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## **Legislative approximation in food safety, related difficulties**

**Ekaterine Burkadze**, Food safety expert.

### **Brief overview**

DCFTA chapter IV (sanitary and phytosanitary measures) includes approximation of Georgia's national legislation with EU legislation in food safety field. The above-mentioned covers food safety, veterinary and plant protection fields' regulatory EU legislation list, as well as approximation timetable. Approximation of Georgia's legislation with EU legislation will be processed step by step from 2015 to 2027. Before approval of concrete normative act, several steps are covered: discussion with all persons concerned, in order to ensure protection of private and public interests.

### **Legislative approximation**

In total up to 300 normative acts has to be approximated to the EU legislation, among them:

- General Juridical document, without changes – 14;
- Regulations in veterinary field – 84;
- Regulations related to placement of food/animal feed as well as animal products on market – 35;
- Food safety regulations – 68;
- Specific rules for animal feed – 16;
- Phytosanitary Regulations – 53;
- GMO related Regulations – 15;

„The EU hygiene package of 2004” includes 6 main legislative acts (**178/2002, 852/2004, 853/2004, 882/2004, 854/2004 and 183/2005**). Law Georgia on food/animal feed, veterinary and plant protection code more or less combines requirements of this package. Still it is the framework and requires secondary legislations to be adopted.

European regulations in food safety, phytosanitary and veterinary fields should to be approved until 31st December, 2016. I will focus on food safety issues, where the following documents have been elaborated, and/or are in the process of elaboration:

- Performance of analytical methods and the interpretation of result according to Directive 96/23/EC (Decision 2002/657/EC);

- Verification of compliance of feed and food law, animal health and animal welfare rules with Directive 882/2004 covering elaboration of audit manuals, as well as official controls (Decision 2006/677/EC);
- Maximum residue level of pesticides in or on food and feed of plant and animal origin (Regulation (EC) No 396/2005);
- Provision of food information to consumers (Regulation (EU) No 1169/2011);
- Nutrition and health claims made on foods (Regulation (EC) No 1924/2006);
- Nutrition claims (COMMISSION REGULATION (EU) No 1047/2012);
- Requirements of health related issues (COMMISSION REGULATION (EU) No 1047/2012);
- Food additives (Regulation (EC) No 1333/2008);
- Addition of vitamins and minerals and of certain other substances to foods (Regulation (EC) No 1925/2006);
- Vitamin and minerals and their forms that can be added to foods, including food supplements (Commission Regulation (EC) No 1170/2009);
- Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (Regulation (EU) No 37/2010);
- Laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (Regulation (EC) No 401/2006);
- 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 (Regulation (EC) No 333/2007).

From July 1, 2016 entered into force November 10th, 2015 Government resolution №581 about adopting technical regulation on microbiological criteria for foodstuffs (Regulation (EC) No 2073/2005), as well as November 9th, 2015 Government regulation №567 about adopting technical regulation on setting maximum levels for certain contaminants in foodstuffs (Regulation (EC) No 1881/2006).

### **Food safety management system in EU**

The main objective of the EU food safety regulations is to ensure high level of consumer protection with regard to food safety. An integrated approach is necessary to ensure food safety from the place of primary production up to end including placing on the market. Each business operator involved in the food chain is obliged to ensure food safety.

In EU one of the significant parts of the food safety management system is HACCP (Hazard Analyses and Critical Control Points), which is mandatory for all food/feed producers. At first, Business operator takes responsibility for food safety. Food safety can be reached by combination of the following steps:

- **Preliminary mandatory programs**, which includes territory, building and working space (e.g. equipment, stuff, washing and disinfection, safety raw material, waste management, cold chain, safety distribution, packaging, food storage, carrying, proper warming etc.)
- **Principles based on HACCP system**, which aims to identify, monitor and control concrete threats (prevention and correction).

#### **Regulation (EC) No 852/2004 on food hygiene:**

- Article 5 requires Establishing, implementing and maintain procedures based on HACCP systems among food business operators; This covers all business operators along the food chain, including stages of producing, refining or distributing, or other related activities.
- Preamble 15 stresses out that principles and practice of *Codex Alimentarius* is mandatory for all business operators.
- Article 7 and 9 requires from member states to foster elaboration, spread and implementation of national guidelines about HACCP based systems, as well as best practices of GHP introduction.

**Regulation (EC) No 183/2005 on Animal feed hygiene:**

- Article 6 requires that beside primary production and related measures, animal feed producers should work out, implement and maintain practice of written procedures based on HACCP.
- Preamble 15 stresses out that it is necessary to use *Codex Alimentarius principles* in any sort of animal feed production, including cases of small business operators.
- Article 20 requires, that EU commission should foster elaboration of European guidelines, in order to ensure introduction of best practices and HACCP Principles, in case of necessity member states should foster elaboration of national guidelines.

**Regulation (EC) No 882/2004) on compliance with feed and food law, animal health and animal welfare rules :**

- Article 3 requires from Member States to confirm that official inspection is held on regular bases, based on risk assessment and with enough frequency.

**Regulation (EC) No 854/2004, the special rules of animal origin food official control.**

- Article 4 states that respective authority should control business operators in accordance with (EC) No 852/2004 and (EC) No 853/2004 regulations.

The EU rules do not apply to primary production for private domestic use, or to the domestic preparation, handling, or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organization. Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of the Regulation (EC) No 853/2004. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible taking account of the principles contained in the *Codex Alimentarius*.

However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer. The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level.

Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.

Food safety is a result of several factors: legislation should lay down minimum hygiene requirements, official controls should be in place to check food business operators' compliance and FBOs should establish and operate food safety programmes and procedures based on the HACCP principles. Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help FBOs attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.

The HACCP requirements should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognize that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses. Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraint. However, flexibility should not compromise food hygiene objectives. Regulation (EC) No 178/2002 prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle. To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health. The registration of establishments and the cooperation of FBOs are necessary to allow the competent authorities to perform official controls efficiently and comply with the Regulation 882/2004. The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety as required by the Regulation 852/2004.

Systems based on the HACCP principles is specific for each business operator and this might have its strengths and weaknesses.

- Strengths: flexibility, considering individuality of risks, environment, activity and capacity of each business operator.
- Potential weaknesses: hereof, there is no unique procedure for each business operator, successful implementation isn't guaranteed.

EU Member States agree that, HACCP is a ground of food safety management and affordable level of procedures based on HACCP does exist. Despite, systems based on HACCP principles are under control, national frame for HACCP introduction differs between Member States.

At this stage, the most important concepts of HACCP aren't fully understood and implemented in EU, especially by business operators. Among those, flexibility is least understood HACCP concept, therefore it isn't appropriately used and evaluated. Especially it relates to animal feed production field.

Manuals are being elaborated in EU is still in process, although some GHP manuals aren't practical for small business operators, because it is too difficult and contains technical details. HACCP system is introduced without considering pre-conditions, this leads to set critical control points for such hazards, which has to be controlled under preliminary programs. CCP concept isn't comprehended correctly. There is much more CCP than adequate management requires. Moreover, sometimes critical barriers are established, which cause difficulties for business operators. Due to lack on competence/knowledge, often some barriers are established, which could not be confirmed. Complicated system of documents and notes is tricky and hard work for businesses. HACCP training is perceived like a "marking points".

- In terms of elaboration of HACCP principles and its introduction, all the competent authorities should have common approach;
- Dialogue between public and private sector should intensify, especially on following topics: flexibility, risk assessment, identifying critical points, verification etc.
- Not only officially adopted GHP manual (e.g. Codex etc ), but also may be used other manuals prepared by competent authorities and other interested parties, which is more flexible.
- Official supervisors of Member States shouldn't separate HACCP from preliminary programs.
- Member States should find ways to simplify administrative work related to documents and notes, however taking into account insuring food safety.

### **Managing of Food safety in Georgia**

Law of Georgia N 6155-IS on Code of Food/Feed Safety, Veterinary and Plant Protection determines requirement for HACCP implementation in FBOs. However, the list of FBOs with mandatory requirement to establish food safety system according to HACCP principles described by Codex Alimentarius is limited by the Governmental Decree N 90 to only slaughterhouses and raw milk processing factories. At the same time, the primary production and so called farmer producers are not under the official control and requirements of food safety are not applied.

These derogations from the key EU Regulations threaten food safety system. For instance, according to National Cheese Sector Research, the unbranded cheese whose provenance is unknown is being sold in bulk in supermarkets and there is high likelihood that this cheese is being produced under inappropriate and uncontrolled conditions. Unfair competition due to cheese made with milk powder being sold as cheese made with raw milk requires improved controls, mainly in "Imeruli cheese" production.

Georgian legislation contains norms to ensure the traceability of food and food ingredients, but it does not provide measures for the adoption of implementing rules to apply these principles in respect of specific sectors.

Food imported to EU need to comply with the general requirements laid down in Regulation (EC) No 178/2002, but as this Regulation is not fully implemented in Georgia, the food and especially cheese products in Georgia is losing opportunity to be exported to EU market.

Scientific advice should underpin legislation on food hygiene. To this end, the National Food Agency as the main food safety authority should whenever and wherever necessary prepare and publicize guidelines, booklets, arrange trainings, public and FBOs awareness increasing activities.

**Summary: Food hazards present at the level of primary production should be identified and adequately controlled to ensure that food safety is not compromised. Food Safety Authorities must prepare guides to good practice and should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides.**

**Official control and approaches must be flexibility to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments.**

**Food Safety Authority must provide procedure of adoption and implementing of traceability of food and food ingredients in respect of specific sectors.**

**The general requirements laid down in Regulation (EC) No 178/2002 must be fully adopted.**

**Approval of the food processing premises by official authorities**

Pursuant to Georgian legislation, legal entities are divided into two broad categories: entrepreneurial legal entities and non-profit legal entities. Individuals may also conduct business as sole proprietors without establishing any separate legal entity. Companies are required to have their own name, management, registered offices and bank accounts. The legal address must be local to ensure the delivery of official correspondence. Limited Liability Company is the most common form of business entity in Georgia. The reason for this is its flexible organizational and management structure and other characteristics that are peculiar to a limited-liability company. In contrast to other types of company, the formalities required to establish and operate a limited-liability company are much less complicated and expensive. The director is the authorized representative of the company, and is entitled to sign contracts, represent the interests of the company before third parties and perform other executive activities. The most significant advantage of this type of company is that the members/shareholders do not bear personal liability for the activities of the company. No requirements exist regarding the nationality or residence of shareholders and company directors. In order to be incorporated, a company must register with the Enterprise Register the local tax office. Incorporation involves state and tax registration. The statutes of a company do not have to be submitted to the Enterprise Register for authorization. The Georgian Entrepreneurs Act provides that the directors must manage a company in good faith. Usually it takes one day to register a limited-liability company. Therefore, starting business in Georgia is very easy and LLC can be FBO and it is only necessary to mention while the registration as the area of working.

Unfortunately, founder of the FBO during registration is not asked for providing information about:

- Registration of premises;
- Its design and construction;
- Awareness of the main food safety legislation requirements;
- Keeping written records of all the suppliers that provide food or any food ingredients;
- Having food safety management procedures in place and keeping up-to-date records of these;
- If staff understands the principles of good food hygiene;
- If health and safety and fire safety arrangements are considered;
- Description of food and drink, etc.

These issues rise only when the NFA inspectors are coming to the FBO for inspection. Such a liberal approach to the establishment of FBOs cause difficulties of their proper registration and creation of the annual plans for inspections. FBOs owners are very often confused to find out that there are many requirements regarding premises, staff competence, record keeping, traceability and food safety. Huge amount of money needs to be paid for renovation of the building, changing the construction and so on.

The proper registration procedure, establishing the requirements for premises and their approval procedure will reduce this kind of surprise expenses. Person who wants to start food business should be aware of the requirement of the national legislation to be able to take appropriate action in advance.

This is European experience and approach. As an example in Wales Centre of Technology, special program is for Bachelors as well as trainings. According to this course following issues are studied:

- Safety of hygiene, health and labour;
- Health control of factory guests;
- Using specific clothes for working staff;
- Basic hygiene norms (washing hands);
- Risk management;
- Safety rules of entering the building, rules of relocation and fire safety;
- Preparing procedures for work;
- Reprocessing of the product;
- Manuals of machinery;
- Principles of HACCP;
- Control and monitoring methods;
- Washing and disinfection;
- Ending the process;
- Procedures of making notes.

Without knowledge on above mentioned issues the certificate cannot be applied, which is mandatory for stuff engaged in food production.

According to information from National Food Agency during inspection in 2012-2015 were detected 5 critical irrelevances:

1. Residue level of temperature is not relevant for animal food production and storage conditions;
2. Instruments and machineries, which have immediate touch with the product, aren't cleaned or disinfected where food/animal productions are reprocessed openly.
3. Chain of technological production is disturbed and it needs reconstruction in production, reproduction and distribution processes.
4. Non-existence of inspection mark on meat, to proof its safety (Veterinary certificate form #2);
5. Ceiling is covered by condensates into the room where products are reprocessed openly.

According to codex, production will be stopped and fined with GEL 1000 in case of detecting critical irrelevances.

For the same period there were detected 5 basic noncritical irrelevances;

1. Disinfection, deratization and disinsection processes are not done completely (agreement, not sufficient facilities for disinfection, deratization and disinsection, registration of implemented activities and used chemicals);
2. Relevance of storage, floor, walls, ceiling and doors with normative acts;
3. Relevance of drinking water with normative acts;
4. Setting up entrances (disinfection barriers);
5. Requirements for water supply (supply of cold and warm water, tanks for water storage and its washing/disinfection).

In case of detecting of noncritical irrelevance, will be given instructions for correction, and the dates will be agreed with administration. In case of inspection after the date will not be improved company will be fined with GEL 400, the fine will be tripled in case of reiteration.

Above mentioned critical and noncritical irrelevances could be prevented. It's crucial to implement relevant registration procedures for this, evaluate the requirements of production infrastructure, person who wants to start the food business, must be determined whether he\she is competent person or not. Health examination has to be done for the staff of company, as well as trainings for reprocessing food, safety and staff hygiene.

Adoption of such kind of legislation will have positive feedback:

- Entrepreneur has information, what kind of regulations and requirements are in interested field;
- Elaboration of vested acts will reveal more complex law requirements
- Requirements improves effectiveness of production and gives opportunities to companies for savings
- Giving distinct legal bases
- Control might be identified in advance
- Protects consumers from threats and mistakes.

Definitely, existing companies should not be closed immediately, transitional period should be given for them, manuals should be prepared, courses for increasing qualification and gaining new skills should be conducted.

**Summary: Registration rules for food companies have to be changed and maximally approach to existing EU practice.**

### **Improvement of laboratory testing capacity**

According to the previously mentioned food sector research, it is clear that the medium tier of the food sector is expanding rapidly with more compliant producers focusing on entering the Tbilisi market and supermarket chains across Georgia. At the same time the legislation of the country is in approximation process with EU regulations causing emerging of national requirements which are new to FBOs.

To come in line with the changing and updating legislation the FBOs must make large number of laboratory tests and analysis for microbiological and chemical contamination, especially antibiotics.

The hazard of antibiotics in dairy products is not well known and wildly defined among FBOs, consumers, also laboratories do not have capacity for testing, and prices are very high.

Especially technical regulation validated in 2016, makes more steepen and complex the requirements of laboratorial researchs. Samples for research is increasing rapidly and parameters for research.

Increasing awareness about microbiological and chemical pollution of food safety for fermers, food companies and for consumers is important for system development. It is mandatory to establish manuals according to the field. . It is necessary to support the laboratory testing improvement process and for the beginning subsidize this sector. The subsidies can done by the governmental programs or with the support of donor organizations widely presented in Georgia.

**Summary: The public awareness campaign regarding food hazard and especially antibiotics should be arranged.**

**Food Safety Authority must support the system of the laboratory testing.**