

FOOD AND AGRICULTURE

1.18

Almost two years after the beginning of the pandemic crisis, the economy is facing new challenges, although the existing problems and difficulties have not been solved. The food industry, like other industries, is facing a difficulties with supply of raw materials, as global challenges caused by problems with transport and human resources in certain world regions. There are no significant changes in the functioning of the local food safety system, bearing in mind the fact that official controls are taking place at the same pace.

What has proven to be a great obstacle to efficient functioning in and in these circumstances, is the physical exchange of documentation with the competent authorities. Also, a transparent and comprehensive risk analysis system would make the flow of goods even more efficient, because with reorganizing existing resources, and focusing on high-risk products, manufacturers and importers, stronger control of those at high risk would be ensured, would be of multiple significance.

Harmonisation of regulations with EU regulations is not proceeding at the expected pace, and implementation in practice remains a major challenge, given the institutions' unclear competence in interpreting regulations. Part of the regulations is harmonized, but most of them are national regulations for which there are no "counterpart" in the EU and neighbouring countries. Such circumstances are an obstacle

to free trade and create certain restrictions on domestic producers in terms of the application of innovative processes and products. The tendency is to modernize obsolete regulations, in order to alleviate restrictions, and on the other hand, the harmonization of certain regulations is further hindered due to the existence of administrative and methodological obstacles to their application in the same way.

The report on the work of the Expert Council for Risk Assessment, established in June 2017, as well as the activities of the Council are still not known to the interested public.

There is still room for improvement. Both in improving the regulatory framework, which would ensure high standards in food quality control, and by applying a uniform approach to control for all participants, both importers and domestic producers. It is extremely important to simplify testing procedures, strengthen transparency while enabling predictability of goods retention. Strengthening the capacity of the Veterinary and Phytosanitary Control Directorates and the National Reference Laboratories, as well as the consistent application and improvement of the risk-based approach, are key to further strengthening the food safety management system. Of great importance for the food business operators, it would certainly be enabling the electronically exchange of data and documentation between state institutions and the economy.

1. FOOD SAFETY LAW

1.29

WHITE BOOK BALANCE SCORE CARD

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
Align the Law on Food Safety and all accompanying bylaws with EU regulations (178/2002 / EC and accompanying bylaws).	2017		√	
Establish a transparent and comprehensive risk analysis system (combination of product, country of origin, manufacturer, destination and importer risk) by all inspection services, with the establishment of a functional IT system and digitization of supervision.	2015			√
By adopting the rulebook, establish uniform rules in the procedures of inspection services in terms of costs, deadlines, field work mechanisms, taking the number of samples, determining the type and number of analyzes during official controls.	2014		√	

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
To harmonize the criteria of the laboratory during control analyzes, with a clearly defined responsibility of the laboratory regarding the interpretation of regulations.	2020			√
Establish a national Food Safety Agency following the example of EU member states and neighboring countries and create conditions for the National Reference Laboratory to perform all tasks provided by law, in order to strengthen the capacity of the food safety system.	2018			√
Create legal conditions for food business operators to place new foods on the market from the list, according to a simplified procedure, and keep the approval procedure for novel foods that are not on the list in Annex 1, according to the EU model.	2020			√
Enable electronic exchange of data between state institutions and the economy	2020			√

CURRENT SITUATION

The Law on Food Safety (hereinafter: the Law) adopted in 2009 has not been fully implemented so far, nor have all the envisaged bylaws been adopted. Amendments to the Law were published in the "Official Gazette of RS", no. 17/2019 and apply from April 1 2019 and new changes to this law are announced.

Amendments to the Law reorganized the division of inspection responsibilities between the competent inspections of the Ministry of Agriculture and the Ministry of Health, which is more closely prescribed for the competent inspections of the Ministry of Agriculture by adopting the Regulation on the type food and official control, as well as the list of mixed foods, in April 2019.

The National Reference Laboratory was opened in 2015. New amendments to the Law define its competence and introduce the term Reference Laboratories, which should entrusts part of the work performed by the National Reference Laboratory. It is envisaged that the Ministries will select reference laboratories through a competition, and that the list of reference laboratories will be published in the "Official Gazette of the Republic of Serbia" and submitted to the ministry responsible for technical regulations, for entry in the register of authorized conformity assessment bodies.

A working group for milk was formed within the Ministry of Agriculture in 2015, but by the middle of 2021, there was no harmonization of the current legislation in the part related to milk safety. The latest amendment to the legislation

from September 2021 extended the application of the maximum permitted content of aflatoxin M1 in raw milk of 0.25 µg / kg, until November 30 2022. Extending the validity of the provision is helpful for milk producers in the territory of the Republic of Serbia, since they would still be able to produce and distribute milk with a slightly higher content of aflatoxin M1, but on the other hand are limited to export it because at EU level, as well as in the surrounding countries, the maximum permitted content of aflatoxin M1 in raw milk is 0.05 µg / kg. On the other hand, current measures allow the import of milk from neighboring countries and the EU whose aflatoxin content exceeds the limit of 0.05 µg / kg. Due to all the above, and primarily due to food safety, it is necessary to focus activities on the application of measures to reduce the presence of aflatoxins in animal feed.

The Expert Council for Risk Assessment was officially formed in April 2017.

The new Regulation on maximum concentrations of certain contaminants in food (SG 81/2019) from November 2019 defines the maximum permitted amounts of contaminants in certain types of food (Annex I), which brings Annex I fully harmonized with EU regulations (1881/2006 / EC). This Regulation also transposes the provisions of EU Regulation 2017/2158, which prescribes mitigation measures to reduce the presence of acrylamide in certain food categories.

Amendments to the Law Article 71 is amended so that the payment of fees for laboratory tests is no longer prescribed by this Law, but prescribes the obligation to pay fees for official controls. In December 2019, amendments to the Law on Republic Taxes were adopted, which prescribe a fee

that refers to the inspection itself and additional costs that are prescribed by product groups, but relate exclusively to shipments that are subject to veterinary and phytosanitary control, not and for consignments under the jurisdiction of the sanitary inspection of the Ministry of Health.

POSITIVE DEVELOPMENTS

The Ministry of Agriculture, Forestry and Water Management and the Ministry of Health started preparing a Guide for the Implementation of Regulations on Maximum Concentrations of Certain Contaminants in Food, Within the PLAC III project. The Guide sets mitigation measures and reference levels for reducing the amount of acrylamide in food, modeled on the European Union Guide.

REMAINING ISSUES

Inconsistency of the Law on Food Safety and certain bylaws with EU Regulations.

- In addition to the provisions of EC 1881/2006, the Rulebook on Contaminants also takes over the requirements of EU Regulation 2017/2158; The Rulebook on the Coffee Products Quality, in addition to the provisions of Directive 1999/4 / EC, also prescribes requirements for categories of coffee products that are not prescribed at the EU level; The Rulebook on Fruit Juices, in addition to the requirements of Directive 2012/12 / EU, prescribes additional requirements regarding the quality of fruit juices. Thus, domestic entities in the food business are placed in a less favorable position compared to entities operating outside the borders of Serbia.
- There is a room for different inspection interpretations.
- Slow transposition of the latest amendments to the regulations in the field of food additives into national legislation.

Lack of a comprehensive risk assessment system by inspection services. No improvement and coordination in the application of risk analysis and assessment methods was observed:

- With the formation of the Expert Council for Risk Assessment, a progress was expected in performing the risk analysis provided by the Law, but this did not happen. The activities of the council are not known to the interested public even after 4 years from its establishment.

- Risk analysis would enable the classification of food business entities into low-risk and high-risk, which would speed up the process of customs clearance and release of low-risk goods. Importers assessed as low-risk could realize savings in money and time by faster receipt of documents and reduced number of sampling at import.
- Risk analysis would reduce the scope of inspections and relieve them of limited resources as resources would be focused on testing high-risk products.
- The publication of the Rulebook on special elements of risk assessment within the scope of sanitary inspection and within the scope of agricultural inspection at the end of 2018, created a framework for starting the risk assessment process, but there is still no uniformity in terms of application between different inspections

Unpredictable business conditions during the procurement of raw materials for food production and marketing:

- Uniform rules do not apply in the procedures of inspection services in terms of costs, deadlines, field work mechanisms, number of samples, determination of type and number of analyzes in laboratory processes,
- Application of different criteria by laboratories in control analyzes, and vaguely defined responsibility of laboratories in terms of interpretation of regulations.

Unclear procedure for placing novel food on the market:

- Irrespective of the fact that the Regulation on Novel foods (SG 88-2018) takes over the list of novel foods that are freely placed on the EU market, the Regulation prescribes an additional procedure by which the Ministry of Health issues permits for placing novel foods on the market for the first time.
- The Rulebook stipulates that the Ministry gives approval based on the Opinion of the Expert Council. It is still not clear why the Expert Council gives each operator an opinion on food for which there is already a relevant scientific opinion from an internationally recognized institution (EFSA), and which has already been taken over from the list in Annex 1 to this Regulation.

The exchange of documentation with the competent authorities is still mostly done physically, which complicates the work of companies and significantly slows down the flow of goods.

FIC RECOMMENDATIONS

- Align the Law on Food Safety and all accompanying bylaws with EU regulations (178/2002 / EC and accompanying bylaws).
- Establish a transparent and comprehensive risk analysis system (combination of product, country of origin, manufacturer, destination and importer risk) by all inspection services, with the establishment of a functional IT system and digitization of supervision.
- By adopting the rulebook, establish uniform rules in the procedures of inspection services in terms of costs, deadlines, field work mechanisms, taking the number of samples, determining the type and number of analyzes during official controls.
- To harmonize the criteria of the laboratory during control analyzes, with a clearly defined responsibility of the laboratory regarding the interpretation of regulations.
- Establish a national Food Safety Agency following the example of EU member states and neighboring countries and create conditions for the National Reference Laboratory to perform all tasks provided by law, in order to strengthen the capacity of the food safety system.
- Create legal conditions for food business operators to place new foods on the market from the list, according to a simplified procedure, and keep the approval procedure for novel foods that are not on the list in Annex 1, according to the EU model.
- Enable electronic exchange of data between state institutions and the economy.

2. SANITARY AND PHYTOSANITARY INSPECTIONS

1.00

WHITE BOOK BALANCE SCORE CARD

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
Adopt the new Law on Sanitary Supervision and executive regulations on the work of sanitary and phytosanitary inspection harmonized with the Law on Inspection Supervision and EU regulations.	2017			√
Adopt the Law on Official Controls and executive regulations on the manner of conducting official controls which would ensure consistent application of uniform rules in the procedures of inspection services in terms of costs, deadlines, field work mechanisms, sampling, type and number of analyses in laboratory processes.	2018			√

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
Prescribe the Law on Republic Administrative Fees to prescribe the costs for the inspection of consignments and additional costs for categories of food that are under the jurisdiction of the sanitary inspection.	2020			√
Modify the Decisions of the competent inspections so as to allow the use of raw materials in production, without the right to release the finished product until obtaining a decision on the release of raw materials.	2017			√
Clearly define the time period required for import procedures for all types of food.	2018			√
Enable electronic data exchange between state institutions and the economy.	2020			√

CURRENT SITUATION

With the division of responsibilities after the adoption of the Amendments to the Law on Food Safety, the phytosanitary inspection of the Ministry of Agriculture, Forestry and Water Management retained the existing competencies for food of plant origin. In the import and export phase, the border phytosanitary is responsible for the control of food of plant and mixed origin, together with the border veterinary inspection. The Sanitary Inspection of the Ministry of Health is responsible for the control of novel foods, foods for specific population groups, food supplements, foods with altered nutritional composition, salts for human consumption, additives, flavours, enzyme preparations of non-animal origin and non-animal auxiliaries and all types of drinking water.

The work of inspections is also regulated by the Law on Inspection Supervision, which has been in force since April 2016. Some inspections are developing models for the application of the Law on Inspection Supervision, but the full harmonization of sectoral regulations with this Law has not yet been completed.

Since 2016, the Ministry of Health has been in the process of passing the Law on Sanitary Supervision, which would regulate the affairs of sanitary supervision in more detail.

The adoption of the Law on Official Controls has been announced.

POSITIVE DEVELOPMENTS

No improvements have been noticed in this area.

REMAINING ISSUES

The Law on Sanitary Supervision and executive regulations on the work of sanitary and phytosanitary inspection in accordance with the Law on Inspection Supervision and EU regulations have not been adopted yet.

There are no deadlines for the adoption of some extremely important executive regulations, such as e.g. Regulation on the manner and methods of conducting official controls, the system of approval and certification, the manner of cooperation with the customs authority and competent authorities of EU Member States and third countries, the manner of inspection, sampling, criteria for determining deadlines for official controls, as well as reporting on implemented official controls and the Regulation on methods of sampling and testing of food in the procedure of official control, etc.

The Law on Republic Administrative Fees, despite the changes adopted at the end of 2020, does not prescribe the amount of the fee for the inspection of shipments and additional costs for shipments that are under the jurisdiction of the sanitary inspection of the Ministry of Health.

The competent inspections do not allow the use of raw materials in production before obtaining the Decision on release for placing on the market, which leads to a loss of time and money.

The time period required for food import procedures is not clearly defined.

The exchange of documentation with the competent bodies is still mostly done physically, which complicates the work of companies and significantly slows down the flow of goods.

FIC RECOMMENDATIONS

- Adopt the new Law on Sanitary Supervision and executive regulations on the work of sanitary and phytosanitary inspection harmonized with the Law on Inspection Supervision and EU regulations.
- Adopt the Law on Official Controls and executive regulations on the manner of conducting official controls which would ensure consistent application of uniform rules in the procedures of inspection services in terms of costs, deadlines, field work mechanisms, sampling, type and number of analyses in laboratory processes.
- Prescribe the Law on Republic Administrative Fees to prescribe the costs for the inspection of consignments and additional costs for categories of food that are under the jurisdiction of the sanitary inspection.
- Modify the Decisions of the competent inspections so as to allow the use of raw materials in production, without the right to release the finished product until obtaining a decision on the release of raw materials.
- Clearly define the time period required for import procedures for all types of food.
- Enable electronic data exchange between state institutions and the economy.

3. QUALITY ASSURANCE, DECLARATIONS ON FOOD PRODUCTS, NUTRITION AND HEALTH CLAIMS 1.25

WHITE BOOK BALANCE SCORE CARD

Recommendations:	Introduced in the WB:	Significant progress	Certain progress	No progress
Define the competence of institutions regarding the interpretation of regulations in the field of food safety and ensure the obligation to apply the official positions of the Ministry to all participants in the chain; ensure uniform interpretation and application of the Regulation and Guidelines on food declaration, labelling and advertising.	2016			√
Adopt executive regulations arising from the Law on Food Safety and harmonize them with EU regulations, such as the Regulation on food with a changed nutritional composition.	2017		√	
Adopt the Regulation on conditions and manner of production and marketing of food for which quality conditions are not prescribed.	2018			√
Adopt Amendments to Article 34 of the Law on Trade in terms of clearly defining that the provisions of this Article do not apply to products to which the provisions of the Law on Food Safety apply, and bylaws prescribing the declaration and labelling of food.	2020			√

CURRENT SITUATION

From June 15 2018 the Rulebook on declaring, labelling and advertising of food (Official Gazette of the RS, No. 19/2017; 16/2018; 17/2020) (hereinafter: the Rulebook), which is largely in line with the relevant EU regulations, is in force. In September 2020, amendments were made to the Rulebook, which refer to the labelling of the country of origin of the main ingredient, as well as information on the absence or reduced amount of gluten in food (harmonization with EU regulations 2018/775 and (EU) 1155/2013). In addition to the Rulebook that prescribes the quality of dietary products, requirements for „lean products“ labelling and reference is given to the rules on information on the absence or reduced amount of gluten in food requirements have been prescribed. Adjustment period is 18 months. In March 2021, the Ministry of Agriculture also published the Instruction for the application of the Rulebook for the Origin of the Main Food Ingredient Stating, which should facilitate the application of the published amendments to the Rulebook.

A number of regulations prescribing the quality of certain food categories are not fully harmonized with the EU, are outdated or there are no regulations in the EU that define the quality of these food categories. Such vertical legislation puts food business operators at a disadvantage compared to producers in the countries of the region and the European Union. The choice of raw materials for production is narrowed and often raw materials that are freely used in the mentioned countries cannot be placed on the market in Serbia without special approvals from the ministry, because they do not comply with quality regulations even though they are food safe. Due to the obsolescence of regulations, the appropriate raw material is often difficult to find and has a higher price. The situation is similar with finished products that do not fit into the categorization of the mentioned regulations.

The Law on Trade, published in the middle of 2019, prescribed the obligation to obligatorily mark the country of production on the labelling of goods in retail trade. Although it was considered that this requirement does not apply to the labelling of food for which the Rulebook on Declaration, Labelling and Advertising of Food is in force and which Article 26 prescribes mandatory indication of the country of origin only for certain categories of food, due to uneven interpretation by inspection and business entities with food in practice makes business more difficult.

POSITIVE DEVELOPMENTS

The Ministry of Health has established a Working Group for the adoption of the Rulebook on Food with a Changed Nutritional Composition, which will ensure the harmonization of requirements with the EU regarding food enrichment. The harmonization of the rules for indicating the country of origin with the rules in the EU, and the adoption of instructions, is a good example of regulations harmonization under the jurisdiction of the Ministry of Agriculture.

By defining the term „lean products“ and adopting rules for the use of this statement, the Ministry of Agriculture has created a basis for unified interpretation and difficulties resolution encountered by producers in practice.

REMAINING ISSUES

The current legal framework does not define the competence and responsibility for the interpretation of regulations in the field of food safety, and over time the practice has been created on the market for laboratories to interpret regulations:

- a. Regardless of the fact that the legal assessment, ie. Determining certain illegalities in business in the exclusive competence of the inspector in accordance with Article 37 of the Law on Inspection Supervision, the inspector, as the competent body, is exclusively guided by the conclusion made by the laboratory, which is often not in line with the official position of the Ministry. This is especially reflected in the interpretation of regulations in the field of labelling, where, despite the existence of the Guide, there are different approaches and interpretations of its provisions.
- b. The official position of the competent Ministry is not a binding act for inspection services.
- c. This practice contributes to the difficult functioning of food business operators, and to the great limitations of long-term planning.
- d. A bylaw has not yet been adopted by Minister of Health, in accordance with the division of competencies referred to in Article 12 of the Law. This bylaw should prescribe in more detail the conditions and manner of production and marketing of food for which quality requirements are not prescribed, which is provided by Article 55 of the Law.

Nonharmonised regulations prescribing product quality with EU regulations:

- a. In October 2020, the Rulebook on the Fruit and Vegetable Products Quality was published, which is entirely of a national character, and therefore is not subject to harmonization with EU legislation. The Rulebook on the Quality of Raw Coffee, Coffee Products, Coffee Substitutes, as well as Related Products, was published in December 2020, and which largely prescribes the placing on the market of these categories, for which there are no requirements at EU level, except for products from instant coffee and instant coffee substitutes. By adopting such regulations, the Quality Group of the Ministry of Agriculture shows a sense of the needs of domestic producers, to define quality parameters for certain product categories, and reduce the possibility of abuse of coffee substitutes. On the one hand, the way of doing business in the internal market is harmonized in the case of products that are clearly categorized, on the other hand, food business subjects are limited, because it further complicates the way of working in the case of no categorized products within Rulebook, especially with related products, there is room for different interpretations.
- b. The Rulebook on Fruit Juices, although harmonized with EC Regulation 2012/12, still has additional requirements regarding the quality of fruit juices, taken from the standards of the European Association of Fruit Juice Producers, which as such in the EU countries have voluntary and not legally binding application, which puts domestic entities in the food business in a less favourable position in relation to entities that operate outside the borders of Serbia.

Inconsistency of the requirements of the Law on Trade and the Rulebook on Labelling, in case of stating the country of origin on the product declaration, prescribe the obligation to state the country of origin of the main ingredient, create a framework for additional problems in practice.

FIC RECOMMENDATIONS

- Define the competence of institutions regarding the interpretation of regulations in the field of food safety and ensure the obligation to apply the official positions of the Ministry to all participants in the chain; ensure uniform interpretation and application of the Rulebook and Guidelines adopted by competent Ministry, adopt Rulebook on conditions and manner of production and placing on the market of food for which quality conditions are not prescribed.
- Adopt executive regulations arising from the Law on Food Safety and harmonize them with EU.
- Adopt Amendments to Article 34 of the Law on Trade in terms of clearly defining that the provisions of this Article do not apply to products to which the provisions of the Law on Food Safety apply, and bylaws prescribing the declaration and labelling of food.