ON HARMONIZATION OF THE CUSTOMS UNION AND EUROPEAN UNION REGULATIONS ON FOOD ADDITIVES SAFETY

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Abstract

The approximation of the Customs Union (CU) and the European Union (EU) Technical Regulations will remove barriers to trade, improve food safety and reduce risks for food manufacturers and their countries.

An analysis of EU and CU laws in terms of technical regulation on food additives and flavours in the internal and foreign markets was done. In particular there were compared EU regulatory requirements N: 1331, 1332, 1333, 1334 of 16.12.2008 and N 231/2012 of 09.03.2012, CU regulatory requirements N 021/2012, 022/2012, 029/2012 and other legislative acts.

The current legislation on Technical regulations in the territory of the CU and EU economic space covers practically all problems on the safety of food manufacturing and production flow (food additives, flavours, enzymes, processing aids, raw materials and other ingredients) in the internal markets as well as crossing third countries borders. The following aspects contribute to this process: terminology harmonization (~80%) in respect of food ingredients, list of food additives, flavouring and biologically active substances used in food products permitted in the CU and EU countries (~80 - 90%), list of requirements on their content in food products (~80%), requirements on genetically modified food sources (GMO and GMS). A further work shall be done to actualize above documents, simplify barriers to trade, products classification harmonization, reach uniformity for product measurement parameters.

An important and useful work on the legislation on Technical regulations and harmonization of food manufacturing and production flow order in the market of food additives, flavours, processing aids and other ingredients was done by the CU and EU governments and commissions. It will help to remove a number of barriers to trade between the CU and EU.

Key words: Technical Regulation, Food additives, Flavours, Processing aids.

1. Introduction

A considerable amount of foodstuffs, raw materials and ingredients from the European Union (EU) circulates on the markets of the Russian Federation and the Customs Union (CU) Member Countries. Apart of the Customs Legislation, a number of Customs Union Technical Regulations (CU TR) control food safety in the CU common economic space. Regulation CU TR No 029/2012 Safety requirements for food additives, flavourings and processing aids is one of the principal guidance documents [1]. In the EC four regulations and a wide range of amendments reveal such aspects and provisions [2-5].

The CU regulations were entered into force in order to remove trade barriers, create clear rules for market operators and to minimize risks of food safety. That is why the authors of the CU TR No 029/2012 and other CU regulations had to harmonies these documents with the European and International legislation for safety in production, market access and circulation of such products as high as possible.

This article gives a comparative analysis of the main regulatory requirements and provisions and their harmonization, offers proposals to keep changes in the legislation of the Eurasian Customs Union regarding food additives, flavourings, enzymes and processing aids up to date.

2. Analysis of regulatory requirements

First of all the fact that the unique Regulation CU TR No 029/2012 controls the free movement of food additives, flavourings and processing aids including enzymes, micro-organisms and other auxiliary substances and materials calls attention [1]. In other words it regulates a wide range of substances and materials different by nature and functional purposes. In the European Union these products are differentiated and are controlled by the following documents: Regulation
(EC) No 1333/2008 on food additives [2], Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods [3], Regulation (EC) No 1332/2008 on food enzymes [4], Regulation (EC) No 1331/2008 about establishing a common authorization procedure for food additives, food enzymes and food flavourings [5]. Food enzymes were differentiated as well. Just so enzymes used to produce food additives are controlled by the Regulation (EC) No 1333/2008. However used directly in food products they are under the Regulation (EC) No 1332/2008.

In the Regulation CU TR No 029/2012 enzymes and enzyme preparations are considered as processing aids. They are widely used in baking and wine industries, brewing, production of alcohol, cheese, organic acids, amino acids, fish and other foodstuffs. At this the enzyme maximum permissible levels in food are harmonized with the (EC) regulatory requirements and directives. Permitted in the EC food enzymes entered in the Community List according to the Regulation (EC) 1331/2008 which establishes a common authorization procedure for food additives, food enzymes and food flavours [5]. Enzymes to be used as food additives are permitted both by the European legislation [6] and international documents. In such a way according to the Codex Stan 192-195 (modified in 2013) the following enzymes are allowed for use: Invertase (INS 1103), Lipase (INS 1104), Lysozyme (INS 1105) and Protease (INS 1101(i)) [7]. The Economic Commission for Europe currently revises a proposal to allow the use of the above enzymes as food additives in the Customs Union territory and to make respective modifications in the Regulation CU TR 029/2012. Only those food additives, enzyme preparations and flavours (flavouring substances) are allowed for use in food in the CU and EC which were tested for safety and included in the List in question [8]. However these Lists should be continuously modified and actualized. This procedure needs a maximum synchronization in the frame of the CU and EC. A new List of enzyme preparations and microorganisms - producers including genetically modified strains allowed for use in food industry is needed for the CU member countries taking international and European requirements into account.

2.1 Terminology

Harmonization of definitions and their meanings in the field of food additives, flavourings, food enzymes and processing aids which are used in the EC and CU documents is essential for the movement of goods across country borders and their circulation on the market. In this respect the Regulation CU TR No 029/2012 Safety requirements for food additives, flavourings and processing aids entered into force 01.07.2013 is harmonized to the utmost with the European legislation [2-5] as it was at the end of 2008. However a number of directives and decisions for terminology, level of use of food additives in foodstuffs and the Community Lists of authorized food additives, flavourings, enzymes, microorganisms appeared during the last 3 years. Therefore the harmonization level of the UC TR No 029-2012 with the above Regulations (EC) is insufficient now and should be urgently actualized.

However there are definitions in the EC and CU documents which meaning are is not revealed completely, is too lengthy and needs refinement. For example the definition ‘flavourings’ is overwhelmed (article 3 in the EC Regulation No 1334/2008 and the correspondent article in the CU TR No 029/2012). A definition has to contain main difference characters. If there are many difference characters it would be better to describe them in nota bene:

‘Flavourings’: products not intended to be consumed as such, which are added to food in order to impart or modify odor and/or taste except for sweet, acid and salt tastes.

Further in nota bene shall be given flavouring compositions and types. Finally a separate terminology for flavouring substances, flavouring preparations, thermal (process) flavourings, smoke flavourings, flavour precursors, other flavourings, food ingredients with flavouring properties, source materials (raw materials), natural flavourings is given. The definition ‘other flavouring’ is not specified and does not have difference characters. The fact that it does not belong to any of the above listed flavourings is not its difference character. So it is necessary to delete this flavouring from the list or specify its definition.

It seems that the Customs Union Commission should consider entry of the definition ‘food ingredient with flavouring properties’ in the regulatory documents as it was done in the Regulation (EC) No 1334/2008 [3]. It ‘shall mean a food ingredient other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contribute significantly to the presence in food of certain naturally occurring undesirable substances’ [3]. Such food ingredients are spices and vegetable herbs with flavouring properties.

Due to the entry into force of the EC Regulation No 231-2012 [9] where the synonym ‘Natural’ is used for a number of food colors (E100, E120, E 140 (i), E141 (i), (ii), E153, E160b (i), (ii), (iii), E160d (ii), (iii),) for the color E160d (i) – ‘Synthetic’, and for the colors E170, E171, E172, E173, E180 – ‘Pigment’ and their manufacturing procedure is given, it is necessary to introduce officially the definition for colors as natural, synthetic and pigment apparently. To all intents the carotene use in the Codex Stan 192-1995 [7] differs by their origin. For example the beta-carotene E160a maximum permissible level in milk drinks is 1000 mg/kg, and for the synthetic one E160a (i) it is only....
150 mg/kg. There are other examples as well. Besides of that the classification of coloring matters and colors as food additives by their origin is given in FEACN of the CU [10] (codes 3203 and 3204) and columns 35, 36 (for the group 32) of the List of products subject to customs entry together with a document (information) of conformity assessment (confirmation) to the requirements of CUTR No 029/2012.

2.2 Lists of authorized food additives, enzymes and flavouring substances

Such Lists in the EC are continuously improved and undergo periodical changes. As for CU TR No 029/2012 the transition period will end on 15.02.2015. By this time it is necessary to introduce corresponding amendments to the Regulation with regard to food additives, flavourings and processing aids together with enzyme preparations and micro-organisms. In accordance with International and European laws enzymes (enzyme preparations) may be used not only as processing aids but as food additives. According to Codex Alimentarius ‘General Standard for food additives’ (Codex Stan 192-1995) updated in 2012 and 2013 [7] it is allowed to use the following enzymes as food additives: Invertase (INS 1103), Lipase (INS 1104), Lysozyme (INS 1105), Protease (INS 1101 (i)). The EC List of authorized food enzymes as food additives is restricted by Invertase (E 1103) and Lysozyme (E 1105) [6]. The full List of enzyme preparations and their production strains (approved as safety) developed by EC includes strains which underwent evaluation mainly in France and Germany. The European council plans to approve this List in accordance with the EC Regulation No 562/2012 in March 2015 [11]. In the frame of the Customs Union it is necessary to develop a new List of enzyme preparations and their production strains (including genetically modified ones) approved for use in food industry of the Customs Union Member Countries and harmonized with the international requirements.

As about the List of flavouring substances a new List of food flavouring substances applied in flavourings was approved by EC Regulation No 872/2012 [12]. It consists of 2543 names. 400 of them will form its part until the end of 2015 and will be removed from the list if have not passed toxicity study. According to this Regulation a List of substances intended for infants shall be developed as well. A List of flavouring substances developed according to the Eurasian Counsel Regulation No 2322/96 and approved in Russia is in force in CU as yet. It should be revised. It is necessary to develop a new List of plants used as source materials in production of flavourings as well.

2.3 Hygiene regulations

In Russia and UC there were missed standards for food additive levels if there were: carriers in food additives, food additives (except carriers) in food additives, food additives (including carriers) in enzyme preparations, food additives (including carriers) in food flavourings and food additives in baby food products. This gap was stopped because EC Regulation No 1130/2011 came into effect [13]. This EC document enriches and differentiates requirements for use of food additives with regard to the above classes. Related changes were made in CU TR No 029/2012. Changes relating to levels of basic substance in food additives and their quality were made in the Amendment 28 of this CU Regulation with the aim of its harmonization with the requirements of Regulation (EC) No 231/2012.

In accordance with the requirements of the Codex Alimentarius [7] and EC Regulations No 1129/2011 [6], No 380/2012 [14] the following food additives were removed from the Annex 2 of CU TR 029/2012: E160f (color), E387 (antioxidant), E554, E555, E556 (carriers, free-flow agents), without E number - Stevia rebaudiana Bertoni, powder of the leaves and their syrup, extracts of the Stevia leaves (sweetener). According to EC Regulation No 1131/2011 [5] the additive Steviol glycosides E960, Stevia’s more pure analogue, was included in the List of authorized food additives. The Acceptable Daily Intake level of not more than 4 mg/kg body weight is set out for this additive. According to Regulation (EC) No 817/2013 [15] it was taken a decision to include the food additive ‘Octenyl succinic acid modified gum Arabic’ E423 in the List of authorized food additives as it was made in the previous case (Annex 2 CU TR 029/2012, as gelling agent, stabilizer, carrier with a maximum level of use in glace and sauce icing of 10 g/kg, in low-calorie soft and juice drinks 1 g/kg [15]. Higher levels of use of the additive E423 are foreseen for volatile oils for preparation of diverse foodstuffs from 60 mg/kg (chewing gum) up to 500 mg/kg for production of bakery, meat, fish and poultry products, edible ices except milk, fruit and vegetable products [16]. The following copolymers are included in the Annex 2 of CU TR 029/2012 as well: E1205 Basic Methacrylate copolymer, E1206 Neutral Methacrylate copolymer and E1207 Anionic Methacrylate copolymer. The area of use of these additives and their maximum levels of use in foodstuffs, more specifically in food supplements (FS) (tablets and capsules), being from 100 to 200 g/kg [1].

New levels for use of phosphoric acid (E338) and ammonium phosphate (E338), potassium phosphate (E340), calcium (E341, E542), magnesium (E343), sodium (E339), pyrophosphates (E450), three phosphates (E451), polyphosphates (E452) in meat products except not processed ones and forcemeat were offered in CU TR 029/2012. These levels correspond to the requirements of Codex Stan [7] and Regulation (EC) No 231/2012 [9], No 298/2014 [17].
The additive E1208 polyvinylpyrrolidone - vinyl acetate copolymer, included in the EC List of authorized additives in accordance with EC Directive N 264/2014 [18], apparently should be included in the List of approved food additives (Annex 2 CU TR 029/2012). The additive E1208 as well as E1205 - E1207 (methacrylate copolymer) is destined for FS tablets and capsules. But its maximum levels for use in foodstuffs are not set out yet.

It is necessary to include sulfur dioxide - sulfates (E220-228) used for stabilization of flavoured basic wine-making materials in the CU List. Maximum levels of not more than 10 mg/kg or ml/l for their use taking all SO2 sources into account are set out in accordance with EC Directive No 59/2014 [19].

2.4 Labeling

Labeling requirements for foodstuffs for retail and information on their packaging or containers and product labels are regulated in the frame of the Customs Union by CU TR No 022/2011 ‘On food products labeling’ [19]. Although these requirements are harmonized to a certain extent with the requirements of the European Regulations No 1333/2008 [2], No 1129/2011 [6], No 1334/2008 [3], No 1332/2008 [4], No 1169/2011 [20], No 872/2012 [12], many questions emerge about labeling of food additives, flavourings, processing aids as part of foodstuffs and as independent products in their own packaging.

In accordance with the Article 4 of CU TR No 022/2011 a label of foodstuffs for retail shall bear the following information: foodstuff name, date of manufacture, shelf life expiry date, conditions for storage. All other information foreseen by the Regulation shall be brought to the consumer’s attention by any means which help him to make a reasonable choice of a food product. At this, names of ingredients including food additives, flavourings, biologically active supplements whose intake may cause allergy or is prohibited in presence of certain diseases shall be listed in the label.

Names of food additives shall bear the following words: food additive or complex food additive with the indication of its function and E or INS number or additive name set out by the regulation CU TR 029/2012.

Names of flavourings shall bear the following words: flavouring, flavouring substance, or flavouring preparation or smoke flavouring or flavour precursor. At this, the word ‘natural’ shall be used only if flavouring substances in its composition were obtained from natural source according to the name of the natural flavouring. For example, natural flavouring ‘Raspberry’, etc.

Enzyme preparations labeling shall bear the following words: enzyme, enzyme preparation with indication of its type and activity, types of production micro-organism, source of origin. However it is allowed for foodstuffs with enzyme preparations not to specify the type of enzyme, its activity and types of production micro-organisms.

Processing aids labeling shall bear the following words: processing aid and its name.

In the case the above ingredients are not intended for retail, the label shall bear the phrase ‘not for retail’.

Posterior EC Regulations have additional requirements for the information that shall bear the label of foodstuffs with sweeteners, colors, extracts, infusions, volatile oils, flavouring preparations containing licorice root, glycyrrhizin acid, caffeine, quinine and other biologically active substances. Today correspondent changes are prepared for CU TR 029/2012 in the Customs Union.

2.5 Risks associated with the use of genetically modified micro-organisms in foodstuffs

Having regard to the Regulation CU TR 029/2012 food additives, flavourings and enzyme preparations shall not contain viable or so called transgenic production strains, which may fall into foodstuffs as well. It can happen because of irregularities in the procedure of the use of commercial strains. Real risks associated with the appearance of the alien gene in a recipient cell exist always to somewhat probability and in certain conditions it is dangerous for human health [21]. CU TR requirements in this regard were developed in accordance with ‘Inventory of Processing Aids’ published by the Codex Alimentarius Commission in 2000 [22]. Guidance procedures for foodstuffs and enzyme preparations produced with the use of genetically modified micro-organisms are directed by Directive of the Ministry of Health of the Russian Federation MU 2.3.1935-04 [23]. Methodical recommendations MR 2.1.10.0067-12 act today together with the above document in the Russian Federation. They establish procedures for evaluation of risks for human health under the influence microbial species on foods. These recommendations help to ascertain whether genetically modified strains of micro-organisms involved in the production of food are safety [24].

These problems in the European Union are guided by EC Regulations No 1331/2008 [5] and 234/2011 [8]. They describe requirements for a risk assessment and risks management for products of each category including new enzyme preparations.

According to the analysis of the above documents and risk management practice associated with the use of genetically modified micro-organisms in foods in CU and EU Member Countries, there is achieved a high harmonization level of the requirements. With that there is the necessity for CU Member Countries to develop a new List of enzyme preparations and production strains for their use in food industry in the Customs Union Common Economic Space.
3. Conclusions

- Consumers risks in EU and CU Member Countries associated with the consumption of dangerous foods decrease because the Legislation on technical regulation of the food production, movement and consumption, source materials and ingredients including food additives, flavourings, and enzyme preparations and processing aids becomes more complete.

- Harmonization of EU and CU Legislation in the field of the technical regulation together with the realization of special, antidumping and compensatory protective measures breaks down trading barriers and makes relations between both spaces more transparent.

- According to the data obtained from the analysis of EU and CU legislative documents on the safety of food products, food additives, flavourings and processing aids, the harmonization level of the requirements on safety and quality of the above products established in the documents is relatively high (more than 60%). There is a tendency for the increase of the harmonization level that is expected to be 80% to 2015.

- Both Parties should make all the possible to harmonization level that is expected to be 80% to 2015.

4. References


