ¹⁴	Yes ¹⁵

¹⁰ Selected articles and annexes include: CU TR 033/2013 “On Safety of Milk and Dairy Products”; CU TR 034/2013 “On Safety of Meat and Meat Products”; CU TR 023/2011 “Technical Regulations on Fruit and Vegetable Juice Products”; Unified Sanitary Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Control (Supervision), Chapter II Section 9. Requirements for Bottled Drinking Water.

¹¹ Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children.

¹² CU TR 027/2012 “On safety of specific types of specialized food products including the therapeutic and preventive dietary food”.

¹³ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

¹⁴ TR 033/2013 “On Safety of Milk and Dairy Products”; CU TR 023/2011 “Technical Regulations on Fruit and Vegetable Juice Products”; CU TR 027/2012 “On Safety of Specific Types of Specialized Foodstuffs Including the Therapeutic and Preventive Dietary Food”; Draft CU TR 201_/00 “On Safety of Alcohol Products”.

¹⁵ Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses and 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.

Attribute	Products	Customs Union Technical Regulations	European Union Regulations and Directives
Product Composition	Water	Yes ¹⁶	Yes ¹⁷
	Wines and Spirits	In Draft Form ¹⁸	Yes ¹⁹
	Coffee and Chicory Extracts	No ²⁰	Yes ²¹
	Fruit and Vegetables Juices Products	Yes ²²	Yes ²³
	Honey	Yes ²⁴	Yes ²⁵
	Sugars	No ²⁶	Yes ²⁷

¹⁶ Uniform Sanitary and Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Supervision (Control), Approved by Decision of the Customs union Commission № 299 dated 28 May, 2010, Chapter II Section 21. Requirements for Mineral Waters, Chapter II, Section 9. Requirements for Bottled Drinking Water, (as amended by Decision of the Customs Union Commission N 456 of 18.11.2010), GOSTs.

¹⁷ Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters and Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

¹⁸ Draft Technical Regulation of the Customs Union "On Safety of Alcoholic Products" (TP TC 201_/00).

¹⁹ Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organization of the market in wine, amending Regulations (EC) No 1493/1999, (EC) No 1782/2003, (EC) No 1290/2005, (EC) No 3/2008 and repealing Regulations (EEC) No 2392/86 and (EC) No 1493/1999; Commission Regulation (EC) No 1607/2000 laying down detailed rules for implementing Regulation (EC) No 1493/1999 on the common organization of the market in wine, in particular the Title relating to quality wine produced in specified regions, Commission Regulation (EC) No 753/2002 of 29 April 2002 laying down certain rules for applying Council Regulation (EC) No 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products, Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails of the European Parliament and the Council of 15 January 2008 on the definition, description, presentation, labeling and protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89.

²⁰ No specific documents adopted by the Customs Union; National GOSTs and GOST Standards of CIS (adopted by Interstate Council on Standardization) GOST-R 51881-2002 Natural instant coffee. General technical specifications. and GOST R 52088-2003 "Natural roasted coffee"

²¹ Directive 1999/4/EC of 22 February 1999 relating to coffee extracts and chicory extracts.

²² TR CU 023/2011-Technical Regulations "On Fruit and Vegetable Juice Products".

²³ Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption

²⁴ No specific documents adopted by the Customs Union; National GOSTs and GOST Standards of CIS (adopted by Interstate Council on Standardization) National Technical Regulations of Customs Union member states e.g. Technical Regulation of the Republic of Kazakhstan "Requirements to safety of honey and bee-keeping products", 05.11.2010.

²⁵ Directive 2001/110/EC of 20 December 2001 relating to honey; Amending 2004/84/EC of 10 June 2004.

²⁶ No specific documents adopted by the Customs Union; National GOSTs and GOST Standards of CIS (adopted by Interstate Council on Standardization) GOSTs included into the list of standards through voluntary compliance, a compliance with Technical Regulation of the Customs Union "On Food Safety" GOST 21-94 Dry sugar. Technical specifications, GOST-R 53396-2009 White sugar Technical specifications, STB 1882-2008 Raw sugar. General technical specifications, GOST 12569-99 Sugar. Rules for receiving and sampling, GOST 12570-98 Sugar. Methods of testing for moisture content and dry matter, GOST 12572-93 Dry sugar and refined sugar. Methods of color testing. GOST 12573-67 Sugar. Methods of testing for ferrous matter. GOST 12576-89 Sugar. Methods of testing for appearance sour, taste and clearness of solution. GOST 975-88 Christallised hydrated glucose. Technical specifications.

²⁷ Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption.

Attribute	Products	Customs Union Technical Regulations	European Union Regulations and Directives
Product Composition	Fruit Jams, Jellies and Marmalades	No ²⁸	Yes ²⁹
	All meat and meat products, excl. poultry	Yes ³⁰	No
	All milk and dairy products, incl.:	Yes ³¹	No
	● Dehydrated Milk	Yes ³²	Yes ³³
	Cocoa and Chocolate	No ³⁴	Yes ³⁵
	All fats and oils, incl.:	Yes ³⁶	No
	● Spreadable Fats	Yes ³⁷	Yes ³⁸
	Gluten in Foodstuffs	Yes ³⁹	Yes ⁴⁰

²⁸ No specific documents adopted by the Customs Union; National GOSTs and GOST Standards of CIS (adopted by Interstate Council on Standardization); GOST 6442-89 Marmalade. Technical Specifications, GOST 28322-89 Fruit and vegetable products. Terms and definitions, GOST R 53118-2008 Jams. General specifications ("Varenie"), GOST R 52817-2007 Jams. General specifications, STB/OP-2012 Marmalade. General Specifications (State Standard of Belarus).

²⁹ Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, Amending Council Directive 2004/84/EC of 10 June 2004 ; Council Regulation (EC) No 1182/2007 of 26 September 2007.

³⁰ CU TR 034/2013 -Technical Regulation of the Customs Union "On Safety of Meat and Meat Products".

³¹ TR 033/2013 -Technical Regulation of the Customs Union "On Safety of Milk and Dairy Products".

³² CU CU TR 033/2013 -Technical Regulation of the Customs Union "On Safety of Milk and Dairy Products".

³³ Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption; Directive 2007/61/EC of 26 September 2007 amending Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.

³⁴ No specific documents adopted by the Customs Union; National GOSTs and GOST Standards of CIS (adopted by Interstate Council on Standardization) GOST 108-76 Cocoa powder. Specifications, GOST R 52821-2007 Chocolate. General specifications, STB 1202-2000 Semi manufactures of chocolate production. Chocolate paste and chocolate glaze. General specifications, STB 1203-2000 Semi manufactures of chocolate production. Grated cocoa nibs. General specifications, STB1204-2000 Semi-manufactures of chocolate production. Cocoa butter. Specifications, STB 1205-2000 Semi manufactures of chocolate production. Cocoa nibs cake and cocoa nibs powder, general specifications, STB1206-2000 Semi-manufactures of chocolate production. Milled cocoa-shells. General specifications.

³⁵ Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption; amended by Regulation (EC) 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny.

³⁶ CU TR 024/2011 "On Oil and Fat Products".

³⁷ CU TR 024/2011 "On Oil and Fat Products".

³⁸ Council Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats.

³⁹ CU TR 027/2012 on safety of specific types of specialized food products including the therapeutic and preventive dietary food Gluten free (Article 6).

⁴⁰ Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labeling of foodstuffs suitable for people intolerant to gluten.

Organoleptic properties, size and shape are a special case of comparison as the Customs Union by the means of reference to standards in its technical regulations sets quality characteristics for most of agricultural products.

This includes Customs Union-recognized standards, as well as national and regional standards (e.g. GOSTs). Standards are category based as well as product based.

Attribute	Products	Customs Union Technical Regulations	European Union Regulations and Directives
Organoleptics (colour, taste, odour, appearance), and size and shape where relevant	Milk and dairy Meat and meat products Fruit and vegetable juice products Bottled drinking water Oils and fats Alcoholic Beverages Food for infants and children (milk, meat and juice based)	Yes ⁴¹	No
	Agricultural products	No ⁴²	Yes – limited set of products focused on 10 fresh fruit and vegetables commodities ⁴³

A general rule applies to compliance with the Customs Union technical Regulations: a manufacturer may choose whether to comply with the technical regulation itself, or with a set of regional standards (GOSTs), a list of which supports each technical regulation. Compliance with these standards is voluntary but meets the requirements for compliance with the technical regulation. Further, in case where norms are absent in the Customs Union technical regulations, national norms of the

member states apply. The GOST standards referenced to in the table above for the Customs Union are only a sampling of the long list of product-specific technical standards. There are many additional standards and technical documents, therefore prior to exporting companies must ensure they comply with the specific technical requirements of not only the Customs Union but also of its member states. These standards are available on-line and in some cases in English⁴⁴.

⁴¹ CU TR 033/2013 "On Safety of Milk and Milk Products"; CU TR 034/2013 "On Safety of Meat and Meat Products"; CU TR 023/2011 "Fruit and Vegetable Juice Products"; CU TR 024/2011 "On Fat and Oil Products"; Draft CU TR 201_/00 "On Safety of Alcoholic Products"; Uniform Sanitary and Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Supervision (Control), Chapter II, Section 9. Requirements for Bottled Drinking Water .

⁴² See, for example, GOSTs included into the list of standards through voluntary compliance, a compliance with Technical Regulation of the Customs Union "On Food Safety": GOST16270-70 "Fresh apples of early ripening. Specifications", GOST 21122-75 "Fresh apples of late ripening. Specifications", STB 2083-2010 "Vegetables green fresh. Requirements at preparations, deliveries and realization", GOST 21713-76 "Fresh peas of late ripening. Specifications"; national rules apply in the case when Customs Union requirements are absent.

⁴³ Products include Apples, Citrus (including clementines, satsumas, oranges, lemons and mandarins), Kiwi Fruit, Lettuce (including curled and broad leaved endives), Peaches and Nectarines, Pears, Strawberries, Sweet Peppers, Table Grapes and Tomatoes). PLUS green bananas at the point of import.

⁴⁴ <http://www.runorm.com/gost-gost-r-standards> as well as other sources including the European Union and USDA but these are unofficial translations and documents in the original language should be consulted prior to exporting.

"Increasingly a number of consumers attach greater importance to the food with specific characteristics in their diet rather than to quantity". This statement was one of the European Union's main justifications for introducing the four European Union quality schemes related to:

1. geographical indications of origin (PDO);
2. protected designations guaranteed (PDI);
3. traditional specialties (TSG), and
4. mountain products (MPs), (voluntary quality term).

These systems became a part of the European Union agricultural product quality policy.⁴⁵ This quest for food with specific properties generates a demand for agricultural products or foodstuffs with an identifiable geographical origin or traditional receipts. In view of the wide variety of products marketed and the abundance of product information provided, the consumer should, in order to be able to make the best choice, be given clear and succinct information regarding the product origin. To meet these consumer needs the European Union developed a set of quality characteristic schemes that focus on product properties associated with certain production area or traditional production method. The intent of these regulations is twofold.

1. The first is to protect product names from misuse and imitation and protect consumers in that products that carry certain designations in fact meet the requirements.
2. The second is to provide producers at all levels the opportunity to capture additional value by creating European Union marks which are used for advertising and promotion of products.

Protected Geographical Indications (PGI) and Protected Designation of Origin (PDO), as well as Traditional Specialty Guaranteed (TSG) and Mountain Products (MPs) establish special rules under which products can be recognized as belonging to one of the European quality schemes; for each food product under the schemes, a separate specifications document is developed. In the

Customs Union, with the exception of alcoholic beverages (the technical regulation is still in the draft form), there is no analogue at present. At the same time, specifications that are developed for each product with PDO and PGI, to a significant extent have a similar structure and contents as GOST standards. Since PDO, PGI, TSG and MPs are a unique interpretation of food quality, a more detailed description of these quality schemes has been included.

Protected Designation of Origin (PDO) covers the term used to describe foodstuffs which are produced, processed and prepared in a given geographical area using recognized know-how (Prosciutto di Parma (Parma ham), Žatecký chmel (Zhatetsky hop)). Protected Geographic Indicators (PGI) indicate a link with the area in at least one of the stages of production, processing or preparation (such as Holsteiner Tilsiter cheese, "Slovenski med", "Gornooryahovski sudzhuk"). The link with the area is therefore stronger for PDOs. Traditional Specialty Guaranteed (TSG) means a traditional agricultural product or foodstuff recognized by the Community for its specific character. The optional quality term "mountain product" is designed for food products originating from mountain areas. The use of corresponding EU symbols on the labels of such products provides consumers with clear and concise information on the product origin and/or character.

Each of these food quality systems have specific requirement for registration, certification and labeling. This is a highly transparent system that has created over 700 registrations by 2011.⁴⁶

Organic/Bio certification is an additional food and agriculture quality scheme within the European Union. Organic production⁴⁷ in the European Union has reached dramatic proportions with consumer spending on organic food products of ~ \$40 billion US in 2012. There are more than 186,000 organic farms across Europe,

⁴⁵ Bio-based and Applied Economics 1(2): 213-229, 2012, Consumers' Awareness and Attitudinal Determinants of European Union Quality Label Use on Traditional Foods, Wim Verbeke¹, Zuzanna Pieniak, Luis Guerrero, Margrethe Hersleth.

⁴⁶ All registrations for PDO, PGI and TSG are kept by a European database called DOOR <http://ec.europa.eu/agriculture/quality/door/list.html>). Also, rules and PGI, PDO and TSG specifications in English language and for British foodstuffs and agricultural products can be found at the relevant UK website <https://www.gov.uk/protected-food-names-guidance-for-producers>. Other EU member states maintain similar websites in their national languages.

⁴⁷ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labeling of organic products and repealing Regulation (EEC) No 2092/91.

cultivating an area of 9.6 million hectares representing about 5.4% of the total agricultural area in the European Union⁴⁸. Further, organic is not limited to crops and food

but includes animals and animal products. By 2011 there were over 2.6 million head of certified organic cattle in the European Union⁴⁹.

Important Notes for Governments, Policy Makers and Industry

Governments, Policy Makers

The [European Union](#) and the Customs Union vary significantly in their approaches to “food quality”. The fundamental difference is that within the Customs Union, all foodstuffs and agricultural products have product-specific regulated quality parameters that are defined in Customs Union Technical Regulations, regional standards or national standards (GOSTs). Alternatively, in the European Union, quality parameters are determined by the market place and are designed by the producer and/or manufacturer to meet consumers stated and unmet needs. In only a few specific cases in the European Union are food quality characteristics regulated.

Further there is not a one-to-one relationship between the Customs Union and European Union legal acts (where they exist in the EU) that cover food quality characteristics. In cases where the corresponding legal acts exist in the European Union and the Customs Union, their scopes do not match in terms of specific products covered; regulated parameters differ on a case-by-case basis. Because of the significant differences in approach between the Customs Union and the European Union harmonization of laws and regulations simultaneously to both Unions by any government or policy makers is impractical and impossible.

The need for having specific technical regulations for each product creates a significant complexity within the legal acts. It has been noted that under the Custom Union regulations there is significant inconsistency as to format and materials included in the technical

regulations. Therefore harmonization with the Customs Union technical regulations can be more difficult.

The [European Union](#) has several specific quality schemes: Geographical Indications (PGI), Protected Designation of Origin (PDO), Traditional Specialty Guaranteed (TSG), optional term “Mountain product” and Organic for agricultural and food products. These schemes are designed to meet the consumers need for information on the products they consume as well as the ever increasing demand for specialty products and organic products. These schemes provide a mechanism through labelling and branding to increase the value of products and thus have the potential to increase farm incomes.

Basically, the two models of approaching food quality create the following significant implications:

- European Union: increased product variability, lower market protectiveness, and higher competition:
- Customs Union: product uniformity, higher market protectiveness, and the need to maintain a high level of standardization.

Governments and policy makers have a significant role in helping industry understand and comply with the quality requirements of the target export markets. To this end governments can develop and carry out trainings through universities, trade associations and other organizations on the specific quality characteristics of products required to meet the Customs Union and European Union regulations.

⁴⁸ Frequently asked questions: Commission proposals for new rules for organic farming, European Commission, Memo, Brussels, 25 March 2014.

⁴⁹ Facts and figures on organic agriculture in the European Union, October 2013.

Industry

Food quality characteristics are regulated in the European Union and Customs Union for different purposes: in the European Union they are used to authenticate the product for consumer and are closely related to labelling; in the Customs Union they are mainly used for identification purposes to determine whether a product is subject to assessment of conformity against Technical Regulations. These differences are significant enough that industry cannot assume that products that meet one Unions' regulation does not confer compliance with the other.

The industry needs to clearly understand what will be required from them in terms of product quality at each of the two markets:

European Union: quality is meeting consumer needs as they are at the time of purchase; therefore certain

investments may be needed to study consumer preferences and adjusting/developing the product accordingly;

Customs Union: quality is meeting a set of prescribed technical requirements; the requirements need to be studied thoroughly and complied with; any alteration to the product shall stay within the established quality parameters, otherwise the market access can be restricted.

Industry is responsible for compliance to either Union's requirements. Companies that wish to export to the Customs Union and/or the European Union must avail themselves of the specific requirements. This can be a complex task in that the details of the technical regulations of the Customs Union and the laws of the European Union are quite different and therefore understanding each one takes time and resources. Further industry must take into account the National and GOST standards when exporting to the Customs Union and member states.



Requirements to Food Labeling in the European Union and the Customs Union

Executive Summary

The globalization of the food industry combined with ever changing consumer preferences and demands has led to explosion in the number and types of food products available to consumers. Traditional food retail stores carry between 10,000 and 60,000 different food items and each year thousands of new food items are introduced. Consumers choose products based on a complex set of criteria such as brand, cost, healthiness, freshness, taste, visual appearance, culture, and lifestyle. These drivers compel retailers and manufacturers to develop communication tools to differentiate their products in the market place in order to retain clients and maximize profits. A critical component in attracting consumers is the labeling. Labeling provides a range of information to consumers such as the product name, manufacturer, price, contents of the product, and directions for use and storage. Some of the product details the labels provide are essential (use-by dates, safety warnings, etc.), other information is considered useful (nutrition labeling, recycling details, etc.).

Governments and policy makers also recognize that labels can convey information that is critical to the health and well-being of vulnerable consumers, and require provision of additional details that allow consumers to make informed choices. This has led to the incorporation of rules on health claims as well as other relevant information to the labeling requirements. Such information ranges from identification of allergens that are fatal to some consumers to declaration of salt, fat, caloric and vitamin content; to information on country of origin, whether the product is organic, and designations indicating how or where a product is produced. All of these particulars are designed to help ensure the health and well-being of consumers and allow consumers to make informed choices based on their specific preferences.

Food labeling laws establish the framework which manufacturers are required to comply with. These laws establish

when labels are required, where on the packaging the labels are placed, and the format and specific content of the labels. These requirements are designed to ensure that consumers receive important and fair information about the foods they consume. The responsibility for compliance is shared between the manufacturer and government agencies. Manufacturers and to some extent importers must ensure that the products that are sold to a specific country or a union comply with the specific labeling requirements defined in the laws and technical regulations of the target market. The government is responsible to ensure through enforcement that the laws and technical regulations are adhered to.

Food labeling laws of different marketplaces have evolved based on the single concept of fair information to consumers, as well as on specific market-related information depending on local practices and consumer expectations. Through international trade, many of the food labeling requirements have been brought to similarity or equivalence; however significant differences remain and there is no single food labeling requirement and format that have been adopted globally.

The complexity of labeling has always been a challenge for the food industry. Compliance with labeling rules requires that food industry develops expertise and experts in labeling who can provide the knowledge needed to ensure that the products are properly and completely labeled in accordance with the requirements of the country in which the products are to be sold. Failure to comply can lead to products being delayed upon importation and/or rejected, both of which cause significant business disruption and financial losses to the buyer and seller of the products.

The Customs Union and the European Union have extensive labeling requirements for food products which are designed to inform and protect consumers. For food business operators, including producers, manufacturers, importers, and food catering compliance with labeling requirements can be a difficult and complex task. The Customs Union and the European Union each have specific requirements that while in general cover the same basic areas, differ by the specifics of what information must be contained on the label and how the information is presented.

¹ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Further, labeling requirements continue to evolve. In the European Union a new Regulation (EU) 1169/2011¹ on Food Information to Consumers entered into force on December 13, 2014 and introduced new requirements and amended the existing ones. The Customs Union is in the process of developing its requirements based on those that exist in the member states and those that

have become the best labeling practice internationally; technical regulation CU TR 022/2011² on food products labeling became compulsory after February 15, 2015 when the transition period ended. Also, the Customs Union continues to develop vertical technical regulations for specific product groups that contain additional labeling requirements as well.

General Comparison between the Customs Union and European Union Legal Frameworks on Food Labeling

The general purpose and intent of food labeling in the Customs Union and the European Union is similar. Labeling should provide consumers with information necessary to make informed decisions, prevent misleading of consumers, and create a degree of uniformity in the labels to facilitate trade within the respective Unions. While both Unions have some degree of commonality in purpose and intent, the European Union further establishes that labels and labeling requirements have a broader contribution to society including simplification of the laws of the Union, ensuring legal certainty, reducing administrative burden, and improving competition.

Ensuring competition is unique to the European Union, and it is recognized that labeling plays a key role in consumer choice and therefore competition within the market place. Further the European Union recognizes that consumer preferences and demands for information will change over time. Therefore, the European Union has established that one of the fundamental purposes of the labeling regulations is to provide sufficient flexibility to be adaptable to consumers changing needs for information.

Food labeling is part of food information and is regulated as such. The Customs Union and the European Union legislation on labeling of foodstuffs is a combination of horizontal and vertical legal acts. The basic horizontal documents set general requirements to food labeling concerning all types of food, and a number of vertical documents regulate additional labeling requirements for selected specific food products or product groups. In the European Union, the number of such specific products that require additional information on the label may seem to be broader than in the Customs Union today, but while the European Union sets such additional

requirements to selected food items, the Customs Union requirements on additional labeling details cover broad food categories. Moreover, the Customs Union is adding significantly to the body of requirements and over time it is anticipated that specific technical regulations for all food products and beverages will be developed and put into force.

The horizontal regulations of the Customs Union and European Union have similar basic labeling requirements – from product name, list of ingredients and quantity contained, to use instructions and nutritional value. Also both Unions have additional labeling requirements for certain products including: infant and baby products, special diet food, organic/bio or environmentally pure products, food products that may contain genetically modified organisms, and food that may have special health effects.

There are differences between the scope or span of the regulations between the Customs Union and the European Union. Both Unions have their own specific labeling requirements for products sold directly to consumers, pre-packed food, and food during transportation. While EU Regulation (EU) 1169/2011 applies to all food sold to final consumer, including that served through catering (except for occasional events like fairs), in the Customs Union food products produced by catering establishments are excluded from labeling requirements. In the case of catering and restaurants the European Union further states that consumers must be informed of specific ingredients such as allergens either through information on the menu or orally communicated to ensure consumers are informed of potential hazards.

² Technical Regulations of the Customs Union CU TR 022/2011 “On food products in terms of their labeling”.

Comparison of Specific Labeling Requirements of the Customs Union and the European Union

While there are significant similarities between the labeling requirements of the Customs Union and the European Union this is not meant to imply that compliance with one or the other confers compliance across both Unions. In fact it is quite the opposite as the specifics of the laws and regulations are quite different and while the differences may seem slight to the casual reader they are in fact significant enough to prevent articles from being placed into circulation in either Union as compliance to all of the specific details is required.

The difference between the two Unions begins with the fundamental definition of labeling and scope of labeling. While both Unions define labeling as any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food, they differ as to when the labeling must be used. In the Customs Union labeling requirements are focused on consumer packaging and transport packaging, and an information carrier must be attached, affixed or enclosed to the product packaging. In the European Union labeling is required in some format on any type of packaging as long as the food inside is intended for final consumer or caterer, and an information carrier can also refer to food, not only be attached, affixed or enclosed (e.g., a menu in restaurant is a carrier of food information to consumers). While this

may seem to be a nuance, it has a significant impact on business operators that wish to supply catering and food service in the European Union as the specific food labeling requirements apply. This is especially relevant as the food sales from the food service industry (hospitality, catering and restaurants) have reached stunning proportions in the European Union with sales in excess of \$184 billion annually between the French and German markets alone³. Therefore compliance to labeling is required for companies to participate in and supply to this significant target export market.

It was mentioned already that at the first glance the requirements for what must be included on the label (mandatory particulars) are the same in the Customs Union and European Union as the basic intent is to provide consumers with specific information. Both Unions require information on content, quantity, naming conventions, use and preparation, identification of certain potential health hazards such as allergens, nutritional value and contact information on each product. Yet the information required and how it is presented varies and in many cases varies significantly. Table 1 contains highlights or summaries of the differences between the two Unions as well as the implications for manufactures and exports.

Table 1 **Labeling Mandatory Particulars – A Comparison between the Customs Union and the European Union**

Requirement	Customs Union ⁴	European Union ⁵	Implications
Language	Food labeling shall be written in the Russian and in the state language of the Customs Union Member State; when sold to Russia, only in Russian	Mandatory food information shall appear in a language(s) easily understood by the consumers of the Member States where a food is marketed therefore	Labels may contain multiple languages and it is important for business operators to identify what languages are required

³USDA Gain Report FR9086 and USDA Gain Report GM13002.
⁴Technical Regulation CU TR 022/2011 "On food products in terms of their labeling".
⁵Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Requirement	Customs Union	European Union	Implications
Packaged Food	Requires labeling for consumer packaging and transport packaging	Requires labeling for consumer packaging and multi-packs as long as they are intended for final consumer; labeling of non-pre packed food is regulated by national laws of member states	Depending on the intended market labeling requirements vary between the two Unions
Appearance, Locations and Size of Text	Labeling shall be clear, readable, adequate and not misleading for consumers; the inscriptions, signs, symbols shall be contrasting to the background to which the labeling is added ⁶	There are specific requirements as to the appearance, location and size of the mandatory product information on the label.	Exporters and business operators must consult the specific requirements for appearance, location and size of text if they wish to export to the European Union.
Name of Product	<p>Only general requirements with regard to the name of food are established and detailed requirements are contained in the product-specific technical regulations⁷</p> <p>General requirements on product name:</p> <ul style="list-style-type: none"> ● Shall allow for classification, characterizing, and distinguishing the product from other food products. ● Shall include physical properties and (or) special food product treatment ● If the food product includes a flavoring this may be indicated ● The name shall not be same or similar or remind names of products for which GOST standards exist, unless the product complies with those ● A number of names are reserved for "classic" products of pre-determined composition; other products cannot be given such names (e.g., cheese cannot be named "cheese" if it contains vegetable oil – it is a "cheese product" then) 	<p>The name shall be understood by consumers in the country of sale, not in the country of production.</p> <p>Food can be given one of the three types of names: legal name (name designated to the product by law), or customary name, or descriptive name.</p> <p>In addition, name must include or be accompanied by a designation of the treatment applied, if any (e.g., dried, frozen).</p> <p>In specific cases the name need to include:</p> <ul style="list-style-type: none"> ● physical condition of the product (e.g., powdered, refrozen); ● "defrosted" where applicable; ● "irradiated" where applicable; ● source of added proteins in meat products where applicable; ● presence of water >5% in meat products; ● formed meat and formed fish; ● designation of minced meat (e.g. % fat content). 	Naming conventions between the two unions vary greatly and must be taken into consideration prior to export to either of the Unions.

⁶ Within the Customs Union only fats and oils and dairy products have specifications as to font size.

⁷ Specific Customs Union naming conventions for meat and meat products, milk and dairy, fruit and vegetable juices, fats and oils and food for special dietary purposes can be found in the product specific technical regulations

Requirement	Customs Union	European Union	Implications
List of Ingredients	There are numerous specific requirements for ingredients	There are numerous specific requirements for listing ingredients. Different from the Customs Union are the requirements on: <ul style="list-style-type: none"> ● Compound ingredients; ● Ingredient as a foodstuff ● Reconstituted ingredients ● Similar or mutually substitutable ingredients that do not change state of the product and present in the amount <2% ● Nano materials 	To a significant extent requirements on the list of ingredients are similar, equivalent or partially equivalent between the European Union and the Customs Union. Partially equivalent is meant to convey that additional requirements are set by either the European Union or the Customs Union. Exporters and business operators must consult the specific regulations to ensure that product labels meet the requirements.
Substances Causing Allergies or Intolerances	There are 15 substances for which specific labeling is required; 14 of them are the same as in the EU (substances causing food allergies or intolerances); the 15th substance is aspartame and aspartame-acesulfame salt; additionally there is specific requirements for "gluten-free" declaration	There are 14 substances (causing allergies or intolerances) for which specific labeling is required; these are the same as in the Customs Union. Aspartame is regulated under a separate regulation. Indications "gluten-free" and "very low gluten" is regulated under a separate regulation	The list of substances causing allergies or intolerances for which labeling is required is nearly identical between the Unions. But there are specific differences as to the wording and how the information is communicated.
Quantity of Certain Ingredients or Categories of Ingredients	No requirements	This is unique to the European Union, and does not have an equivalent in the Customs Union.	Exporters and business operators wishing to export to the European Union must comply.
Net Quantity of the Food	Units of measure to be used depending on whether the product is solid or liquid Requirements to quantity declaration with regard to multi-pack packages Quantity declaration for foodstuffs placed in liquid media	Units of measure that can be used depending on whether the product is solid or liquid Requirements to quantity declaration with regard to multi-pack packages Quantity declaration for foodstuffs placed in liquid media	Specific requirements to quantity declaration with regard to multi-pack packages are different: Customs Union indicates a total (combined) quantity of packages in the multi-pack package, and number of packages inside. European Union indicates an individual quantity of each package in the multi-pack package as well as number of packages inside.

Requirement	Customs Union	European Union	Implications
Manufacture Date	This is unique to the Customs Union and does not have an equivalent in the European Union	No requirements	Manufacture date means the date of the end of the process of production of particular types of food products. This must be incorporated into the labels for products exported to the Customs Union.
"Use by" or "best before date"	The terms "use by" or "best before" are used interchangeably but there are specific formats detailed as to how the information is provided.	"Best before..." is used to indicate a date of minimum durability of a food, or, in other words, the date by which the food retains its specific consumer properties when properly stored. For foods which, from a microbiological point of view, are highly perishable, the term "use by" shall be used. Beyond the date the product is considered potentially unsafe.	The distinction between "best before" and "use by" is only made in the European Union and they are not interchangeable and therefore it is important that the proper term be used for export to this market. Formatting of the information is different between the Unions and therefore exporters and business operators must comply with differing specifications.
Any Special Storage Conditions and/ or Conditions of Use <i>Example: Once opened keep refrigerated and consume within 3 days</i>	These are required and set by the specific technical documents	Storage conditions are established by manufacturer	Exporters to the Customs Union must familiarize themselves with the specific technical documentation for each product or product category to ensure compliance
Name or Business Name and Address of the Food Business Operator or Importer	The name of food manufacturer shall be indicated. The name shall be a legal name, not the name of doing business It is mandatory to indicate both the manufacturer name and the importer name It is important whether location of the manufacturer is the same as location of the facility, and if they are different, both addresses must be indicated	Any business operator under whose name the food is marketed, who may not be the manufacturer Only importer name in case of import It is sufficient to indicate only one address, as chosen by the operator	For exporters and business operators each Union has different requirements as to the information required on the label with regards to manufacturer, facility and which organization(s) must be indicated
Country of Origin or Place of Provenance Labeling (COOL)	Not required. Partially covered by the indication of manufacture address	Is unique to the European Union and was designed to inform consumers from where their foodstuffs came from and covers a range of products ⁸	This is specific to the European Union. Exporters and manufacturers must comply with specific details on COOL with regard to specific products as indicated in the regulations.

⁸ Honey, milk, meat, fruit and vegetables and processed fruit and vegetables, nuts, olive oil and fishery and aquaculture products.

Requirement	Customs Union	European Union	Implications
Instructions for Use <i>For example: Quick frozen peeled cooked shrimps: Do not thaw. Put in the boiling water and cook for 3 minutes</i>	It is required to put recommendations and (or) restrictions on use, on cooking of food products in cases where without such recommendations or restrictions using the food item is difficult, or may harm the consumers' health or property, lead to reduction or loss of palatability characteristics of food products.	The textual instructions for use of a food shall be indicated in such a way as to enable appropriate use of the food.	In the European Union textual descriptions are required but these can be supplemented by the use of pictograms.
Beverages with more than 1.2 % by Volume of Alcohol	Currently not required, however a draft Technical Regulation "On Safety of Alcoholic Products" has been developed. Until it is adopted and in force, falls under the national regulations	All pre-packed drinks with an alcoholic strength of more than 1.2 % (abv) must be labeled with an indication of alcoholic strength by volume	Manufactures and exporters to the Customs Union need to be aware that a new technical regulation on alcoholic products has been drafted and will be implemented in the future. Till then, they shall comply with national laws of the Customs Union member states.
Nutritional Declaration	<p>Nutrition value does not have to be specified for flavorings, chewing gums, coffee, natural mineral water, bottled drinking water, food additives, raw food products (mushrooms, products of farm animals and poultry slaughter, fish, vegetables (including potatoes), fruits (including berries), sodium chloride, herbs, spices, vinegar, tea.</p> <p>May be omitted for certain other types of foodstuffs if Customs Union technical Regulations for particular types of food products allow for this.</p> <p>Mandatory for all other foodstuffs. The nutrition value of food products specified in the labeling thereof shall include the following indicators:</p> <ul style="list-style-type: none"> ● Energy value (caloric content); ● Protein, fat, hydrocarbon quantity; ● Vitamins and mineral substances quantity. 	<p>Nutritional declaration does not apply to food supplements, natural mineral water, but it applies without prejudice to the requirements set for food for special diets.</p> <p>Nutritional declaration applies to all other food stuffs not specifically excluded.</p> <p>The mandatory nutrition declaration shall include the following:</p> <ul style="list-style-type: none"> ● energy value; and ● the amounts of fat, saturates, carbohydrate, sugars, protein and salt. <p>In addition, may include an indication of the amounts of one or more of the following:</p> <ul style="list-style-type: none"> ● mono-unsaturates; ● polyunsaturates; ● polyols; ● starch; ● fiber; ● any of the vitamins or minerals that are specially listed and present in significant amounts 	<p>In the EU nutrition declaration becomes mandatory in December 2016.</p> <p>Nutritional labeling requirements differ greatly between the Customs Union and European Union nutritional information, what information is required, how the information is determined and how it is presented.</p> <p>Therefore prior to export the manufacturer and exporter must consult the relevant requirements.</p>

Requirement	Customs Union	European Union	Implications
Lot Identification	This requirement is mandatory for food in transport packaging and establishes that on a transport packaging information shall be placed that allows for identifications of a lot of food product	According to a separate legal document, all pre-packed foodstuffs (in consumer packages) must bear on the label a manufacturing or packaging lot reference ⁹ , a system which is harmonized throughout the European Union. The lot reference allows consumers to trace the product in the event of any dispute or health risk.	It is important that manufacturers and exporters to the European Union understand what is specifically required in terms of information and format with regard to lot identification as well as the definition of a "lot" as it impacts labeling compliance
Single Mark of Circulation at the Market	This requirement only applies to the products put into circulation in the Customs Union. The single mark of circulation is placed only on products that passed all conformity assessment procedures (according to technical regulations). Foodstuffs that comply only with the CU TR on Food Labeling (but have not passed conformity assessment procedures according to other applicable technical regulations) cannot bear the single mark of circulation at the market	No equivalent requirements for food products exist	For the potential exporters to the CU market, it is important to remember that the single mark is a visual evidence of completing conformity assessment procedures. It can not be obtained otherwise, and is illegal to be used on the label without completing conformity assessment procedures.

Beyond the general labeling requirements prescribed by the Customs Union and the European Union for specific categories of products and/or for communication of specific information additional labeling particulars are

required for specific products or product categories. In some cases these requirements are elaborated in both Unions, in other cases they are Union-specific.

Table 2 Summary Products, Categories or Information for which Specific Labeling is Required

(Note: "No" means that no additional requirements on labeling are established beyond the general requirements applicable to all foodstuffs or their broad categories)

Product or Category	Customs Union	European Union
Natural Mineral Waters	Yes	Yes
Foodstuffs for Particular Nutritional Uses	Yes	Yes
Infant Formula	Yes	Yes

⁹ Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs.

Product or Category	Customs Union	European Union
Processed Cereal-Based Foods and Baby Foods for Infants and Young Children	Yes	Yes
Foods Used in Energy-Restricted Diets for Weight Reduction	Yes	Yes
Dietary Foods for Special Medical Purposes	No	Yes
Foodstuffs Treated with Ionizing Radiation	Yes	Yes
Quick-Frozen Food	No	Yes
Production and Labeling of Organic Products	Yes	Yes
Traditional Specialties Guaranteed	For Milk partially	Yes
Geographical Indications and Designations of Origin	No; the draft technical regulations "On Safety of Alcoholic Products" includes only definitions that are similar to the European Union	Yes
Food and Feed (GMO)	Yes	Yes
Novel Foods and Food Ingredients	No	Yes
Health Claims	Yes	Yes
Food Supplements	No	Yes
Labeling of Wine and Certain Other Wine Sector Products	No, but draft technical regulations "On Safety of Alcoholic Products" includes definitions that are similar to the European Union	Yes
Coffee and Chicory Extracts	No	Yes
Caffeine and Quinine	Yes	Yes
Identification and Labeling of Beef and Veal	Yes	Yes
Oils and Fats/Spreadable fats	Yes	Yes
Preserved Milk	Yes	Yes
Edible Caseins and Caseinates	Yes, but limited	Yes
Fruit Juices and Similar Products	Yes	Yes
Fruit Jams and Sweetened Chestnut Purée	No	Yes
Aromatized Drinks	No	Yes
Spirit Drinks/Alcoholic Beverages	No, but draft technical regulations "On Safety of Alcoholic Products" includes definitions many of which are similar to the European Union	Yes
Sugars	No	Yes
Cocoa and Chocolate	No	Yes
Honey	No	Yes
Fishery and Aquaculture Products	No	Yes

When at the Customs Union level specific requirements to labeling of certain foodstuffs listed above do not exist, they may exist in the Customs Union member states, and are based on national laws and/or GOST or other state standards. Therefore for products like sugars, cocoa, honey etc. the national provisions and GOST/state standards must be consulted prior to exporting to specific countries within the Customs Union.

Finally, the use of logos or marks associated with specific food safety management systems (FSMS) that are based on voluntary private standards and include HACCP¹⁰ requirements are allowed within the Customs Union and the European Union, but the use of these is regulated differently. The basic difference is that in the European Union the use of such marks is applicable on all carriers accompanying the product except for its packaging, while in the Customs Union it is allowed on the packaging as well.

In the European Union, rules for use of voluntary standards (as well as their certification marks) are dictated by the owners of the standards and are not set by the European Union; because such standards and logos are voluntary, EU legal acts do not address this issue at all, leaving it to the owners of the standards. Private standards on HACCP-based FSMSs shall be clearly distinguished from legally compulsory HACCP requirements: they have very different scopes, and while the private standards are certifiable, no certification of mandatory HACCP is made. In this regard, a special remark should be made about the use of marks containing the word HACCP. As HACCP is compulsory in the European Union by EU Regulation 852/2004¹¹ for all food business operators dealing with all foodstuffs other than primary products, no inscriptions or marks like "HACCP certified", "manufactured according to HACCP" or the like can appear on the labels of food sold in the European Union. There are three reasons for this:

- HACCP is compulsory and does not give a company any distinctive feature compared to other companies;
- HACCP certification is not required by the European Union regulations; compliance with HACCP is checked through audits by official control authorities and the result is a facility approval;
- HACCP refers to general conditions under which product has been produced or handled, not to any specific characteristics the product has.

At the same time, the EU law does not restrict food business operators from using marks of the private standards; however, as the use of such marks is a part of commitments assumed by FBOs at voluntary certification, FBOs shall follow rules on use of the logos/marks established by the owners of the standards. For example, International Standardization Organization established that ISO certification marks shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity¹². ISO certification marks can be placed only on other carriers, like company brochures, advertisements, and so on.

The Customs Union established¹³ that packaged food product labeling may include additional information, including, inter alia, marks of various voluntary certification systems. It shall be interpreted as allowing to put marks of certification against GOST standards, because GOST standards are product standards (versus system standards) and the rules of GOST certification system support this. But it shall not over-rule procedures and policies of owners of voluntary FSMS standards, even when certifications are offered by the same certification bodies as those offering GOST certification. In practice, it means that general rules established by the owners of the FSMS standards shall apply; in particular, placing certification marks of these standards on product labels is not acceptable.

¹⁰ HACCP – Hazard Analysis and Critical Control Points.

¹¹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Article 5.

¹² ISO/IEC 17021:2011 "Conformity assessment. Requirements for bodies providing audit and certification of management systems", Section 8.4.1 (Reference to certification and use of marks").

¹³ CU TR 022/2011 "Food products in terms of their labeling", Clause 4.1.3.

Important Notes for Governments, Policy Makers and Industry

Governments and Policy Makers

The labeling requirements of the European Union and the Customs Union are detailed and well elaborated. While in general the labeling requirements are quite similar, as they are designed to provide basic information relevant to health and well-being of consumers, the specific requirements differ. Therefore simultaneous harmonization to both Unions is impractical and impossible.

The differences in labeling requirements between the Customs Union and the European Union can be found on three levels: the highest level of scope, purpose and intent, the level of general requirements, and the level of specific requirements to particular foodstuffs. Therefore in order to model one or the other of the Unions' laws and technical regulations policy makers will need to take into consideration the specific requirements at all policy levels as well as the implications for industry.

In the Customs Union while horizontal requirements to labeling exist, specific additional requirements are set separately for large groups of foodstuffs in vertical Technical Regulations and in some cases through national laws established by the individual member states. In contrast the European Union relies on a set of horizontal regulations to define labeling requirements that are generally the same for all except for a limited set of food products.

Furthermore, since labeling requirements are not static in either EU or CU and are undergoing further elaboration, governments wishing to harmonize with one or the other of the Unions must be prepared to change their laws and have the legal basis that is flexible enough to allow for further changes of laws and/or technical regulations over time.

There are some special designations in the European Union that are not a part of the Customs Union law, including special designations for products by name, designations for specific geographical locations, and traditional preparation.

In addition, the European Union requires that information on food products are communicated to consumers directly at food establishments such as restaurants. This

requirement is designed to ensure that, i.e., those consumers who are affected by food allergens will receive information that can protect their health and well-being.

Finally while not specifically reviewed in this document, a part of intent of the European Union labeling law is to facilitate the accessibility of food information to the visually impaired. With the aging of the population in the European Union access to information for those with visual impairment represents an opportunity to improve well-being of its citizens. This intent while not fully realized may provide a starting point for labeling requirements that meet the needs of an important socially vulnerable segment of the population.

Due to the complexity of labeling requirements in the European Union and Customs Union it is recommended that the governments, trade associations, and educational institutions develop specific labeling manuals and training courses for the industry to help ensure compliance of products to the target market destinations. These courses should range from introductory overview courses to product or commodity specific training and educational materials.

Industry

While the differences in food labeling rules between the two markets do exist, they do not prevent compliance. Industry has the capability to meet the general and specific requirements of each of the Unions. It will require that labels for each Union be prepared separately, and this is not only a matter of the language, as no one label will meet all of the requirements of either market by default.

Importantly, in the Customs Union labeling is one of the requirements that comprise a set of specifications for mandatory conformity assessment (in the form of declaration of conformity); non-compliance may result in no access to the Customs Union market. At the same time, industry must remember that where there are no requirements of the Customs Union, national rules of member states apply, and be aware of those as well.

According to the EU Rapid Alert System of Food and Feed (RASFF), imported products that do not comply

with the labeling requirements are not rejected: usually the missing or incorrect information can be corrected by, for example, attaching an additional sticker to the label. Because the Customs Union technical regulation CU TR 022/2011 on food labeling has just come in full force (transition period for its application ended on February 15, 2015), it is not clear how such issues will be addressed. It is not likely that attaching a sticker would be a common solution, as in such case additional issues with regard to conformity assessment of the sticker according to CU TR 005/2011 "On Safety of Packaging" may arise.

At the level of specific labeling requirements the differences between the Customs Union and European Union are quite numerous and therefore before industry places a product in the respective market they must ensure that the products labels conform to the specific requirements. Further, industry must recognize that compliance with one trading bloc does not ensure compliance with the other. This will entail some additional investments into development and production of market-specific labels.

While one of the keys to marketing a product can be the use of various voluntary food safety management standards logos and marks on a product label, as it may instill consumer confidence in the product, food business operators must recognize that the use of "HACCP Certified" or its analogs is not acceptable in the European Union, and the use of certification marks "ISO 22000:2005 certified" is against international practice and ISO rules. Alternatively "HACCP Certified" is acceptable in the Customs Union and is quite often found on food product labels.

For industries wishing to provide products to the EU food service market (which is a significant target market) they must comply with the general and specific food labeling laws and regulations of the European Union. Alternatively, if the industry wishes to supply to the food service market in the Customs Union, the labeling requirements will depend on the type of packaging (consumer or transport packaging), and food service businesses do not have to provide information to consumers under CU TR 022/2011.



Food and Food-related Articles and Materials that Require Special Authorization

Executive Summary

The Customs Union and the European Union have established that there are types of food, classes of substances and/or materials that when either added to food or come in contact with food require special authorization to be placed on the market and shall meet special requirements to ensure food safety. These include novel food, food supplements, food additives and packaging and articles and materials in contact with food. Novel food basically is food produced with completely new untraditional technologies or being absolutely unfamiliar to consumers. Dietary supplements also require special authorization as they are consumed to improve the health and well-being of consumers. Food additives which are chemicals specially added to food to improve its taste, flavor or color, or to enable technological processes shall also go through authorization procedure to establish their safety. Food packaging and food contact materials as they have the potential to leach chemicals into the food shall be tested first to establish they are food-grade. Governments and consumers are concerned with the possible human health effects of these substances and materials and therefore they are treated separately under each Union's regulatory environment.

These are broad groups of substances, materials and articles that require authorizations; each group has its own laws and technical regulations, scopes of the regulations, definitions, authorization procedures, and specific requirements. This makes each area unique and requires a separate discussion for each general topic. Further, while it is possible to conduct a comparative analysis between the European Union and the Customs Union for novel foods and food additives as the scopes of legal acts are similar, in the cases of dietary supplements and food contact materials the scopes of the laws between the Customs Union and the European Union are significantly different and therefore a direct one-to-one comparative analysis could not be fully conducted; the approach to analysis was modified in order to provide the appropriate information for business operators and governments.

These areas are highly technical and complex. The body of laws, regulations, directives, technical regulations and

standards is significant and detailed. While this executive summary and the in-depth companion document summarize the most important issues and details, it should be noted that the number of nuances for every substance, material or article that business operators may wish to export to either market is massive. Therefore it is especially important for business operators prior to exporting a product or material to either Union that they undertake a specific review of the relevant laws, guidance documents, and technical regulations. Further, it must be noted that compliance with the Customs Union or the European Union does not necessarily confer compliance with the other as the specifics differ significantly between the two Unions. For example, in the area of food additives, of the 500 or so food additives that are included into the EU and CU lists, there are 43 which are approved for use in the Customs Union but not in the European Union. Similarly, there are 19 food additives which are approved for use in the European Union which are not approved for use in the Customs Union.

These topic areas are not static and undergo changes as new information, new materials, new substances and technologies are made available. Due to the ever changing environment of the regulatory systems, lists of approved and not approved substances change overtime which requires that companies continue to monitor these areas and review the specifics prior to developing a product and exporting to either of the trade Unions.

For governments wishing to model or harmonize with either the Customs Union or the European Union this is possible and practical. Harmonization will take significant time and effort as both Unions have complex and detailed regimes for these subject areas. What is not possible is the simultaneous harmonization to both Unions as the approach and specific differences between the Customs Union and the European Union are significant enough to render this impractical and impossible.

For governments evaluating modeling or harmonization with either Union there are two key differences that they should note. The Customs Union regulatory system is focused on the use of conformity assessment (for foodstuffs - in the form of conformity declaration). The conformity assessment is based on ensuring food safety through the use of testing to determine if the final foodstuffs meet a specific technical specification. The European Union system is based upon a risk-based approach from farm-to-fork where risks are identified, mitigated, and controlled through preventive methods, and the role of enforcement

regime is to verify that the controls are effective. This difference becomes apparent especially in the specific topic areas of novel foods, food additives, dietary substances, and food contact materials as it creates significant differences in the approach between the Customs Union and the European Union to authorization and introduction of new materials and technology.

The second systemic difference between the Customs Union and the European Union which is especially obvious when it comes to special authorizations is in the details of intent. At a high level the intent of both Unions is the same: to protect consumer health and well-being; to ensure free movement of goods within the respective Unions; to protect consumer from being misled; and to protect the environment. These intents are common to both Unions and in general are basic for governments to meet the needs of their people. However, the differences lie in what goes after these general high-level intents.

The Customs Union law does not specify any further intents or considerations. The European Union further elaborates its intent to include such areas as transparency in the production and handling of food which drives the requirements for traceability within the regulatory

environment. The European Union requires that prior to authorization to place such substance, material or article on the market it must be preceded by an independent scientific risk assessment of the highest possible standard for the risks that the substance, material or article can pose to human health, with an opportunity for all EU members to rise their concerns; this lengthens the authorization process. Further, when conducting the evaluation other legitimate factors relevant to the matter are taken into consideration including societal, economic, traditional, cultural, ethical and environmental factors and the feasibility of controls which can lead to specific requirements for controls, imposing limitations on amounts of materials used, specific restrictions in applications, and labeling. Finally, such substances, materials, and articles should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information which sets the stage for continuous change that can impact not only the authorization status, but also how they are used and in what quantities. These specific detailed intents are some of the reasons why there are significant differences between the Customs Union and the European Union in the details of the respective regulatory environments.

Novel Food

Globalization of the food supply chain, search for new products and tastes have led to development and use of new ingredients and technologies in the food sector. New ingredients from Africa, Asia and Latin America have added new flavors, colors, and tastes to the food industry repertoire creating a variety of new and unique food products. Advances in science and technology such as nanotechnology offer new ways to improve food safety through packaging and food treatments. For each new ingredient, flavor, color, and technology that is applied to food there are concerns as to the influence and impact these will have on human health. One of the primary roles of government in both Unions is to protect consumers from harm, product adulteration and being misled, and therefore both Unions have established specific legal provisions to govern the introduction of foods

items in this category of novel foods into the market place^{1,2}.

At a high level the scope and definitions of novel food are similar in the CU and EU: they broadly cover foodstuffs which have not been used for human consumption to a significant degree within the marketplace previously. The scopes of novel food regulations in both Unions encompass food with new or deliberately modified primary molecular structure. The scopes include foods consisting of or isolated from microorganisms, fungi or algae, plants and animals. However, there are differences which are important to understand for industry wishing to export to either Union and for governments that intend to harmonize with one or the other of the Unions. Key differences between the Customs Union and the European Union

¹ European Union: Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

² Customs Union: novel food falls under the scope of CU TR 021 "On Food Safety" as one of its objects of regulation. In particular, definition of "novel food" (or, as sometimes translated, "food of a new type") is given in Article 4, and further rules are outlined in Article 27 (State registration of novel food) and Article 28 (Procedure for state registration of novel food) that directly deal with novel food.

include how each of the Unions considers the following elements of the scope of regulatory requirements: the inclusion/non-inclusion of food ingredients, food additives and flavorings, extraction solvents and enzymes,

genetically modified organisms, use within the territory, new production processes, nanomaterials, and novel food/food ingredients used in food supplements (summarized below in Table 1).

Table 1 Key Differences in the Scope of Regulatory Requirements on Novel Food between the Customs Union and the European Union

Topic Area	Customs Union	European Union
Food Ingredients ³	Food ingredients not directly included; the scope includes only food	Includes novel food and novel food ingredients
Food additives and flavorings	Included	Excluded and are subject to separate regulations ^{4,5}
Extraction solvents and food enzymes	Not clearly specified but can be interpreted as included ⁶	Excluded but are subject to separate regulations ^{7,8}
Genetically modified organisms	Included	No longer included but are subject to separate regulations ⁹
Use within territory ¹⁰	Covers items not in use within the area of the Customs Union	Covers items that were not in use to a significant degree within the Community before May 1997
New production process	Not Included	Includes food produced through new production processes that substantially change its composition
Nanomaterials	Specified as a type of novel food	Falls under the category "new production process" ¹¹
Novel food/food ingredients used in food supplements	Not included	Foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorization

³ Refer to notes 1 and 2.

⁴ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

⁵ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavorings and certain food ingredients with flavoring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC.

⁶ In the Customs Union, food enzymes and extraction solvents should fall under the definition of "novel food" and the scope of the CU novel food rules, because they are covered by the general definition of "food product" established by the same technical regulation CU TR 021/2011.

⁷ Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

⁸ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

⁹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

¹⁰ Limiting the scope to the use within certain territory is an important difference because food habits, traditions and technologies may vary significantly between countries and traditions, and a food item that has already become consumed within one area may be novel to the other area. It is important that neither the European Union nor the Customs Union recognize authorizations of novel food from other countries or regions valid within their territories.

¹¹ This is a demonstration of how flexibility and broad category identification works. EU Regulation 258/97 was adopted in 1997, while engineered nanomaterials (ENM) first came into spotlight of European Food Safety Authority (EFSA) only in 2006; legal definition of engineered nanomaterials was established only in 2011 by Regulation (EU) 1169/2011 on Food Information to Consumers. Still, because of the way the EU Novel Foods Regulation was designed back in 1997, it allows to include the ENM into its scope. It should be noted that in 2011 EFSA adopted Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, as it is deemed that a more serious toxicological study of ENM safety is needed. The Guidance is available at http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=TM3012980.

With respect to the future, as new technologies (ingredients and processes) are developed there are differences in how these can be regulated by each Union. The Customs Union approach to defining novel foods is through the use of an exhaustive definition which implies, based on the Customs Union legal framework, that only foods that have the described characteristics within the specific novel foods definition can be recognized as novel. This implies that in cases where new technology or food incorporating the new technology does not have the characteristics described in the Customs Union specific novel foods definition, these foods may not be considered novel and therefore are not subject to the specific Customs Union novel food requirements¹². The European Union has offered a definition of novel food but instead identified criteria and categories of products that fall under its scope, and as one of the criteria of “novelty” lists new processes technologies; as new ingredients and processing methods are developed and/

or incorporated into food such ingredients and food are subject to the provisions of the European Union novel food regulations. Therefore for industry wishing to export to either Union it is important to determine if the use of the new technology falls within the scope of the novel foods regulations prior to introduction into the market place.

Prior to placing a novel food in the marketplace both Unions have an authorization process which includes rules for placing the food on the market and suspension. Further both Unions have provisions on maintaining a novel food Catalogue and lists of authorizations/registrations and notifications. Table 2 summarizes key requirements within both Unions for authorization (registration), suspension and cataloguing novel foods. It is important to note that there are differences between the two trading Unions which can be found by comparing the highlighted requirements in Table 2.

Table 2 Highlighted Requirements within the Customs Union and European Union for the Registration, Suspension and Cataloguing of Novel Foods

Topic	Customs Union	European Union
Rules for Placing the Food on the Market	<p>Must go through state registration.</p> <p>Through registration, foodstuff is assessed against a criteria of food safety.</p> <p>Once registered, such food item will not be considered novel food in the future, and will not be subject to state registration by another applicant and under other names.</p> <p>After the novel food item is registered, it is subjected to the general rules of conformity assessment adopted and has no expiration date.</p>	<p>Must go through authorization.</p> <p>Through authorization, foodstuff (foods and food ingredient) is assessed against the following criteria: must not present a danger for the consumer, mislead consumer, nor be nutritionally disadvantageous for consumer.</p> <p>Once authorized, is still considered novel but does not require authorizations by other applicants.</p> <p>Once authorized, will be monitored and re-evaluated.</p>

¹²It is important to note that at the time of writing of this report the Customs Union had not registered any novel foodstuffs and therefore interpretation of new technologies within the novel food definition and rules has not been demonstrated, making this an area for future interpretation.

Topic	Customs Union	European Union
Registration/ Authorization Process	<p>To obtain a state registration of novel food, an applicant shall submit an application and documentation that confirms safety of such products that includes: results of examination (testing) of the samples of novel food products that were carried out in an accredited testing laboratory, as well as other documents confirming safety for human life and health; and information, obtained from any reliable sources, about their impact on human body confirming absence of adverse health effects.</p> <p>No information during the registration process is communicated to other Customs Union member states.</p>	<p>EU law establishes 3 types of permissions which vary by requirements (more specifically, by risk assessment procedure).</p> <p><i>Permission based on initial assessment</i>¹³. For products being placed on the market for the first time the request shall contain a copy of the studies and any other material which is available to demonstrate that the food or food ingredient complies with the criteria and appropriate proposal for the presentation and labeling.</p> <p><i>Permission by authorization decision</i>¹⁴. Authorization decision shall be taken where an additional assessment is deemed necessary and requires that such additional assessment is carried out by the European Food Safety Authority (EFSA). The risk assessment must demonstrate that these products do not pose any risk to health or the environment.</p> <p><i>Permission through notification</i>¹⁵. A simplified procedure is applied to certain types of novel food and food ingredients that do not require a risk assessment. Can only be used if items are: foods and food ingredients consisting of or isolated from micro-organisms, fungi, algae, and plants; food ingredients isolated from animals; are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein; and the equivalency is supported by scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies designated by member states.</p> <p>In any of the three permission types, all EU member states receive communications during the authorization process and can raise concerns or ask additional questions</p>
Responsible Bodies	Agency on State Registration of Novel Foods ¹⁶	Bodies responsible for approvals and authorizations of novel foods and ingredients include both nationally designated authorities and the European Commission
Risk Assessment	Implied but not specifically addressed as a part of The Agency for Registration of Novel Foods review of the application documentation	<p>Importance of risk assessment is emphasized.</p> <p>The procedure provides for a notion of equivalence to existing foods and food ingredients, and in certain cases a risk assessment has to be carried out by EFSA</p>

¹³ Regulation (EU) 258/97, Articles 4 and 6.

¹⁴ Regulation (EU) 258/97, Articles 7 and 8.

¹⁵ Regulation (EU) 258/97, Articles 3(4) and 5.

¹⁶ At the time of writing this body had not been established

Topic	Customs Union	European Union
Suspension Procedure	State registration of novel foods may be terminated or suspended only by the Agency on State Registration of Novel Foods in cases of infliction of harm revealed in the course of state control (surveillance) and upon decision of judicial authorities of the Customs Union member-state	Member States are authorized to suspend or restrict provisionally the marketing and use in their territory of any novel food or food ingredient if they believe that its use constitutes a health hazard or a risk to the environment.
Novel Food Catalogue and Lists of Authorizations and Notifications	At the time of writing, a Unified Register of Novel Foods has not been publically established	The Commission maintains a separate list of authorizations ¹⁷ and notifications ¹⁸ on novel foods and ingredients. In addition, there is publically accessible database which contains information on all items including those that have not been authorized; the data base is called "Novel Food catalogue" ¹⁹ it is a living database but has no legal status.
Duration of the Registration/ Authorization Procedure	5 business days	No time frames established; in practice, can take up to 2 years

Recently, in European Union a draft regulation was proposed to repeal Regulation (EC) No 258/97 on Novel Foods. It calls for the creation within the European Union of a centralized authorization system and to enhance application of risk assessment to novel foods. The new draft was developed to provide greater clarity and to simplify the authorization process for applicants. Further the proposed regulation also introduces an authorization process for foods, which are new in the European Union but are traditional in other countries.

If a history of safe food use can be demonstrated in a third country and there are no food safety objections from the European Food Safety Authority (EFSA) or EU Member States the food will be allowed to be placed on the European market on the basis of a notification from the third country's food business operators²⁰. It is unclear if/when the new draft Regulation repealing Regulation 258/97 will be adopted; until then, the current rules are in force.

¹⁷The EU list of authorizations of novel foods and food additives can be accessed at http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

¹⁸The EU list of notifications on novel foods and food additives can be accessed at http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf#page=71

¹⁹The Novel Food Catalogue can be accessed at http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod_search/index.cfm.

²⁰This information has been taken from the web-site of Lex Alimetaria <http://www.lexalimentaria.eu/ing/news/75-reform-of-eu-regulation-on-novel-foods-a-step-forward-.html>.

Dietary Supplements

It is important to note that within legal acts of the Customs Union and the European Union with regard to substances that can be described broadly as dietary supplements there are significant differences in terminology used. The differences are significant enough that it does not allow the establishment of a strong correlation between the two regulatory environments and therefore the ability to conduct a direct comparative analysis is not possible.

In the European Union, relevant laws and regulations²¹ focus on concentrated sources of two types of nutrients: vitamins and minerals that are marketed and sold separate from the food product; these are called food supplements. In the Customs Union²² the focus is on a broad range of substances that are added to food or consumed separately and are called biologically active supplements (BAS); no specific provisions focused only on vitamins and minerals exist. The Customs Union definition of BAS includes food fibers, pollen, fish and marine species, algae, probiotic microorganisms, meat and milk raw materials, proteins, amino acids and their complexes, vegetable oils, animal and vegetable lipids, as well as vitamins and minerals. For most of the Customs Union's biologically active supplements there are no corresponding specially focused legal acts in the European Union. Depending on the type of the material used in the Customs Union's BAS, these may be fully or partially covered under EC Regulation 258/97 on Novel Foods and Food Ingredients. In addition, depending on the Customs Union's BAS origin and nature, their use in food, and claims that are to be made on the label, there may be corresponding requirements in the EU Regulation (EC) No 1924/2006 on nutrition and health claims made on labels (note: in December 2016, new rules on nutrition claims will enter into force based on Regulation (EU) 1169/2011 on Food

Information to Consumers; but the current health claims rules will stay in force).

While a direct comparison of biologically active supplements (Customs Union) and food supplements (EU) between the Unions cannot be made it is important that industry and governments have an understanding of what process are required to place biologically active substances (Customs Union) or food supplements (European Union) on the market.

Within the Customs Union biologically active substances are registered according to Technical Regulation CU TR 021/2011, and more specifically, several standards referred to in the Technical Regulation as control tools: GOST R 4.1.1672-03 "Guidance on methods of control of quality and safety of biologically active food supplements" and Methodological Guidelines MUK 2.3.2.721-98 "Determination of safety and efficacy of biologically active food". Only those biologically active supplements that have successfully completed state registration can be placed on the market; registration also covers production (manufacturing), storage, shipment (transportation) and sale. Registration procedure requires that a complete package of documents is submitted to the Agency for Registration of Specialized Food Products, including:

- an application in an established format;
- the results of examination (testing) of samples of biologically active supplements carried out in an accredited testing laboratory;
- other documents confirming safety and conformity of such products to the requirements of applicable Customs Union technical regulations; and
- information about the intended use.

²¹ In the European Union, the regulated area covers "food supplements" (not to be confused with "food additives"). According to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, food supplements are defined as "concentrated sources of nutrients (vitamins and mineral salts) or other substances with a nutritional or physiological effect, alone or in combination, which are marketed in dose form (e.g. capsules, tablets, sachets, etc.) in order to supplement a normal diet". Effective legal acts on food supplements cover only vitamins and minerals.

²² Within the Customs Union, technical regulation 021/2011 "On Food Safety" contains the definition of "biologically active supplements" (or, in some translations, "biologically active additives"), which are "natural and (or) identical to natural biologically active substances, as well as probiotic microorganisms, intended for consumption together with food or mixing into food products". These biologically active supplements/additives can be viewed broadly as dietary supplements beyond vitamins and minerals which are used for the production of enriched food. Biologically active supplements/additives include plants or plant extracts, animal origin substances, microorganisms, fungi, etc. They belong to specialized food products, and can be based on vitamins and mineral substances, but also on food fibers, pollen, fish and marine species, algae, probiotic microorganisms, meat and milk raw materials, proteins, amino acids and their complexes, vegetable oils, animal and vegetable lipids, etc. These types of BAS are listed in point 1.9 of Annex 2 "Microbiological safety criteria" of CU TR 21/2011.

Upon successful submittal of the completed document package consideration of documents is to be finalized within 5 business days. If approved, information about the name of the biologically active supplement and its applicant will be entered in the Unified Register of Specialized Food Products and like other specialized food products, the registrations has no expiration date. If denied the applicant will be notified²³. State registration may be terminated or suspended by the Agency for Registration of Specialized Food Products in case of non-conformity to the requirements of the present technical regulation revealed in the course of state control, and upon decision of judicial authorities of the Customs Union member state.

The Customs Union technical regulation CU TR 021/2011 establishes certain limits for the amount of biologically active supplements when they are part of enriched foodstuff. In particular, the amount of each biologically active supplement used for enrichment in enriched food products shall be brought to the level of consumption in 100 ml or 100 g or a single serving of such products of at least 5 percent of the daily intake's level (CU TR 021/2011, Article 7 (12)). The amount of biologically active supplements derived from plants and (or) their extracts in a total BAS daily dose shall range from 10 to 50 percent of the amount of their single therapeutic dose defined for the use of such substances as medicines. These are further delineated for biologically active supplements for food for children aged between 3 and 14 years and herbal teas for infants; for infants it is only allowed to use plant raw materials specified in Annex 8²⁴ of the CU TR 021/2011 (Article 8(10)). The CU TR 021/2011 also excludes the use of biologically active supplements from certain plants or products of their processing, species of animal origin, microorganisms, fungi, or biologically active substances that pose a health risk to humans and animals (listed in Annex 7 of CU TR 021/2011 (Article 8 (11))²⁵. Finally, biologically active supplements should conform to hygiene requirement of food safety (Annexes 1, 2, and 3 of CU TR 021/2011) as well as specific microbiological criteria and maximum levels of chemical contaminants, mycotoxins, banned pesticides, dioxins, melamine and nitrates.

Within the European Union approved food supplements are regulated by Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Only vitamins and minerals fall under food supplements; moreover food supplements may only contain the vitamins and mineral salts laid down in Annex I of the Directive, and the vitamin and mineral formulations listed in Annex II of the Directive, singly or in combination. The presence of vitamins and minerals in any of the two Annexes means they are authorized. No additional authorization is required by the EU law; however, to facilitate efficient monitoring of food supplements, member states may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model or example of the label used.

The European Union Commission is responsible for establishing the purity criteria for substances contained in food supplements as well as the maximum and minimum quantities authorized. As excessive intake of vitamins and minerals can result in adverse effects, the Directive provides a possibility to establish a maximum safety level in food supplements designed to ensure that consumers will not ingest too high a dose of the particular vitamin or mineral under normal use. The dosage amounts have not been set at the EU level yet, but the process to develop these levels has begun. On this clause, a special ruling of the European Court of Justice (ECJ) was adopted in 2010. The ECJ ruled that, so long as the Commission has not set the upper safety limits for food supplements, Member States remain competent to adopt legislation on those limits. In doing this, they must use the principles of risk assessment. Moreover, in the absence of limits established by the Commission, member state can establish a maximum amount of certain substances as a zero level, virtually restricting such supplements on their territory²⁶.

The EU Member States may not prohibit or restrict trade in food supplements which comply with this Directive, except where they find that the products pose a public

²³ The legal acts of the Customs Union do not articulate if there is an appeals process or if appeals are possible.

²⁴ Annex 8 Species of Plant Raw Materials for Manufacturing of Biologically Active Food Additives for Children from 3 to 14 Years Old and Baby Herbal Teas (Herbal Drinks) for Infants.

²⁵ Annex 7. List of Plants and Products of their Processing, Species of Animal Origin, Microorganisms, Mushrooms, and Biologically Active Substances, Prohibited for Use as Part of Biologically Active Food Additives.

²⁶ See Case C-446/08 by the European Court of Justice, published at Lex Alimetaria http://www.lexalimentaria.eu/ing/attachments/034_ECJ-446-08.pdf.

health risk. Where such risk occurs, a Member State may temporarily suspend or restrict application of the provisions of the Directive²⁷.

Food supplements may not include claims such as preventing, treating or curing human disease. When including such claim on a product, it is no longer considered a food supplement, but a medicinal product and must meet another set of requirements.

With regard to use of substances other than vitamins and minerals in food supplements, in 2008 a special Report was published by the EU Commission²⁸. The Commission concluded that the existing Community legal instruments are satisfactory. Consequently, it is not necessary to lay down specific rules for substances other than vitamins or minerals for use in food supplements. The market for food supplements is extremely varied from one Member State to another. The use of these substances is therefore subject to the rules in force in national legislation without prejudice to any other Community provisions which are applied to them. However, the Commission does not rule out the possibility of carrying out a supplementary analysis, examining the conditions for the addition of these substances to foodstuffs in general, since they are now being added to ordinary foodstuffs.

The fact that substances other than vitamins and minerals are not regulated at the Community level, does

not mean they are not regulated in member states. The member states have national laws regulating substances other than vitamins and minerals in food supplements. For example, in 2012 Italy adopted a Decree on Food Supplements Containing Herbal Substances and Preparations which established a list of permitted herbals in the manufacturing of food supplements; this Decree mirrored similar legal acts adopted in Spain and Denmark²⁹.

In the EU, Health claims are a significant part of the requirements related to food supplements. Within the EU, Regulation (EC) 1924/2006 on nutrition and health claims made on foods³⁰ lays down harmonized rules across the European Union for the use of nutrition claims such as "low fat", "high fiber" or health claims such as "reducing blood cholesterol". Health claims have to be substantiated by generally accepted scientific data. The health claims can be made not only on food supplements but on other substances as well as long as they are part of food intended for final consumers. Health claims cannot be made on foodstuffs as a whole, only on a substance contained in the food; foods bearing claims that could mislead consumers shall be eliminated from the market. The rules for making health claims are detailed, and it is important to note that for most of vitamins and minerals as food supplements, certain health claims are already registered, including specific conditions of their use. Such claims can be found in the EU Register of Nutrition and Health Claims Made on Foods³¹.

²⁷ For the details, see Article 12, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

²⁸ Report from the Commission to the Council and the European Parliament of 5 December 2008 on the use of substances other than vitamins and minerals in food supplements COM(2008) 824, http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/COMM_PDF_COM_2008_0824_F_EN_RAPPORT.pdf

²⁹ Lex Alimentaria, <http://www.lexalimentaria.eu/ing/news/69-italy-pushes-forward-restrictions-on-botanicals-in-food-supplements.html>

³⁰ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

³¹ <http://ec.europa.eu/nuhclaims/>

Food Additives

Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example to color, to sweeten or to help preserve foods. Food additives such as vinegar, salt and sugar have been used for centuries to assist for such purposes. Until the 20th century there were relatively few kinds of additives, but during the last hundred years with a dramatic development of food industry there has been a significant increase both in the number and usage of food additives.

Food additives are only permitted if they are deemed safe and perform useful functions (many additives frequently have more than one function). Food additives that are deemed safe based on the best scientific knowledge available are approved for use, receive approval numbers and are identified both by these numbers and by their names. In many regions of the world including the European Union and Customs Union, it is common to see food additives identified with an E number³². Importantly, with the growth of consumer awareness, food additives E-numbering, has become recognizable by consumers. It is critical to understand that E-numbers were first introduced in Europe and are used to indicate food additives that are *permitted* in the European Union. However, it is not uncommon for food additives that have lost their approval in the EU (and, consequently, their “E”), still bear the “E” in other countries.

For many consumers “E number” has a negative connotation with something chemically unnatural to food, if not poisonous. However, some additives with E numbers are common and familiar substances. For example, vitamin C is approved as E300. Some food additives have natural origin; others are synthetic and artificially produced. Those that are of natural origin can be derived from animal or plant sources, which is important for groups of consumers with specific religious, cultural or ethical needs.

Each additive is expected to be of a standard composition, and this is ensured by developing specifications and purity criteria for food additives. Because food additives are supposed to have a targeted effect, they are

usually approved for use under certain conditions, in particular, for specific foodstuffs only, and in a certain amount. In some cases, usually for certain traditional foodstuffs no food additives are allowed.

There are other substances more or less similar to food additives and often confused with food additives, e.g., flavorings, food enzymes, processing aids. In most cases they are not assigned with an “E” number and in some cases do not require a safety assessment, but still there are rules for using them in food production.

At a high level the regulations of food additives within the Customs Union and European Union are similar in intent and purpose. The significant differences between the Unions can be found in the specific details of the control processes and in the specifics of which products are approved for use. The rules concern not only manufactures of food additives but also food processors who use food additives in their products. These specifics are important to companies wishing to export food products to either Union as approval of a food additive in one Union does not infer approval in the other. One of the most common reasons for foodstuffs being denied entry into the European Union is presence of unauthorized food additives.³³ For governments the specifics of the registration/authorization of food additives, control over their use and suspension of authorizations are important as the differences between the two Unions are significant and therefore simultaneous harmonization to both Unions is not practical.

The intent and purpose of food additive regulatory control in both Unions at a high level is the same in that within the Customs Union and European Union the objectives are the protection of consumer health and life, to establish common requirements within their respective trading block, to ensure the free movement of goods, protect consumers from being misled, and environmental protection. Due to the historical nature of the use of food additives and existence of national rules in member states of each Union prior to formation of a respective common market, there is an inherent complexity in both Unions in this area of regulatory control, which

³² However, other numbering systems exist as well, and, for example, in the Customs Union it is acceptable to identify food additives on the food labels by E number or by INS number (this numbering system is maintained by Codex Alimentarius Commission).

³³ The Rapid Alert System for Food and Feed 2013 Annual Report, http://ec.europa.eu/food/safety/rasff/docs/rasff_annual_report_2013.pdf

makes a comparative analysis complex. This complexity is made more difficult as the control mechanisms of the two Unions are significantly different, and to add to the complexity, the definitions of classes of food additives differ. Finally the specific food additives that are allowed or not allowed in each Union differ as well. Therefore the authors have provided a simplified comparison of the similarities and differences between the Unions but recommend that for companies and governments reading of a more in-depth analysis will be required to fully understand the specifics of each Unions' approach and details related to each food additive.

The scope of the regulatory requirements of food additives is similar between the Customs Union³⁴ and the European Union³⁵; in both cases it covers similar areas: authorization, establishment of community lists, conditions of use of the food additives, including maximum levels and food categories to which food additives can be applied, labeling and specifications and purity criteria. However, it does not mean that inside each area specific requirements are similar. The key difference between the two Unions is that the European Union legal requirements do not cover processing aids (except when processing aids are food enzymes); while in the Customs Union processing aids are directly mentioned as one of the objects of technical regulation. Also, while the Customs Union Technical Regulation 029/2012³⁶ establishes requirements to production, storage, transportation, sale and disposal of the substances within its

scope, the European Union regulations of the so called *Package on Food Improvement Agents* does not contain any such requirements, because food additives, enzymes and flavorings fall under the definition of "food" and aspects related to production, transportation, storage, etc. are regulated by the Regulations of the Food Hygiene Package (in particular, EC Regulations 852/2004, 853/2004, 854/2004).

The definition of food additive used in the European Union regulations and in the Customs Union CU TR 029/2012 are equivalent. At the same time, EU Regulation 1333/2008 lists a number of exclusions from the definition of food additive³⁷ that refines the scope of the definition. For example, in the European Union substances should not be considered as food additives when they are used for the purpose of imparting flavor and/or taste or for nutritional purposes, such as salt replacers, vitamins and minerals. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for coloring and food enzymes should also not fall within the scope of Regulation 1333/2008. Such and other nuances do not become clear from the definition of food additive established in the Customs Union; one needs to carefully check the text of CU TR 029/2012 and all annexes to determine if an ingredient is or is not a food additive.

An important note must be made on two terms widely used in the EU and the Customs Union legal acts on

³⁴In the Customs Union the scope of the regulatory requirements on food additives is established in technical regulation CU TR 029/2012 "Safety Requirements for Food Additives, Flavorings and Technological Aids".

³⁵On 16 December 2008, the regulations of the so called Package on Food Improvement Agents were adopted (Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorization procedure for food additives, food enzymes and food flavoring; Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97; Regulation (EC) no 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives; Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavorings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC). Importantly, the Regulations of the Package on Food Improvement Agents replaced earlier existing directives, which significantly changed the set of sector-specific legal requirements that existed earlier in the EU and increased the level of harmonization between the member states. The regulations have also been supported with implementing legal acts (called "implementing regulations").

³⁶Technical Regulation of the Customs Union CU TR 029/2012 "Safety Requirements for Food Additives, Flavorings and Technological Aids".

³⁷The following are not considered to be food additives in the European Union: (i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties; (ii) foods, whether dried or in concentrated form, including flavorings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary coloring effect; (iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods; (iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralization with sodium or potassium salts (liquid pectin); (v) chewing gum bases; (vi) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolytic enzymes; (vii) ammonium chloride; (viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten; (ix) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function; (x) caseinates and casein; (xi) inulin.

food additives, because these terms do not seem to be corresponding, but in fact are. The terms are “quantum satis” (EU) and “in accordance with technical documentation” (Customs Union).

There are cases where no legal maximum limits are established for the use of food additives or other substances used for technological purposes in foodstuffs. In such situations the European Union law prescribes to follow the principle of “*quantum satis*”, which in Latin means “the amount which is needed”. In the same situation, the Customs Union CU TR 029/2012 prescribes to follow “technical documentation” which has to be available from the food additive manufacturer, and where, in the absence of legal maximum limits, the manufacturer maximum limits are established. The manufacturer, when establishing such recommended limit, shall take into account that the substance must not exceed the levels necessary for achieving a technological effect.

The key difference is that according to the European Union regulations, a food processor takes the decision and responsibility to decide the amount of such substance which is to be added. According to the Customs Union rules, even if no limit is established in technical regulations, a food processor cannot decide how much to use; he has to refer to manufacturer’s technical documentation for the substance in question.

The authorization and use of food additives is regulated by both Unions. The specifics of each are quite different and impact companies wishing to export to either trading Union.

The Customs Union requires that food additives placed on the market and used by food processors be from the list of authorized substances made part of CU TR 029/2012; that food additives must have successfully passed state registration³⁸ and be accompanied by a

³⁸ According to Decision No. 880 of the Customs Union Commission of December 9, 2011 “On Adoption of the Technical Regulation of the Customs Union “On Food Safety”, the following substances (food additives, complex food additives, flavorings, plant extracts as flavoring substances and raw materials, starter cultures of microorganisms and bacterial starter cultures, processing aids, including enzymes) are subject to state registration according to the rules applied to specialized food. State registration is one of the forms of conformity assessment used in the Customs Union. The substances shall be subject to state registration in the manner provided in Article 24-26 of CU TR 021/2011, and the registration shall be completed by February 15, 2015. It is expected that by that date all substances currently in use will pass state registration



Quantum satis

It has its origins as a quantity specification in medicine and pharmacology, where a similar term *quantum sufficit* has been used (abbreviated Q.S.). Essentially it means “Add as much of this ingredient as is needed to achieve the desired result, but not more.”



declaration of conformity issued by each manufacturer of food additives or an authorized representative within the territory of the Customs Union.

There are several key points about the authorization of food additives in the Customs Union that should be highlighted.

- Neither CU TR 029/2012 nor Uniform Sanitary, Epidemiological and Hygiene Requirements establishes a process or procedure for authorization of new food additives. Therefore it is unclear as to the process for authorization of new food additives that are developed in the future.
- As food additives and flavorings are included in the definition of “food products” established by CU TR 021/2011 “On Food Safety”³⁹ requirements and procedures established to food products apply to food additives and flavorings including conformity assessment, CU TR 029/2012 refers to relevant articles of CU TR 021/2011. It is important to note that processing aids are not listed in the definition of “food products” under CU TR 021/2011 and therefore it is unclear as to whether all of the rules established for food products are applicable to food processing aids (except for state registration as mentioned in the next item).
- According to Decision No. 880 of the Customs Union Commission, the following substances (food additives, complex food additives, flavorings, plant extracts as flavoring substances and raw materials, starter cultures of microorganisms and bacterial starter cultures, processing aids, including enzymes) are subject to state registration according to the rules applied to specialized food⁴⁰. This requires that the applicant (manufacturer or importer) submits an application along with documentation of test results performed by a laboratory accredited within the Customs Union as well as other evidence that that substance is safe and that the substance must be in the relevant list of approved substances, and must meet

the relevant safety criteria. It is important to note that this regulation does not apply to the registration of new food additives and to updating the list of approved food additives; instead it applies to new manufacturers, importers or distributors of an existing approved food additive.

- Food additives and flavorings, may be novel, and as such, novel food additives and flavorings are subject to the authorization rules for novel food.
- As for the food additives and flavorings, they are subject to conformity assessment by means of declaration of conformity which differs based on the type of production and laboratory used for testing⁴¹. Note that the time validity for the declaration of conformity is established by an applicant but, depending on the declaration scheme, has certain limits.
- The state control (supervision) for compliance with the requirements of the Technical Regulation CU TR 029/2011 shall be carried out according to the procedures established by the national legislation of the Customs Union member state. Therefore each member state can have differing control procedures related to their specific laws and regulations.
- The Customs Union technical regulations do not provide for a review of food additives based on new information and data. As such it is unclear under what process food additives will be reviewed and possibly removed from the approved substances in the future.

Contrary to the Customs Union approach, the European Union law focuses not on registration of already approved food additives, but rather on assessing safety of food additives **before** they are added to the all-Union list of approved food additives, as well as on re-evaluation.

The European Union establishes that in order to protect human health, the safety of additives, enzymes and flavorings for use in foodstuffs for human consumption

³⁹ Article 4, CU TR 021/2011: “food products – products of animal, plant, microbiological, mineral, artificial, or biotechnological origin, that are natural, processed or reprocessed and are intended for human consumption, including specialized food products, packaged potable water, potable mineral water, alcoholic products (including beer and beer-based drinks), non-alcoholic beverages, biologically active additives (BAA), chewing gum, ferments and starter cultures of microorganisms, yeast, food additives and flavorings, as well as food raw material”.

⁴⁰ Clause 3.5(4), Decision of the Commission of the Customs Union “On Adoption of Technical Regulation of the Customs Union “On Food Safety” No. 880 of December 9, 2011. As mentioned, all the listed substances shall pass the state registration procedure according to articles 24-26 of CU TR 021/2011.

⁴¹ Scheme 1D: For serial production, with carrying out the production control and testing of samples by the manufacturer in a testing laboratory or in an accredited testing laboratory. Scheme 2D For a products lot, with testing in the laboratory at the choice of the applicant (in a testing laboratory or in an accredited testing laboratory), Scheme 3D For serial production, with carrying out the production control by the manufacturer and with testing in an accredited testing laboratory.

must be assessed before they are placed on the Community market. Only authorized food additives, flavorings and food enzymes can be used for production of foodstuffs or food additives. Authorization means that a substance is in the List of Approved Food additives. Within the context of the European Union regulatory norms the term “assessment” means the use of risk based process to determine the safety of these materials.

There are several key points about the authorization of food additives in the European Union that should be highlighted:

- Regulation (EC) No.1331/2008 lays down a common procedure for the assessment and common authorization of food additives, enzymes and food flavorings. Since many food additives, flavorings and enzymes had already been approved before 2008, authorization covers both new substances, and re-approval of already approved substances. Importantly, the re-approval is in progress and will be completed by 2020. It is anticipated that by 2020 all substances, first of all food additives, will be re-evaluated for safety in the light of new scientific data.
- The common authorization procedure, or the procedure of updating the Community lists of approved substances generally includes the initiation of the process, risk assessment by the European Food Safety Authority (EFSA), adoption of decision and finally updating the lists by the European Commission.
- Regulations (EC) No 1332/2008 (food enzymes), (EC) No 1333/2008 (food additives) and (EC) No 1334/2008 (flavorings) establish specific criteria according to which the substances are assessed for authorization. The part of authorization process is also to determine conditions of use, in particular, for what food or food category a substance can be used, and in what amount.
- The common procedure lays down the arrangements for drawing up and updating the EU lists for each category of substances. Only substances included in these lists are authorized on the Community market. Therefore, when a new substance is authorized, it means that relevant list will be updated.
- The regulations establish that all authorized substances are included into relevant Community lists. They are assigned a number (in the format of three or four figures), prefixed by letter “E” which indicates that the substance is authorized. When an authorization is revoked, the substance may keep its number, but loses its “E” when/if referred to in European Union official documents.

- As long as a food additive, flavoring or food enzyme is authorized, it can be used by food manufactures according to the established conditions of use without further approvals.
- If an emergency is connected with one of the substances on the authorized lists, the Commission shall take emergency actions according to Regulation (EC) No 178/2002.
- EFSA shall ensure the transparency of its activities by making public its opinions and any extensions of periods for the provision of additional information. Along with transparency, provisions of relevant regulations provide for confidentiality. The manufacturer of a substance shall indicate which information he deems confidential when the application is submitted. The Commission shall then determine which information in the application for authorization is confidential and shall notify the applicant accordingly. After being made aware of the Commission’s opinion on the confidential aspects, the applicant may withdraw its application so as to preserve the confidentiality if it does not agree with that opinion.

There are significant differences between the approval and registration processes between the Customs Union and the European Union. Key differences include:

- In the Customs Union no procedures have been established for updating Lists of authorized food additives and other similar substances. The Lists exist as a result of a process beyond the effective technical regulations which means that there is no process for manufacturers of new food additives to add additional substances to the Customs Union market. The European Union has a well elaborated procedure for authorization of new additives and other substances and adding them to the authorization lists. This procedure is lengthy, takes months if not years, and involves a thorough safety assessment by EFSA.
- In the Customs Union there is no delineated procedure for removing a substance from the List of approved substances in view of a new safety data. Whereas European Union has a procedure removing substances from the authorization lists.
- The Customs Union requires that all manufacturers and their representatives who wish to sell approved food additives or substances in the Union, must submit each substance for the conformity assessment procedure (in the form of declaration of conformity). In the European Union once a food additive or other substance has been approved for use, it can be manufactured by any company as long as it complies with specifications.

- During the procedure of state registration in the Customs Union *only already established authorized substances* are evaluated against the existing requirements. There is no similar procedure in the EU. However, during the EU authorization procedure, a new substance goes through an in-depth risk assessment, and new requirements for its use are elaborated.

For companies exporting to the Customs Union and/or the European Union an understanding which food additives and substances used, in what format and in what amount is critical to ensuring compliance of the respective products. Each Union has determined which products are approved, how the various products can be used and at what levels. Both Unions have extensive lists that contain over 500 different substances. While the lists of both Unions are positive (include only approved substances), they are organized differently. In the Customs Union the list is organized by sequential number in the ascending order (from E100 to E1521), and for each additive its functional classes are listed. The European Union has organized its respective list by functional classes (26 classes) on the basis of the principal technological function of the food additive⁴². It is important to note that allocation of a substance to one functional class shall not preclude it from being used for other functions.

It is also important to emphasize that when working with the lists of authorized substances, attention needs to be paid not only to the identification numbers and names of the substances, but also to their conditions of

use, including specific foods they are allowed for and the levels of use.

Within the Customs Union conditions of use of food additives and flavorings are established in separate annexes to CU TR 029/2012 under the titles "hygiene norms". They are detailed and specific to each of the hundreds of substances and need to be consulted in each case.

The European Union also establishes conditions of use and maximum limits for food additives and other similar substances; they can be found in respective Regulations (1332/2008, 1333/2008, 134/2008), and databases are available online⁴³. The databases contain thousands of records and while they are relatively simple to use, again we recommend that prior to manufacturing and exporting food additives, flavorings, and processing aids and/or products that contain these, companies should conduct an in-depth analysis to determine the specific requirements.

As mentioned above, there are differences between the EU and the CU approval lists. Appendixes 1 is a summary of food additives and substances that are approved for use in the Customs Union but not in the European Union of which there are 43. Appendix 2 is a summary of those food additives that are approved in the European Union and not in the Customs Union of which there 19. A caution to the reader: these lists are not static and subject to change as the European Union continues its process of re-evaluation and approval of new Food Additives and substances.

⁴² Food enzymes: the list is based on Regulation (EC) 1332/2008 (Annex II) and Commission Implementing Regulation (EU) No 1129/2011; food additives: the list is based on Regulation (EC) 1333/2008 (Annex II) and Commission Regulation (EU) No 1130/2011; flavorings: the list is based on Regulation (EC) 1334/2008 and Commission Implementing Regulation 872/2012.

⁴³ Database on food additives is available at: https://webgate.ec.europa.eu/sanco_foods/main/?sector=FAD&auth=SANCAS. Database on food flavorings is available at https://webgate.ec.europa.eu/sanco_foods/main/?sector=FFL&auth=SANCAS.

Materials and Articles in Contact with Food

Materials and articles in contact with food are all materials and articles intended to come into contact with food, such as packaging and containers, kitchen equipment, cutlery and dishes, parts of food processing equipment. These can be made from a variety of materials including plastic, rubber, paper, metal, etc. Safety of food contact materials must be evaluated as chemicals can migrate from the materials into food. The safety of food contact materials is regulated in the European Union as well as in the Customs Union through a number of legal acts.

While both Unions regulate food contact materials there are significant differences between the legal scopes. Currently within the Customs Union only packaging and closure are regulated as materials and articles in contact with food (Customs Union technical regulation CU TR 005/2011)^{44,45}. In the Customs Union a technical regulation on safety of food contact materials has been drafted but at the time of writing of this report it had not been finalized and put out for public discussion. In the European Union the scope of Regulation (EC) 1934/2004 (on materials and articles in contact with food)⁴⁶ is much broader and includes a range of contact materials intended to come into direct or indirect contact with food. Specifically, the scope includes: packaging materials, cutlery and dishes, processing machines, (e.g., conveyor belts), containers used in transport, materials and articles in contact with water for human consumption such as bottles, and materials that are used to manufacture articles that are expected to come into contact with food or transfer their components to foods (normal and foreseeable use). The breadth of the European legislation is significant and only overlaps with the Customs Union in the area of packaging and closures. These differences

are especially important for companies which intend to export to the European Union in that for example, rubber as a food contact material is listed in the European Union but is not covered by Customs Union except for some hygienic criteria.

As the scope of the Customs Union laws and regulations for food contact materials is limited to packaging and closures, the direct comparative analysis between the Customs Union and European Union will be limited to these subject areas.

Key areas of comparative analysis include the scope and specific requirements, labeling, authorization, and manufacturing, safeguard measures, and specific measures (technical requirements).

Scope and Specific Requirements

There are significant differences between the scope of the Customs Union technical regulation 005/2011 and the European Union legal acts on various food contact materials and articles.

Legal Framework. The European legal framework for food contact materials and articles presents a very different approach to that of the Customs Union. Within the European Union the regulatory framework for food contact materials and articles is based on a hierarchy of laws that builds upon a basic regulation⁴⁷, that is then further elaborated in additional legal acts to include a systematic risk based approach to manufacture of food

⁴⁴ Technical regulation of the Customs Union 005/2011 "On Safety of Packaging" (it should be noted here that the scope of this technical regulation covers packaging and closure both for foodstuffs and non-food products); Uniform Sanitary and Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Supervision (Control). Chapter II, Section 16. Regulations on Materials and Articles of Polymer and Other Materials Intended to Come into Contact with Food Products and Mediums.

⁴⁵ The Uniform Sanitary and Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Supervision (Control) have a slightly different approach to determining the range of food contact materials it covers. These materials are listed by codes of Commodity Nomenclature of Foreign Economic Activity (CNFEA) of the Customs Union; these codes are based on two criteria: type of material, and type of equipment. In most cases the codes specify the type of material used to make articles, and then within the category, are divided by specific articles (names of equipment, utensils, etc.).

⁴⁶ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

⁴⁷ Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

contact materials⁴⁸, to specific laws as necessary for various classes and types of materials⁴⁹. This provides the European Union with a framework that is broad and adaptable to the rapidly changing technology from new biodegradable packing and new chemical additives designed to increase shelf-life, to the incorporation of sensors that can indicate the safety of the product.

The Customs Union approach of conformity assessment in which a packaging or closure material is deemed safe by meeting specific criteria based on testing is effective, but requires that detailed specifications be determined prior to introduction in the market place. This means that the CU legal framework mostly comprises technical specifications for already existing and approved packaging and closure.

Chemical Migration. With respect to migration of chemicals, the European Union requirements state that there shall be no migration causing danger to health and the migration of chemicals shall not cause a change in composition and organoleptic properties of the food-stuff in contact. In the Customs Union, the requirements establish that there must be no harmful migration as well and migration limits are set for particular materials. Neither the Customs Union Technical Regulation 005/2011 nor the Unified Sanitary Requirements specify whether composition and organoleptics are taken into account by the specific hygiene criteria and migration limits. However, based on past experience it can be inferred that the Customs Union hygiene criteria do take into account the need to ensure no change in composition and organoleptics.

CU TR 005/2011 sets specific hygiene criteria and migrations limits and prescribes how the testing in model media shall be conducted. The European Union does not establish such particulars, instead the European Union rules establish that harmful migration happens “under no condition”. Such wording brings the Customs Union

and European Union to a similarity. The European Union wording does provide flexibility to adapt as new data becomes available and new materials due to the generality of the term. Further the European Union member states are free to decide about specific implementation of this requirement.

Safety. Safety is the common requirement in both Unions. In the Customs Union safety has a broader interpretation comparing to the European Union. In the Customs Union safety includes limits on the harmful migration of chemicals into food as well as physical (general) safety and reliability (e.g., not causing cuts or scratches on hands, stable to breakage, not exploding)⁵⁰. In the European Union migration of chemicals is included but no EU food safety regulations include physical safety of articles as these aspects of general safety are covered by the European General Product Safety Directive No 2001/95⁵¹.

In the Customs Union packaging requirements (including food packaging) establish additional norms other than safety – they are related to storage, transportation and recycling of packaging and closure materials. Except for recycling, there are no corresponding requirements established in the European Union law. On the other hand, in the EU a separate body of requirements is focused on good manufacturing practices for materials and articles in contact with food⁵².

Recycling. With respect to recycling, EU Regulation 1935/2004 favors recycling but does not set specific requirements. Recycling of packaging as a type of food contact materials is addressed in Packaging Waste Directive 94/62/EEC⁵³, and specific requirements to recycled cellulose film and recycled plastic are set by separate directives. In the Customs Union, no specific requirements are set on the recycling processes, and they are governed by national laws of member states.

⁴⁸ Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

⁴⁹ Plastics (Regulation EU/10/2011); ceramics (Directive 84/500/EEC); regenerated cellulose film (Directive 2007/42/EC); recycled plastics (Regulation (EC) 282/2008); active and intelligent materials (Regulation (EC) 450/2009); vinyl chloride monomer (Regulation EU/10/2011); release of nitrosamines (Directive 93/11/EEC); certain epoxy derivatives (Regulation 1895/2005/EC)

⁵⁰ Annex I to the CU TR 005/2011.

⁵¹ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

⁵² Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. Manufacturers must establish a quality assurance system (taking account the personnel required to put the system in place and the size of the business) and a quality control system following the detailed manufacturing regulations, for example the processes involving printing inks.

⁵³ European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

Active Materials and Intelligent Packaging. The requirements of European Union take into account the specifics of active materials and intelligent packaging⁵⁴. This is not covered by the Customs Union CU TR 005/2011.

Labeling of Food Contact Materials and Articles

Overall, while there are certain similarities, there also are many major and minor differences between the European Union and the Customs Union requirements to labeling of food contact materials and articles, including packaging and closures. Below is a discussion of key differences between the Unions.

Indication of Material being Food Grade. The means of indicating that a material/article is food-grade in the European Union includes the use of words, instructions and the glass-and-fork symbol. In the Customs Union requirements, only the symbol shall be used. Also, in the Customs Union a crossed glass-and-fork symbol is used for packaging that is not intended for food contact (no detailed rules have been established)⁵⁵.

Traceability. The European Union rules clearly require that labeling contains information for the purposes of traceability. In the Customs Union the labeling requires particular information be placed on the label (e.g., manufacturer and date of manufacturing). This does allow a degree of traceability that in some cases, depending on the record-keeping system of the food business operator, may be similar to the level of traceability required in the European Union.

Identification. It is mandatory in the Customs Union to identify the packaging by number and abbreviation of the material it is made of. In the European Union such identification is voluntary.

Consumer Information. The Customs Union rules establish that the labeling of packaging and closures shall also contain "information for consumers," without specifying what information is required or the form of such information. Comparing this requirement with wordings in other articles of CU TR 005/2011 it can be inferred that such information shall be placed on the packaging if it cannot be recycled. There are no similar requirements for consumer information on packaging in the legal acts of European Union.

Recycling labeling. In the European Union while efforts are made on reducing packaging waste and facilitating recycling of packaging materials, recycling is voluntary as is the respective labeling. In the Customs Union, TR 005/2011 establishes that the labeling of packaging and closures shall contain (among other particulars), information on possibility of recycling in the form of Mobius Loop. The wording of this requirement is vague and leaves room for interpretation. It is unclear whether all packaging and closures shall be marked (with Mobius Loop for recyclable items, and in an unclear way for non-recyclable items), or whether it is assumed that all of the packaging is recyclable, or whether, if the packaging is recyclable, then it shall be marked with Mobius Loop. Based on experience and evaluation of numerous Customs Union approved labels it can be inferred that most likely the intention is to label articles when all of the packaging is recyclable. The Customs Union Technical

⁵⁴ Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. "Active food contact materials and articles" means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food (definition from Article 2.2(a) of Regulation (EC) No. 1935/2004). See more information, for example, in EU Guidance to the Commission Regulation (EC) No 450/2009, DG SANCO, 23 November 2011, available at: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_active_and_intelligent_scof-cah_231111_en.pdf; *Active and Intelligent Packaging: Innovations for the Future*, K. Huff, Department of Food Science and Technology, Virginia Polytechnic Institute and State Univ. Blacksburg, Va. Active packaging systems are developed with the goal of extending shelf life for foods and increasing the period of time that the food is high quality. Active packaging technologies include some physical, chemical, or biological action which changes interactions between a package, product, and/or headspace of the package in order to get a desired outcome. The most common active systems scavenge oxygen from the package or the product and may even be activated by an outside source such as UV light. Active packaging is typically found in two types of systems; sachets and pads which are placed inside of packages and active ingredients that are incorporated directly into packaging materials. Intelligent materials and articles means materials and articles which monitor the condition of packaged food or the environment surrounding the food packaging with a time-temperature indicator is an example of an intelligent packaging. Time-temperature indicators are meant to give information on whether a threshold temperature has been exceeded over time and/or to estimate the minimum amount of time a product has spent above the threshold temperature (time temperature history) e.g. from the moment the food it is packed until consumption. The indication is often a visual signal. A positive visual signal could indicate that a product is not fresh anymore or not suitable to be eaten.

⁵⁵ Article 6 of CU TR 005/2011.

Regulation does not elaborate on the responsible party for placing the mark on the packaging including in the case of imported packaging and closure. Further it is unclear how and if at all the use of the Mobius Loop complies with generally accepted international practice and globally recognized standards. Internationally Mobius Loop is used based on the ISO 14021:1999 “Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling)”, and placing the symbol on an item is voluntary even if the item is recyclable indeed; also, to place the Mobius Loop on a package, beyond the recyclability, other conditions shall be observed, including there must be accessible facilities to recycle the item. According to CU TR 005/2011, Mobius Loop symbol is mandatory, and there are no additional conditions, other than recyclability of an item.

Labeling of Active Packaging Materials. The European Union has established a set of rules that require additional specific information to be placed on the label of “active materials”. For example, when a product contains a sachet, the sachet must be labeled as non-edible with the statement “do not eat” to avoid consumer consumption of the material; elements of an intelligent packaging whenever they are perceived as edible shall be labeled in a similar manner. When technically practical, a special symbol should be added as well. Within the Customs Union there are no specific requirements for labeling of “active materials/intelligent packaging”.

Authorization

In the European Union and the Customs Union authorization procedures exist for materials and articles intended to come into contact with food, including packaging and closures. They differ in process based on the respective Union’s fundamental approach to food safety control.

In the Customs Union, for each packaging/closure introduced by a manufacturer, *whether the specific packaging or closure is new or not*, he must complete the assessment of conformity process within the requirements of TR TU 005/2011 and other relevant technical regulations of the Customs Union. The assessment of conformity is done through execution of declaration of conformity by a manufacturer (or an authorized representative, or an importer) based on tests results from an accredited laboratory.

In the European Union, authorization procedures apply to new substances, materials, and articles made of new substances and/or materials not yet listed in regulations, and the procedure shall be made once before the substance is first put into manufacture. The process is based on a thorough risk assessment done by EFSA⁵⁶ to determine that the substances, materials, and articles made of new substances and/or materials have sufficiently demonstrated that they do not present risks to human health. In some member states, additional requirements may apply for individual business operators⁵⁷. At the same time, in the European Union for selected groups of food contact materials and articles it is required to develop a declaration of compliance⁵⁸.

⁵⁶ EFSA Note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorization (based on Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization. SCF/CS/PLEN/GEN/100 Final of 19 December 2001).

⁵⁷ SANCO E6/KS (26/09/2013). Summary of the National Legislation on Food Contact Materials.

⁵⁸ For several groups of materials and articles intended to come into contact with food, as a specific measure it is required to accompany them with a declaration of compliance. A written declaration shall state that such materials and articles comply with the specific rules applicable to them. Declaration of compliance shall accompany the following materials and articles in contact with food: Plastics, Recycled plastics, Ceramics, Active and Intelligent materials. Appropriate documentation shall be available to demonstrate the compliance. The documentation shall be made available to the competent authorities on demand. In the absence of specific measures, member states can adopt national provisions to require declarations of compliance.

Manufacturing

In the European Union it is required that manufacturers of food contact materials and articles implement good manufacturing practices based on quality assurance programs and quality control procedures⁵⁹. In the Customs Union the manufacturing requirements are limited to the process control for serial manufacturing of packaging/closures. This requirement, combined with the detailed quality control methods established by GOST standards referred to in the Customs Union TR 005/2011⁶⁰ may ensure a similar level of control as the European Union requirements with a major exception in that the Customs Union requirements on process control only refers to the process of manufacture of packaging/closure, but not of substances thereof, or other processes (steps) like transportation, distribution, etc. Also specifically "Active" packaging materials are not covered in the Customs Union technical regulations or GOST standards.

Safeguard Measures

The Customs Union and European Union have safeguard measures that foresee suspension, restriction, or ban for food contact materials and articles (European Union) or packaging/closure (Customs Union) under certain conditions. Such conditions however, are different for the European Union and the Customs Union. In the European Union safeguard measures apply for the approved food contact materials and articles when it becomes known that for any reasons they present a danger to human health. In the Customs Union safeguard measures apply if packaging/closure does not comply with technical regulations which includes non-compliance being related to food safety issues and/or other issues not related to endangering human health.

Specific Measures

The specific measures in the European Union on materials and articles in contact with food are quite broad

and range from the criteria of purity and specific conditions of use to limits on migration, collection of samples, traceability and establishing the list of substances authorized for use in the manufacture of materials and articles that are intended to come into contact with food⁶¹. In the European Union these are only developed for selected materials and articles⁶².

In the Customs Union, specific measures basically cover only the issue of migration from packaging/closure in contact with food, but are developed for all materials used in manufacture of packaging within the scope of CU TR 005/2011.

A special case remains active materials and intelligent packaging which is regulated in the European Union through special measures, but not regulated in the Customs Union.

It is advisable for companies wishing to export to the Customs Union and/or the European Union also to consult national legislation referred to in the Customs Union TR 005/2011 and the referenced GOST standards.

Also, since the rules applicable to food contact materials and articles are very technical, for further reading on the European Union legislation it is recommended to study individual regulations and directives, and guidance documents on their application. A good example of such freely available guidance document is a publication by United Kingdom's Food Standards Agency: "Explanatory Note: Legislation Controlling Materials and Articles Intended to Be Brought into Contact With Food", July 2009⁶³. As for the Customs Union, Belarusian State Institute of Metrology (BelGIM) developed Methodological Recommendations on Application of Technical Regulation of the Customs Union CU TR 005/2011 "On Safety of Packaging". At the time of writing an official copy of the document was not freely downloadable from the Belarusian website; and was offered for purchase from the Institute⁶⁴.

⁵⁹ Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

⁶⁰ Approved by Decision of the Customs Union Commission No. 769 of August 16, 2011.

⁶¹ A complete list of the requirements are found in the EU Framework Regulation (EC) 1935/2004.

⁶² Materials and articles include: ceramics; regenerated cellulose; plastics; recycled plastics; active and intelligent materials and articles, Nitrosamines and Certain epoxy derivatives

⁶³ <http://multimedia.food.gov.uk/multimedia/pdfs/foodcontguide010709.pdf>

⁶⁴ <http://www.belgim.by/uploaded/pdf/MR%20upakovka.pdf>

Considerations

This report covers a range of materials and food related commodities – novel food, dietary supplements, food additives and other substances for technological purposes, food contact items and materials – each with its own regulations, regulatory environment, and specifics. For all these materials, substances, articles special authorization/registration procedures apply. In each case there are similarities and differences in how specific issues are addressed in the European Union and the Customs Union.

Cross-Cutting Differences

- **Transparency.** The norms and rules established in the European Union provide more clarity and transparency with respect to those of the Customs Union. This refers to authorization procedures and reasoning for specific requirements. While in most cases it might not be important for food business operators, sometimes, when there are significant differences in particular requirements, transparency can help to better understand the intent and specificity of the regulations.
- **Detailed intents.** Legal acts in European Union clearly define not only the purpose of adoption, but also an intent (or intents) of the legal acts. Detailed intents are not specified in the Customs Union regulations. Detailing intents helps significantly in understanding the essence of legal requirements and also to anticipate and comply with possible future changes in the requirements.
- **Flexibility.** The European Union requirements are significantly more flexible than the norms in the Customs Union. It does not mean that they are loose. Instead flexibility means that they are more adaptable to changes and innovations that may happen in the food industry, as well as to new scientific data that may reveal possible food safety issues related, for example, to the approved substances or safety criteria.
- **Risk assessment.** In the European Union authorization procedures for novel food, food supplements, food additives, flavorings, food contact materials and articles are all based on risk assessment. This gives scientific soundness to authorization decisions, as well as to new norms, food safety criteria, etc. In the Customs Union, decisions are taken on a scientific basis as well but the specific basis is unclear and remains unknown as it is not made public and/or cannot be accessed by the public in any format.
- **Scope of the requirements.** In general, the scopes of requirements on various commodities analyzed in this report differ between the European Union and Customs Union. Sometimes the differences are minor; in other cases they are major. For example a major difference, is the very low correspondence between requirements on dietary supplements, which are understood as vitamins and minerals in the European Union, and biologically active supplements in the Customs Union for which vitamins and minerals are only a small part of substances covered. Other examples refer to; GMO excluded from novel food regulation in the European Union but covered by novel food rules in the Customs Union, food contact materials and articles in the European Union versus packaging and closures in the Customs Union.
- **Length of the procedures.** State registration and conformity assessment procedures used in the Customs Union are much faster than authorization procedures in the European Union. This may seem favorable for food business. But, at the same time, conformity assessment procedures apply to all food manufacturers, irrespective of whether the food they produce is already authorized or not. In the European Union authorization procedures are quite lengthy, but as long as an authorization is granted, no further specific approvals are needed for individual food business operators.
- **Steps and nuances of the procedures.** With regard to all groups of requirements analyzed differences were identified on specific aspects of authorization procedures: availability of information, the network of bodies responsible for approvals and authorizations, time limits, dissemination of data, and suspension procedures.
- **Objects of the authorization (registration) procedures.** In most cases, in the European Union authorization procedures are established for commodity when the commodity is first put into circulation. In the Customs Union, authorization or registration procedures apply to commodities that are first put into circulation by each individual manufacturer (importer), if such commodities subject to state registration.
- **Number of legal acts.** There are relatively few legal documents in the Customs Union. In contrast, the European Union has numerous regulations,

directives, and guidance documents covering these commodities. Consequently, while the legal acts of the Customs Union are relatively few in number the content is specific and in such detail that it makes the documents cumbersome to use. Alternatively, within the European Union legal acts are more structured but as the number of documents is significantly larger there is the potential to overlook or miss critical documents.

For governments in third countries some of the practices used in the European Union and the Customs Union can serve as good examples, in particular, flexibility and transparency of European norms and the setting up strict time limits for some official procedures in the Customs Union. Also, some specific highly technical norms, for example lists of approved food additives can be used as benchmarks for countries who do not wish to undertake the time and expense to achieve the level of scientific research and risk assessment as is available in the European Union.

For food businesses considering export to one of the markets, it is recommended to pay additional attention to the following:

- Identify the legal acts applicable to your specific product;
- Check whether the specific product falls under the scope of regulations in the target trading Union;
- Check if authorization is required and if yes, what are the specific rules, anticipated duration of the procedure, and expected costs;
- For those who target the market of the Customs Union – check which forms of conformity assessment are applicable to your product, and what specific related provisions of conformity assessment apply;
- For those who plan to use items that require authorizations – check if the item you plan to use is authorized at the target market (for example, check if a food additive is authorized); check whether the authorizations are accompanied with specific conditions of use (for example, for food additives – maximum limits, restrictions to use in certain products);
- Finally, these areas are rather complex and detailed and we recommend that guidance documents and training be specifically developed for the government and industry.

Annex 1**List of Food Additives Authorized in the Customs Union but NOT Authorized in European Union**

Nº	E-number	Name of food additive
1	E143	Fast green FCF
2	E181	Tannins, food grade
3	E201	Sodium sorbate
4	E225	Potassium sulfite
5	E231	Orto-phenylphenol
6	E232	Sodium O- phenylphenol
7	E236	Formic Acid
8	E265	Dehydroacetic acid
9	E266	Sodium dehydroacetic acid
10	E303	Potassium ascorbate
11	E314	Guaiac resin
12	E409	Arabinogalactan
13	E430	Polyoxyethylene (8) stearate
14	E467	Ethyl hydroxyethyl cellulose
15	E480	Diocetyl sodium sulpho-succinate
16	E484	Stearyl citrate emulsifier
17	E264	Ammonium acetate
18	E328	Ammonium lactate
19	E329	Magnesium lactate, dl
20	E342	Ammonium phosphates
21	E359	Ammonium adipates
22	E365	Sodium fumarates

Nº	E-number	Name of food additive
23	E381	Ferric ammonium citrate
24	E384	Isopropyl citrates mixture
25	E386	Disodium EDTA
26	E387	Oxystearin
27	E510	Ammonium chloride
28	E518	Magnesium sulphate
29	E539	Sodium thiosulphate
30	E542	Bone phosphate
31	E580	Magnesium gluconate
32	E636	Maltol
33	E637	Ethyl maltol
34	E905d	Mineral oil (high viscosity)
35	E905e	Mineral oil (medium and low viscosity)
36	E907	Hydrogenated poly-1-decene
37	E928	Benzoyl peroxide
38	E1400	Dextrins, roasted starch white and yellow
39	E1401	Acid treated starch
40	E1402	Alkaline treated starch
41	E1403	Bleached starch
42	E1405	Starches enzyme-treated
43	E1503	Castor oil

Annex 2**List of Food Additives Authorized in European Union but NOT Authorized in the Customs Union**

Nº	E-number	Name of the food additive
1	E123	Amaranth
2	E127	Erythrosine
3	E154	Brown FK
4	E173	Aluminum
5	E180	Litholrubine BK
6	E239	Hexamethylene tetramine
7	E243	Ethyl lauryl arginate
8	E284	Boric acid
9	E285	Sodium tetraborate; borax
10	E1105	Lysozyme
11	E964	Polyglycitol syrup

Nº	E-number	Name of the food additive
12	E969	Advantame
13	E423	Octenyl succinic acid modified gum Arabic
14	E499	Stigmasterol-rich plant sterols
15	E512	Stannous chloride
16	E1205	Basic methacrylate copolymer
17	E1206	Neutral methacrylate copolymer
18	E1207	Anionic methacrylate copolymer
19	E1208	Polyvinylpyrrolidone-vinyl acetate copolymer



Laboratory Control and Food Safety Criteria in the European Union and the Customs Union

Executive Summary

The ability to provide safe and nutritious food domestically and for export is a shared responsibility of industry and governments. In order to deliver on this commitment, governments and industry must have the ability to identify and control food safety hazards. Food safety hazards are biological, chemical or physical agents that can be found in food or in contact with food that have the potential to cause an adverse health effect. These hazards are found throughout the food supply chain and are a significant public health concern. To ensure that food is safe, governments have established specific rules and acceptable levels of presence of hazards in food and in this way differentiate safe food from unsafe food. All food that is placed on the market must comply with the safety levels of hazards presence in food, and in some cases, for especially dangerous substances, zero acceptable levels are established. The safety levels are not arbitrary: they are based on substantial scientific research, and as new scientific information becomes available, safety levels for food hazards are revised. To effectively assess presence of hazards in food, it is important to have adequate laboratory capacity, to use statistically sound sampling techniques, and reliable, accurate and repeatable analytical test methods.

The Customs Union and the European Union have a long history of controlling hazards in food to ensure the safety of the food that consumers eat and drink. Both Unions have established systematic approaches in which hazards are determined; allowable limits are established; and schemes for sampling, testing and reporting the results have been instituted. The approach to food safety control differs between the two Unions. The Customs Union food safety control system to a significant extent is based on conformity assessment in which food products are deemed safe based on a comparison with product specifications as outlined in legal

acts; the comparison is done through testing of the final products attributes including food safety parameters. Therefore, in the Customs Union, the key to ensuring safe food is to conform/verify that the final product conforms in all aspects with the technical regulations and/or specific standards. In the European Union the food safety control is at its core a risk-based process in which hazards are identified and controlled at all levels in the food chain from farm-to-fork through preventive methods rather than testing of final products. The differences in these two approaches lead to significant differences in establishment of hazards, setting of acceptable limits for chemicals, pesticides, pathogenic microorganisms, veterinary medicines residues, authorization of products and substances, testing, sampling and the role of laboratories within the respective systems.

The comparative analysis of the Customs Union and European Union requirements on acceptable limits for pathogens, pesticides, veterinary drugs, chemicals as well as sampling, testing and laboratories is a highly complex scientific and technical set of topic areas. To help to better understand this legal analysis we have included into this document some basic information about hazards, as well as examples of specific comparisons for illustrative purposes. Considering that the Customs Union microbiological criteria, acceptable limits for contaminants, pesticides and veterinary drugs are very detailed and organized in a rather complex manner in the technical regulations, and are not easy to be immediately grasped by people unfamiliar with the Customs Union system, summary overview tables have been prepared and are available as part of the expanded version of the report. Since specific parameters are set for food categories, and in the Customs Union and the European Union food categories are organized based on different principles and criteria, it is not practical to prepare a category-by-category (or product-by-product) comparison for microbiological criteria and contaminants. In view of the complexity of the topic areas we must point out that for businesses wishing to export to either EU or CU it is key to conduct an in-depth specific analysis of legal provisions relevant to products they wish to export as each foodstuff and class of foodstuffs has specific requirements that must be met.

Microbiological Criteria for Foodstuffs – Approaches and a Comparison of Parameters

Microbiological hazards (bacteria, viruses, fungi, protozoa, parasites, yeasts) in foodstuffs are a major source of food-borne diseases in humans. Foodstuffs of animal and plant origin may present a significant threat to health first of all due to microbiological contamination; microbiological hazards can be naturally occurring and come into food chain with the raw material, or can contaminate food at any food chain step. Foodstuffs should not contain microorganisms and their toxins or metabolites in quantities that present unacceptable risk for human health. Microbiological criteria are tools that can be used in assessing the safety and quality of foods. Requirements on microbiological criteria are established in the Customs Union and the European Union in legal acts that form an important part of the food safety regulatory framework.

Within the area of food microbiology there are several important aspects that guide the approaches of the Customs Union and the European Union to food safety microbiological control.

1. Not all microorganisms are harmful and therefore it is not a purpose of food processors or regulators to kill 100% of microflora in food. For example, some bacteria cultures are the basis for the preparation of yogurt and cheese and therefore should not and cannot be eliminated from certain foodstuffs.
2. In some instances harmful (pathogenic) microorganisms are harmful to humans in all cases. Other organisms are only harmful under certain conditions, for example organisms can rapidly take advantage of favorable conditions that allow rapid growth and therefore become a human health hazard (conditionally pathogenic or opportunistic pathogens)¹.
3. Presence of some microorganisms that are pathogens clearly says that the food is unsafe (e.g., contamination with *Salmonella*). Presence of other microorganism as indicated by the measurement of Total Plate Count² does not necessarily mean that food is unsafe. Instead a high Total Plate Count is an indicator that the total microbial count in the product is high which suggests that the conditions of production were not hygienic enough to meet the required norms. High levels of indicator organisms are used as a test for hygienic production as well as an indication that the product may contain pathogenic microorganisms in concentrations high enough to be of concern.
4. Within some bacteria families, some bacteria are more harmful than others. For example, within the class of coliforms (rod-shape bacteria), one of the species that includes harmful bacteria strains is *Escherichia Coli (E.Coli)*; most of *E.Coli* strains are harmless, but some serotypes can cause serious foodborne infection; the most pathogenic serotype is *E.Coli O157:H7*.
5. Some microorganisms are spoilage microorganisms – they cause spoilage (which is a tactile, visual and olfactory or flavor change that is unacceptable) but very rarely render food unsafe. For example high levels of certain yeasts and bacteria can cause formation of carbon dioxide gas in packaging which leads to packaging swelling and exploding at storage. While this is not a direct food safety risk it is a significant risk to the product stability, durability and product acceptability in the market³.
6. In some cases, infection is caused not by bacteria, but by a toxin that the bacteria produce. For example in humans, respiratory

¹ For example, ready-to-eat foods can support the growth of pathogenic (food poisoning) bacteria and must be kept at certain temperatures to minimize the growth of any pathogens that may be present in the food or to prevent the formation of toxins in the food. Examples include, but are not limited to, sandwiches, kebabs, sushi, takeaway foods and bakery products. Ready-to-eat foods usually include a number of ingredients which may or may not be cooked.

² Total Plate Count is also referred to as Standard Plate Count or Aerobic Plate Count. A similar criterion used in the Customs Union is total number of mesophyll aerobic and facultative anaerobic bacteria. A standard plate count will not differentiate between the natural microflora of a food, spoilage microorganisms, organisms added to fermented foods or pathogenic microorganism. It cannot be used to predict the safety of the product and will be influenced by the storage conditions of the product. Depending on the product, a high standard plate count may indicate that the product may have been prepared unhygienically or stored inappropriately.

³ <http://www.foodsafetymagazine.com/magazine-archive1/junejuly-2012/flavors-should-burst-not-packages/>

passages, skin and superficial wounds are common sources of *Staphylococcus aureus*, and when *Staphylococcus aureus* is allowed to grow in foods, it can produce a toxin that causes illness⁴.

7. When a material is sampled the larger the sample size is, the more likely that that microorganisms may be detected. It is simply a matter of statistics: the more samples are taken the more likely it is to find an organism. Therefore a sample size of 5 grams may yield a negative result (no pathogen found), whereas when a 100 gram sample is tested, a positive result may be found.
8. As food is highly complex material or matrix and is not uniform, the more samples are taken, the more representative the samples are of the total amount of product. For example if one is testing production of 1000 kg of meat in a single batch, then the more samples are taken in different places in the 1000 kg, the more representative the sample is of the total 1000 kg versus a single sample taken at 1 place. Therefore, increasing the number of samples increases the potential to detect undesirable microorganisms.

While the Customs Union and the European Union have specific controls for microorganisms in food the approaches they use are significantly different. The Customs Union has a combination of vertical and horizontal legal acts that are used for establishing microbiological requirements to foodstuffs: they combine general requirements set for all foodstuffs in a horizontal CU TR 021/2011 "On Food Safety" with additional requirements established in

vertical product-specific technical regulations; in a combined form they can be found in the Uniform Sanitary, Epidemiology and Hygiene Requirements for Products Subject to State Control (Supervision)⁵. At the same time, it shall be kept in mind that as a general rule, when a product-specific technical regulation is adopted, the relevant section(s) of the Uniform Sanitary, Epidemiology and Hygiene Requirements loses its validity for products covered by the scope of the technical regulation. Therefore, the Customs Union has a significant body of technical regulations that establishes specific types and quantities of microorganisms that are allowed in food⁶. The European Union approach is purely horizontal: all microbiological criteria for all foodstuffs are consolidated in one Regulation (EC) No 2073/2005 "On microbiological criteria on food". This Regulation is a part of the EU preventive approach to food safety and is tightly linked to other food safety tools (first of all HACCP) and relevant legal acts⁷.

Microbiological requirements of the Customs Union are focused on a combination of pathogens as well as indicative and spoilage microorganisms in finished products. This is due to the intent and regulatory framework of the Customs Union that is based on finished product conformity assessment as a mechanism to control food safety and quality as well as food identification. The European Union microbiological criteria are targeted at specific hazards, specifically those microorganisms that are directly associated with foodborne

⁴ Although cooking destroys the bacteria, the toxin produced is heat stable and may not be destroyed. Staphylococcal food poisoning occurs most often in foods that require hand preparation, such as potato salad, ham salad and sandwich spreads. Sometimes these types of foods are left at room temperature for long periods of time, allowing the bacteria to grow and produce toxin. Good personal hygiene while handling foods will help keep *S. aureus* out of foods, and refrigeration of raw and cooked foods will prevent the growth of these bacteria if any are present.

⁵ Customs Union Technical Regulation 021/2011 "On Food Safety"; Customs Union Technical Regulation 005/2011 "On Fat and Oil Products"; Customs Union Technical Regulation 023/2011 "On Fruit and Vegetable Juice Products"; Customs Union Technical Regulation 027/2012 "On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food"; Customs Union Technical Regulation TR CU 033/2013 "On Safety of Milk and Dairy Products"; Customs Union Technical Regulation TR CU 034/2013 "On Safety of Meat and Meat Products". Importantly, microbiological criteria are also set by the Uniform Sanitary and Epidemiological and Hygienic Requirements for products subject to sanitary and epidemiological supervision (control), Chapter II, Part 1, "Requirements for safety and nutrition value of food products". As it is explained in the Explanatory Note to the Technical Regulation CU TR 021/2011, the requirements, including on microbiological safety, are based on national laws of the Customs Union member states and on international requirements.

⁶ Due to the significant size of each Customs Union technical regulations, it is advisable in each particular case to refer to the applicable clauses and annexes of the relevant legal acts.

⁷ In addition to Regulation (EU) 2073/2005, microbiological requirements are established on raw milk (in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin), however they are not food safety requirements. As explained in Regulation (EC) 2073/2005, microbiological criteria have been established based on Codex Alimentarius guideline "Principles for the establishment and application of microbiological criteria for foods, CAC/GL 21- 1997"; in addition to this, existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken into account. The criteria are also based on the advice of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) and the Scientific Committee on Food (SCF) of the European Commission in laying down microbiological criteria. Also, European Food Safety Authority (EFSA) provides its scientific opinions and support where it comes to scientific assessment and review of various food hazards, including microbiological hazards.

diseases. Such hazards are controlled through preventive or control measures under HACCP programs, and the compliance is verified through official HACCP audits by a competent authority. Microbiological tests are used as an instrument of verification of HACCP effectiveness. This focus on specific hazards is a reflection of the intent and supporting legal framework of the European Union targeted at prevention of production of unsafe food; other issues related to quality and possible spoilage are not controlled through enforcement. In addition, as the Customs Union approach is based on

final product controls and testing, the Customs Union technical regulations do not establish microbiological requirements for production processes. In contrast, due to the European Union's preventive and risk-based approach, control of pathogens is required during production processes as well (legal criteria are established for specific process steps, usually at the end of the manufacturing process), and safety is verified again when foodstuffs are at the market. These differences are summarized in Table 1 below.

Table 1 Comparison of Groups of Microorganisms for which Microbiological Criteria are Established in the Customs Union and the European Union

Customs Union – Groups of Microorganisms	European Union – Groups of Microorganisms	
Criteria for finished products (upon conformity assessment before putting into circulation)	Criteria for products placed on the market (finished products/food safety criteria)	Criteria for production processes (in-process products (usually end of manufacturing)/process hygiene criteria)
Pathogens	+	+
Conditional pathogens	-	+
Indicator microorganisms	+ (in one case only, <i>E.coli</i> in live bivalve mollusks and shellfish ⁸)	+
Spoilage microorganisms	-	-
Live cells	-	-

From the human health perspective, the most important for comparison of the CU and EU microbiological criteria are pathogens. In fact, pathogens are the only group

of microorganisms for which a comparison is possible, because it is the only *common* group covered by the Customs Union and European Union norms (Table 2).

⁸Live bivalve mollusks and live echinoderms, tunicates and gastropods (Clause 1.2.5 of Chapter 1 "Food safety criteria" of Annex 1. "Microbiological criteria for foodstuffs", Commission Regulation (EC) 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

Table 2

Comparison of Specific Pathogens for which Microbiological Criteria are Established in the Customs Union and the European Union

Pathogens covered by microbiological criteria according to the Customs Union technical regulations	Pathogens covered by microbiological criteria (food safety criteria) according to European Union regulations
Pathogenic microorganisms incl. <i>Salmonella</i>	<i>Salmonella</i>
	<i>Salmonella typhimurium</i> , <i>Salmonella enteritidis</i>
<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>
<i>Enterobacter sakazakii</i>	<i>Cronobacter spp.</i> (<i>Enterobacter sakazakii</i>)
<i>Yersinia Spp.</i>	Not covered ⁹
<i>Staphylococcus enterotoxins</i>	<i>Staphylococcal enterotoxins</i>
Not covered	Shiga-toxin producing <i>E. coli</i> ¹⁰ (STEC) O157, O26, O111, O103, O145 and O104:H4
Not covered ¹¹	Histamine

Both Unions apply rigorous microbiological controls to ensure food safety. While the objectives of food safety are achieved by both systems, there are systemic and specific differences that have an impact on businesses wishing to export to either or both Unions. For governments, while harmonization with either Union is possible, it is not practical or reasonable to simultaneously harmonize due to the significant differences in approach to microbiological control.

The major differences in approach to microbiological control are summarized below and include:

- The Customs Union approach of conformity assessment requires greater testing of the final food product for a wider range of criteria including those related to quality, spoilage, and food safety. The European Union's approach is based on a risk-based system from farm-to-fork which by design is focused on preventative and control measures through production process based on HACCP principles and focused on specific food safety related microorganisms.
- The food safety control in the Customs Union focuses on end-product testing before the product is placed on the market, whereas the

European Union control system focuses on prevention of product non-conformities throughout the manufacturing process. Therefore while in the Customs Union the focus is on final product testing, the European Union testing when required is conducted at all levels of the food supply chain and includes in-process testing (usually at the end of the manufacturing process) and testing of end-product after it is placed on the market to ensure that the product is safe through its shelf-life.

- Requirements of the Customs Union establish that foodstuffs must comply with general microbiological criteria established in CU TR 021/2011 and additional criteria under the scope of product-specific technical regulations. Foodstuffs for which product-specific technical regulations have not been developed yet or have not entered into force, shall comply with general microbiological criteria. Within this context only the microbial tests which are directly specified for a specific product are carried out. Therefore, it is not possible to test a product for a microorganism that is not listed in the specific product specification even if new scientific data indicates that this may be of concern.

⁹ Yersiniosis as a disease from *Yersinia Spp.* does not occur frequently. It is rare unless a breakdown occurs in food processing techniques. <http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm070040.htm>.

¹⁰ A novel strain of *Escherichia coli* O104:H4 bacteria caused a serious outbreak of foodborne illness focused in northern Germany in May through June 2011; all in all, 3,950 people were affected and 53 died, 51 of whom were in Germany.

¹¹ Histamine is not covered by the Customs Union microbiological requirements (instead, it is covered in other sections of technical regulations as a different type of hazard).

- The European Union microbiological criteria are not specific to a particular product but instead are established across broad product categories. Further special clauses of the Regulation (EC) 2073/2005 give right to competent authority to test for other microorganisms in case of food safety concerns, and oblige food business operators to identify other relevant microorganisms as significant microbiological food safety hazards within their HACCP control programs, allowing the European Union to expand the list of microorganisms tested as needed¹².
- While in the Customs Union HACCP is mandatory for food manufactures, microbiological requirements are set for the final products before they are placed on the market, and are not integrated into implementation of HACCP programs throughout the food chain to the extent as in the European Union.
- Customs Union technical regulations do not set requirements on microbial criteria for production processes, while in the European Union part of microbiological criteria are focused on production processes and process hygiene (they are called process hygiene criteria).
- Some of the Customs Union microbiological criteria are established for the purposes of product identification only (with the aim of conformity assessment, e.g., for fermented dairy product); in the European Union no such microbiological criteria are established.
- The food categories for which microbiological criteria are established in the Customs Union and the European Union, while may seem different and not easy to correlate, in fact cover to the most extent similar food categories. The one significant exception is grouping of foods in the European Union by their ability or inability to support the growth of *Listeria monocytogenes* (LM). This grouping refers to ready-to-eat foods, and as such the two categories (ready-to-eat, able to support the growth of LM, ready-to-eat, not able to support growth of LM¹³) cover many foods, that otherwise would not be covered by other food categories. To help producers to decide to which group their products belong, the European Union Commission has developed a special guidance document¹⁴. No such grouping is used in the Customs Union legal acts.
- The Customs Union technical regulations do not establish other requirements for food business operators with regard to microbiological criteria in addition to the requirement to comply with specific limits; the European Union regulatory framework includes many additional requirements related to the application of microbiological criteria, including the obligations to conduct additional studies, take certain actions in case of non-conformities, analyze trends in test results and improve processes.
- The Customs Union technical regulations establish sampling plan requirements for a relatively small number of cases; for the remainder, sampling plans are established through GOST standards and Methodologies that are referred to by each particular technical regulation. Testing methods are established by GOST standards and Methodologies. The European Union requirements on microbiological criteria are set in close connection with the sampling plan and reference testing method for each criteria in Regulation (EC) 2073/2005.
- There are differences in technical aspects:
 - In many cases the Customs Union and the European Union microbiological criteria require different number of samples to be taken;
 - In many cases the European Union microbiological criteria use units of measure for the tolerance limits that are not applicable in the Customs Union;
- At the level of specific combinations of microorganism/product there are many differences between food safety criteria in the Customs Union and the European Union;
- Specific tolerance limits of microbiological criteria as established by the Customs Union and the European Union legal acts are similar in some cases, and different in other cases.

¹² The competent authority shall verify compliance with the rules and criteria laid down in Regulation (EC) 2073/2005 in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other microorganisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis (Article 1, Regulation (EC) 2073/2005 on microbiological criteria in food).

¹³ Some examples: ready-to-eat foodstuffs able to support the growth of LM: pre-packed sliced cooked meat, smoked salmon, soft cheese; ready-to-eat foodstuffs not able to support the growth of LM: ice cream, hard cheese, products with shelf life of less than 5 days e.g. sandwiches and some unpackaged delicatessen products if prepared in store.

¹⁴ Commission Staff Working Document Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

For potential food exporters the differences between the Customs Union and the European Union as listed above are significant and compliance with one Union does not necessarily mean compliance with the other. With regards to the Customs Union, food businesses and exporters should be prepared for extensive microbiological testing for many microorganisms when they present their products to the Customs Union market. For business operators and exporters who present their

products to the European Union market, they should be prepared for microbiological testing as well, which will, most likely, be restricted to a limited number of microorganisms, but in many cases will be done according to statistically more stringent rules. Further, the tolerance limits between the two Unions may vary. Therefore businesses wishing to export must understand how the regulations are organized and refer to specific criteria in each particular case for each market place.

Contaminants in Food

Contaminant (European Union) or “potentially dangerous substance” (Customs Union) generally means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination¹⁵.

Contaminates can include toxic elements such as lead and mercury, pesticides (DDT), chemicals (melamine and dioxin), naturally occurring substances (aflatoxin), and in the Customs Union can include such things as hydrocyanic acid, radionuclides, and methyl alcohol^{16,17}. Since contamination is generally considered to have a negative impact on the food safety and may imply a risk to human health, governments take measures to minimize contaminants in foodstuffs.

In order to protect the health and well-being of consumers by ensuring the safety of food, both the Customs Union and the European Union have established a number of regulations to control the types and quantities of contaminants found in food. The Customs Union, as part of the end-product conformity assessment process, has developed a combination of vertical and horizontal technical regulations that establish the requirements on contaminants in foodstuffs. The Customs Union technical regulations combine general requirements set for all foodstuffs in a horizontal CU TR 021/2011 “On Food Safety”¹⁸ plus additional requirements which have been established for milk and dairy products¹⁹, meat and meat products²⁰, fats and oils²¹, juice products²², grains²³, food for special diets²⁴. Additional specifics on food contaminants are detailed in the Uniform Sanitary and Epidemiological and Hygienic Requirements for products subject to sanitary and epidemiological supervision

¹⁵ Article 1.1, Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food and is similar to implied meaning within the Customs Union for “potentially dangerous substances”.

¹⁶ Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition. On further analysis, it is important to note that contaminants do not include physical impurities.

¹⁷ In some of the Customs Union technical regulations, “potentially dangerous substances” are listed as an independent list of substances; in other technical regulations, they are part of “hygiene safety requirements”; in the former case, hygienic safety requirements also cover other aspects or chemicals added to the foodstuffs, or objects that are present in food but are not contaminants.

¹⁸ Note that amendments are being prepared for the CU TR 021/2011; the period for collecting public comments has finished on July 3, 2014. For details of draft amendments, see http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Pages/10_04_2014_project.aspx.

¹⁹ Customs Union Technical Regulation CU TR 033/2013 “On Safety of Milk and Dairy Products”, Annex 4. Permissible levels of oxidative deterioration and content of potentially dangerous substances in dairy products, dairy composite products for nutrition of pre-school and school-age children.

²⁰ Customs Union Technical Regulation CU TR 034/2013 “On Safety of Meat and Meat Products”, Annex 3. Hygienic Safety Requirements of Slaughter Products Intended for Infant Foods.

²¹ Customs Union Technical Regulation CU TR 024/2011 “Technical Regulation on Oils and Fats”, Annex 1. Requirements to permissible levels of food safety indicators of oil and fat products”.

²² Customs Union Technical Regulation CU TR 023/2011 “Technical Regulation on Fruit and Vegetable Juice Products”.

²³ Customs Union Technical Regulation CU TR 015/2011 “On Safety of Grain”.

²⁴ Customs Union Technical Regulation CU TR 027/2012 “On Safety of Special Types of Specialized Foodstuffs, Including Medical Diet Foods and Preventive Diet Foods”.

(control)²⁵ (however one should remember that the Uniform Sanitary Requirements are not applicable to the products for which product-specific technical regulations have been developed); specific requirements are based on the national laws of member states and on international requirements. In the European Union the approach to the legislation on control of contaminants is purely horizontal: all requirements to contaminants in food are consolidated in one Regulation (EC) 1881/2006 on maximum levels of contaminants in foods²⁶ and are developed according to a common unified procedure which is applied across all member states.

To prevent food with dangerously high level of contaminants entering into the market place, maximum limits²⁷ for contaminants are established. These limits are based on toxicological studies that determine how much of the substance can cause negative effect on human health, given the amount of consumed product(s) containing such substance. The threshold amount of substance that can be safely consumed according to the toxicological studies is called TDI (tolerance daily intake), ADI (acceptable daily intake), and ARfD (acute reference dose for a one-time consumption of a large quantity of the substance). TDIs are established for harmful chemicals that cannot be avoided (e.g., contaminants that come from environment); ADIs are established for harmful chemical substances content of which in food can be managed through good practices (e.g. pesticides). Therefore the establishment of ADIs, TDIs and ARfDs are expected to be scientifically objective as they are based on thorough toxicological research of mammalian reactions to chemical substances. As such these studies are always conducted on animals and then extrapolated to humans using several safety factors. Due to these safety factors, in practice, maximum limits for contaminants are established well below the thresholds at which a negative impact on human health is possible.

Within the Customs Union food products cannot be put into circulation at the market if they do not comply with "hygiene safety requirements" which mainly cover

contaminants. Maximum limits of contaminants are always a product/contaminant combination; maximum limits are not established for each product/contaminant combination, instead, they are established based on the principle whether a substance can be present in the product. The technical regulations also establish that sampling and testing for compliance with hygiene safety requirements shall be done using rules and methods listed in the *List of standards containing the rules and methods of examination (testing) and measurement, including the rules for sampling that are required for application and meeting of the requirements of technical regulations and carrying out of assessment (confirmation) of products' conformity*²⁸.

The European Union Regulation (EC) 1881/2006 on maximum levels of contaminants in foods covers a wide variety of foodstuffs, but the range of foodstuffs is less than that in the Customs Union. The maximum limits are established based on the available Codex Alimentarius standards, and the opinions of the Scientific Committee on Food (SCF) and European Food Safety Authority (EFSA). The approach to identification of the food categories and specific contaminants for which maximum limits are established is based on the vulnerability of the target group of consumers, the likelihood of occurrence of a contaminant in a specific foodstuff, the toxicity of contaminants, and consumption patterns in the European Union.

In some cases the food categories are divided into sub-categories depending on additional specific criteria or risk factors related to the manner of production, processing techniques applied, and/or readiness for use. For example, whether the plant origin products were grown in the open air or under cover (e.g., in a greenhouse), and in what season (cold or hot): such criteria for the grouping food products are used for establishing the maximum levels of nitrates in lettuce as an example, as the growth conditions can significantly impact the concentration of nitrates²⁹. Regulation (EC) 1881/2006 also established other rules for food business operators

²⁵ Uniform Sanitary and Epidemiological and Hygienic Requirements for products subject to sanitary and epidemiological supervision (control). Chapter II, Part 1. Requirements for safety and nutrition value of food products.

²⁶ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

²⁷ In Codex Alimentarius documents, it is common to use the word "limit" (maximum residue *limit*); in the EU documents, the word "level" (maximum residue *levels*) is commonly used. They designate the same concept.

²⁸ Such Lists are approved for each food-related technical regulation of the Customs Union.

²⁹ Another example is whether the products are ready for consumption as such or are subject to further process steps, for example sorting, as in some cases sorting technics may reduce the level of contaminant. In particular, such approach is adopted for setting maximum levels of mycotoxins, in particular aflatoxins in nuts, including hazelnuts.

in addition to the requirement to comply with the maximum levels of contaminants, as well as requirements for foods that do not comply with the maximum levels.

In general in the CU and the EU many of the contaminants for which maximum levels are established are similar. There are some differences such as toxic elements, harmful impurities or impurities of metal, and radionuclides Cesium-137 and Strontium-90; those are only covered by the Customs Union³⁰. There are others such as methyl alcohol, caffeine, and quinine that are covered by the Customs Union regulations on contaminants (i.e., specific sections of technical regulations or their annexes), but in the European Union they are excluded from regulations on contaminants and are covered by other regulations instead.

There are several additional differences between the Customs Union and the European Union in the area of maximum residue limits that must be considered by businesses wishing to export and governments wishing to model either Union's requirements.

- In the Customs Union foodstuffs are organized into categories/subcategories for the purposes of contaminants MRLs based on the same criteria/principles as for other hazards in food. In the European Union, in some cases additional criteria were introduced to categorize foodstuffs for the purposes of setting MRLs on contaminants, for example, whether the product is subject to handling or processing techniques that can reduce the level of contamination, and therefore it is important to correctly determine the food category the product falls within.
- In the European Union, Regulation (EC) 1881/2006 includes references on relevant TDI (tolerance daily intake) or ADI (acceptable daily intake) based on which maximum levels of contaminants were established for specific food categories and subcategories. The TDIs and ADIs are listed in the Preamble of the Regulation (EC) 1881/2006, as well as sources of information (specific scientific studies done based on risk assessment principles). Maximum levels established by the Customs Union technical regulations are based on scientific research as well, however, since no scientific studies or TDIs/ADIs are referenced within the technical regulations and are not readily available,

in cases where the values of maximum limits differ between the Unions it is difficult to determine the reasons and explanations of the differences.

- Specific MRL values in some cases are the same in the Customs Union and the European Union, and in other cases they differ. For example, with regard to patulin in apples, in the Customs Union the limits are set for apples and *all* product thereof (0.05 mg/kg). In the European Union the MRL on patulin is set for *solid* apple products, including apple compote, apple puree intended for direct consumption at 25 µg/kg (0.025 mg/kg), which is twice lower than in the Customs Union.
- In multiple cases, when in both the European Union and the Customs Union MRLs are established on the same contaminant, their scope covers different products. For example in the case of patulin, the Customs Union MRL in addition to apples covers tomatoes and products thereof; in the EU no MRLs on patulin are established for tomatoes and relevant products.
- In the Customs Union the unit of measure used to express values of maximum levels is mg/kg; (milligrams per kilogram) in the European Union the unit of measure is µg/kg (micrograms per kilogram). Conversion between units is a factor of 1000. However, readers must be attentive to units of measure as this is a significant difference.
- The law of the Customs Union does not establish any specific rules on contaminants, other than the responsibility to observe the MRLs. The European Union law establishes additional requirements on the Community monitoring and reporting, the rights to temporarily suspend MRLs, and specific rules on food that fails to meet MRLs.
- In the Customs Union, most of food products, especially primary products are covered by MRLs on radionuclides. In the European Union radionuclides are not considered a concern, and MRLs apply only to mushrooms imported from certain countries that suffered consequences of Chernobyl nuclear plant disaster.

Since there is a significant number of case-by-case differences between the MRLs established in the Customs Union and the European Union, it is important that business operators and exporters consult relevant legal acts for specific MRL values prior to exporting to the respective markets.

³⁰ Radionuclides in the European Union are only controlled in mushrooms supplied from third countries affected by the consequences of Chernobyl nuclear plant disaster.

Maximum Residue Limits (MRLs) for Residues of Pesticides

The yield of agricultural and horticultural crops can be severely reduced as a result of infestation by pests and diseases. In order to protect crops before and after harvest, plant protection products are used. Plant protection products (this term is commonly used in the European Union), or pesticides (the term is popular in the Customs Union) (insecticides, fungicides, herbicides), are chemical formulations containing an active substance and other ingredients. Active substances are substances or microorganisms including viruses, having general or specific action against harmful organisms and are the essential components of plant protection products.

Plant protection products or pesticides include insecticides, acaricides, herbicides, fungicides, plant growth regulators, rodenticides, biocides, etc. Pesticides are used to kill, repel or control pests; influence the life processes of plants; destroy weeds or prevent their growth; and/or preserve plant products. Pesticides could have severe undesirable effects if they are not strictly regulated. Therefore governments establish maximum residue limits (MRLs) for pesticide residues in food; MRLs are always established for a combination of specific food product and active substance of a pesticide.

Using one active substance many various pesticides can be produced, so the total number of pesticides globally is significantly greater than the number of active substances. MRLs for pesticides are based on their active substances and are established according to scientific studies. The best practice and a recommendation of the Codex Alimentarius Commission is to base such studies within the framework of risk assessment.

ADIs/TDIs and ARfDs are key to indicate safety of a substance. Based on the ADI/TDI, a maximum residue level (MRL) for the substance in the crop is established. The MRL is always lower than ADI or TDI (note that ADI/TDI is set for a kilo of body weight). The MRL cannot be higher than the ADI/TDI as the residue would exceed

amount that can be safely consumed. Where through the toxicity studies it has been established that a substance demonstrates mutagenic (can cause gene mutations), carcinogenic (can cause cancer) or teratogenic (can damage fetus) effect, the substance is not authorized for use. When an ADI or TDI for the substance is established, it is valid for all of the foods containing the substance and does not change between foods. However, the MRL for the substance will differ from food product to food product, because MRLs are established based on exposure and other factors. Instructions on application of pesticides (including how and how much to apply, when to apply, and how many days before the harvest) are designed to ensure that MRLs are met.

It is important to understand that the totality of the requirements on pesticides in general includes three sets of requirements: pesticide approval procedures addressed to manufacturers, suppliers, importers of pesticides; requirements on application of pesticides addressed to farmers or entities involved in production of primary products; and maximum residue limits (as a category of food safety criteria) addressed to all groups including food manufacturers. Requirements on enforcement are usually a part of general official control procedures.

In order to ensure the health and wellbeing of consumers, the Customs Union and the European Union regulate and set limits for pesticide residues in food. The Customs Union combines general horizontal regulation CU TR 021/2011 "On Food Safety"³¹ with product-specific technical regulations. Further, two parts of Chapter II of Uniform Sanitary and Epidemiological and Hygienic Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control) include requirements on pesticides³². The requirements are developed on the basis of the legislation of the Customs Union Member States and effective international law documents. The European Union has a significant number

³¹ Customs Union Technical Regulation 021/2011 "On Food Safety" (for all food products), Annex No. 3. Hygienic Safety Requirements for Food Products.

³² Two parts of Chapter II of Uniform Sanitary and Epidemiological and Hygienic Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control) cover pesticides as well: Part 1. Requirements for safety and nutrition value of food products, Part 15 "Requirements for Pesticides and Agrochemicals", and Part 1 (on food safety and hygiene requirements) of Chapter II of the Unified Sanitary Requirements similar to the technical regulations mentioned above, establishes the requirements as to the presence in food of banned pesticides. Part 15 establishes procedures for the approval of pesticides and MRLs for pesticides. Note that Part 1 does not apply where product-specific technical regulations exist.

of horizontal legislation that relates to approval³³, MRLs³⁴, and use of pesticides³⁵. The use of broad horizontal legislation provides the member states with a common platform creating a harmonized system across the EU. The purpose of the harmonization is to ensure protection of consumers while facilitating internal and external trade, encouraging a reduced use of pesticides and a wider application of good agricultural practices, as well as increasing consumer awareness of the pesticide residues and the possible risk.

From the perspective of the scope, legal acts in both Unions cover a broad range of plant and animal food-stuffs including raw and processed products for which pesticide MRLs are established. In both Unions MRLs are set with respect to the impact on the environment (soil, water and air), their impact on humans at all levels of use including people engaged in application as well as the local surrounding population, and the impact on non-target animals, insects, and plants. The Customs Union only applies the pesticide MRLs to food whereas in the European Union the pesticide MRL requirements also apply to feed. This broader expansion of the legal scope to feed in the European Union is in recognition that segregation of plant products such as grains for application only as feed or food is difficult if not impossible under the current agribusiness

environment, and therefore to ensure the safety of consumers, pesticide regulations shall apply to feed as well^{36,37}.

In order for a pesticide to enter the market place, both Unions have established authorization and MRL determination procedures. At a high level these procedures include similar activities in that the manufacturer must prepare a dossier of information that establishes that the product is functional, includes safety data, actual residue levels in the product as well as in air, water, and soil, and specific product samples for use. This data is then evaluated by appropriate authorities, MRLs are established, and lists of active substances and pesticides are published.

The differences between the Customs Union and the European Union are found in the details.

- In the Customs Union authorization of a pesticide is conducted according to the laws of each member state. While there is a general authorization process established³⁸, each member state authorizing body has the responsibility to follow the laws of their nation. In the European Union there is a common uniform system for authorization for all member states with the risk assessment being carried out by a single agency – the European Food Safety Authority (EFSA).

³³ Evaluation, marketing, use and lists of approved substances: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, and Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Two regulations on implementation, Directive 91/414. Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I, Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC.

³⁴ MRLs: Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, Setting data requirements for active substances: Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Setting data requirements for plant protection products: Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

³⁵ Marketing of plant protection products: Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Sustainable use of pesticides: Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

³⁶ Article 2 of Regulation (EC) No. 396/2005.

³⁷ There are a few exclusions to the application of Article 2 of Regulation (EC) No 396/2005. This Regulation shall not apply to the products where it may be established by appropriate evidence that they are intended for: the manufacture of products other than food or feed; or sowing or planting; or activities authorized by national law for the testing of active substances. Maximum residue levels for pesticides set in accordance with this Regulation shall not apply to products intended for export to third countries and treated before export, where it has been established by appropriate evidence that the third country of destination requires or agrees with that particular treatment in order to prevent the introduction of harmful organisms into its territory.

³⁸ The basic framework and criteria of the safety, toxicological and hygiene assessment are described in Part 15 of Chapter II of the Uniform Sanitary Requirements.

- In the Customs Union the submitted data must include information on the nutrition value and organoleptic properties (in addition to safety data) of food products for which the specific MRL is applicable. The European Union process is focused only on risk to humans, environment, and non-intended organisms, and therefore changes in organoleptic properties are not a part of the assessment and are instead left to the market place to determine their acceptability.
- The risk assessment process in the European Union provides that if a substance is determined to be a carcinogen, mutagen, endocrine disruptor, substances toxic for reproduction or is very persistent, it shall not be approved, unless exposure to humans is negligible. It is unclear if this aspect is a part of the Customs Union risk assessment process for pesticide authorization.
- In the Customs Union the pesticide manufacturer must provide data that establishes the acceptable daily intake (ADI). In the European Union the data must include data that establishes ADI, acute toxicity (AT) with the Acute Reference Dose (ARfD). These require a broader set of analysis and testing by the manufacturer.
- Importantly, clause 5 of Part 15, Chapter II of the Customs Union Uniform Sanitary, Epidemiology and Hygiene Requirements states that “when no MRL for a pesticide in a certain food is established, and/or there is no approved analytical test method for its active substance, such food (crop) cannot be listed as crop for which application of the pesticide is approved.” This places the burden on the manufacturer to submit and gain approval for test methods for the active substance. There are no similar requirements within the European Union in that test methods for active substances can be based on a variety of standards or new test methods as long as they meet the requirements of procedures on establishing analytical methods.
- A key intention of the European Union is to reduce pesticide risks through the use of good agricultural practices (GAP); data for the use of a pesticide is based on its application according to GAP³⁹. Within the Customs Union the manufacturer determines the use and application rates and provides those to the appropriate authorities for consideration, but no reference to GAP is made.
- Both Unions provide lists of active ingredients. In the Customs Union this list contains approved and non-approved substances (e.g., DDT is listed as well) and it is unclear which are approved or not approved⁴⁰. In the European Union lists of active substances and their MRLs are compiled into a database. The database contains a history of each authorization, so pesticide active substances that were once authorized but subsequently lost their authorization, or did not pass the safety assessment can be found there as well, but their status is clearly marked. The EU Commission maintains this database as a web-based portal of pesticides and actives substances⁴¹.
- In the Customs Union, MRLs are set only for those crops, for which a pesticide has been approved. To the contrary, in the European Union, MRLs are set for the crops for which pesticides are approved (in most cases, as a definitive MRL) and for all other crops as default MRLs of 0.01 mg/kg (at the lowest level of analytical determination). This means that in the European Union the number of MRLs is significantly greater which creates stronger basis for monitoring.
- There are significant numbers of case-by-case differences with regard to specific MRL levels as set by the Customs Union and the European Union regulations. There also are differences in ADI levels based on which MRLs are established.

For potential exporters of agricultural products and food to either market it is key to understand and meet the current pesticide MRLs established for the specific commodities. The exporters of agricultural crops need to know which pesticides are authorized at the target market and what are the MRL requirements at the stage of growing or production of other primary agricultural commodities. For those who are involved in agricultural production connected with application of pesticides, it is equally important to get familiar with the national pesticide authorization lists of the Customs Union member states before they begin the production intended for export.

³⁹ Good Agricultural Practices are a collection of principles to apply for on-farm production and post-production processes, resulting in safe and healthy food and non-food agricultural products, while taking into account economic, social and environmental sustainability. They include a range of practices that cover soil, water, crop and fodder production, crop protection, animal production, animal health and welfare, harvest and on-farm processing, energy and waste management, human welfare, health and safety, and wildlife and land use. These are voluntary in the European system and are tailored to the specific type of and size of production.

⁴⁰ Annex 15.1*Hygienic Standards for Concentration of Pesticide Active Substances in Environmental Objects, Food Raw Material and Food, Part 15 Chapter II of the Uniform Sanitary and Epidemiological and Hygienic Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control).

⁴¹ http://ec.europa.eu/sanco_pesticides/public/?event=homepage

Maximum Residue Levels for Residues of Pharmacologically Active Substances

The primary purpose of the legislation on pharmacologically active substances used in veterinary medicinal products is to ensure the protection of consumers against possible harmful effects resulting from exposure to residues of veterinary medicinal products present in foodstuffs. These negative effects can be due to chemical toxicity of some veterinary medicinal products, and most importantly, when antimicrobial substances including antibiotics are used - due to the development of resistance to antibiotics in bacteria. Many antibiotics used on animals are the same as those used in humans. Because bacteria become resistant, it is more difficult to treat human disease with antibiotics.

Generally, antibiotics can be administered to animals (such administering sometimes is referred to as “non-human use”) for two major purposes: for therapeutic reasons, i.e., to treat a disease, and in the form of a feed additive to promote growth. Certain antibiotics, when given in low, sub-therapeutic doses, are known to improve feed conversion efficiency (more output, such as muscle or milk, for a given amount of feed) and/or may promote greater growth, including by affecting gut flora⁴².

According to OIE, over 60 % of human infections are zoonotic in nature⁴³. As established by FAO, WHO and OIE, there is a clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials including antibiotics (antimicrobial resistance (AMR)). These consequences include infections that would not have otherwise occurred, increased frequency of treatment failures (in some cases death) and increased severity of infections. Evidence shows that the amount and pattern of non-human usage of antimicrobials have an impact on the occurrence of resistant bacteria in animals and on food commodities and thereby human exposure to these resistant bacteria. The foodborne route is the

major transmission pathway for resistant bacteria from food animals to humans. The consequences of antimicrobial resistance are particularly severe as pathogens that are resistant to antimicrobials develop and flourish. Antimicrobial resistance is an increasingly serious threat to global public health. AMR develops when a micro-organism (bacteria, fungus, virus or parasite) no longer responds to a drug to which it was originally sensitive. This means that standard treatments no longer work; infections are harder or impossible to control; the risk of the spread of infection to others is increased; illness and hospital stays are prolonged, with added economic and social costs; and the risk of death is greater—in some cases, twice that of patients who have infections caused by non-resistant bacteria. The consequences of antimicrobial resistance are particularly severe when pathogens are resistant to antimicrobials critically important in humans^{44,45}.

The importance of control of pharmacologically active substances is a significant area of emphasis for the Customs Union and the European Union. This is by far the most complex area of comparative analysis and therefore the most difficult. Due to the complexity and significant differences this section will focus on those areas that are the most relevant to the reader. A more detailed analysis can be found in the expanded companion report and its annexes. Further, due to the complexity it is important to note that for business operators wishing to export to one or both of the Unions they must first conduct an in-depth analysis of the requirements of each Union prior to export. For governments it is possible to model one or the other of the Unions but it would be impossible to harmonize the system in such a way that a single set of regulations would meet the requirements of both Unions simultaneously.

The differences begin with how pharmacologically active substances are defined and interpreted within the

⁴² The Merck Veterinary Manual. Growth Promotants and Production Enhancers. Available at: http://www.merckmanuals.com/vet/pharmacology/growth_promotants_and_production_enhancers/antimicrobial_feed_additives.html#v4694978

⁴³ OIE Bulletin. Veterinary and Medicinal products. No.2010-1.

⁴⁴ Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment. Geneva, December 1 – 5, 2003.

⁴⁵ Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment. Geneva, December 1 – 5, 2003.

two Unions. The technical regulations and other legal acts of the Customs Union do not establish any definitions relevant to pharmacologically active substances or their residues or maximum residue levels. The wordings that are commonly used are “veterinary preparations” “residues of veterinary preparations” and “acceptable levels of residues”. When acceptable levels of “residues of veterinary preparations” are established, actually they are established for active substances. In all other cases when requirements refer to veterinary preparations, what is meant is the entire drug which includes inserts and additives (adjuvants), not only its pharmacologically active substance itself. The European Union law clearly defines the terms “residue”⁴⁶, “maximum residue limit”⁴⁷ and “residue of pharmacologically active substance”⁴⁸. In fact, “acceptable level of residue of veterinary preparation” (as used in the Customs Union legal acts) means the same as the term “maximum residue level (MRL) of pharmacologically active substance” as used in the European Union law. However, in all other cases “veterinary preparation” (Customs Union) is not equal to “pharmacologically active substance” (European Union). This becomes important as one conducts an analysis to determine if a specific pharmacologically active substance is allowed in either Union, as the terms cannot be used interchangeably and great care needs to be taken in the reading and determining what is or is not approved.

⁴⁶ Article 2(c), Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. “Residue” means a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health.

⁴⁷ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. “Maximum residue level” means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or µg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food.

⁴⁸ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. “Residues of pharmacologically active substances” means all pharmacologically active substances, expressed in mg/kg or µg/kg on a fresh weight basis, whether active substances, excipients or degradation products, and their metabolites which remain in food obtained from animals.



The problem (AMR) is so serious that it threatens the achievements of modern medicine. A post-antibiotic era— in which common infections and minor injuries can kill—is a very real possibility for the 21st century.

ANTIMICROBIAL RESISTANCE Global
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Each Union has a specific set of regulatory instruments that are used to control pharmacologically active substances, their approval, registration, MRLs, specific uses and publication of their lists. In the Customs Union relevant legal acts are based on horizontal technical regulations⁴⁹, vertical technical regulations⁵⁰ and other legal instruments⁵¹. The Customs Union regulations are augmented by national laws of the member states on issues where the CU regulations are not established. This augmentation applies to authorization and registration procedures for pharmacologically active substances or veterinary preparations, establishment of MRLs, and placing substances to the authorization lists⁵². The Customs Union does not publish a list of *banned or prohibited* substances, however the following general rule applies: when a substance is not authorized then it cannot be used. The Customs Union list⁵³ of *authorized* veterinary preparations is in fact a set of links to the three lists of member states. In addition, member states' national registration lists of veterinary preparations in most cases do not specify active substances for the registered preparations (except for in Russia), which makes it difficult to determine if a specific active substance is approved for use. Finally, in the Customs Union Registration List which consists of the national registration lists of the three member states some active substances can be registered in all three member states, others in only one of them. Thus it is quite possible that

a preparation that is approved in Russia may not be approved in Kazakhstan.

The European Union has established a uniform set of horizontal laws for all 27 member states that covers authorization and supervision of pharmacology active products⁵⁴, MRLs⁵⁵, monitoring⁵⁶ and marketing⁵⁷ of these products as well as a specific ban on antimicrobial growth promoters⁵⁸. Through this uniform set of laws and regulations the European Union ensures free trade among the member states, supports exports, encourages the use of pharmacologically active substance in a manner that minimizes the risk of their presence through reduced use, promotes application under good agricultural practices and consumer awareness of the pharmacology active substances and the possible risk they pose.

In the Customs Union the requirements on presence of residues of pharmacologically active substances are established for both raw material and processed ready-to-eat food of animal origin, including meat and products thereof, milk and dairy products, eggs and products thereof, fish and products thereof, and honey. Additionally, requirements are established for presences of certain substances in food for babies and children, and food for pregnant and nursing women. In the Customs Union requirements on residues are established for two

⁴⁹ Customs Union Technical Regulation 021/2011 "On Food Safety" (for all food products).

⁵⁰ Custom Union Technical Regulation CU TR 034/2011 "On Safety of Meat and Meat Products".

⁵¹ Part 2 of Chapter II of the Uniform Sanitary, Epidemiology and Hygiene Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control) sets maximum residues levels (MRLs) of pharmacologically active substances.

⁵² Uniform Sanitary, Epidemiology and Hygiene Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control) establish a general requirement on putting together a single (uniform) list of therapeutic substances used in veterinary medicine, however it does not specify what minimum information shall be included into the list, or how it shall be maintained; the member states hold their national authorization lists according to their national procedures.

⁵³ Ibid.

⁵⁴ Regulation (EC) No 726/2004 that repealed Regulation (EEC) No 2309/935 lays down a Community procedure for the authorization and supervision of medicinal products for human and veterinary use and establishes a European Medicines Agency.

⁵⁵ Maximum residues levels in the foodstuffs of animal origin are established by Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue levels in foodstuffs of animal origin.

The establishment of the MRLs is conducted according to Regulation (EC) No 470/2009 on establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.

⁵⁶ Monitoring of presences of prohibited substances, including antimicrobial growth promoters, steroids, hormones is performed based on Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

⁵⁷ The basic rules governing the marketing of veterinary medicinal products within the European Union are set by the codified Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

⁵⁸ A separate set of regulations establishes a ban on antimicrobials (antibiotics) that are used as growth promoters. Until the ban, they were used by adding them to animal feed. The ban was introduced gradually until they were phased out completely by Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

types of active substances. The first group includes several antibiotics such as laevomycetin, tetracycline group, streptomycin, penicillin that are controlled in all raw material and food products, including processed ready-to-eat food (e.g., sausages, cheeses) of animal origin, whether it is produced inside the Customs Union or imported to its territory. For these antibiotics threshold levels are established at the level of analytical determination below which their residues are not allowed (and can not be found). The second group of substances covers active substances that are controlled for imported raw materials and animal products at the point of entry to the Customs Union and upon their supply for processing, and only if a manufacture or supplier declares that they were used on food producing animals. According to the rules of entry into force of CU TR 034/2013 "On safety of meat and meat products", MRLs on such substances enter into force when a list of regional standards that establish testing methods is compiled and published to support CU TR 034/2013. The list of standards has been published already, but at the time of writing it does not include specific testing methods.

In the European Union, there is a single list of MRLs established for active substances, which are controlled both in the products of animal origin produced within the European Union and imported from third countries regardless of whether they are intended to be marketed as such or are supplied for further processing.

In order to provide some insight into the complexity of rules on the use of pharmacologically active substances and their MRLs, below is a comparative summary between the Customs Union and the European Union rules for the substances (antibiotics) that in the Customs Union are controlled in all food products of animal origin, as well as substances that are not authorized in the EU but are registered in the CU (Table 3). This is only a non-exhaustive summary but it will give the reader some idea of the complexity of the area as well as the need to conduct a detailed analysis prior to exporting to either of the trading blocks. One should also be aware that there are certain discrepancies within technical regulations of the Customs Union (they can be found in the main report).

As was mentioned, within the Customs Union there is differentiation in the control of pharmacologically active substances. There is a general group that is controlled for all products (see above) and another group of substances controlled on the basis of information on their



Laevomycetin (Chloramphenicol) is a potent, broad spectrum antibiotic drug that is used to treat a variety of diseases in animals. It is authorized only for use in Russia in animals for dairy and meat and is not on the authorized lists for Belarus or Kazakhstan.



Table 3**Comparison of Pharmacologically Active Substances that are controlled in the Customs Union in all food products of animal origin, with the European Union**

Pharmacologically active substance	Customs Union	European Union	Comments
Laevomycetin (Chloramphenicol)	Registered only in Russia	Prohibited	In the Customs Union not allowed in all products at the level of analytical determination (LAD) <0.01 mg/kg (CU 021/2011); in meat and meat products at LAD <0.0003; and in milk and dairy products at LAD <0.0003 starting from 01.07.2015. In EU no MRL is established because the substance is prohibited.
Tetracycline group	Registered in all member states	Authorized	In the Customs Union the threshold above which the residues are not allowed is <0.01 mg/kg. In the European Union MRL for milk and meat is 0.1 mg/kg.
Penicillin and derivatives	Registered	Authorized	In the Customs Union residue of penicillin is not allowed at the level of analytical determination of < 0,004 in milk (CU 021/2011); for meat and meat products MRLs are set for residues of each specific derivative (CU 034/2013). In EU MRLs are set for residues of each specific derivative in milk and meat
Grizin	Registration is unclear; presumably not registered in any of the member states	Prohibited	The substance is not registered in the Customs Union member states (unless it is registered under a trade name), however, in the Customs Union the residues are not allowed at <0.05 mg/kg in meat and poultry and product thereof. In EU no MRL is established because the substance is prohibited.
Dapsone, Ronidazole, Dimetridazole, Nitrofurans (including furazolidone), Metronidazole	Registered	Prohibited	All substances except Dapsone registered at least in one Customs Union member states, and a threshold at LAD of <0.1mg/kg is established. In EU no MRL is established because the substance is prohibited.
Clotrimazole, Aminotrizole (aminotrozole):	Registration unclear; presumably not registered in any of the member states	Prohibited	Not registered in the members states of the Customs Union (unless under a different trade name), and a threshold is established (not allowed at LAD <0.1mg/kg). In EU no MRL is established because the substances are not listed. Non-listing means no safety assessment has been done
Bacitracin	Registered only in Russia	Banned as a growth promoter; Authorized as a therapeutic drug with the restrictions for lactating cows and also on rabbits	In the Customs Union not allowed in all meat (including poultry), and products thereof at <0.02. In the European Union no MRL is established because the authorized use is strictly restricted

use provided by the manufacturer (supplier) of slaughter products at the time when they are imported into the customs territory of the Customs Union or supplied for processing.

The differences with regard to MRLs exist with approximately 20% of substances listed in the two Customs Union lists⁵⁹ and the European Union MRLs list⁶⁰.

The Customs Union MRLs are generally harmonized with European Union MRLs on **therapeutic substances** (Regulation (EU) 37/2010) with some exceptions, and with European Union MRLs on unavoidable **carry-over residues** of pharmacologically active substances used as **feed additives** in **non-target** animals (Regulation (EC) 124/2009⁶¹), but they are **not** harmonized with the European Union MRLs on pharmacologically active substances used as feed additives in **target animals** (in EU the MRLs for target animals are established in individual regulations approving each feed additive). The EU feed additives MRLs with which the Customs Union list is not harmonized, in all cases refer to different types of poultry and rabbits as target species. There are multiple instances of such differences where it comes to MRLs in meat, including poultry meat, and a few in case of MRLs in milk.

In most cases where differences exist between the Customs Union and the European Union in MRL **values**, MRLs of the Customs Union are stricter. This is due to the fact that the Customs Union MRLs are harmonized with European Union MRLs on unavoidable carry-over residues of feed additives in **non-target** animals which are much lower than MRLs in target animals (this is because when a feed additive is not intended for a certain species, it can only get into the non-target animals through cross-contaminated feed; when a feed additive is intended for a species, the animals consume much bigger amounts of the substance as it is directly given to them)⁶². Generally, it means that in such cases products that comply with the Customs Union MRL criteria, will meet the European Union criteria as well. However, this also may mean that in reality some feed additives cannot be used for poultry intended to be sold at the Customs

Union market, because it would not be possible to meet the Customs Union MRLs (as MRLs for non-target species extend to poultry).

In some cases European Union MRLs have broader scope (cover a wider range of animal species) than MRLs for corresponding substances in the Customs Union, or additional MRLs are set for certain animal species. These differences exist on a case-by-case basis.

In the cases where the differences are related to **authorizations** of active substances, the EU requirements are stricter than in the Customs Union: several substances that are registered in the Customs Union member states are prohibited in the European Union. Additionally, many substances authorized in the European Union have restrictions on their use, for example cannot be used on egg or milk producing animals.

Within the group of substances controlled in the Customs Union in case where the manufacturer (supplier) of slaughter products declares their use during importation or supplying for processing), the differences exist with regard to the following substances.

Meat, including poultry meat:

- Differences between the Customs Union and European Union in MRLs for meat (muscle) of all food producing animal species, including poultry as relevant, with regard to the following substances: apramycin (aminoglycosides), sarafloxacin (quinolones), monensin, lasalocid (ionophores), nitrofurans (including furazolidone), metronidazole/dimetridazole, flavomycin (streptotricyn), diclazuril, nicarbazin, amprolium, robenidine, narasin, salinomycin, halofuginone, decoquinate. Differences relate to authorizations, MRL values and MRL scopes in terms of animal species covered.
- Many pharmacologically active substances listed in the European Union are authorized with restrictions on use; for example they cannot be used on animals that produce milk or eggs for human consumption (Apramycin (aminoglycosides), Paromomycin (aminoglycosides),

⁵⁹ CU TR 034/2013 and Uniform Sanitary, Epidemiology and Hygiene Requirements (for the Customs Union).

⁶⁰ Commission Regulation (EU) 37/2010 on MRLs of pharmacologically active substances in food.

⁶¹ Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed.

⁶² The European Union MRLs on carry-over residues of feed additives in non-target animals are based on assumption that not more than 3% of feed is unintentionally cross-contaminated with the residues.

Kanamycin (aminoglycosides), Spectinomycin (aminoglycosides) all substances of sulfanilamide group (sulfanilamides), trimethoprim (diaminopyrimidin derivatives), thiamphenicol (florfenicols), florfenicol (florfenicols), flumequine (quinolones), ciprofloxacin / Enrofloxacin / pefloxacin / ofloxacin / norfloxacin (fluoroquinolones), sarafloxacin (quinolones), danofloxacin (quinolones), difloxacin (quinolones), oxolinic acid (quinolones), spiramycin (macrolides), tilmicosin (macrolides), tylvalosin (macrolides), avilamycin, doxycyclin (tetracyclines), benzylpenicillin / penethamate (penicillin group), Ampicillin (penicillin group), amoxicillin (penicillin group), cloxacillin (penicillins), dicloxacillin (penicillins), oxacillin (penicillins), diclazuril, toltrazuril.

Milk:

- Lasalocid (ionophores), nitrofurans (including furazolidone), metronidazole/dimetridazole, flavomycin (streptotricyn), diclazuril. Differences relate authorizations and MRL scopes in terms of animal species covered.
- Some pharmacologically active substances listed in the European Union are authorized with restrictions on use.

Producers/importers targeting the Customs Union market as well the European Union market must ensure that their products comply with MRLs established for pharmacologically active substances of therapeutic medicines and feed additives. To achieve this, it is important to check the MRL in the Customs Union technical regulations, check the registration status of a veterinary preparation in the State Registration lists of the Customs Union member states, check if the substance is included into any of the two MRL lists of the European Union, check if the substance is approved in the European Union as a feed additive, and find an MRL of the substance for tissues/products of the target animal(s). Checking relevant provisions of the Customs Union and the European Union legal acts is especially important for producers of poultry meat, as differences between the CU and EU are multiple and significant. Depending on the target export market producers may change their strategy of rearing the poultry intended for export and decide not to use therapeutic drugs and feed additives as a part of the rearing regime.

Approaches to Laboratory Control, Sampling and Testing

The ability to provide safe food domestically and with trading partners is a shared responsibility of governments and industry. In order to deliver on this commitment, governments and industry must have the ability to conduct specific measurements to demonstrate that the systems and procedures of food control deliver a safe products. These measurements range from such things as weight and fat content, to quantity of additives or nutrients added to a product, to the ability to measure and determine quantities of pathogens, mycotoxins, heavy metals, pesticides, and pharmacologically active substances. The ability to conduct repeatable, valid, and accurate measurements is dependent upon laboratory controls, sampling and testing.

The Customs Union and the European Union have established defined sampling and testing regimes for

products as well as roles and responsibilities, and accreditation of laboratories within their respective legal frameworks⁶³. Yet the focus of the two regimes is quite different. Within the Customs Union testing, sampling and laboratories are a part of the overall conformity assessment process whose end-product is ensuring food safety through documents establishing conformity to the technical regulations. In the European Union the food safety system is designed on a risk-based process approach to ensuring food safety through preventive measures at all levels in the food chain from farm-to-fork. To this end, in the European Union laboratories, testing and sampling provide an integral role in the establishment and monitoring of risks throughout the process of official control. It is through the combination of establishing risks, controlling and monitoring these risks that the European Union ensures the safety of its food

⁶³ Customs Union Technical Regulation CU TR 021/2011 "On Food Safety". Decision No 27 of 11 December 2009 CU agreements in the field of technical regulation further defines requirements for mutual recognition. Decision 834 of 18 October 2011 on the Regulation on the common procedure of joint inspections of objects and sampling of goods (products) subject to veterinary control Section X, line 133. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Title II Official Controls by Members States Article 12(1).

and agricultural products. Further, the European Union incorporates enabling trade outside of the European Union as a key element of their food safety program, and therefore laboratories have a significant role in the global community. In order to enable trade, laboratories are mandated to provide training and support specifically to developing economies to ensure that the governments and industry have access to the proper tools to ensure the safety of products entering the European Union⁶⁴.

The differences in approaches to food control between the Customs Union and the European Union creates specific differences between the Unions with respect to laboratories, sampling, and testing.

Within the context of laboratory control there are several differences that should be highlighted.

- One of the keys to having a successful laboratory program is to ensure that the laboratory maintains a quality system and the technical competencies in order to conduct the appropriate tests. Within the Customs Union laboratories are accredited by the appropriate National body based on the national standards⁶⁵. In this case the accreditation is at the sole discretion of the National Accreditation Body. In the case of the European Union laboratories also have to be accredited by a third party. The European Union has established that laboratories must be accredited to the ISO 17025⁶⁶ standard by a body that is internationally recognized, and it is not required that the national standards body provide the accreditation. Instead accreditation of the laboratory can be done by any body or organization internationally recognized to carry accreditations to ISO 17011⁶⁷. In this way, laboratories within the 27 member states of the European Union are held to the same uniform standard.

- Within the Customs Union it is expected that each country have the capacity and capability to provide the necessary laboratories required for all tests. As laboratories are expected to support the conformity assessment process testing includes product attributes such as weight, color, acidity as well as key food safety parameters such as microbial, heavy metals, pesticide residues, and pharmacologically active substances. This creates a significant burden on the countries both in terms of financial as well as technical resources⁶⁸. In the European Union countries can leverage resources or use laboratories of other countries within the European Union. In this way, member states can share the financial and human resource burden of laboratory control and thus reduce the costs for each of the member states.
- Within the Customs Union it is implied but not specifically stated that National reference laboratories should be established. Within the European Union reference laboratories are specifically established and funded⁶⁹. These range from laboratories on food additives, GMO, BSE, melamine in milk and dairy products, to *Salmonella* and pesticide residues⁷⁰. Each of these laboratories plays a critical role in the food control program in the European Union and globally as they are established as global reference laboratories for many countries outside of the European Union. In this global role they develop new test methods, provide support to countries throughout the world in key technical areas, provide key support globally for disease outbreaks, and provide training and knowledge transfer for laboratories in emerging markets as a way to help improve the laboratory capacity globally. During the Highly Pathogenic Avian Influenza outbreaks Weybridge laboratory in the United Kingdom provided critical support to countries throughout the world as initially they were 1 of only 3 laboratories globally that could test for this disease.

⁶⁴ Regulation (EC) No. 178/2002, Commission decision of 12 August 2002 Regulation (EC) No 852/2004, implementing Council directive 96/23/EC, Regulation (EC) No 882/2004, Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation (EC) No 854/2004.

⁶⁵ Each of the members of the Customs Union has adopted a national standard for laboratory accreditation based on ISO 17025. Russian Federation GOST-R 17025, Belarus STB ISO / IEC 17025-2007, and Kazakhstan ST RK ISO/IEC 17025-2007.

⁶⁶ ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories".

⁶⁷ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Article 12.

⁶⁸ Based on work completed by T&M Associates globally.

⁶⁹ Regulation (EC) No 882/2004 Title III Article 32, Community Reference Laboratories.

⁷⁰ To find specific reference laboratories within the European Union check the link http://ec.europa.eu/food/food/controls/reference_laboratories/index_en.htm.

The need for adequate sampling is fully recognized and codified by the Customs Union⁷¹ and European Union⁷² but sampling is not the same within the Unions.

- Within the legal framework of the Customs Union sampling is a part of the conformity assessment process. Sampling is done to ensure the product meets the requisite technical regulations. Under the technical regulations, specific GOST standards and national standards of the member states, sampling is carried out to support the issuance of conformity documents. As such, samples are used to validate a variety of parameters including pathogens, residues of pesticides, veterinary medicines, heavy metals, radionuclides, mycotoxins. While the need for sampling is defined in the Customs Union technical regulations, the procedure of sampling, or in other words how the samples are to be taken, by whom, what tools are to be used, sample size, the use of composite size, product sampling plans, etc. are not defined in the corresponding GOST and national standards. This can create significant differences between the test results not only from laboratory to laboratory but also from product sample to product sample.
- Within the European Union sampling is linked to testing as it is recognized that the act of sampling is the single largest contributor to the reliability and accuracy of the test results. The European Union is very specific as to by whom samples are taken, what tools are used, how many samples, the preparation of composite samples to provide

a representative sample of the totality of the material. Sampling techniques, labeling, transportation are clearly defined and take into account the difference between samples of animal, plant and mixed origin as well as the state of the material (liquid or solid). The European Union is specific as to how results from the corresponding testing are reported including uncertainty and determining compliance. Sampling procedure takes into account the specific target that is to be tested and the impact that temperature will have on the sample. Further, sampling is conducted at all levels of the food chain domestically and for imports based on risk using well defined sampling process and procedures. Samples are taken to examine products for pathogenic microorganisms⁷³ including specific pathogens⁷⁴, pesticide residues⁷⁵, mycotoxins⁷⁶, heavy metals⁷⁷, nitrates⁷⁸, pharmacologically active substances⁷⁹, and pathogens⁸⁰.

- In the Customs Union sampling for domestic and imported products is in fact conducted at the sole discretion of the inspector. Within the European Union sampling is performed to ensure that the controls under the HACCP program are effective. Inspectors take samples based on risks, sampling is done according to a unified set of sampling plans and procedures to ensure that samples are consistent and uniform.
- In the Customs Union national sampling plans are not applied as the Union does not use risk-based approach as a basis for ensuring safe food. The European Union legislation provides for Community sampling plans that are tied to the

⁷¹In the Customs Union there are two primary legal acts that provide the legal basis for sampling: technical regulation of the Customs Union CU TR 021/2011 "On Food Safety", and Regulation on Common Procedure of Joint Inspections of Objects and Sampling of Goods (Products) subject to veterinary control (surveillance) (approved by Decision of the Customs Union Commission No. 834 of 18 October 2011). In addition, Regulation on a Procedure of State Sanitary-and-Epidemiologic Supervision (control) Over Persons, Vehicles, and Goods Crossing Customs Border of Customs Union (approved by Decision of the Customs Union Commission № 299 of May 28, 2010) provides the legal basis for sampling at borders.

⁷²Regulation (EC) No 882/2004, Article 10 establishes that sampling is a part of the official control activities and provides the legal basis for sampling.

⁷³Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, Article 3.

⁷⁴See, for example, Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*, Version 3 – 20/08/2012, European Union Reference Laboratory for *Listeria monocytogenes* (EURL Lm).

⁷⁵Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.

⁷⁶Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

⁷⁷Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

⁷⁸Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.

⁷⁹Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products.

⁸⁰Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs Chapter 3.

risks. Each year thousands of samples are taken and analyzed that are focused on understanding the risks of specific substances and general categories of substances.

- The European Union recognizes that over time, taking into account progress in science, technology and methodology, emerging and/or new target biological or chemical hazards and information from risk assessments, there may be a need for review, and therefore the EU has a process for amending requirements.

Laboratory analysis which is the ability to identify and measure constituents of a foodstuff or feedstuff is critical to ensuring safe food. It is the analysis which provides the basis by which declarations of conformity for food products are issued in the Customs Union. In the European Union laboratory analysis provides the information that is needed to ensure that risk-based food control processes and systems are effective and deliver safe food. Testing and analysis are highly interdependent upon laboratories and sampling, as without properly equipped and capable laboratories, or proper and effective sampling, testing cannot provide the reliable, reproducible, verifiable and accurate results required to meet their mission.

The Customs Union⁸¹ and the European Union⁸² have an established legal basis for testing and analysis as part of their food control program. In the Customs Union testing (like sampling, as described above) is established as part of the conformity assessment process. In the European Union analysis/testing is clearly established as part of the overall food control system. Further, the European Union establishes that analysis methods shall comply first with Community rules, second with internationally accepted protocols, and third with methods that are developed in compliance with scientific protocols, thus providing flexibility to develop new test methods as needed in the future.

The most significant difference in testing between the Customs Union and the European Union is in the approach to test methods.

- Within the Customs Union test methods and specific requirements to testing are codified in the approved lists to support each technical regulation and are established in GOST standards (or other national standards that are approved regionally within the Customs Union). While this does create a degree of uniformity, it also limits the laboratories to use only specific approved methods. This limits or precludes the use of alternative testing methods or new technology and therefore constrains the laboratories in their work as they cannot use new methods which have been developed and validated by others.
- The European Union and its predecessor the EEC recognized that testing and the results that are obtained can have a critical impact on the economies of the Union members. As such they began a program to harmonize testing. But the European Union does not harmonize test methods themselves instead they developed a set of criteria by which test methods are to be established. So long as a test method meets the specified criteria the method is considered to be valid as are the results and therefore they are accepted across the European Union. This gives the laboratories the freedom to use a variety of methods, take advantage of new technologies for testing, and provide the European Union with the ability to adapt over time to emerging new risks. Further, the European Union sets rules for reporting results that include the use of uncertainty and measurement error and in this way can communicate the precision of the measurement. It is also required that validation of methods is carried out, including the use of multi-laboratory testing to establish uncertainty and validity of the methods.

⁸¹ Customs Union Technical Regulation CU TR 021/2011 "On safety of food products", Articles 5 and 20 "Rules of Circulation on the Market".

⁸² Regulation (EC) No 882/2004 of the European Union line 12 and Article 11.

Important Notes for Governments, Policy Makers and Businesses

The Customs Union and the European Union have established rigorous controls over safety of food placed on their markets. They in general achieve objectives of food safety, but through fundamentally different approaches and therefore very different legal frameworks, regulations, systems and procedures. The major differences relate to the following:

Final product testing and conformity assessment in contrast to prevention through a wide application of risk-based food safety systems (HACCP)

The food safety criteria of the Customs Union are designed in a way that they are focused on testing of the final products for compliance with multiple regulatory requirements. The food safety criteria cover all food-stuffs and a lot of potential hazards with both high and low risk of occurrence, as well as agents in food that are not hazards per se, but can indicate the probability of the hazard occurrence. While in the Customs Union HACCP principles are a part of regulations as well, they in fact are integrated into the conformity assessment activity at a very limited level. The European approach to food safety criteria, to the contrary, relies more on hazard prevention through HACCP, and testing requirements are established for only those hazards that are significant for safety of a particular product. As a consequence the food testing in European Union is more targeted, and the number of tests is reduced.

Responsibility

The Customs Union technical regulations set exhaustive food safety criteria, and a manufacturer must ensure that the food he produces meets them. In the European Union, it is a responsibility of a food business operator to identify additional relevant food safety criteria beyond those established by regulations, and to develop control for them under a HACCP-based program. Further, with regard to some of the food safety criteria, in particular, microbiological criteria, it is also a right of a food safety authority to test the food for additional criteria in case of a food safety concern.

Transparency

All food safety criteria should be based on sound scientific grounds. The Customs Union and the European Union have scientific framework applied for setting specific requirements. However, in the Customs Union the source of specific provisions is the law of the member states, and scientific justifications are not publically available. In the European Union decisions on establishing food safety criteria are taken at the Community level and are transparent, including public availability of scientific justification for each criteria.

For each group of hazards, for which food safety criteria have been set, there are similarities and differences. The differences are summarized below.

Microbiological Criteria:

- Some of the microorganisms for which food is tested, are different between the Customs Union and the European Union.
- In the Customs Union, to a much greater extent the focus is made on testing for indicative microorganisms; in the European Union, microbiological safety criteria are established for pathogens.
- The microbiological requirements of the Customs Union are focused on testing of the product before it is put into circulation. The European Union law has established microbiological criteria to test for safety of products placed on the market during their shelf-life, and process hygiene criteria to test for acceptability of production techniques and processes.
- In some limited number of cases according to the Customs Union technical regulations microbiological criteria are used for the purposes of product identification.
- Some differences exist in sampling procedures.
- Some differences relate to technical aspects, for example with regard to units of measure.
- The European Union has a special approach to control of *Listeria monocetogenes* in ready-to eat food; this approach is not applied in the Customs Union
- The values of microbiological criteria differ in some cases.

Maximum Residues Levels for Residues of Pharmacologically Active Substances:

- There are significant procedural differences with regard to registration and approval of veterinary drugs and establishing MRLs for pharmacologically active substances between the Customs Union and the European Union.
- In the Customs Union, safety data and evaluation summaries for the approved substances are not in the public domain. In the European Union such information is publically available.
- There are significant differences with regard to prohibited substances and control of their residues in food of animal origin between the Customs Union and European Union.
- In the Customs Union, a limited number of pharmacologically active substances are controlled in all food of animal origin as part of conformity assessment, and the majority are controlled in raw material according to information of their use upon entry into the Customs Union or upon supply for processing. In the European Union, all pharmacologically active substances are controlled uniformly regardless the product is produced locally or imported.
- The majority of MRLs in the Customs Union are harmonized with the European Union MRLs established for pharmacologically active substances of **therapeutic** drugs, and MRLs for unintentional carry-over of pharmacologically active substances used in **feed additives** into **non-target animals** through cross-contaminated feed. However, the Customs Union MRLs differ significantly from EU MRLs with regard to pharmacologically active substances used in feed additives for **target** animal species. This creates a situation where in the Customs Union the MRL values are significantly lower in many cases versus the European Union. This in practice can make it impossible to use certain feed additives during production of certain animal species (in most cases poultry/broiler meat) when they are intended for the Customs Union market.
- There are significant differences between the Customs Union and European Union in MRLs for poultry meat and only few differences in MRLs for milk.
- When determining which MRL applies to your product, a special attention should be paid to the scope of MRLs established by relevant legal acts of both the EU and the Customs Union (in terms of animal species covered and target organs/products).

Contaminants:

- Generally, the Customs Union legal acts establish a much wider list of contaminants than European Union; there also is a difference in the products covered by maximum levels (MLs): in the Customs Union MLs on contaminants are set for almost all foodstuffs; while in the European Union this list is quite large but it does not cover all food.
- The most significant differences in specific contaminants for which MRLs are established is radionuclides. Radionuclides are controlled in a wide range of food products in the Customs Union, but only mushrooms from certain countries are controlled for radionuclides in the European Union.
- There are case-by-case differences between specific MRLs established in the Customs Union and European Union regulations.
- The Customs Union does not establish additional procedures on contaminants addressed to the Member States. In the European Union law additional procedures are established for example, community monitoring and reporting.

Plant Protection Products (Pesticides):

- Pesticide MRLs in the Customs Union only cover food. In the European Union they also cover feed as it is recognized that segregation of feed such as grains between those intended for humans and for animals is not possible under the current agribusiness regime.
- There are differences in authorization procedures and setting of MRLs. In the Customs Union this is done according to the procedures of member states and in the European Union according to a multi-stage procedure that includes both the member state and the Community level.
- Scientific justification for pesticide MRLs are publically available in the European Union and are not available in the Customs Union.
- For food products for which MRLs are established the most important difference is that in the Customs Union MRLs are set only for those crops, for which a pesticide has been approved. In the European Union, MRLs are set for the crops for which pesticides are approved as specific MRLs and for all other crops and primary products (including of animal origin) as default MRLs of 0.01 mg/kg (at the lowest level of analytical determination). This means that in the European

Union the number of MRLs is significantly greater, which creates stronger basis for monitoring.

- There are case-by-case differences with regard to specific MRL levels as set by the Customs Union and European Union regulations. There also are differences in ADI levels (toxicological parameter of acceptable daily intake) based on which MRLs are established, which means that scientific data used to establish MRLs is not similar. For potential exporters of agricultural products and food to either market the most important is to be aware of the current pesticide MRLs established for their commodities.

In general, the European Union framework for the control of microbiological and chemical hazards in food is more risk-based. The differences listed above should make a potential food exporter ready for extensive testing for microbiological and chemical safety criteria when the products are intended for the market of the Customs Union. The positive side to this is that the testing will be limited only to those microorganisms specified in the applicable technical regulations or relevant standards. Those who present their product to the European Union market should be ready for testing as well, which will, most likely, be limited to a smaller number of microorganisms and substances, but in most cases will be done according to statistically more stringent rules.

Because of the nature of some hazards, in particular, pharmacologically active substances and plant protection products, and the fact that they are deliberately used, it is important to know the requirements of the target market before the production of food begins, as the level of their residues is a direct consequence of the conditions of use. In some cases, producers will have to revise production strategies and refuse from using some substances (for example, certain feed additives or pesticides).

In the either case, it is important to understand the differences in the approaches between the two systems, know how to read the regulations correctly and how to interpret them, and refer to specific criteria in each particular case.

With respect to laboratories, sampling and testing (analysis) there are significant difference between the Customs Union and the European Union approaches. Fundamentally this is due to the differences in approaches to ensuring food safety. The Customs Union approach of control of food safety based on conformity

assessment and issuance or declarations of conformity regards laboratories, sampling, and testing as the most important tool to determine conformity. Further, the Customs Union provides limited specificity as to how laboratories are to operate and what competencies are required. Similarly sampling is limited in specificity as to how many samples are taken, where the product is sampled, what tools the product is sampled with. The Customs Union does not describe how many samples are to be taken depending on the nature of the sample, the matrix of the sample, or the state of the sample. Sampling and testing is determined by a series of vertical product-specific standards comprised of GOST and national standards of member states. Since the Customs Union does not have a full-fledged risk-based system, it does not have all-union risk-based sampling plans nor does it have detailed harmonized methods for sampling. Official laboratories in general operate within national ISO 17025 accreditation system but in many cases are not accredited internationally.

As the European Union's food control system is based on a risk-based approach, laboratories, sampling and testing play a far greater role in the overall program. The European Union has a much greater degree of specificity in roles and responsibilities for laboratories and uses ISO 17025 as the core of the accreditation system for food laboratories creating a transparent framework based on international standards for accreditation. Further, laboratories are expected to provide additional support to the community in terms of their role in food safety. They are expected to support the inspection agencies, provide support in times of disease outbreak, develop new standards and train laboratory personnel in developing markets as a way to help ensure the safety of the food stuffs imported from abroad.

In the case of sampling the European Union is highly specific. The European Union clearly defines sampling plans, techniques, tools, labeling, and transportation in the regulations. The regulations describe how sampling is conducted for different types of targets and food matrixes. The regulations describe considerations dealing with transportation and sample integrity, traceability, and sampling precautions. The European Regulations take into consideration that sampling and testing will change over time based on new technologies, information and risks and have a process to amend and adapt existing regulations to ensure they are kept relevant and current with the risks. The European Union has a keen understanding that in order to compare results across the

27 member states it is necessary that they have common definitions and a clear understanding of what is intended and meant by key terms related to sampling and have projects specifically to ensure that harmonization occurs.

For governments wishing to harmonize their laws and regulations to both Unions the stark differences in approach make this fundamentally impractical if not impossible. The approaches dictate the functions and therefore as they are so different it would be impossible to harmonize to both. With regards to laboratories, sampling and testing the European Union provides possible examples of how government may want to approach these three areas.

Laboratory accreditation to ISO 17,025 by a body that is internationally recognized to grant ISO 17011 accreditations would help ensure that the results from said laboratories would be internationally accepted, and provide the support required to ensure the safety of the food products domestically and internationally.

Further, the approach the European Union has established in allowing their member states to recognize laboratories in other member states as part of their control program allows countries to save significant financial resources in that it reduces the burden of having a broad range of underutilized and expensive laboratory capacity within their countries as they can leverage the capacity in another country.

In the area of sampling and sampling protocols the European Union has a well-established set of procedures

that provide the specificity needed to reproduce the results. These can easily become the basis from which a country can rapidly develop appropriate sample protocols for a range of products.

In the area of testing the European Union policy of allowing countries to use specific methods as long as they conform to a set of criteria allows for the flexibility that a country needs in order to provide the appropriate tests to ensure food safety. It is not always necessary to have the latest expensive and difficult-to-operate equipment (e.g., PCR⁸³) when a simple plate test is just as acceptable and at a significantly lower cost. The flexibility the European Union has within its legal framework allows for this.

For business operators and exporters the difference between the European Union and the Customs Union approaches to food safety criteria will require that they be knowledgeable in the requirements of whichever market they choose to export into. In addition, business operators and exporters will need to ensure that to whichever Union they export to if they have samples tested prior to shipment they must ensure that the samples have been taken in the appropriate manner consistent with the respective requirements. They will also need to ensure that the tests that are performed meet the specific testing requirements of the market they are exporting to, and that the laboratory that conducts the testing has the systems and processes in place to ensure the quality of the results; moreover, in case of export to the Customs Union, only authorized laboratories located in the Customs Union can be used.

⁸³ Polymerase chain reaction (PCR) is a molecular biology technique used to amplify a single copy or a few copies of a piece of DNA across several orders of magnitude.

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