



UKRAINIAN SANITARY
AND PHYTOSANITARY
LAWS APPROXIMATION TO EU
ACQUIS UNDER ASSOCIATION
AGREEMENT INCLUDING
AGREEMENT ON DEEP
AND COMPREHENSIVE
FREE TRADE AREA (DCFTA)

APROXIMÁCIA UKRAJINSKÝCH SANITÁRNYCH A FYTOSANITÁRNYCH PRÁVNYCH PREDPISOV EURÓPSKEMU ACQUIS V ZMYSLE ASOCIAČNEJ DOHODY VRÁTANE DOHODY O PREHĹBENEJ A KOMPLEXNEJ ZÓNE VOĽNÉHO OBCHODU

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I. Introduction

The question of safety and quality of food is very important for every citizen. This issue has become priority for all governments, food producers, sellers and their customers. Ukraine has a rich and long history in the agricultural and food processing industries thanks to an abundance of fertile

Abstract (EN)

The paper reviews the achievements to date in legal approximation in the sanitary and phytosanitary (SPS) field in Ukraine. Effective regulatory approximation in the SPS field was critical to anchoring the reform process in Ukraine and to fostering further progress in EU's relations with this Eastern Partnership (EaP) country. This paper highlights three major problems in Ukraine that were hindering reform in the SPS field: inconsistency between Ukrainian and EU food safety legislation, lack of uniformity between animal health law regimes, absence of a single SPS regulator. Legal implementation of approximated legislation still remains as key challenge. The paper offers recommendations to improve the Ukraine's approach so that the Deep and Comprehensive Free Trade Area (DCFTA) is part of the Association Agreement (AA) between the EU and the Republic of Ukraine could fulfill its potential.

Keywords (EN)

European Union (EU), Ukraine, SPS, DCFTA, association agreement

soil. Performance in the sector before reforms was still weak despite favorable natural resources. Outdated food safety regulations and practices were limiting Ukraine's potential in agribusiness by hindering exports and investment. Clearly food safety was an underestimated threat to the health of

Abstrakt (SK)

Príspevok sa zaoberá prehľadom dosiahnutých výsledkov pri zosúladení právnych predpisov v oblasti sanitárnych a fytosanitárnych (SFS) opatrení na Ukrajine. Efektívne regulačné zbližovanie v SFS oblasti bolo rozhodujúce jednak pre ukotvenie reformného procesu na Ukrajine a jednak pre posilnenie vzťahov medzi EÚ a touto krajinou východného partnerstva. Príspevok sa zameriava na tri hlavné problémy, ktoré bránili zavedeniu reformy v sanitárnej a fytosanitárnej oblasti: nesúlad ukrajinského práva a práva EÚ v oblasti potravinovej bezpečnosti, nejednotnosť pri legislatíve týkajúcej sa zdravia zvierat, chýbajúci jednotný SFS regulátor. Právna implementácia zosúladenej legislatívy aj naďalej zostáva jednou z kľúčových výziev. Príspevok obsahuje odporúčania pre Ukrajinu, ktoré by zabezpečili, aby sa Dohoda o prehĺbenej a komplexnej zóne voľného obchodu stala súčasťou asociačnej dohody medzi EÚ a Ukrajinou a aby sa naplno využil potenciál tejto dohody.

Kľúčové slová (SK)

Európska únia (EÚ), Ukrajina, SFS, DDCFTA, asociačná dohoda

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Ukraine's citizens and to the competitiveness of one of its most important industries.

After the signing of the Ukraine-European Union Association Agreement only a few Ukrainian poultry farms were eligible to export their products to the EU as well as a number of manufacturers of casein, fish and honey, that was due to inconsistency between Ukrainian and European laws on food safety and lack of necessary certification obtained by Ukrainian enterprises. SPS chapter of EU-Ukraine AA/DCFTA is analyzed from the perspective of institutional harmonization between Ukraine and the EU in the comprehensive research⁽¹⁾ published by Uliana Rusetska. Kataryna Wolczuk discusses in the policy brief(2) bilateral actions that should be taken in order to reach EU-Ukraine SPS uniformity successfully. SPS harmonization as EU governance tool towards Eastern Partnership is examined in article(3) written by Julia Langbein. SPS trade barriers are explored in the working document⁽⁴⁾ prepared by Michael Emerson and in the conference research paper presented by Marie-Luise Rau⁽⁵⁾. In working document⁽⁶⁾ prepared by authors Denis Cenusa, Tamara Kovziridse and Veronika Movchan punitive responses to Ukrainian SPS laws approximation to the EU acquis are investigated.

II. Material and methods

The major provisions of reform of Ukrainian SPS system in relation to European SPS rules are analyzed on the examples of amendments to Laws of Ukraine on food safety and animal health. Their clauses related to uniformity of SPS measures are investigated with implementation of methods of legal and comparative legal analysis. Data for this

- ⁽¹⁾ RUSETSKA, U., 2014: How could agricultural trade between Ukraine and the EU benefit from institutional harmonization? -A Regression Discontinuity Approach. Uppsala: Swedish University of Agricultural Sciences, Department of Economics. Thesis No 863. ISSN 1401-4084. Cited from http://stud.epsilon. slu.se/7000/1/Rusetska U 140710.pdf
- (2) WOLCZUK, K., 2014: Ukraine and the EU: Turning the Association Agreement into a Success Story. In European Policy Centre Policy Brief [online]. [Retrieved 2014-10-20]. Cited from http:// dx.doi.org/10.2139/ssrn.2430226
- $^{(3)}$ LANGBEIN, J., 2014: European Union Governance towards the Eastern Neigbourhood: Transcending or Redrawing Europe's East-West Divide? In JCMS: Journal of Common Market Studies, vol. 52, no. 1, pp. 157-174.
- (4) EMERSON, M., 2014: Trade policy issues in the Wider Europethat led to war and not yet to peace. In CEPS Working Documents, no. 398. ISBN 978-94-6138-408-9.
- (5) RAU, M.-L., 2014: Conquering the EU market with new comprehensive trade agreements - Simulating DCFTAs between the EU and neighbour countries. In EAAE 2014 Congress Agri-Food and Rural Innovations for Healthier Societies. Ljubljana: Biotechnical faculty of University of Ljubljana and Slovene Association of Agricultural Economists, pp. 1-14. [Retrieved 2014-10-19]. Cited from: https://www.conftool.pro/eaae2014/index. php?page=browseSessions&print=head&abstracts=show& form_session=42
- (6) MOVCHAN, V. et al., 2014: Russia's Punitive Trade Policy Measures towards Ukraine, Moldova and Georgia. In CEPS Working Documents, no. 400. ISBN 978-94-6138-414-0

research are derived from the official publications of the Verkhovna Rada of Ukraine on the implication of changes made to SPS regulations for Ukraine. The alternative sources are Decrees of the Cabinet of Ministers of Ukraine on approximation of SPS laws in Ukraine to EU acquis, as well as researches on implication of SPS legislation harmonization on the European Union and Ukraine, completed by international researchers.

III. Results and discussion

International standards in the sanitary and phytosanitary (SPS) sphere

The inclusion of international food standards to the SPS Agreement (the WTO Agreement on the Application of Sanitary and Phytosanitary Measures) and the TBT Agreement (the WTO Agreement on Technical Barriers to Trade)(7) has provided the same rules for all countries that are engaged in the agricultural and food products trade. The SPS and TBT Agreements have also created new opportunities for developing countries and for countries with transitional economies in order to boost economic development through increased exports of agricultural and food products.

Also there are Codex Alimentarius general standards for food additives and contaminants and toxins in foods that contain both general and commodity-specific provisions. The Codex Alimentarius General Standard for the Labelling of Prepackaged Foods covers all foods in this category.

Codex Alimentarius guidelines fall into two categories: principles that set out policy in certain key areas; and guidelines for the interpretation of these principles or for the interpretation of the provisions of the Codex Alimentarius general standards.

There are free-standing Codex Alimentarius principles covering: addition of essential nutrients to foods; food import and export inspection and certification; establishment and application of microbiological criteria for foods; conduct of microbiological risk assessment; risk analysis of foods derived from modern biotechnology.

2 EU's requirements for the state control system in the field of food safety and animal feeding stuffs as a basis for equivalence

European Union calls for a fundamental change concerning approximation of Ukrainian national laws to the EU legislation in order to reform the state control system in the field of food safety and animal feeding stuffs.

The efficiency of food control system is essential to protect the health of consumers. In addition, the control system is especially important for the creation of the environment in which the parties can ensure the safety and quality of food

⁽⁷⁾ Agreement on the Application of Sanitary and Phytosanitary Measures, 1867 U.N.T,S. 493.

imported by third countries and inspect imported food according to national requirements.

After serious incidents related to food safety that have occurred in the 1990s, the EU was forced to revise and introduce new legal mechanisms to ensure food security in Member States. Also in years 2004 - 2005 comprehensive package of legislation on food hygiene and animal feeding stuffs was passed. In addition to the aforementioned regulation more specific animal feeding stuffs and food legislation has been implemented that covers various areas such as: animal feeding, including veterinary feeding stuffs; zoonoses; animal by-products; residues and contaminants; and control animal diseases that affect public health; labeling of feed animal feeding stuffs and food; pesticides, animal feeding stuffs and vitamins, food additives, trace elements, mineral salts and other additives; materials in contact with food; quality and compositional requirements; drinking water; ionization; new foods and genetically modified organisms.

The operation of national control systems remains a responsibility of the individual Member States. This general EU framework consists of three main elements: the first element represents operational criteria established at EU level that should be fulfilled by competent national authorities. These criteria form the starting point from which the Department of the Commission on Food and Veterinary (FVO) carries out audits of competent authorities, so that develops a consistent, comprehensive approach to the audit of national control systems; the second element develops guidelines for EU's monitoring. This process promotes coordinated development of national strategies and specifies priorities on the basis of the risk and sets up the most effective control procedures. EU strategy determines comprehensive, integrated approach to controlling. These guidelines also provide recommendations on the development of systems for documenting processes of control measures and their results, and on establishing performance indicators; the third element of the general framework improves administrative cooperation in sphere of development and operation of control systems. It provides support for EU efforts to maintain the exchange of best practices between national competent authorities, including the promotion of mutual assistance among Member States through integration and amendments to the existing legal system.

The Regulation 882/2004/EC includes among others the following provisions: official controls that are performed by Member States should enable them to verify and implement coercive measures in order to fulfill EU legislation and national laws of the Member States on food and animal feeding stuffs; for this purpose measures of official control should be carried out regularly and determined on the basis of existing or predicted risk; authorities with official control competence in Member States should comply with operational criteria to ensure their effectiveness, efficiency and impartiality; staff performing official controls should receive appropriate training preparation for the competent performance of their duties; certain tasks concerning control may be delegated to independent regulatory authorities (including privately-owned) only by applying well-defined terms; methods of sampling and analysis should be validated according to

internationally accepted rules and respectively used by accredited laboratories; in case when arises any non-compliance with laws during official controls appropriate actions should be taken, including administrative and penal sanctions. These measures and sanctions should be effective, preventing future violations and commensurate with the fault; more plans for emergencies should be made that determine the measures to be applied in case of emergencies in the field of food and animal feeding stuffs products; if official controls require intervention carried out by more than one Member State, competent authorities of Member States involved in it should provide each other administrative assistance; FVO inspections and audits should be conducted to verify the effectiveness of national control systems; there should be EU framework for the training of control staff in Member States to ensure consistency of decisions taken by these personnel.

In the Regulation 882/2004 Commission have introduced new approach in which all major aspects of the control are combined into one integrated process for all food and animal feeding stuffs products. The cycle of monitoring under this new approach includes four main stages.

Stage 1. The European Commission in cooperation with Member States outlines while taking into account the principle of subordination general guiding principles on the structure and organization of national control systems in general and on scope, content and implementation of national control plans. These guiding principles are designed to promote harmonized approach for control, to cover the entire action spectrum of EU legislation and all food and animal feeding stuffs sectors and all stages of production and consumption chain. They facilitate the use of best practices concerning abovementioned key principles at all levels of control in each Member State and specify main performance indicators to be applied in assessing and auditing national control plans.

Stage 2. Member states are required to prepare a longterm integrated national control plan and provide it to the

Stage 3. On the basis of long-term national control plan the European Commission regularly conducts general audit of activities associated with the control of each Member state, which may include selective enforcement at the regional, local/district level and at the level of individual organizations in order to test certain aspects of the control system. This general audit may be accompanied by further audits of certain sectors or certain critical points of control on any level, including investigation of emergencies.

Stage 4. One year after the implementation of control plans and annually thereafter, Member State are required to submit to the Commission a report which, if necessary, updates their initial plan in the way that: new legislation has been introduced or modified to meet EU requirements; important changes have been made in the structure and functioning of control systems; or adjustments have been made in their control plans.

Control system of food products according to EU legislation is based on the following principles:

- 1. Maximizing risk reduction through the application of prevention principle most fully as possible throughout the entire food chain.
- 2. Differentiation between areas of risk assessment and risk

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management.

- 3. Application of precautionary principle in certain cases.
- 4. Conducting control without any prior notification, except in cases when such a notice is required for carrying out control activities in an appropriate manner, for example when auditing food products safety assurance system based on HACCP principles.
- 5. Transparency of control system.
- 6. Shifting attention from the control of finished product to the effectiveness assessment of providing food safety in production (systems designed on the principles of HACCP). Tests of food products/food raw materials are considered as an essential element for monitoring programs and as a means of validation/verification of safety management systems.
- 7. Law enforcement measures and penalties for the violation of legislature should be effective, commensurate with the fault and prevent breaking of laws in the future. In addition, there is an appropriate division of tasks in control system. In its essence it is quite easy: everyone in his place should be involved in ensuring food products safety and finding partners over the entire food distribution network.

For instance, owners of food production and processing enterprises make up the basis of ensuring safety at local level. They have primary responsibility for food products safety, regardless of whether it is an industrial manufacturer, farmer, baker or restaurant owner. Employees of local and district authorities for food safety and animal health surveillance conduct selective control of food products safety and quality management system. In the national system for monitoring food safety Delimitation of competences among authorities exists in the national system for monitoring food products safety. Namely, there is a body that develops legislation and risk management measures in this area, which is also responsible for the selection of appropriate measures. Scientific work is conducted by risk assessment institutions, whose main task is to provide consulting assistance for authority that develops legislation and various measures for managing risks and makes independent scientific conclusion. In addition, assistance to the main agency for development of legislation is also provided by consumer protection authority.

The main characteristic features of the food control system in the EU

- 1. Defining organizational structure and operating conditions of the official control system at national, regional and local levels.
- Assignment to one or more competent authorities responsibility for organizing the entire control throughout food chain of food products; if it is assigned to several competent bodies, obligatory description of coordination methods between these bodies should exist.
- 3. Provide competent authority/authorities with the right to delegate certain tasks to supervisory bodies, moreover, control authorities may be privately owned.
- 4. Developing and implementing national long-term control plan and preparing annual report on national long-term control plan implementation.
- 5. Setting requirements for functioning of competent and

- regulatory authorities (operational criteria).
- 6. Conducting audits of national food control system in order to assess its effectiveness.
- Auditing all competent authorities and control bodies for conformity assessment of their activities that must comply with requirements established by law and national control plan.
- 8. Nationwide categorization of all food industry enterprises based on several degrees of risk (usually high, medium and low) and planning of control in accordance with this categorization.
- 9. For purposes of border control loads of products undergo one or more of following types of control depending on degree of risk that is carried by these products: most often-documentary check, identity verification, physical verification (organoleptical and/or instrumental tests).
- 10. Existence of operational permit only for products of animal origin; for all other products there is procedure of informing competent authority by manufacturer about beginning of goods-producing or about significant changes in this production.
- 11. Accreditation of all supervisory authorities in accordance with EN 45004 (ISO17020).
- 12. Accreditation of all laboratories that perform tests for purposes of state control according to standard EN/ISO/IEC 17025.
- 13. Setting specific requirements for reference laboratories and specialization of reference laboratories by type of testing or animal diseases.
- 14. Defining lists of information that is received by officials of competent authorities and official control bodies during official control of market participants and is classified as confidential information.
- 15. Introduction of mechanisms for monitoring official control system by society through regular reporting to public about planning of activities and their results.

There are main subsystems (vertical components) of control over food products in the EU: subsystem of animal health control; subsystem of animal welfare control; subsystem of veterinary drugs (and their residues) control; subsystem of feed and animal nutrition control; subsystem of animal source foods (ASF) control; subsystem of spongiform encephalopathy and animal by-products control; subsystem of animal source foods and animals import control; subsystem of plant health control; subsystem of plant protection products (and their residues) control; subsystem of food products and food hygiene control; subsystem of imported plant-origin food products control.

It should be noted that, as a rule, each competent authority in the EU is entrusted with management of some or all of these control subsystems.

3 Ukrainian SPS legislation approximation with EU acquis as instrument for EU-Ukraine AA/DCFTA implementation

The new Law no. 1602-VII of 22 July 2014 on food safety drafted with the support of EU experts was passed by the

Parliament of Ukraine. This Law no. 1602-VII of 22 July 2014 was an important step in reforming the food safety control system based on farm to table principle in Ukraine, according to EU legislation and standards.

The need for reform was based on the persistence of the Ukrainian food safety control system that had existed largely unchanged since 1991, and bilateral commitment to implementation of the EU-Ukraine Association Agreement including the Deep and Comprehensive Free Trade Area. (8)

The EU experts of the EU-funded projects "Improvement of Food Safety Control System in Ukraine" (IFSSU) and "Implementation of Ukraine's Commitments under WTO and ENP frameworks in the rural sector" have been actively leading the development and drafting of the new Law no. 1602-VII of 22 July 2014. They worked in close cooperation with the food safety legislation experts of the donor organization IFC (supported with funds from the Austrian Ministry of Finance), as well as the European Business Association and the American Chamber of Commerce in Ukraine. The European Union provided assistance to the State Service for Food Safety and Protection of Consumers in improving the food safety control system based on farm to fork principle in Ukraine. The IFSSU Project was part of the EU's 10 million Comprehensive Institution Building (CIB) Programme for food safety in Ukraine. The main goal of this EU project was to promote the improvement of the food safety system based on farm to table principle in Ukraine by bringing legislation, institutional infrastructure and state control of Ukraine in accordance with regulatory and administrative policies and practices in the European Union. The objectives of the IF-SSU project were: improving the food safety control system in Ukraine based on farm to fork principle by bringing this system to relevant European and international standards, involving the private sector and civil society representatives; promoting institutional reform of Ukrainian food safety control system; harmonization of Ukrainian laws in the sphere of food safety based on farm to table principle with the EU legal framework; training for employees of regulatory authorities and supervisory agencies, veterinarians, customs staff and other government services providers whose activities are related to the field of food safety based on farm to fork principle; promoting the creation of national data management system and rapid information exchange (notification about risks) for food and animal feeding stuffs, that would have characteristics similar to the RASFF (Rapid Alert System for food and animal feeding stuffs in the EU); promoting the network optimization of national reference labs and laboratories of official controls, providing laboratories that were selected on the basis of their strategic location with new equipment, software and technical assistance; promoting the creation of national systems for data management and information systems for laboratories, public control authorities, and obtaining and processing data about import and export; modernization and improvement of training program and system of continuous professional development. There were

three key components of this project: 1. institutional reform and public control; 2. veterinary and food safety; 3. information systems and data management.

The main condition for the Ukrainian livestock products access to the EU market was approved by the Verkhovna Rada of Ukraine Law no. 1602-VII of 22 July 2014 on food safety⁽⁹⁾. The implementation of basic elements envisaged in this Law no. 1602-VII of 22 July 2014 had to be completed in one year, id est to adopt a series of bylaws as well as substantially reform the new regulatory authority that was created.

Government of Ukraine created the State Service for Food Safety and Protection of Consumers(10) on the basis of the State Veterinary and Biosecurity Service, the State Inspectorate for the Protection of Consumer Rights and the State Sanitary and Epidemiological Service. Its authority is based on the previous functions of the State Veterinary and Phytosanitary Service of Ukraine and encompasses the State Sanitary Service, Agricultural Inspection, and Consumer Rights Agency.

Ukrainian Law no. 1602-VII of 22 July 2014 "On amendments to certain legislative acts of Ukraine regarding food products" harmonizes legislation in Ukraine with EU laws in the field of food safety and quality, ensures a high level of protection of human health and consumer interests, as well as creates transparent conditions for business activities and increases the competitiveness of Ukrainian foodstuffs and facilitates the reduction of their prices. Normative acts in the given field of legal regulation are: the Constitution of Ukraine, the Code of Ukraine on Administrative Offenses, The Criminal Code of Ukraine, the Commercial Code of Ukraine, Laws of Ukraine "On the safety and quality of food products", "On the baby nutrition". Additional spending from the Ukrainian state budget was not required for the implementation of the Law no. 1602-VII of 22 July 2014.

This Law no. 1602-VII of 22 July 2014 concerns the clarification of terms and their definitions in foods, exercise of the powers of central executive bodies. Certain licensing procedures were canceled that were not compatible with EU legislation; responsibility for the offenses was being established. It was provided that the single supervisory authority for all food products would be created, auto-regulatory mechanism of market operators on the basis of the general requirements of the legislation on food hygiene would be implemented. The Law no. 1602-VII of 22 July 2014, excluding certain standards, came into force within a year after its official publication. Food products and other objects of sanitary measures which meet the requirements which were in effect before the Law no. 1602-VII of 22 July 2014 was adopted but do not meet the requirements of the Law no. 1602-VII of 22 July 2014 may be held or be put into circulation within a year. The mentioned food products and other objects of sanitary measures can be

⁽⁸⁾ Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part OJ L 161, 29.5.2014, p. 3-2137 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV).

⁽⁹⁾ Закон України "Про внесення змін до деяких законодавчих актів України щодо харчових продуктів" від 22.07.2014 № 1602-VII. Офіційний вісник України від 26.09.2014, № 75, том 1, стор. 7, стаття 2122, код акту 73945/2014.

⁽¹⁰⁾ Постанова Кабінету Міністрів України "Про оптимізацію системи центральних органів виконавчої влади". Схема від 10.09.2014 № 442. Офіційний вісник України від 23.09.2014, № 74, стор. 57, стаття 2105, код акту 73930/2014.

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in circulation in the Ukrainian market until the expiry date.

The above-mentioned legislation provides implementation of European principles for the regulation of GMOs, in particular concerning registration of GMO sources rather than products made from them.

According to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004, the mechanism of self-regulation by market operators is established on the basis of general legal requirements on food hygiene. In other words, the state establishes general requirements for food hygiene, and association operators develop based on them detailed requirements, which must be approved by the competent authority. (11) If the inspector monitors hygiene requirements of the company, which performs the following detailed requirements, it is believed that the company also meets the general provisions of the law in this area. In this way the likelihood of ambiguous interpretation of general law provisions is reduced significantly, and therefore unjustified state interference in activities of operators is also decreased. Implementation of this Law enables to introduce a mechanism of self-regulation in food market.

Experience of implementing Ukrainian Law no. 771/97-BP of 23 December 1997 "On safety and quality of food products" since 2006 has shown that state control procedures without detailing requirements are not transparent and considered as financial and administrative burden for market players and significantly increase the food cost without providing real consumer safety protection.

The objectives of the Law no. 1602-VII of 22 July 2014 "On amendments to certain legislative acts of Ukraine regarding food products" are to: establish detailed requirements concerning state control procedures for foodstuffs on Ukrainian market and imported food products according to European practice, create a mechanism for self-regulation by market players that is based on the general legal requirements for food hygiene.

Implementation of these norms should reduce corruption component in food industry, protect consumers from unscrupulous food production, reduce the cost of Ukrainian-made foodstuffs and enables increased consumption by Ukrainian citizens.

 $^{(11)}~$ Règlement (CE) n° 854/2004 du Parlement européen et du Conseil du 29 avril 2004 fixant les règles spécifiques d'organisation des contrôles officiels concernant les produits d'origine animale destinés à la consommation humaine. OJ L 139, 30.4.2004, p. 206-320 (ES, DA, DE, EN, IT, PT, FI, SV) OJ L 139, 30.4.2004, p. 206-321 (EL) OJ L 139, 30.4.2004, p. 206-319 (FR) OJ L 139, 30.4.2004, p. 206-318 (NL) Special edition in Czech: Chapter 03 Volume 045 P. 75 - 119 Special edition in Estonian: Chapter 03 Volume 045 P. 75 - 119 Special edition in Latvian: Chapter 03 Volume 045 P. 75 - 119 Special edition in Lithuanian: Chapter 03 Volume 045 P. 75 - 119 Special edition in Hungarian Chapter 03 Volume 045 P. 75 - 119 Special edition in Maltese: Chapter 03 Volume 045 P. 75 - 119 Special edition in Polish: Chapter 03 Volume 045 P. 75 - 119 Special edition in Slovak: Chapter 03 Volume 045 P. 75 - 119 Special edition in Slovene: Chapter 03 Volume 045 P. 75 - 119 Special edition in Bulgarian: Chapter 03 Volume 056 P. 132 - 176 Special edition in Romanian: Chapter 03 Volume 056 P. 132 - 176 Special edition in Croatian Chapter 03 Volume 010 P. 33 - 77.

In order to fulfill goals and objectives of this Law no. 1602-VII of 22 July 2014 amendments were introduced into Ukrainian legislation: the Code of Ukraine on Administrative Offenses no. 8074-X of 7 December 1984, the Commercial Code of Ukraine no. 436-IV of 16 January 2003, Laws of Ukraine no. 771/97-BP of 23 December 1997 "On the safety and quality of food products", no. 142-V of 14 September 2006 "On the baby nutrition", no. 2498-XII of 25 June 1992 "On veterinary medicine", no. 2918-III of 10 January 2002 "On drinking water and drinking water supply", no. 1103-V of 31 May 2007 "On the state system of biosafety in creating, testing, transporting and using genetically modified organisms (GMOs)" and the Cabinet of Ministers of Ukraine Decree no. 46-93 of 10 May 1993 "On standardization and certification" were changed.

The Law no. 1602-VII of 22 July 2014 (On amendments to certain Ukrainian laws concerning food products) as it was passed allows to: increase the level of protection of consumers' interests and human health; improve the state control system in the field of food safety, taking into account EU legislation, and minimize the negative consequences of unwarranted government interference in the production and circulation of food products; regulate legal relations among executive authorities, food business operators and food consumers and determine procedure for providing safety of food that is produced and in circulation, imported (sent) to the customs territory of Ukraine and/or exported (sent) thereof; implement effectively the liability of producers and regulatory authorities for violation of legislation on food safety.

Basic products from animal husbandry were the only category of goods that Ukraine temporarily was not able to export to the EU immediately after the ratification of the Ukraine-European Union Association Agreement. In particular, it was milk and meat with the exception of poultry already exported to the EU successfully. After the signing of the Ukraine-European Union Association Agreement (12) significant number of operating Ukrainian milk processing plants complied with all applicable EU requirements according to experts, so these dairy processors eventually became eligible to export their products to the European market. In this case EU inspectors had major complaints not about milk processing in Ukraine, but about the quality of the raw cows' milk as the raw material for industrial dairy products.

Before the Law no. 1648–VII of 14 August 2014 "On amendments to certain legislative acts of Ukraine regarding the identification and registration of animals" (13) was passed, the imperfection of Ukrainian legislation had made it difficult to monitor epizootic situation in the country and provide the population with safe and healthy food of animal origin.

- (12) FINAL ACT between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, as regards the Association Agreement OJ L 278, 20.9.2014, p. 4-5 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV).
- (13) Закон України "Про внесення змін до деяких законодавчих актів України щодо ідентифікації та реєстрації тварин Верховна Рада України" від 14.08.2014 № 1648-VII. Офіційний вісник України від 26.09.2014, № 75, том 1, стор. 76, стаття 2123, код акту 73946/2014.

Furthermore, the Ukrainian legislation in the field of animal identification and registration was not consistent with EU legislation that created barriers to entry into the European Union and blocked the supply of Ukrainian meat and dairy products to the EU market and other developed countries.

Thus, in case of enzootic situations (local outbreaks of livestock diseases) the presence of animals, about which there is no information in the Unified State Register of farm animals, reduces efficiency, and sometimes makes it impossible to implement necessary measures for localization and liquidation of relevant diseases and therefore prevent epizootics (epidemics among farm animals).

Also, under the previously existing system, consumers were buying meat and milk derived from animals that were not registered in the Unified State Register of animals, id est animals which health status was not verified and not confirmed by relevant documents: cattle passport, sheep/goat registration certificate. This was due to the fact that checking procedure was not possible in order to find evidence that tells from which particular cow milk was derived and then transported to the processing plant or sold in the market.

Only in case of introduction of the mandatory identification and registration of all farm animals, as provided by the EU legislation, the state can guarantee citizens that they consume milk and meat products of known origin and derived from registered animals' health status of which is subject to examination and, therefore, such products are safe.

Ukrainian Laws in the given field of legal regulation are: "On animal breeding", "On veterinary medicine"; "On identification and registration of animals" and other normative legal documents.

The Law no. 1648-VII of 14 August 2014 "On amendments to certain legislative acts of Ukraine regarding the identification and registration of animals" introduced compulsory identification and registration of all animals in the Unified State Register of farm animals. The Law no. 1648-VII of 14 August 2014 established the system of continuous monitoring of the health of all animals (cattle, pigs, horses, sheep and goats) and veterinary-sanitary conditions of all households. Expenses concerning works and services on identification and registration of animals, kept and bred by population, were compensated from the state budget.

Provisions of this Law no. 1648-VII of 14 August 2014 aim at: creating conditions for ensuring more efficient and effective detection, localization, control and liquidation of animal diseases; clarifying rights and obligations of farm animal owners and public authorities; ensuring the possibility of electronic document circulation in the area of animal identification and registration.

Established by this Law no. 1648-VII of 14 August 2014 the identification and registration of all animals on the Ukrainian territory of Ukraine enabled full control over veterinary-sanitary condition of stock farms and the origin of meat derived from animals, facilitated the identification of animal diseases in personal peasant farms or private households and monitoring over the of animals among farms.

In order to ensure obligations fulfillment by farm animal owners and keepers to carry out the identification and registration of animals the Law no. 1648-VII of 14 August 2014 provides establishing liability for violation of legislation in

In addition, the Law no. 1648-VII of 14 August 2014 provides a mechanism for financing operations of identification and registration of farm animals belonging to vulnerable groups. Thus, the Law no. 1648-VII of 14 August 2014 establishes that the identification and registration of livestock owned by natural person may be carried out by other legal persons, including business entities. The legal relationship between business entity and natural person concerning reimbursement of expenses for the identification and registration of farm animals must be set out by the agreement between them, which must be concluded in writing.

The Law no. 1648-VII of 14 August 2014 was designed to harmonize laws of Ukraine with the EU legislation in the field of identification and registration of farm animals and create necessary and sufficient conditions for the fulfillment of following tasks: providing the population with safe and healthy food products of animal origin; monitoring the epizootic situation in the country; bringing legislation of Ukraine in line with EU laws and ensuring access for Ukrainian meat and milk products to the EU market.

The Law no. 1648-VII of 14 August 2014 provides clarification of terminology, rights, duties of legal relations entities in the field of animal identification and registration, framework that sets out ways of financing the works on identification and registration of farm animals and basis for legal regulation of responsibility for violations of the law in this area.

In particular, this Law no. 1648-VII of 14 August 2014 determines procedures for: establishing the identification of all agricultural animals kept on Ukrainian farms of all ownership types; introduction of the group identification number; implementation of identification, centralized government database which records livestock movements and slaughter of cattle; fulfilling the right of businesses and individuals to keep animal records and submit data in either electronic or paper format to the Unified State Register of animals; determining the period during which the farm animal registry administrator is required to enter figures that are defined in legislation as well as draw up and issue identification documents; setting requirement on ensuring access to information from the Unified State Register of animals; establishing detailed course of action and conditions for movement of animals.

The passage of the Law no. 1648-VII of 14 August 2014 "On amendments to certain legislative acts of Ukraine regarding the identification and registration of animals" resulted in: providing reliable control over cattle health and veterinary-sanitary conditions of facilities where livestock are kept, movement of stock all across Ukraine, as well as over safety and origin of animal products; simplifying the process of animal identification and registration arising from the use of the group identification number and registration in the Unified State Register of animals; improving livestock product market governance and prediction due to obtaining rapid and reliable information about animals concerning sex, age, breed affiliation, location of animals through getting statistical data from the Unified State Register of animals for

regions or districts; increasing the effectiveness of preventing all sorts of shenanigans when performing cattle trade operations, introducing a system of livestock insurance under condition of confirming animal ownership rights; establishing identification and registration of cattle which are kept and bred by natural persons; ensuring more effective detection, localization, control and liquidation of cattle diseases that have spread on the territory of Ukraine, preventing the circulation of farm animals that are sick; achieving the proper level of animal health protection and associated with it human health protection; providing access for Ukrainian meat and dairy products to the EU market.

Comparative legal analysis of the contents of EU--Ukraine AA/DCFTA and Swiss-EU ATAP

Sanitary and phytosanitary measures between the European Community and the Swiss Confederation are regulated by provisions included in sectorial Agreement on trade in agricultural products between the European Community and the Swiss Confederation (ATAP) of 21 June 1999, O.J. 2002, L 114/132 in contrary to EU-Ukraine SPS measures regulation that is covered by the Deep and Comprehensive Free Trade Agreement (DCFTA) of 27 June 2014, O.J. 2014, L 278, as part of a broader Association Agreement (AA) between the EU and Ukraine of 21 March 2014, O.J. 2014, L 161.

More specific objectives of EU-Ukraine AA/DCFTA Chapter 4 clearly aim at facilitation of bilateral trade in SPS-related agricultural products by improving communication and cooperation, ensuring full transparency which corresponds to Article 7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) signed 15 April 1994, entered into force 1 January 1995, 1867 UNTS 493 in accordance with subsection (e) of section 1 of Article 59 of EU-Ukraine AA/DCFTA, reaching common understanding, establishing mechanisms and procedures, in comparison to terms of Agreement on trade in agricultural products between the European Community and the Swiss Confederation (ATAP)⁽¹⁴⁾ that very generally defines legal mechanism for bilateral trade in animal feeding stuffs, plants, plant products and other goods to which plant health measures are applied and originating from their territories or imported from third countries, as well as for bilateral trade in live animals and animal source foods.

Provisions of Article 64 of EU-Ukraine AA/DCFTA which address SPS harmonization concerning trade in agricultural commodities determine regulatory approximation of SPS measures for all product groups and at the same time aligning of SPS standards is set out in Annexes to the Agreement

between the European Community and the Swiss Confederation regarding only one category of agricultural goods According to Annex 5 of the Agreement between the European Community and the Swiss Confederation the Parties are to undertake to approximate their legislation on animal feed with a view to facilitating trade between them in such products. The list of products and groups of products for which the legislative provisions of the Parties are considered by the latter as achieving the same effects and, where applicable, the list of legislative provisions of the Parties considered by the latter as achieving the same effects must be as set out in Appendix 1 to Annex 5 to Agreement between the European Community and the Swiss Confederation. (15) By contrast, more emphasis is placed on capacity building in Ukraine and also on bilateral capacity building under Section 2 of Article 64 of EU-Ukraine AA/DCFTA. Ukraine was obliged to develop a comprehensive strategy that included SPS legislation approximation to EU acquis in accordance with Section 1 of Article 64 of Ukraine AA/DCFTA in connection with implementation of provisions of Chapter 4 and Annex IV-A, Annex IV-B, Annex IV-C to Chapter 4 of EU-Ukraine AA/ DCFTA under Section 4 of Article 64 of EU-Ukraine AA/ DCFTA. According to Section 3 of Article 64 of EU-Ukraine AA/DCFTA requirement is imposed to monitor fulfillment of action plan that is included in Annex 5 to Chapter 4 of EU-Ukraine AA/DCFTA for approximation process implementation and was designed to achieve SPS legislation uniformity between the EU and Ukraine in the context of subsection (b) of Section 3 of Article 64 of EU-Ukraine AA/DCFTA.

Import checks as specified by paragraph 1 of Section A of Annex XI to Chapter 4 of EU-Ukraine AA/DCFTA could be physical, identity or documentary and their adaptation as stated by Section 6 of Article 72 of EU-Ukraine AA/DCFTA must meet conditions required for its approval that are listed in Annex XI to Chapter 4 of EU-Ukraine AA/DCFTA. Under Section 5 of Article 72 of EU-Ukraine AA/DCFTA import checks could be replaced or reduced for some commodities for which the Parties reciprocally approved each other's controls. Agreement on trade in agricultural products between the

⁽¹⁴⁾ Decision of the Council and of the Commission concerning the scientific and technological cooperation Agreement of 4 April 2002 relating to the conclusion of seven agreements with the Swiss Confederation; OJ L114 of 30/04/2002, p.1.

⁽¹⁵⁾ Agreement between the European Community and the Swiss Confederation on trade in agricultural products - Final Act -Joint Declarations - Information relating to the entry into force of the seven Agreements with the Swiss Confederation in the sectors free movement of persons, air and land transport, public procurement, scientific and technological cooperation, mutual recognition in relation to conformity assessment, and trade in agricultural products OJ L 114, 30.4.2002, p. 132-368 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV). Special edition in Czech: Chapter 11 Volume 041 P. 159 - 406. Special edition in Estonian: Chapter 11 Volume 041 P. 159 - 406 Special edition in Latvian: Chapter 11 Volume 041 P. 159 - 406. Special edition in Lithuanian: Chapter 11 Volume 041 P. 159 - 406. Special edition in Hungarian Chapter 11 Volume 041 P. 159 - 406. Special edition in Maltese: Chapter 11 Volume 041 P. 159 - 406. Special edition in Polish: Chapter 11 Volume 041 P. 159 - 406. Special edition in Slovak: Chapter 11 Volume 041 P. 159 - 406. Special edition in Slovene: Chapter 11 Volume 041 P. 159 - 406. Special edition in Bulgarian: Chapter 11 Volume 028 P. 3 - 250. Special edition in Romanian: Chapter 11 Volume 028 P. 3 - 250. Special edition in Croatian Chapter 11 Volume 060 P. 133 - 369.

European Community and the Swiss Confederation is one of the 'Bilateral I' agreements of 1999 and Switzerland enjoys the benefits of EU member states and EEA countries on free movement of agricultural goods - but without having lost any sovereignty or decision-making power. The Parties to Agreement on trade in agricultural products between the European Community and the Swiss Confederation abolished border checks on the products and groups of products listed in Appendix 1 to Annex 5 to Agreement on trade in agricultural products between the European Community and the Swiss Confederation. Border checks that are conducted by Ukraine and the EU as referred to in Subsection (d) of Section 1 of Article 76 of EU-Ukraine AA/DCFTA must be simplified while becoming more transparent and ensuring increased efficiency with respect to objectives of Chapter 5 of EU-Ukraine AA/DCFTA that are stated in Article 75 of EU-Ukraine AA/DCFTA regarding balanced approach to legitimate trade issues, prevention of fraud and increasing border control effectiveness. Import authorization was canceled for agricultural products listed in Annex IV-A and Annex IV-C(2) to Chapter 4 of EU-Ukraine AA/DCFTA under Section 3 of Article 69 of EU-Ukraine AA/ DCFTA. Paragraph 4 of Section A of Annex 4 does not specify exactly to what maximum extent the Party to EU-Ukraine AA/DCFTA could apply protective measures in case if checks which fully comply with Section 1 of Article 72 of EU-Ukraine AA/DCFTA reveal non-conformity with requirements and/ or standards and only states that the importing Party to EU-Ukraine AA/DCFTA has the right to take measures proportionate to the risk involved.

EU-Ukraine AA/DCFTA provisions as stated in Section 2 of Article 67 of Chapter 4 of EU-Ukraine AA/DCFTA concerning information exchange are aimed mainly at bilateral exchange of information about changes in SPS regulation in the context of legislation approximation in this area as referred to in Article 64 of EU-Ukraine AA/DCFTA. Importance of enhancing mutual understanding with regard to performance of SPS official control structures and mechanisms of the Parties to EU-Ukraine AA/DCFTA using reports of international audits made public is stressed by Section 1 of Article 67 of EU-Ukraine AA/DCFTA. The Parties to Agreement on trade in agricultural products between the European Community and the Swiss Confederation established bilateral exchange of information, in particular, the Parties to Agreement on trade in agricultural products between the European Community and the Swiss Confederation send to each other: details of the competent authority or authorities, their geographical jurisdiction and sphere of competence; a list of laboratories entrusted with conducting analyses for the purposes of controls; where applicable, a list of points of entry within their territory for the various types of products; their programmes of controls to ensure that products comply with their legislation on animal feed. Mutual notification of contact points, bilateral cooperation concerning transmission of legislative documents is required for both Parties to EU-Ukraine AA/DCFTA and obligation to inform well in advance of amendments made to EU SPS laws is imposed only on the EU by Section 3 of Article 67 of EU-Ukraine AA/ DCFTA. Transparency of SPS measures according to provisions of Article 67 of EU-Ukraine AA/DCFTA is determined

to be obligatory condition for SPS application during import or export of agricultural commodities in order to prevent unfair and discriminatory trade practices.

If, following the consultations, the Parties to Agreement on trade in agricultural products between the European Community and the Swiss Confederation fail to reach agreement, the Party to Agreement on trade in agricultural products between the European Community which requested the consultations may take suitable interim protective measures. By comparison with Agreement on trade in agricultural products between the European Community and the Swiss Confederation EU-Ukraine AA/DCFTA do not contain provisions which enable the Party to EU-Ukraine AA/DCFTA impose temporary protective measures if agreement after consultations could not be reached.

IV. Conclusion

Ukraine must remain engaged in implementing its approximated legislation concerning SPS and animal well-being (welfare) to directives and regulations of the European Union in accordance with list of EU acquis specified in EU-Ukraine AA/DCFTA. Still exists the need for bilateral cooperation not only on the harmonization of laws, but also regarding further strengthening of relevant institutional capacities. Active involvement of Ukraine is required in the work of Subcommittee on SPS measures created under EU-Ukraine AA/DCFTA, which will conduct regular monitoring of the implementation of the approximation and provide appropriate recommendations. Ukraine must implement comprehensive strategy concerning DCFTA SPS chapter provisions, which will serve as a framework regarding the implementation of EU-Ukraine AA/ DCFTA objectives. Separate agricultural agreement between Ukraine and the European Union that must be more detailed in comparison to terms of EU-Ukraine AA/DCFTA SPS Chapter/Annexes and clauses of which should be similar to provisions of Annex 11 (please see Appendix for further details) on animal health and zootechnical measures applicable to trade in live animals and animal products to Agreement on trade in agricultural products between the European Community and the Swiss Confederation could be negotiated if Ukraine's EU accession process would be never-ending.

V. Appendix

Annex 4 to the Agreement on trade in agricultural products between the European Community and the Swiss Confederation (ATAP) of 21 June 1999

Annex 4 (on plant health) to the Agreement between the European Community and the Swiss Confederation facilitates trade between the Parties in plants, plant products and other objects subject to plant-health measures, originating in their respective territories or imported from third countries.

The Parties note that they have similar legislation concerning protective measures against the introduction and propagation of harmful organisms by plants, plant products or other objects having equivalent results in terms of protection against the introduction and propagation of organisms harmful to plants or plant products listed in Appendix 1

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as provided for in Article 1. The same is also true of planthealth measures taken in respect of plants, plant products and other objects introduced from third countries.

The Parties mutually recognise the plant passports issued by the organisations originating from the Parties to this Agreement. Such passports attest conformity with their legislation and should meet the documentary requirements laid down therein for the movement on the respective Parties' territories of plants, plant products and other objects.

Plants, plant products and other objects as listed in Appendix 1 as provided for in Article 1 which are not subject to the plant passport arrangements applying to trade within the two Parties' territories may be traded between the two Parties without any plant passport, without prejudice, however, to other documents required under the Parties' respective laws, and in particular documents forming part of a system for tracing the origins of such plants, plant products and other objects to origin.

Plants, plant products and other objects not subject to plant-health measures in either Party may be traded between them without documentary, identity, or plant-health checks in connection with plant-health measures.

Where either Party intends to adopt a plant-health measure in respect of plants, plant products and other objects, it shall inform the other Party.

Each Party may lay down, by reference to similar criteria, specific requirements concerning movements of plants, plant products and other objects, regardless of their origin, within and to zones in its territory, where warranted by the plant-health situation in those zones.

Each Party carries out plant-health sampling checks at a rate not exceeding a certain percentage of consignments of plants, plant products and other objects listed in Appendix 1 as provided for in Article 1. That percentage is proposed by the Working Group on Plant Health and set by the Committee is determined by plant, plant product or other object in accordance with the plant-health risk. On the date of entry into force of this Annex, that percentage was 10 %.

If either Party intends to apply derogations with respect to part or all of the territory of the other Party, it should inform the latter in advance, indicating its reasons. Without prejudice to the possibility of bringing the planned derogations into force immediately, consultations should be held as soon as possible between the two Parties with a view to finding appropriate solutions.

If either Party applies derogations with respect to part of its territory or a third country, it should inform the other Party in advance, indicating its reasons. Without prejudice to the possibility of bringing the planned derogations into force immediately, consultations should be held as soon as possible between the two Parties with a view to finding appropriate solutions. Each Party agrees to joint checks being carried out at the request of the other Party to assess the plant-health situation and measures having equivalent results.

With a view to ensuring equivalence in application of the detailed rules for applying the legislation covered by this Annex, each Party should, at the request of the other, agree to visits of experts from the latter on its territory, to be arranged

in cooperation with the official plant-health organization responsible for te territory concerned.

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