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FOOD ADDITIVES UNDER DCFTA

POLICY PAPER

USAID GOVERNING FOR GROWTH (G4G) IN GEORGIA

22 MARCH 2016

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DELOITTE CONSULTING LLP

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REPRESENTATIVE: REVAZ ORMOTSADZE

AUTHOR(S): TBSC CONSULTING

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Reviewed by:	Nino Chokheli, GoG Capacity Strengthening Component Lead, Bondo Bolkvadze, Customs Advisor
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ACRONYMS

AA	Association Agreement
ADI	Acceptable Daily Intakes
ANS	Nutrient Sources Added to Food
BfR	Federal Institute of Risk Assessment (Germany)
BGBl	Federal Law Gazette (Germany)
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection (Germany)
BMG	Federal Ministry of Health (Germany)
BTSF	Better Training for Safer Food
BVL	Consumers and Food Security (Germany)
DCFTA	Deep and Comprehensive Free Trade Area
DG SANCO	European Commission, Health & Consumer Protection Directorate-General
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FA	Food Additive
G4G	Governing for Growth in Georgia
GMO	Genetically Modified Organism
HACCP	Hazard Analysis Critical Control Point
Länder	Federal Lands (Germany)
mg/kg-bw/day	Milligram Per Kilogram-Body-Weight Per Day; a Standardized Measure of Exposure to a Particular Food Additive
MS	Member State
NCP	National Contact Point
NFA	National Food Agency
NRL	National Reference Laboratory
SSI	State Sanitary Inspectorate
UHT	Ultra-High Temperature
USAID	United States Agency for International Development

CONTENTS

1 EXECUTIVE SUMMARY

The Association Agreement (AA) and Deep and Comprehensive Free Trade Agreement (DCFTA) with the European Union (EU) offer Georgia a framework for modernization. At the same time, it requires an extensive approximation of norms and regulations in various sectors, including food additives. New regulations required by approximation can cause high compliance costs, particularly in the food processing sector which is underdeveloped in Georgia compared to EU countries.

Very importantly, the AA and DCFTA do not obligate Georgia to copy laws verbatim from the EU. Rather, approximated laws need not be more trade-restrictive than necessary to fulfill a legitimate objective.

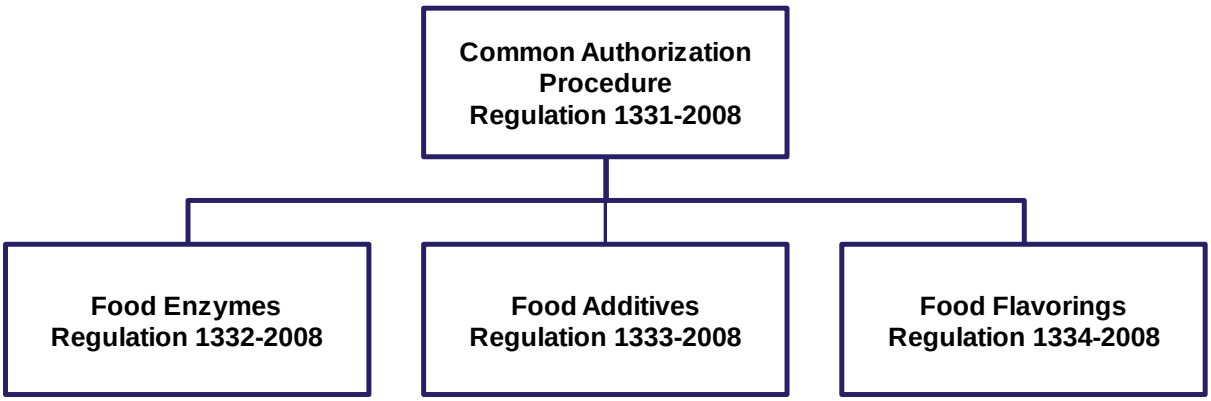
This policy paper covers approximation requirements from the AA and DCFTA in the area of food additives. Food additives are only one element of food safety. Food safety also includes a number of hygiene-related matters, ingredients, flavorings and enzymes; these other elements are not part of this policy paper.

The authors of this policy paper met with key informants (experts), representatives of government and business and organized a public-private dialogue to understand concerns vis-à-vis new food additive requirements. Also e-mail communication was used with representatives of several EU and Member Countries' institutions involved in food safety.

Their comments and insights were synthesized into a number of policy issues and recommendations for solving the root causes of the policy issues as shown in this policy paper.

The DCFTA requires approximation to EU regulations concerning food additives as shown schematically in the following chart.

Chart 1: DCFTA approximation to EU regulations.



Food additives and this policy paper concern primarily Regulation (EU) No. 1333-2008 (food additives; center bottom) and less so Regulation (EU) No. 1331-2008 (common authorization procedure; top), plus a number of implementing regulations for both.

To the end, food additive regulation rests on a list of substances that can be added to foods for a technological objective. Regulation (EU) No. 1333-2008 contains a positive list of food additives that are permitted, as well as the types of foods in which particular food additives can be used. Use of the Community list is mandatory. Countries can specify more restrictive limits on food *produced in their country* but they cannot impose that more restrictive list on foods *produced elsewhere and sold in their country*. Details on the requirements and the implemented practices in Germany and Poland are shown in the body of this policy paper.

There are six policy problems as follows. Several of these problems are not unique to food additives; they extend to other food safety issues as well.

- Georgia's regulations on food additives are out of date and do not at all meet the approximation requirements of the association agreement;
- Georgia does not have the delegated competencies or staff that would permit enforcement of food additive requirements if they existed;
- Knowledge of modern food additive technologies is limited among Georgian food operators;

- Georgia does not have implemented regulations that would permit enforcement of food additive requirements if they existed;
- The laboratory infrastructure for testing for food additive infringements is weak;
- Funding for most food additive matters is very limited.

Solving the root causes of these problems requires implementing a number of recommendations as follows. Each recommendation is greatly elaborated in the body of this policy paper.

- Georgia should adopt the Community list of food additives (shown in regulation (EU) No. 1333-2008) unchanged;
- Regulations should be created to enable official but voluntary certification of foods as meeting the requirements of the Community list;
- Mandatory monitoring and enforcement, with penalties, should be put in place after a two-year transitional process;
- Compliance of imports with the community list should be required by January 1, 2017;
- Food businesses should have access to effective informational tools and methods;
- A network of accredited laboratories should be created for food additive testing;
- A project should be undertaken to set a budget for all the preceding recommendations.

2 INTRODUCTION

The AA and the DCFTA with the EU offer Georgia a framework for modernization by opening the EU market via removal of customs tariffs and quotas and by an extensive approximation of norms and regulations in various sectors. At the same time, the negative impacts on Georgian producers from the approximation of laws should be minimized and the approximation process should run as harmlessly as possible.

New regulations required by approximation can cause high compliance costs.[1] This is particularly true in the agriculture and food processing sector which is quite underdeveloped in Georgia compared to EU countries. Given this state of development, as new rules and laws are adopted it is important to have intensive dialogue with all stakeholders so that potential compliance costs are identified as early as possible in the policy-making process and, where possible, minimized by changing the approximation details.

Very importantly, the AA does not obligate Georgia to copy laws from the EU. Approximated laws need not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks that non-fulfillment objective would create. Annex XI-A of the AA provides general principles for the evaluation of progress in the approximation process, namely:

> The sanitary, phytosanitary and animal welfare law of Georgia shall be gradually approximated to that of the Union, based on the approximation list of the EU sanitary, phytosanitary and animal welfare law. That list shall be divided into priority areas that relate to measures, as defined in Annex IV to AA. For this reason, Georgia shall identify its trade priority areas.

Georgia must approximate domestic rules to the EU acquis by either:

- Implementing and enforcing through the adoption of additional domestic rules or procedures to incorporate the rules of relevant EU acquis;
- By amending existing relevant domestic rules or procedures to incorporate the rules of the relevant EU acquis.

In either case, Georgia must:

- Eliminate any laws, regulations or any other measures inconsistent with the approximated domestic legislation;
- Ensure the effective implementation of approximated domestic legislation.

Georgia must prepare specific tables of correspondence demonstrating the approximation for general and specific legislation, including food safety area.

[1] Compliance costs are often, but not always, high. Given a particular objective (*i.e.*, meet requirement to approximate legislation and achieve other social aims), there is usually more than one way of achieving the objective. Those different ways can have quite different compliance costs.

3 METHODOLOGY

Preparation of this policy paper comprised desk review of numerous documents (many listed in the Bibliography) and in-depth interviews with domestic and foreign key experts, government staff (*e. g.*, Ministry of Agriculture of Georgia (MoA), National Food Agency (NFA), NFA's Scientific-Research Center) and food businesses. Additional in-depth interviews were conducted with experts on food additives. Also e-mail communication was used with representatives of several EU and member countries' institutions involved in food safety.

At the beginning, we studied existing research papers concerning food additives and the draft EU-Georgia approximation plan. All EU regulations concerning food additives were selected and deeply analyzed. A comparison to the existing Georgian legislation was conducted in order to find similarities and gaps.

Finally, a draft document with main findings including problems and recommendations were presented to the interested parties in form of public discussion and additional adjustment was made according to the comments.

4 SCOPE OF THIS POLICY PAPER – WHAT ARE FOOD ADDITIVES?

This policy paper addresses food additive requirements within the general food safety regulation. It is important to distinguish the boundary of food additives, so that discussion of food-additive-specific issues can be focused. This section briefly describes that demarcation.

Food safety refers to measures taken to ensure that food is safe to consume (*i.e.*, healthfulness). It covers food processing, allowed ingredients, expiration dates and so forth.

This policy paper concerns only food additives, within the larger issue of food safety. To define what a food additive is, it is best to start with what a food additive is not. Substances that are normally and traditionally consumed as food by humans are food ingredients. Food ingredients, on their own or in combination with other food ingredients, are not food additives. As a result, ingredients such as beef, wheat, sugar or peanuts are not food additives. Nearly all Genetically Modified Organisms (GMO) are food ingredients, and hence are not food additives.

Natural and artificial flavors (substances, both natural and artificial, that are added to food for flavoring purposes), that are typically not consumed as food on their own, are not food additives. For example, spices and artificial smoke flavorings are not food additives.

Food enzymes and fermenting organisms (*e.g.*, pectin from fruit, intentionally added yeasts and bacteria) are not food additives.

Residual amounts of substances used as processing aids that do not have a technological purpose in the final product are not food additives. For example, residual lye in olives is not an additive.

Unintentional or intentional contamination (*e.g.*, with a pesticide) is a very important food safety issue, but it is not a food additive issue (because there is no technological objective from the use of the pesticide). On the other hand, the use of a banned substance for a technological objective is a food additive issue; for example, use of ethylene glycol as a sweetener.

What is left are largely food additives. Food additives are substances, not normally consumed as food themselves, not normally used as a characteristic ingredient of food whether or not it has nutritive value, that are intentionally added to a food to achieve a technological objective, such as increase shelf-life or improve mixing of other ingredients. Food additives are not necessarily artificial; for example, pigments extracted from a plant usually used as colorant in other food is considered to be a food additive. Food additives can also be added to other food additives, to flavorings and to food enzymes. Often food ingredients are used for the same technological purpose (*e.g.*, egg white to promote emulsion-mixing between oil and vinegar). In this case, those food ingredients remain food ingredients; they are not food additives since they are normally used as a characteristic ingredient of the food, even though they are used to accomplish some technological objective.

5 APPROACH OF EUROPEAN UNION TOWARDS FOOD ADDITIVES

In 2008 current EU-level regulations were promulgated. One regulation required the European Food Safety Authority (EFSA) to perform scientific risk-based assessments on all food additives then in use in the EU.[2],[3] In each case, the EFSA was to determine, based on scientific evidence, 1) if the food additive was safe, 2) the list of technological objectives (uses) for the food additive and 3) the maximum level of the food additive in the final product. In each case the analysis was to consider the typical consumption of the food additive in a typical person's entire diet; that is, while a food additive in one food may not be particularly large, if added to the same food additive typically consumed in all products then the cumulative level of the food additive could be unsafe. The risk-based analysis also considered alternative food additives and processing methods, perhaps better researched, that could be used to achieve the same technological objective without the use of the food additive in question.

In addition to food additives being safe, the EU also requires that any used food additive must have advantages and benefits for the consumer and must not mislead the consumer. Benefits include preserving nutritional quality of the food; meeting needs of consumers with special dietary needs; enhancing keeping quality or stability; improving organoleptic properties, but not so as to mislead the consumer; or aiding in the manufacturing, processing, preparation, treatment, packing, transport or storage of food.

Since 2008 the list of approved food additives (Community list) has expanded to include 333 substances.[4] In each case, the EFSA and the European Commission (the body that approves amendments to the Community list) have concluded that, based on the best available scientific data and risk-based analysis, the substance is safe when used as a food additive for the specified purpose at or below the maximum specified level. Each approved food additive is given an E-number, a number with an E prefix (*e.g.*, E131 – Patent Blue V).[5] The E-number for food additives added by a food producer and the technological objective (*e.g.*, coloring) must be shown on the label along with its intended technological objective (*e.g.*, E131 as coloring agent).[6] Other countries use the same numbering system but without the prefix E.

All foods produced or sold in the EU, including ready-prepared foods, are expected to use only food additives that are on the Community list, and then only for the specified technological objective and at or below the specified maximum level.

5.1 EUROPEAN UNION REGULATIONS

Four regulations adopted in 2008 are the basis of regulation of food improvement agents, including food additives, at the EU level, as shown in the following chart. This Policy Paper only concerns Regulation (EC) No. 1333-2008 (the Community list of food additives) and food additive aspects of Regulation (EC) No. 1331-2008 (how food additives are put on the Community list).

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[2] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings.

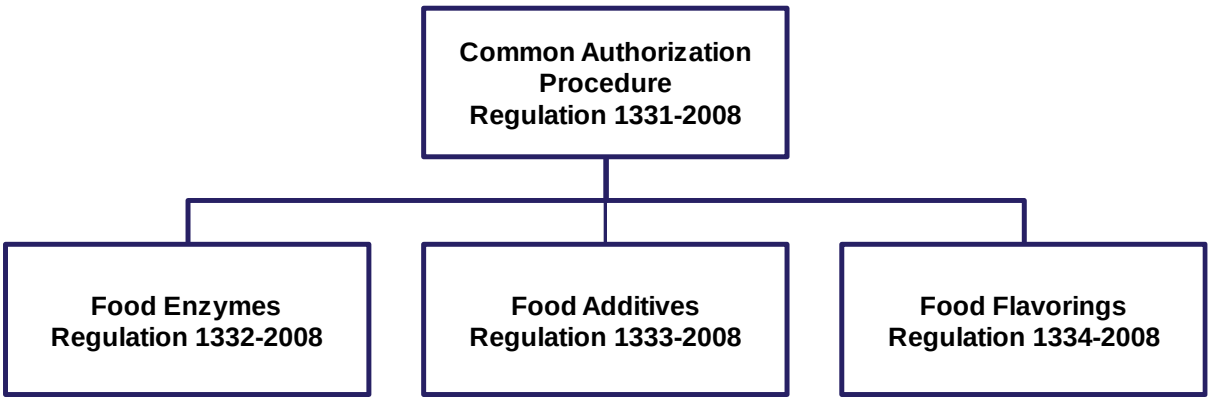
[3] Risk assessment *is* providing scientific advice on food-related risks to support decision-making. Risk assessment *is not* policy making, setting or enforcing legislation, approving or disapproving products for sale, food labeling, and food quality, trade issues including import/export controls, traceability or investigation of food fraud. All those excluded matters are a function for risk management, performed by the European Commission and member state bodies.
http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/InfographicsRiskARiskM.png

[4] As of April 1, 2015 the Community list includes 40 colors, 19 sweeteners and 274 additives other than colors or sweeteners.

[5] Patent Blue V consists essentially of the calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfop-henyl-methylidene) 2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary coloring matters together with sodium chloride and/or sodium sulphate and/or calcium sulphate as the principal uncolored components. The potassium salt is also permitted. Purity levels, other allowed organic compounds and maximum levels of heavy metals are specified.

[6] However, the use of the an E-number does not necessarily mean that the food additive is currently on the Community list. For example, Red 2G (E128) was taken off the approved list in 2007 when new data suggested it was not as safe as previously believed.

Chart 2: Structure of Food Additive Regulations in the EU



REGULATION (EC) NO. 1331-2008

Regulation (EC) No. 1331-2008 sets out a standard method of adding substances to the Community list. It applies to food enzymes (Regulation (EC) No. 1332-2008), food additives (Regulation (EC) No. 1333-2008) and food flavorings (Regulation (EC) No. 1334-2008). The EFSA is responsible for creating and maintaining separate lists for food enzymes, additives and flavorings, with amendments to the list being approved by the European Commission. The three lists are inter-connected since food additives can appear in listed food enzymes and flavorings.

The Regulation specifies:

> "The authorization to place substances on the market must be preceded by an independent scientific assessment, of the highest possible standard, of the risks they pose to human health. This assessment, which must be carried out under the responsibility of the EFSA, must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the member states.
>
> … information relating to the safety of a substance, including, but not limited to, toxicological studies, other safety studies and raw data as such, should under no circumstances be confidential."[7]

The initiative to assess a new food additive for inclusion on the Community list can come from the Commission, a member state or an interested party. The common procedure ends with the Commission adopting a regulation updating the Community list (or not). Through April 2015 there have been 51 amendments to the Community list, with many changes to individual food additives in each amendment.

When sufficient information is available, EFSA sets an Acceptable Daily Intake (ADI) for each food additive and then maximum allowable amounts in foods, considering all sources of the food additive, that is, if the same food additive is used in two common foods, then the sum of those two foods is used for setting the maximum allowable amounts in foods.

Regulation (EC) No. 1331-2008 requires that by 2020 EFSA re-evaluate all food additives authorized for use in the EU prior to 20 January 2009. All substances authorized under previous legislation are allowed until their review by EFSA is complete. The re-evaluation is scheduled as follows:

- Food colors, end of 2015 (currently listed in Directive 94/36/EC);
- All additives other than colors and sweeteners, end of 2018 (currently in Directive 95/2/EC);
- All sweeteners, end of 2020 (currently listed in Directive 94/35/EC).

EFSA works through a Scientific Panel including prominent scientists from across Europe. Their consideration of scientific facts before making a recommendation to the Commission is quite detailed and specific as reflected in the following extract from a plenary meeting discussing Litholrubine (E 180), a red mono-azo dye.

[7] *Op. cit.*, Regulation (EC) No. 1331-2008.

> "The Panel noted that the highest anticipated exposure to Litholrubine BK is 1700-fold lower than the identified effect level of 100 mg/kg-bw/day in female rats. Therefore, the Panel considers that it is unlikely there would be a significant safety concern for humans from the current *single authorized use* of Litholrubine BK in *edible cheese rinds*."[8]

Since 2008 the EFSA has invested countless man-years and hundreds of millions of USD in scientifically reviewing and establishing the Community list of food additives. Although their work has not been without controversy, it is generally regarded as the most comprehensive science- and risk-based analysis of food additives that has ever been done. It an ongoing process as new information is developed on existing food additives and as new additives are considered for inclusion on the Community list.[9]

REGULATION (EC) NO. 1333-2008

The previously described Regulation (EC) No. 1331-2008 concerns *the method* through which the Community list is prepared and amended. Regulation (EC) No. 1333-2008 is the actual Community list.

Regulation (EC) No. 1333-2008 lists the substances that can be used as food additives (the Community list), the technological objectives for which the substances can be used and limits on additions. The Regulation also covers the use of food additives in food enzymes and flavorings. The Regulation gives the technical specifications of food additives and specifies rules on the labeling of food additives when they are sold, in bulk, as food additives.

A particular food additive can be approved for one technological objective but not for another, or for one food type but not for another. There are 26 categories of technological objective as shown in an Attachment. As examples, the first three technological objective categories are as follows:

> "Sweeteners: substances used to impart a sweet taste to foods or in table-top sweeteners.
>
> Colors: substances which add or restore color in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colors within the meaning of this Regulation.
>
> Preservatives: substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms."[10]

Food additives not on the Community list cannot be used in foods.

> "No person shall place on the market a food additive or any food in which such a food additive is present if the use for the food additive does not comply with this Regulation."

In addition, the Regulation specifies the (relatively few) food additives that can be used in each type of food. For example, unflavored pasteurized and sterilized milk (including UHT) can only contain E331 (sodium citrates) and E338-452 (phosphoric acid, phosphates, di-, tri- and polyphosphates). Foods are divided into 137 different types, each with its own unique list of approved food additives. Of the overall 333 food additives, only 12 are approved for use in all categories of foods; of the 12, seven are gases (*i.e.*, carbon dioxide, argon, helium, nitrogen, nitrous oxide, oxygen, hydrogen).

Even more restrictions on food additive use apply to certain traditional products. For example, with a couple of exceptions (*e.g.*, *Neuzeller Kloster* Brewery and *Schwarzer Abt*) no food additives can be used in German beer except propellant gas (CO_2 gas). Traditional French bread can contain no food additives.

An Annex contains labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children".

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[8] Minutes of the 14th Plenary Meeting of the Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS); Held in Parma on 13-15 April 2010; Adopted on 22 June 2010 at the 15th Plenary Meeting.
[9] Any newly developed food additive must go through the EFSA Scientific Panel and be approved by the Commission before it can be used in foods produced or consumed in the EU.
[10] *Op. cit.*, Regulation (EC) No. 1333-2008, as amended April 1, 2015.

All enforcement of the Regulation is done by member states, with regular reporting to the Commission.

> "Member states are to carry out official controls in order to enforce compliance with this Regulation.
>
> Member states shall maintain systems to monitor the consumption and use of food additives on a risk-based approach and report their findings with appropriate frequency to the Commission and the Authority."[11]

EFFECT OF THE TWO REGULATIONS

The effect of the two regulations is that there is a common list of allowed food additives that applies to the entire EU, and to all food imports to the EU. While the Community list is long and complex (333 food additives, 26 technological objective (use) categories, about 137 food types), it is nevertheless well organized and easily accessible. Using tools provided by EFSA and member states, a food producer can relatively easily find those additives that are permitted for any particular type of food. Likewise, citizens have relatively easy access to the Community list and the scientific background for each food additive on the Community list. The materials are available in EU languages, but not in Georgian.

EFSA also maintains a Comprehensive Food Consumption Database, a source of information on food consumption across the EU and within a number of member states.

5.2 IMPLEMENTATION OF REGULATION (EC) NO. 1333-2008 IN GERMANY

As noted previously, all enforcement of Regulation (EC) No. 1333-2008 is done by member states. Practices used by member states can provide guidance to Georgia as it sets its own path. The approach used by Germany is described in this section.

LEGAL BASIS AND NATIONAL REGULATORY FRAMEWORK

In Germany all EC Directives concerning food additives have been transposed into national law through the following legislation:

- Food, Contact Materials and Animal Feed Code[12]
- Statutory Order on the Approval of Food Additives for Technological Purposes[13]
- Statutory Order on Requirements for Food Additives and the Placing on the Market of Food Additives for Technological Purposes.[14]

In general terms, there are two types of national legislation related to food additives at the Federal level: regulations and administrative provisions. Regulations are addressed to business operators and published in the Federal Law Gazette (*Bundesgesetzblatt – BGBl*). Administrative provisions are addressed to the competent authorities and published in the Official Gazette (*Bundesanzeiger*).

The list of allowed food additives in Germany is fully harmonized with the Community list. German and EU food law prohibits all food additives which are not specifically approved for the technological objective and food group shown in the Community list. On German labels, food additives are listed under *Inhalt*. As a rule, their names are encoded by the E-number.

COMPETENT AUTHORITIES

Since Germany is a federal state, the Federal Lands (*Länder*) participate in the process of the legislation by the Bundesrat (upper house of the German Federal Parliament). Therefore, in Germany, there are two levels of competencies related to monitoring and control of food additives: Federal level and Land level.

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[11] *Ibid.*
[12] *Lebensmittel-, Bedarfsgegenstände-, und Futtermittelgesetzbuch – LFGB,* of April 26, 2006 (BGBl. I p. 945), as amended by Article 12 of the Act of February 26, 2008 (BGBl. I p. 215).
[13] *Zusatzstoff- Zulassungsverordnung – ZZulV* of January 29, 1998 (BGBl. I pp. 230, 231), as amended by Article 3 of the Statutory Order of September 30, 2008 (BGBl. I, p. 1911).
[14] *Zusatzstoff-Verkehrsverordnung – ZVerkV* of January 29, 1998 (BGBl. I pp. 230, 269), as amended by Statutory Order of December 15, 2008 (BGBl. I, p. 2522).

On the Federal level, the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) is responsible for drafting and implementing legislation, including legislation to transpose EU legislation. BMELV is responsible for coordinating the monitoring of use and consumption of food additives. The competences of BMELV also include development of measures in the field of risk management and the selection of appropriate measures.

As part of their practical work activities, the Ministry is supported by the Federal Office for Protection of the Rights of Consumers and Food Security (BVL). BVL coordinates the work between the Federal level, state bodies and EU bodies.

Scientific work is conducted by the Federal Institute of Risk Assessment (BfR) and four other Federal scientific research institutes. BfR is the focal point for coordination between EFSA and several Federal ministries (the BMELV, the Federal Ministry of Health (BMG) and the Federal Ministry for Environment, Nature Conservation and Nuclear Safety (BMU)). BfR's task is to provide BMELV information and consulting support through independent scientific expertise. Scientists at BfR participate in the corresponding EFSA working groups as EFSA assesses existing and new food additives.

Experts from universities, Land authorities, Federal and research agencies are appointed as members of the BfR work with EFSA. BfR also has contacts with Federal ministries responsible for monitoring activities in consumer protection. Scientific institutions involved in Germany in tracing, identifying, assessing and managing risks in the areas of food, feed, animal welfare and plant health are included in this exchange of information.

INFORMATION FOR BUSINESSES

Food producers have access to web information, newsletters, brochures and the expert staff. A focal point is Bundesamt für Verbraucherschutz und Lebensmittelsicherheit. Substantial information is provided to businesses on-line. One website in particular shows the additives that are permitted in each food group. The information provided is sufficient for a food producer to have clear guidance on what can and cannot be done, though it should be applied to a particular recipe by a qualified individual. This would be a normal part of new product development.

A European Commission initiative on Better Training for Safer Food (BTSF) organizes trainings in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules. The BTSF trainings provide the best specialists and trainers in the field, state-of-art science and up to date information on the legal regulations and their practical implementation. The training courses are organized in various locations in Germany or other EU countries.

Applications (from business or others) for adding new food additives to the Community list are submitted either directly to the European Commission, Health & Consumer Protection Directorate-General (DG SANCO) or to the Federal Ministry of Food and Agriculture which then forwards the application to the European Commission.

ENFORCEMENT

At local level, the responsibility of enforcement and food control goes to the 16 individual Lands.

Employees of municipal and district authorities monitor food safety and carry out supervision through random checks of products and management systems. The Federal Ministry coordinates supervision activities at the Land level. In turn, representatives of the Lands closely cooperate with Federal authorities, for example, when it comes to the harmonization of Federal quality control programs and product safety, as well as in the event of crises related to food products.

The staff involved in food control are food inspectors and scientifically trained experts like food chemists, veterinary and medical doctors. All staff are civil servants.

Penalties for breaking rules take several forms, including strict civil liability for damages and penalties both often with a reversal of the burden of proof for health hazards caused by a food producer.

The Federal Office of Consumer Protection and Food Safety contributes towards food safety with a wide range of measures. It grants authorizations and jointly coordinates monitoring programs with the federal states.

LABORATORY INFRASTRUCTURE

In Germany, official food control is regulated by the Government and cannot be privatized. There are 49 accredited state laboratories. There are an additional 18 laboratories designated to perform official control

analyses. The BfR is designated as a national reference laboratory for these purposes. All laboratories are accredited to ISO 17025 by one of the accreditation bodies in Germany as there is no central accreditation body established.

With regard to food additives, all 67 laboratories designated to perform official food control analysis in the Lands are authorized to perform official control analysis for food additives.

Hessian Land Laboratory in Wiesbaden, a typical example of a laboratory, is designated to perform official food control analysis in the Land of Hessen. The Land of Hessen has about six million residents; this is only about 50 percent larger than Georgia, so the following measures of size could be appropriate for Georgia, keeping in mind that the 74 laboratories in Germany handle the entire population of 81 million (one laboratory per 1,1 million inhabitants).

Hessian Land Laboratory has about 100 staff in three departments responsible for food analysis, among whom are 25 to 30 are food chemists and 50 to 75 are other technical staff. Personnel are adequately trained. The laboratory has been accredited according to ISO 17025 by the German Accreditation Body SAL (Staatliche Anerkennungsstelle der Lebensmittelüberwachung) since 1998. The scope of accreditation covers several analytical methodologies. Individual methods are not mentioned in accreditation documents. The list of analytical methods used in the laboratory includes quantitative determination of most common food additives.

OUTREACH

In 2015 BfR's budget was 89,7 million EUR. The staff is 802, including 323 scientists.[15] In 2014, BfR carried out approximately 3 140 risk assessments and was involved in 18 EU projects and 25 projects of the German Research Society (DFG) and other federal agencies. In 2014 BfR scientists serve on 407 national and international committees.

5.3 IMPLEMENTATION OF REGULATION (EC) NO. 1333-2008 IN POLAND

As noted previously, all enforcement of Regulation (EC) No. 1333-2008 is done by member states. Practices used by member states can provide guidance to Georgia as it sets its own path. The approach used by Poland is described in this section.

LEGAL BASIS AND NATIONAL REGULATORY FRAMEWORK

The foundation of food legislation in Poland is the Food and Nutrition Safety Act of August 25, 2006. Violations of the Act and food regulations can lead to criminal charges and damage claims from consumers under civil law, all settled by the courts. Food safety actions by the Government are often based on science- and risk-based analyses, but final decisions on legality rests with the courts.

Three regulations apply to food additives and implementation of EU Regulation (EC) No. 1333-2008:

- The Polish Minister of Health Regulation on Permitted Additives of April 22, 2011;[16]
- The Polish Minister of Health Regulation on Specifications and Criteria of Purity of Additives of October 12, 2007 as amended on December 23, 2010 and April 22, 2011;[17]
- Minister of Health Regulation on Solvent Extraction, which can be Used in the Production of Food of February 18, 2011.[18]

A final regulation specifies the list of additives which can be used in Poland under other conditions than in the EU.

- The Polish Minister of Health Regulation of September 18, 2008 Concerning the Allowed Additives with Ammendment of August 9, 2010.[19]

[15] This is about 10 staff members per one million citizens. A comparable organization for Georgia would have a staff of about 35.
[16] Polish Journal of Law 2011, No. 91, pos. 525.
[17] *Ibid.*
[18] Polish Journal of Law 2011, No. 52, pos. 272.
[19] Polish Journal of Law 2009, No. 17, pos. 96.

COMPETENT AUTHORITIES

The Polish Ministry of Health is responsible for public health policy and food safety including food additives. It prepares draft legislation as needed. The Chief Sanitary Inspectorate (Główny Inspektorat Sanitarny) is within the Ministry and is the competent authority for food safety in Poland. The Chief Sanitary Inspectorate cooperates with the Ministry of Agriculture and Rural Development and the Ministry of Environment on matters regarding food safety. It also coordinates and supervises the activities of the State Sanitary Inspectorates that are responsible for local control of all aspects of food safety including food additives.

The Chief Sanitary Inspection has a specialized staff prepared for public health protection, equipment for investigations and a network of 346 Sanitary-Epidemiological Stations including 16 at the region (*voivode*) level, 209 at the district (*powiat*) level, 5 in ports and 16 in railway health services. At district and local levels, specialists within the Chief Sanitary Inspectorate and the Ministry of Agriculture and Rural Development are responsible for enforcing food laws and carrying out food inspections, including matters related to food additives.

The risk management measures within the Chief Sanitary Inspectorate are based on scientific risk assessments carried out by the National Food and Nutrition Institute and the National Institute of Public Health – National Institute of Hygiene.

The National Reference Laboratories are within the Chief Sanitary Inspectorate.

The Customs Service, subordinate to the Ministry of Finance, is responsible for the border control of food. The Customs Service cooperates with the General Veterinary Inspectorate on controls of export and import of animals and food of animal origin and the Chief Sanitary Inspectorate on export and import of food of plant origin.

INFORMATION FOR BUSINESSES

The Department of Food Safety and Veterinary Matters is responsible for the informing food businesses on regulations concerning food additives and other food-related matters. Food businesses also are supported by newsletters, TV, print media and personal contacts with relevant experts. The State Sanitary Inspectorate also arranges training sessions on new legislation.

All food businesses must be registered, which greatly facilitates the dissemination of information to food businesses. The State Sanitary Inspectorate maintains a list of establishments in each district; the Inspectorate can suspend or withdraw a food business' approval if necessary.

ENFORCEMENT

Sanitary-Epidemiological Station inspectors perform controls, including taking samples, concerning: the health quality of food; the use of authorized food additives and other ingredients; hygiene of production and distribution of foodstuffs (including Hazard Analysis Critical Control Point (HACCP); catering and materials and articles in contact with food. They supervise food products placed on the market. Where food products of animal origin are manufactured or stored in a production plant which also manufactures other food products, the controls may be carried out by the General Veterinary Inspectorate or the State Sanitary Inspectorate. There are annual sampling plans, with each year's plan focusing on different food types.

Work is at an advanced stage to develop a risk analysis system for controlling establishments, which will eventually be operated electronically. At present, the frequency of inspections is based on specific ordinances, or laws.

The State Sanitary Inspectorate has set up a risk assessment team comprising more than 30 experts from several national-level scientific institutions.

LABORATORY INFRASTRUCTURE

Several scientific institutes in Poland are reference laboratories; they also provide specific support in the preparation of annual sampling plans, risk assessment and the training of State Sanitary Inspectorate staff. There is a network of laboratories consisting of 16 regional laboratories, with 50 branches. Accreditation of laboratories in accordance with EN ISO 17025 is obligatory.

OUTREACH

In the food safety area, some 1,000 staff are employed at regional (voivode) level and some 2 500 at the district (poviat) level. That level of investment is about 92 staff per million residents.

6 SUMMARY OF DCFTA REQUIREMENTS REGARDING FOOD ADDITIVES

The Government approved the National Action Plan for the implementation of the AA between the EU and Georgia in September 2014.[20] In 2016 Georgia is to approximate Regulation (EC) No. 1333-2008 concerning food additives. The whole process for approximating other food-related regulations (*i.e.*, all food safety, sanitation, hygiene, labeling issues) will be completed in 2022.

Specific requirements and dates in the National Action Plan and concerning food additives are as follows:

1. Regulation (EC) No. 1333-2008 (food additives and the Community list) in 2016;
2. Regulation (EC) No. 1331-2008 (common authorization procedure for food additives, food enzymes and food flavorings) in 2017;
3. Regulation (EU) No. 234-2011 (implementing Regulation (EC) No. 1331-2008) in 2018;[21]
4. Regulation (EU) No. 257-2010 (implementing the re-evaluation of approved food additives in Regulation (EC) No. 1331-2008) in 2018;[22]
5. Regulation (EU) No. 231-2012 of 9 March 2012 (specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333-2008) in 2019;[23]
6. A number of other regulations concerning food enzymes and flavorings 2020 through 2022.

Item 1) will require the most changes within Georgian food producers (concerning the food additives they use) and within the Government (for monitoring for compliance matters). Items 2) through 4) (concern adding substances to the Community list) will affect Georgian cooperation with on-going processes in the EU rather than requiring significant changes within Georgia *per se*. Item 5) will be automatically be met if Georgian food producers source food additives from suppliers who meet EU requirements. Georgian producers of food additives would be much more affected by item 5). Item 6) does not concern food additives except to the extent that certain flavorings contain food additives.

The approximation process for Regulation (EC) No. 1333-2008 will go through several stages. First, the project has been sent to structural units and entities of the Ministry of Agriculture and other subordinate organizations.[24] When internal discussions are complete, results will be sent to the Ministries of Economy and Sustainable Development, Health and Labor and Environment for review and revision. The project will then be published and public debate will begin.

In the next step, the project will be sent to the Government office, the Prime Minister, the Economic Council and the European Commission. All comments and recommendations will be taken into account and regulations finalized. After the Prime Minister approves the final regulations, they will be published and enter into force.

Georgian food businesses who sell processed food products, whether for domestic consumption or export and whether packaged or freshly prepared, will need to adjust their recipes and labels to comply with the requirements of Regulation (EU) No. 1333-2008 (*i.e.*, the Community list of approved food additives and their uses). It is anticipated that significant training of Georgian food businesses and recipe reformulation will be required. Active cooperation with the food industry and supporting them to increase their capabilities is within the overall goal of the approximation process.

It is expected that the NFA and the Revenue Service will redouble their efforts at monitoring and sampling food enterprises concerning compliance with food additive requirements. Laboratories will need to be upgraded to provide the analyses needed for monitoring.

Once these steps are taken and with good implementation and enforcement, the Georgian consumer will be able to be as certain as EU citizens that their foods contain only approved food additives. Food producers will be able to export products to the EU without additional testing to ensure compliance with EU requirements; a non-tariff barrier will be removed.

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[20] Governmental Decree No. 1516 on September 3, 2014.
[21] Regulation (EU) No. 234-2011 of March 10, 2011 implementing Regulation (EC) No. 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings.
[22] Regulation (EU) No. 257-2010 March 25, 2010 setting up a program for the re-evaluation of approved food additives in accordance with Regulation (EC) No. 1333/2008 on food additives.
[23] Regulation (EU) No. 231-2012 of March 9, 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333-2008.
[24] A working group has been set up within the Food Department of the Ministry of Agriculture.

7 CURRENT STATUS OF FOOD ADDITIVE REGULATION IN GEORGIA

Food additives (and other food safety issues) are regulated in Georgia through an Order of the Ministry of Labor, Health and Social Affairs dating from 2001.[25] This Order is very old; it needs to be thoroughly revised or replaced to meet the requirements noted in the previous section.

Interviews with key informants revealed that, for all practical purposes, no routine monitoring of compliance to the requirements of the Order is done by the Government. Occasionally the Government does undertake action in regard to a specific incident.

In a practical sense, this means that food additive requirements in Georgia are an entirely voluntary matter for food businesses. Businesses and key experts revealed that most businesses have a very poor understanding of food additive issues. This does not mean that businesses are unconcerned; rather they are simply uninformed. Given current arrangements, there is no particular incentive for businesses to become better informed.

Finally, there are no laboratories in Georgia accredited for testing for food additives.

To the end, one could conclude that practically speaking food additives are not regulated in Georgia today.

[25] Order of the Ministry of Labor, Health and Social Affairs No. 311/N of August 16, 2001; ''Food Additives Using Sanitary Rules and Norms''.

8 PROBLEM STATEMENTS

A number of industry and governmental stakeholders were consulted when preparing this policy paper. The stakeholders eagerly described their concerns related to food additives. Those concerns were added to appreciable desk research.

To the end, in this section we describe food additive concerns and issues. These issues and concerns are summarized into the six problem statements.

8.1 GEORGIA'S REGULATIONS ON FOOD ADDITIVES ARE OUT OF DATE AND DO NOT AT ALL MEET THE APPROXIMATION REQUIREMENTS OF THE ASSOCIATION AGREEMENT

Georgia's food additive regulations were promulgated in 2001 and have not been fully updated since. As a result, those regulations certainly cannot approximate the requirements of EU Regulation (EC) No. 1333-2008, promulgated seven years later.

It is likely that updating existing regulations piecemeal to match approximation requirements would be more difficult than essentially creating an entirely new regulatory structure.

Until Georgia's regulations on food additives are updated and implemented, Georgian manufactures will continue to have difficulties exporting food products to the EU. In addition, Georgian citizens will not benefit from the most current scientific results on the safety of particular food additives.

8.2 GEORGIA DOES NOT HAVE THE DELEGATED COMPETENCIES OR STAFF THAT WOULD PERMIT ENFORCEMENT OF FOOD ADDITIVE REQUIREMENTS IF THEY EXISTED

Food additive (and other food safety) requirements in the EU are largely self-enforced by food business operators. Food business operators are motivated to do this because 1) it is the right thing to do and 2) there are well developed monitoring and testing methods to detect intentional or unintentional violation of the rules. Over time, businesses become more familiar with requirements, become aware of penalties for non-compliance and, not surprisingly, compliance improves.

By their nature, food additive (and other food safety) monitoring and testing is local. For food businesses, violations occur at the local factory, local restaurant or local shop. Many, even most, foods are consumed throughout the country, and potential violations can be spotted nearly anywhere, but again locally at the point where the potential violation is spotted. Human nature suggests that some type of local solution is most appropriate for this industry.

As a result, member states in the EU mostly enforce food additive (and other food safety) requirements at the local level. In a practical sense, this means that local staffs determine who to monitor (within guidelines from the national level), when to monitor, when to collect samples following standard protocols and so forth. This is done locally with locally-based staff, who may be representatives of a national-level ministry or agency.

Unfortunately, at present Georgia has neither the required number of people nor budget for this level of scrutiny and monitoring. As a result, for at least the foreseeable future compliance will largely depend on ensuring that food business operators well understand what they need to do to comply with requirements, backed up with knowledge of the (relatively small) risk they face if they do not behave properly.

The consequence of this is that Georgia should expect a rather long shakeout phase, during which compliance with new food additive requirements will be spotty at best.

Member states in the EU went through a similar shakeout phase. If one looks at the results of monitoring done over the years, the number of violations has fallen significantly as food business operators have learned what is required, again backed up with the risk of sanctions if monitoring shows them in violation of regulations.

8.3 KNOWLEDGE OF MODERN FOOD ADDITIVE TECHNOLOGIES IS LIMITED AMONG GEORGIAN FOOD OPERATORS

Discussion with food business operators shows two distinct groups. Large companies with prominent brands in prominent industries have good knowledge of food additives and their proper use. We cannot say if they follow EU requirements, but at least they are aware of them. In a practical sense, food business operators cannot export to the EU today without knowing and following the requirements of Regulation (EU) No. 1333-2008; consequently, exporters are already familiar with the requirements.

Approximating Regulation (EU) No. 1333-2008 will require that all businesses use the Community list of food additives. Many food business operators, all those that do not export to the EU today, have only a rudimentary knowledge of food additive requirements. They are not aware of Georgian requirements because the 2001 Regulation is not well followed. They are not aware of EU requirements because they do not export to the EU. Among these businesses, we found that lack of knowledge comes more from not having access to information in an easy-to-understand and utilize form than from a fundamental reluctance to use the proper food additives.[26]

Implementation of changes will be very difficult until food business operators become familiar with requirements and easy ways to implement changes are available.

8.4 GEORGIA DOES NOT HAVE IMPLEMENTED REGULATIONS THAT WOULD PERMIT ENFORCEMENT OF FOOD ADDITIVE REQUIREMENTS IF THEY EXISTED

Most member states in the EU have a long history of enforcement of food additive (and other food safety) requirements. Over time, they have developed the human capital infrastructure needed to monitor and test compliance, particularly at the local level where most monitoring work (leading to enforcement) is done.

Georgia does not have that luxury. Most of the human capital infrastructure that Georgia once had at the local level was lost before 2010.

As a result, Georgia will need to redevelop this human capital infrastructure if it is to properly enforce food additive (and other food safety) requirements as they are promulgated. In the meantime, Georgia will largely have to rely on voluntary compliance by businesses or some type of third-party certification, financed by food businesses; this is a common approach in the EU for certain interests (*e.g.*, animal welfare).

In addition to this, in Georgia the import of the food additives is not controlled and their identification is a very difficult.

8.5 THE LABORATORY INFRASTRUCTURE FOR TESTING FOR FOOD ADDITIVE INFRINGEMENTS IS WEAK

By definition, food additives are very minor ingredients in a food. Generally, all one can conclude from a gross examination of the product is that a food additive, of some type, was used for a particular technological objective (*e.g.*, something was used as an emulsifier). Sometimes a visit to a producer is sufficient to shed light on the case. Often, particularly in contentious cases, there is a need to formally test a suspect product to determine if only approved food additives were used.

Proper testing requires a proper network of testing labs. At present in Georgia there are no labs that are accredited for testing for food additives, at least accredited so that the results would be acceptable within the EU. The absence of proper laboratories stems from not emphasizing this subject in the past and the resulting low funding level for labs in the country.

Georgia will not be able to credibly claim that it has a functioning food additive enforcement mechanism until a proper network of laboratories exists.

[26] In all our secondary research we did not find any particular complaints among businesses about the switch to only approved food additives. This may be because food additives have always been regulated in the EU, but more at the member state level than at the EU level, as is the case today.

8.6 FUNDING FOR MOST FOOD ADDITIVE MATTERS IS VERY LIMITED

All that we spoke with told us that investment in food additives, and other aspects of food safety, is simply not adequate. This includes investment in people, methods, labs and so forth.

9 RECOMMENDATIONS

Based on the problem statements noted in the previous section, this policy paper recommends a number of actions. The recommendations address the problems noted previously plus other practical matters that arose during the preparation of this paper.

9.1 GEORGIA SHOULD ADOPT THE COMMUNITY LIST OF FOOD ADDITIVES (SHOWN IN REGULATION (EU) NO. 1333-2008) EQUIVALENTY

The purpose of the Community list is to ensure the safety of food additives in foods sold in the EU. The Community list shows those food additives that can be used in foods. If a substance is not shown on the Community list, or if a substance on the Community list is used for an unapproved technological objective, then the food cannot be sold in the EU. The Community list is the result of in-depth science-based analyses done by the EFSA and its related Panel on Food Additives.

By adopting the Community list Georgia will immediately become party to the most comprehensive and most well researched positive list of food additives in the world.[27] The NFA should be appointed the Georgian counterpart for food additive matters, if it not already so.

The Community list should be adopted in an equivalent way; there is no need to customize the Community list for the Georgian situation. However, food consumption patterns of Georgian households should be closely analyzed to determine if there are radical differences from practices in European households that would cause the daily intake of particular food additives in Georgia to exceed the Acceptable Daily Intakes (ADI) on which the Community list is based. That is, if Georgian eating habits are radically different from European eating habits, then there is a risk that a food additive (from all foods) that is below the ADI in Europe could be above the ADI in Georgia. A problem with the ADI is very unlikely, but research should be done to confirm this.

A list of ingredients and food additives typically used by food businesses in Georgia should be compiled and compared to the Community list.[28] Problematic substances or foods will fall into three groups. The first group are substances which are used in Georgia but are not on the Community list. Over time as the Community list is phased in, the use of these substances in Georgia should be reduced and eliminated. This should not be a particular technological problem as there are almost always alternatives from a technological objective perspective.[29]

The second group are ingredients or food additives that 1) are used in Georgian traditional cuisine, 2) are not generally used in the EU and therefore 3) have never been evaluated for inclusion on the Community list. If these substances are truly irreplaceable in Georgian cuisine, then they should be submitted to the European Commission for research and approval for inclusion on the Community list, following the provisions of Regulation (EU) No. 1331-2008. It is unlikely that there are any such food additives in use in Georgia, but this should be studied and confirmed.

The third group are traditional Georgian foods where more restrictive food additive rules should apply.[30] The Community list includes a handful of such limitations today.[31] If there are any such Georgian foods, then the restrictions that would be imposed should be submitted to the European Commission for inclusion on the Community list. The restrictions would likely apply only to foods produced in Georgia, not to those produced elsewhere. Such Georgian foods could, of course, be sold throughout the EU. Requesting the more restrictive

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[27] A positive list shows those substances that can be used in foods. A negative list shows those substances that cannot be used in foods. The EU has a positive list. The US generally has a negative list.

[28] Although the Community list concerns food additives, and not ingredients *per se*, it is possible that extracts from some ingredients in Georgian cuisine could be excluded from the Community list.

[29] Note that food additives are used only to achieve a technological objective, not to affect flavor or healthfulness. In most cases, there is at least one food additive that can be used to achieve a particular technological objective in a particular type of food. If there is not such a food additive on the Community list, then this is because it was concluded (based on scientific results) that including any food additive for that particular technological objective for that particular type of food was unsafe.

[30] Traditional foods generally mean foods that have been in common use for a generation, more than 25 years. Traditional foods do not include foods targeted to specialized consumers (*e.g.*, babies, children). Requirements for specialized consumers are already considered in the Community list.

[31] *e.g.*, German beer, French bread.

food additive rules on the few, if any, traditional Georgian foods can be done at any time in the future; there is no hurry.

By accepting the Community list, and their equivalency, Georgian food businesses will have a clear list of what can be used as a food additive in Georgia. Implementation will be phased permitting Georgian food businesses to adjust their recipes in a step-by-step process. Over time, the assurance that Georgian foods contain only safe food additives will increase. Georgian consumers will no longer need to be suspicious of foods produced in Georgia. Georgian businesses will also be able to more easily export food products to the EU.

9.2 BUSINESSES AND GOVERNMENT SHOULD BE GIVEN SUFFICIENT TIME FOR IMPLEMENTATION

The existing list of food additives has not been updated a long time. Therefore, businesses will require sufficient time to prepare for the new list (Community list). We think that costs are not high, however sufficient time for adjustment is still needed. This time should be productively used by the authorities to effectively communicate about the pending changes.

Some will claim that Georgia businesses cannot afford to comply with a new updated list of approved food additives (*i.e.*, the Community list). While this should be researched thoroughly, including analyses by sector, preliminary analysis suggests that costs will not be high.

There are two types of costs that Georgian businesses might face as they comply with the Community list. First, there is the one-time cost of adjusting recipes. This is a real cost, but one that food businesses routinely face whenever they develop a new product; each new product has its own set of food additives. As we reviewed materials available about the Community list, it became clear that finding candidate substitutes for any technological objective is not particularly difficult because the Community list is essentially prescriptive.[32] If it is difficult to find a suitable substance, then there is a food safety reason for it being so. To the end, this will be a one-time effort and cost, and if educational resources are made available in Georgian then the one-time cost will not be prohibitive; businesses will need to decide to “just do it”.

Second is the ongoing cost of different, and presumably safer and better quality, food additives. This is almost certainly not a large amount per kg of food produced. Food additives are used in very small quantities, only enough to achieve the desired technological objective. Rough calculations suggest that using comparable quantities of food additives that are twice as costly (with good traceability) will increase the production cost of one kg of food by one or two Tetris.[33] This is a real production cost increase, and will result in higher prices for consumers. On the other hand, that price increase of perhaps three to five Tetris per kg for consumers will produce benefits coming from safer food additives and the knowledge among consumers of the increased safety of food additives in Georgian foods generally.[34]

As for businesses, the government also will require sufficient time to ensure complete equivalence of the Community list as well as its implementation, capacity scale-up and effective execution.

We think that appropriate time for these changes should be no earlier of one year.

9.3 REGULATIONS SHOULD BE CREATED TO ENABLE OFFICIAL BUT VOLUNTARY CERTIFICATION OF FOODS AS MEETING THE REQUIREMENTS OF THE COMMUNITY LIST

To reach the state when the enforcement of food additive control is considered effective in Georgia, will require quite some time after the Community list is adopted. However, there are businesses that wish to export foods to the EU now. Waiting for until the EU acknowledges the effective enforcement of the Community list, isn’t acceptable for businesses that are ready to export right now.

[32] For example, if you are making product X then the Community list shows the specific food additive Y that can be used for technological objective Z.
[33] The amount would vary a lot by type of food additive. In any case, there would be an increase only when the existing food additive is no longer permitted.
[34] For example, a 350 gm package of cookies currently selling for 3,50 GEL will now sell for 3,52 GEL.

To meet the immediate needs of these exporting businesses, regulatory provisions should be created to permit official but voluntary third-party certification of food businesses as meeting the requirements of the Community list. In parallel, to enforcement the Community list among all food businesses, start with those businesses that wish to export to the EU now. Those businesses are highly motivated to use only food additives on the Community list, to make a switch now, to accept monitoring to assure compliance and to pay the cost of doing so.

The voluntary third-party certification should apply to an entire food business, not to individual products. Ensuring compliance, and communicating that to trading partners, is much easier when the entire business is included.

A small but effective monitoring and enforcement scheme should be developed for those food businesses that choose to participate. This scheme should become the root of the eventual monitoring and enforcement scheme that applies to all food businesses.[35]

A positive list and label seal for businesses that have gone through the voluntary third-party certification process (and related monitoring) should be maintained and widely disseminated. The export of food products to the EU should be prohibited for food businesses not on the positive list.

The meaning of the label seal should be communicated to Georgian consumers, so that companies are motivated to go through voluntary third-party certification even if they do not export to the EU. We were told that Georgian consumers are very worried about food additives. The voluntary third-party certification seal will help consumers feel more confident of Georgian foods with the label seal.

The official but voluntary third-party certification scheme should be a public-private partnership. The official nature of the certification should be greatly emphasized. Businesses who choose to go through the certification process should pay a large portion of incremental costs. The number of participating businesses and their characteristics (*e.g.*, number of product types, production volumes) should be forecasted and fees set to cover incremental staff and testing costs. As the number of participating businesses increase the fees should be reduced over time.

The official but voluntary third-party certification scheme should be approved by the EU. In 2010 there were more than 400 voluntary certifications in the EU (*e.g.*, organic production). The Georgian scheme should cover food additives.[36] It is likely that the EU will require assurance that the voluntary third-party certification scheme is only an interim measure, until enforcement of the Community list applies to all food businesses in Georgia.

There will be several benefits from creating an official but voluntary certification system. Exports by Georgian businesses to the EU and elsewhere will be greatly and immediately facilitated; in principle, any country that accepts imports from the EU should accept imports from Georgia. Certified exporting businesses will be able to use the label seal on products sold domestically, permitting Georgian consumers to make better informed purchase decisions. Over time, other food businesses will be motivated by competitive pressures to become voluntarily certified themselves.

To the end, use of an official but voluntary certification scheme will greatly facilitate the enforcement of the Community list in all Georgian food businesses.

9.4 IMPORTED FOOD ADDITIVES MUST BE CONTROLLED MORE RIGOROUSLY

The EU is a market of 500 million people. It is a very attractive market for any food producer in the world. If a producer cannot, or chooses not, to export to the EU (likely meaning the producer does not or cannot comply with the Community list of food additives) then there is *prima facia* evidence that the safety of the products is questionable.[37] In this case, the product is excluded from the EU market. The same exclusionary rule can and should apply to Georgia.

[35] Experience gained with these businesses will guide later work to cover all food businesses.
[36] Conceptually, there is no reason the official but voluntary certification scheme could not cover other food safety issues, though these are not considered in this policy paper.
[37] There are of course many reasons why a food business might not export to the EU. For this policy paper we focus only on food additive issues.

Inspection of imported food additives by different companies in Georgia should be made in accordance with Community list. The border inspection for hygiene and safety of the imported food additives should be conducted when accredited laboratory is in place in the country. Implementing this recommendation will increase the safety of food imports to Georgia.

There will be costs related to this recommendation, as existing lower-cost suppliers will no longer be able to import foods into Georgia. While the loss of lower-cost suppliers is regrettable, the direct benefit of doing so is the increase in the safety of imported foods in Georgia. If Georgia wishes to increase the safety of foods in Georgia, then it can only do so by prohibiting the import of foods that do not meet Community list requirements.

9.5 FOOD BUSINESSES SHOULD HAVE ACCESS TO EFFECTIVE INFORMATIONAL TOOLS AND METHODS

Compliance with the Community list requires that food businesses 1) become aware of the requirements and 2) take steps to change existing recipes and food additive suppliers. A very significant outreach program should be implemented to facilitate both these steps.

All food businesses should be contacted in multiple ways to ensure that they are aware that changes to food additive requirements are coming and where they can obtain needed information. The very extensive materials available online in all EU member states (including the Community List) should be translated into Georgian and made available to food producers. The methods and most appropriated forms for the dissemination of information should be designed. Business operators should be well prepared and must be offered special training, online courses, including the Webinar's, SMS services. A small cadre of food chemists should be created to help businesses decide how to change the food additives in their recipes or how to best achieve a particular technological objective.[38] The cadre of food chemists should be well informed about natural additives that could be used to accomplish the desired technological objective. A list of available sources of food additive suppliers who meet EU purity requirements should be prepared and maintained; inclusion on the list should depend only on the food additive supplier having the required EU certifications for the products offered.[39]

Implementing this recommendation will ensure that the changes that food businesses must implement will be as easy and as well informed as possible. The difficulty and cost of changes will be real, but this recommendation will reduce those problems as much as possible.[40]

9.6 A NETWORK OF ACCREDITED LABORATORIES SHOULD BE CREATED FOR FOOD ADDITIVE TESTING

An effective monitoring system for food additives, as required by Regulation (EU) No. 1333-2008, requires accredited laboratory testing of food products. The testing might be required as a quality assurance method by a food business or as part of an investigation of a suspected violation of the Community list. At present there is no accredited laboratory in Georgia that can test for food additives.

Initially, a single national reference laboratory for food additive testing should be created.[41] The accredited laboratory should be properly equipped and staffed to permit suitable certifications. The development of the laboratory should be facilitated by creating a twinning arrangement with a well-qualified laboratory in Europe. Ideally, the laboratory should be a public-private partnership, but the realities suggest that at the outset it will be more public than private.

Developing a national reference laboratory, with proper certifications, will take time. However, the need for testing is immediate, given the official but voluntary third-party certification scheme described previously. As an interim measure, one of the existing laboratories might be designated as a reference laboratory and develop formal relations with a small number of reference laboratories in the EU to perform tests on request. Requests

[38] For example, if a particular food colorant not on the Community list is used today, the food chemist can easily recommend an alternative that is on the Community list for the particular type of food.
[39] Suppliers will be readily available since the EU, with its 500 million consumers, already has such suppliers.
[40] The EU tries to reduce the burden of regulations by using risk-based schemes with mainly general horizontal regulations covering common aspects of foods, such as food additives. There are some vertical regulations for specific products, such as milk, meat, and poultry. The EU approach introduces norms only so far as necessary for safety, making it more cost effective and business-friendly.
[41] The laboratory should probably cover other types of food safety testing. However, this policy paper concerns only food additives.

within Georgia should be given to the reference laboratory who, in turn, would submit the samples to the EU laboratories for testing.

Laboratory testing done in Europe will be expensive. However, it won't be more expensive than for Georgia to create proper national reference laboratory in a few months' time, if that was even possible. Testing in Europe has the added benefit of being immediately available.

Over time, the one national reference laboratory should be expanded to include a number of such laboratories. Practice in the EU suggests that one laboratory per one million citizens is needed. This means that eventually Georgia should have three such laboratories. Significant external assistance should be found to expand the network and to develop staff.

If funding and capacity is available, the national reference laboratories should be free to pursue research such as new applications and re-evaluation of already authorized food additives and safety assessment of natural food additives.

9.7 A PROJECT SHOULD BE UNDERTAKEN TO SET A BUDGET FOR ALL THE PRECEDING RECOMMENDATIONS

Implementing the previous recommendations will be costly; therefore Government will need to apply significant resources. The certification process will be costly, but partially financed by self-selected companies who wish to export to the EU. Creating the permanent food additive monitoring and enforcement mechanism will require significant staff, even if the staff is shared with other food safety issues. Providing timely food additive information in Georgian to food businesses will require appreciable resources, particularly in languages and IT. Investing in national reference laboratories will be costly to say nothing of testing fees that will need to be paid to existing laboratories in Europe.

To our knowledge, no comprehensive assessment of implementation costs has been made for food additive requirements. A full assessment of costs should be made. Costs should be divided into one-time investment costs and on-going operational costs. The imprecision of estimates should not stand in the way of making a best-informed estimate of costs. The analysis should not be at all influenced by "what can we afford", since the purpose of the budget is to determine what compliance with the Community list will require.

The manner in which these costs will be financed should be decided. Some startup costs can be borne by businesses involved in the official but voluntary third-party certification scheme. Some costs can be borne by the EU adjustment funds. Other costs will need to be borne by the Government.

The availability of a well-informed budget will permit more informed decision-making on each of the previous recommendations. As noted in previous recommendation, there should be a two year transition period before mandatory monitoring and enforcement begins in year three. Consequently, the budgets noted in this recommendation should be for at least four years.

APPENDIX

FUNCTIONAL CLASSES OF FOOD ADDITIVES IN FOODS AND OF FOOD ADDITIVES IN FOOD ADDITIVES AND FOOD ENZYMES[42]

1. 'sweeteners' are substances used to impart a sweet taste to foods or in table-top sweeteners
2. 'colors' are substances which add or restore color in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colors within the meaning of this Regulation
3. 'preservatives' are substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms
4. 'antioxidants' are substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and color changes
5. 'carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavoring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use
6. 'acids' are substances which increase the acidity of a foodstuff and/or impart a sour taste to it
7. 'acidity regulators' are substances which alter or control the acidity or alkalinity of a foodstuff
8. 'anti-caking agents' are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another
9. 'anti-foaming agents' are substances which prevent or reduce foaming
10. 'bulking agents' are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value
11. 'emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff
12. 'emulsifying salts' are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components
13. 'firming agents' are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel
14. 'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff
15. 'foaming agents' are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff
16. 'gelling agents' are substances which give a foodstuff texture through formation of a gel
17. 'glazing agents' (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating
18. 'humectants' are substances which prevent foods from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium
19. 'modified starches' are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached
20. 'packaging gases' are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container
21. 'propellants' are gases other than air which expel a foodstuff from a container
22. 'raising agents' are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter
23. 'sequestrates' are substances which form chemical complexes with metallic ions

[42] Regulation (EC) No 1333/2008 of The European Parliament And of The Council of 16 December 2008 on food additives.

24. ‘stabilizers’ are substances which make it possible to maintain the physiochemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilize, retain or intensify an existing color of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food
25. ‘thickeners’ are substances which increase the viscosity of a foodstuff
26. ‘flour treatment agents’ are substances, other than emulsifiers, which are added to flour or dough to improve its baking quality.

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USAID Governing for Growth (G4G) in Georgia

Deloitte Consulting Overseas Projects LLP

Address: 85 Z. Paliashvili Street, Tbilisi

Phone: +995 322 240115 / 16

E-mail: info@g4g.ge