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# Correlation of the International and National Institutional and Legal Regulations of Applying Some Aspects of Technical Barriers in Practices of Ukraine and the European Union

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**Summary:** This study contains the attempt of the comprehensive approach to issues of the correlation of concepts, provisions and obligations of States and their associations with respect to technical barriers to trade (in particular, technical regulations, standardization, certification, and accreditation, conformity assessment procedures and market surveillance systems) enshrined in international world treaties (in particular, the Agreement on Technical Barriers to Trade (TBT), which is binding for Member-States in the system of the WTO treaties) and regional multilateral and bilateral treaties (for example, the Association Agreement between Ukraine, from one part, and the European Union, European Atomic Energy Community, and their Member-States, from the other part, dd. June 27, 2014). The particular attention is paid to the national, including unified (or that being in the process of unification/adaptation), institutional and legal provision in this area, most notably in Ukraine and the European Union (first of all, the Regulation of the European Parliament and of the Council No. 765/2008/EC and Decision of the European Parliament and of the Council No. 768/2008/EC of 9 July 2008). The performance by Ukraine at the domestic/national level of its international obligations in accordance with the Association Agreement 2014 has been separately considered in terms of technical regulations and standardization, accreditation, conformity assessment procedures and market surveillance systems and their implementation (adaptation, entrenchment) in relevant regulatory legal, and organizational and institutional forms.

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**Keywords:** Technical barriers; non-tariff methods; technical regulations; the WTO Agreement on Technical Barriers to Trade; the TBT Agreement; the EU-Ukraine Association Agreement 2014; standardization, certification, accreditation, conformity assessment procedures and market surveillance systems; technical regulation in trade.

## 1. Introduction

Goods and technologies (methods for their cultivation, extraction, and production) can be potentially dangerous (including harmful) for human life and health, and the environment. On the one hand, as a result of the aforementioned, States apply the non-tariff measures in the form of technical requirements (means, barriers) for the protection, in the first place, of national commodity consumers against potential risks. And on the other hand, technical norms and standards can be introduced by countries to restrict the undesirable competition in the domestic market, and to protect national commodity producers against it, and thus, such measures become additional obstacles in foreign economic activity and contradict the principles of freedom and liberalization of international trade. That is, the application by States or regional economic integrations of technical barriers as means of the non-tariff regulation of foreign trade depends on the purpose, for which they are introduced, and therefore, a comprehensive and all-encompassing approach to their study and settlement is required. The complexity and self-sufficiency of the system are based on the correlation and interdependence of the international (world and regional) and national (domestic) entrenchments of concepts, provisions and obligations of States and their associations regarding technical barriers to trade (in particular, technical regulations, standardization, certification, accreditation, conformity assessment procedures and market surveillance systems). However, it is worth specially focusing on the fact that “technical harmonization” is important not by itself, but as an element of the sophisticated system/mechanism of internal and external markets functioning (movement and exchange of goods and services), their instruments and their institutional and legal support.

Undoubtedly, the main special multilateral international treaty in the said area is the WTO Agreement on Technical Barriers to Trade (hereinafter – the TBT Agreement), which contains three mechanisms for reducing trade barriers related to the product requirements, namely (Preamble<sup>1</sup>): – restrictions on the establishment of such requirements as a specific purpose and a necessary measure

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<sup>1</sup> *Uhoda pro tekhnichni bariery u torhivli* vid 15.04.1994 r. [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/981\\_008](http://zakon2.rada.gov.ua/laws/show/981_008). (in Ukrainian).

for its achievement; – inducement to harmonization of the requirements based on international standards, etc.; – encouragement to support developing countries. Accordingly, the WTO Member-States must perform the assumed obligations at both international and national levels, in particular to coordinate their actions with existing international commitments (for example, the content of bilateral agreements, national regulatory legal acts, etc.).

The determinative bilateral international treaty for modern Ukraine is the Association Agreement between Ukraine, from one part, and the European Union, European Atomic Energy Community, and their Member-States, from the other part, dd. June 27, 2014 (hereinafter – the Association Agreement). The Association Agreement is an international treaty of the complex nature, because the cooperation envisaged therein covers a wide range of interstate relations and all spheres of the economy; it lays the legal foundations for the mutual cooperation and proclaims its principles. A particular component of the Association Agreement, in view of the subject matter of the study, is a comprehensive program of adaptation/harmonization of legal rules/fundamentals (including the regulatory environment) in trade-related areas to the relevant EU requirements/standards. In particular, the free trade area between the European Union and Ukraine provides for the abolition of import duties, reduction in non-tariff barriers to trade, liberalization of services markets, ensuring transparency and predictability of regulations of the Ukrainian domestic market in accordance with the European and international standards, approximation of internal policies of Ukraine, including in the field of protection of the consumer's rights, to the generally accepted rules of international and European practices, ensuring the bilateral customs cooperation, etc.

We should particularly emphasize that one of the association agreement conclusion principles (“mixed external competence”) is based on the EU Court of Justice's judgment on the case of *Demirel*<sup>2</sup>, namely related to the formation of special relationship and participation commitments, within certain limits, of non-EU countries within the system of the Union<sup>3</sup> (for example, in the customs sphere<sup>4</sup>, or common procedures, namely regarding technical barriers (technical regulations, standardization systems, conformity assessment accreditation, etc.).

<sup>2</sup> C-12/86, *Demirel v Stadt Schwäbisch Gmünd* case, [1987] ECR 3719, para. 7 and 28.

<sup>3</sup> See: HOLDGAARD, R. *External Relations Law of the European Community: Legal Reasoning and Legal Discourses*. Kluwer Law International, 2008, p. 206 (para. 12.3.1.1.); LOCK, T. *The European Court of Justice and International Courts*. Oxford University Press, 2015, pp. 100–113 (Chapter 3.IV.B); MENDEZ, M. *The legal effects of EU agreements: maximalist treaty enforcement and judicial avoidance techniques*. Oxford Studies in European Law: OUP Oxford, 2013, 374 p.

<sup>4</sup> SCHRÖMBGES, U., WENZLAFF, O. Doubts regarding the origin of goods based on OLAF mission reports vs protection of confidence. *World Customs Journal*, 2011, vol. 5, No. 1, p. 92.

Due to the performance of international obligations by States and their associations, coordination and harmonization among them of actions in certain spheres of the socio-economic life, in particular regarding the technical regulation (technical barriers) system, the special attention should be paid to relevant national regulatory legal acts and institutions, as a manifestation of the immediate state of affairs in one or another area<sup>5</sup>. That is, the study of the practice and status of the national institutional and legal regulation of technical barriers in Ukraine and the EU is important, both in terms of the correlation, interdependence and performance of their own international obligations under the TBT Agreement, and mutual ones in accordance with the Association Agreement, and for the identification of problems and next steps of collaboration.

## **2. Correlation of the provisions of the WTO Agreement on Technical Barriers to Trade and Association Agreement between Ukraine and the EU**

Technical barriers to trade are any state control and restriction measures related to the technical requirements for imported goods, when they are used as a means of restricting access of goods of a foreign production/origin to the domestic market of a country<sup>6</sup>. In order to prevent the restrictive effect of technical barriers to international trade, while maintaining their protective function for security of States, their population, flora, fauna and the environment, the Agreement on Technical Barriers to Trade, also referred to as “Standards Code”<sup>7</sup>, was elabo-

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<sup>5</sup> It is interesting for Ukraine to study the experience of approximation (harmonization, adaptation) of laws in different spheres, in particular related to technical barriers, both within the EU itself, and of the countries which a while ago worked their way to the EU and now are its members. See, for example: BRENTON P., SHEEHY J., VANCAUTEREN M. *Technical Barriers to Trade in the European Union: Importance for Accession Countries*. CEPS: Working Document No. 144. April 2000, 27 p.; ŠIŠKOVÁ, N. *Základní otázky sblížení českého práva s právem ES*. Codex Bohemia, 1998, 336 p. (in Czech); CHEVASSUS-LOZZA, E., MAJKOVIČ, D., PERSILLET, V., UNGURU, M. *Technical barriers to Trade in the European Union: Importance for the new EU members. An assessment for agricultural and food products*. Paper prepared for presentation at the 11th congress of the EAAE (European Association of Agricultural Economists), The Future of Rural Europe in the Global Agri-Food System Copenhagen, Denmark, August pp. 24–27, 2005 etc.

<sup>6</sup> DANYLTSEV, A. V., DANYLOVA, E. V., ZAKHAROV A. V. *Osnovu torhovoï polytyky y pravyly VTO*. M.: Mezhdunar. otnosheniya, 2005, p. 127. (in Russian).

<sup>7</sup> OSYKA, S. H., PIATNYTSKYI, V. T. *Svitova orhanizatsiia torhivli*. K.: «K.I.S.», 2004, p. 283. (in Ukrainian).

rated within the framework of GATT during the Tokyo Round (1973-1979) of multilateral trade negotiations.

The issue of technical barriers to international trade, in addition to the regulation at the global (universal) level within the WTO, is also reflected in regional agreements, for example in the Association Agreement between Ukraine, from one part, and the European Union, European Atomic Energy Community, and their Member-States, from the other part, dd. June 27, 2014<sup>8</sup>.

In accordance with Article XI of the Marrakesh Agreement establishing the WTO<sup>9</sup>, the EU as a customs territory and Ukraine as a State (Article XII)<sup>10</sup> are members of the WTO<sup>11</sup>, and therefore, parties to the Agreement on Technical Barriers to Trade<sup>12</sup>. As a result, having signed the Association Agreement, its parties (Ukraine and the EU) must abide by international obligations arising from the participation both in this Agreement and in those related to the WTO membership<sup>13</sup>, including the TBT Agreement. The question arises as to the correlation between the TBT Agreement and Association Agreement themselves.

In analyzing the provisions of the TBT Agreement<sup>14</sup> and Association Agreement (Chapter 3, Articles 53-58)<sup>15</sup>, it should be noted that:

- The TBT Agreement consists of a preamble, 15 articles and three annexes; in the Association Agreement, Chapter 3 consisting of six articles (Articles

<sup>8</sup> *Uhoda pro asotsiatsiiu mizh Ukrainoiu, z odniiei storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony vid 27.06.2014 r.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/984\\_a11](http://zakon2.rada.gov.ua/laws/show/984_a11). (in Ukrainian).

<sup>9</sup> *Uhoda pro zasnuvannia Svitovoi orhanizatsii torhivli vid 15.04.1994 r., m. Marrakesh.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/995\\_342](http://zakon2.rada.gov.ua/laws/show/995_342). (in Ukrainian).

<sup>10</sup> *Protokol pro vstup Ukrainy do Svitovoi orhanizatsii torhivli vid 05.02.2008, m. Zheneva.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/981\\_049](http://zakon2.rada.gov.ua/laws/show/981_049). (in Ukrainian).

<sup>11</sup> *World Trade Organization, WTO.* [online]. Available at: <https://www.wto.org/>.

<sup>12</sup> *Uhoda pro tekhnichni bariery u torhivli vid 15.04.1994 r.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/981\\_008](http://zakon2.rada.gov.ua/laws/show/981_008). (in Ukrainian).

<sup>13</sup> See: HOLDGAARD, R. *External Relations Law of the European Community: Legal Reasoning and Legal Discourses*. Kluwer Law International, 2008, pp. 276–287 (para. 15.2.1.1.); MENDEZ, M. *The legal effects of EU agreements: maximalist treaty enforcement and judicial avoidance techniques*. Oxford Studies in European Law: OUP Oxford, 2013, 374 p. (Chapter IV); SCHILDBERG, B. *How are Technical Barriers to Trade treated in EU Trade Agreements? Recommendations for the Development Friendly Design of EPA Negotiations related to Technical Barriers to Trade*. Braunschweig, 2007, 21 p.

<sup>14</sup> *Uhoda pro tekhnichni bariery u torhivli vid 15.04.1994 r.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/981\\_008](http://zakon2.rada.gov.ua/laws/show/981_008). (in Ukrainian).

<sup>15</sup> *Uhoda pro asotsiatsiiu mizh Ukrainoiu, z odniiei storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony vid 27.06.2014 r.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/984\\_a11](http://zakon2.rada.gov.ua/laws/show/984_a11). (in Ukrainian).

53-58) and Annex III to Chapter 3 are devoted to the issue of technical barriers.

- The EU and Ukraine in Article 54 of the Association Agreement confirmed their existing rights and obligations under the TBT Agreement.
- Although, both agreements do not explicitly define the concept “technical barriers to trade”, they use the same terminology: technical regulations and standards (including packaging, marking and labeling requirements), and conformity assessment with the reference in the Association Agreement (paragraph 1 of Article 53) to the TBT Agreement (Annexes 1-3).
- The provisions of the Association Agreement (paragraph 2 of Article 53), as well as paragraph 1.5 of Article 1 of the TBT Agreement, do not apply to sanitary and phytosanitary measures, nor to purchasing goods by public authorities for needs of their own production or consumption (paragraph 1.4 of Article 1 of the TBT Agreement).
- Paragraph 1 of Article 55 of the Association Agreement defines the technical cooperation on technical barriers somehow broader and in more details: “The Parties shall strengthen their cooperation in the field of technical regulations, standardization, market surveillance, accreditation and conformity assessment procedures with a view of increasing mutual understanding of their respective systems and facilitating access to their respective markets”. That is, the said provision is in line with the Preamble of the TBT Agreement, in particular: “Recognizing the important contribution of international standards and conformity assessment systems for production efficiency and facilitating the conduct of international trade; non-creation of unnecessary obstacles to international trade and taking measures necessary for the protection of security interests of countries, human, animal or plant life and health, and of the environment, or for the prevention of fraud and discrimination”<sup>16</sup>.
- The particular attention should be paid to the fact that Article 55 of the Association Agreement entrenches a non-exhaustive list of areas and subjects of harmonization and unification in the field being studied, namely “the initiation of a dialogue on regulatory legal issues at both horizontal and sectoral levels”, and also paragraph 2b): “by respective organizations, public or private, responsible for metrology, standardization, testing, market surveillance, certification and accreditation”, including within the framework of “European organizations” (paragraph 2d), the WTO and the United Nations Economic Commission for Europe (UNECE)<sup>17</sup> (paragraph 2f), and in Ukraine (para-

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<sup>16</sup> See: C-100/96, *The Queen v MAFF, ex parte British Agrochemicals Association Ltd* case, [1999] ECR I-1499.

<sup>17</sup> *The United Nations Economic Commission for Europe, UNECE*. [online]. Available at: [http://www.unece.org/oes/nutshell/member\\_States\\_representatives.html](http://www.unece.org/oes/nutshell/member_States_representatives.html)

graph 2c) of Article 55). And the TBT Agreement operates with the following terminology: “preparation, adoption, and application of technical regulations, standards, and conformity assessment by central government bodies (Article 2), local government and non-government bodies (Article 3), international and regional systems (Article 9)”.

- This is the TBT Agreement, which calls all the WTO Members, including both the EU and Ukraine, to actively participate in the work of international standardization organizations, in particular: – the International Organization for Standardization (ISO)<sup>18</sup>, which, for example, has the Product Conformity Assessment Committee (CASCO), the Committee for the Protection of Consumer Rights (COPOLCO), and the EuropeAid Development and Cooperation Committee (DEVCO)<sup>19</sup> in its structure; – the International Standardized Testing Organization (ISTO)<sup>20</sup>; – the International Electrotechnical Commission (IEC)<sup>21</sup>; – the International Telecommunication Union<sup>22</sup> (ITU)<sup>23</sup>, the structure of which has the ITU Telecommunication Standardization Sector (ITU-T)<sup>24</sup>; – the Codex Alimentarius Commission<sup>25</sup>; and the International Organization of Legal Metrology (OIML)<sup>26</sup>. In addition, Ukraine fully en-

<sup>18</sup> *International Organization for Standardization, ISO*. [online]. Available at: <https://www.iso.org>

<sup>19</sup> Ukraine, as a full-fledged member of ISO since 1993 (represented by the National Standardization Body SE “UkrNDNC” (Ukrainian Research and Training Center of Standardization, Certification and Quality), is a member-country of CASCO, and DEVCO Committees, and an observer-state of REMCO, and COPOLCO Committees. Ukraine also performs functions as a secretariat in ISO/TC218, is a member of 119 technical committees, and an observer in 217 technical committees.

For more details, see [online]. Available at: <http://uas.org.ua/ua/zagalni-vidomosti-pro-dp-ukrndnts/kerivnitstvo/generalniy-direktor-dp-ukrndnts/pershiy-zastupnik-generalnogo-direktora-direktor-institutu-standartizatsiyi/viddil-mizhnarodnogo-regionalnogo-mizhderzhavnogo-spivrobotnytstva/spivrobotnitstvo-z-mizhnarodnimi-organizatsiyami/>. (in Ukrainian); <https://www.iso.org/member/2172.html>

<sup>20</sup> *International Standardized Testing Organization, ISTO*. [online]. Available at: <http://www.isto.ch/>.

<sup>21</sup> *International Electrotechnical Commission, IEC*. [online]. Available at: <https://www.iec.ch/dyn/www/f?p=103:5>.

For more details, see [online]. Available at: <http://uas.org.ua/ua/zagalni-vidomosti-pro-dp-ukrndnts/kerivnitstvo/generalniy-direktor-dp-ukrndnts/pershiy-zastupnik-generalnogo-direktora-direktor-institutu-standartizatsiyi/viddil-mizhnarodnogo-regionalnogo-mizhderzhavnogo-spivrobotnytstva/spivrobotnitstvo-z-mizhnarodnimi-organizatsiyami/>. (in Ukrainian); [https://www.iec.ch/dyn/www/f?p=103:16:0:::FSP\\_ORG\\_ID:1030](https://www.iec.ch/dyn/www/f?p=103:16:0:::FSP_ORG_ID:1030)

<sup>22</sup> The International Electric Communication Union (International Telecommunication Union, ITU), is sometimes called the International Telecommunication Union.

<sup>23</sup> *International Telecommunication Union, ITU*. [online]. Available at: <https://www.itu.int>

<sup>24</sup> *The ITU Telecommunication Standardization Sector, ITU-T*. [online]. Available at: <https://www.itu.int/ru/ITU-T/Pages/default.aspx>

<sup>25</sup> *Uhoda pro tekhnichni bariery u torhivli* vid 15.04.1994 r. Annexes 1, 3. [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/981\\_008](http://zakon2.rada.gov.ua/laws/show/981_008). (in Ukrainian).

<sup>26</sup> *International Organization of Legal Metrology, OIML*. [online]. Available at: <https://www.oiml.org/en>

asures the participation of respective national bodies not only in international organizations, but also in European ones (paragraph 7 of Article 56 of the Association Agreement).

- Article 56 of the Association Agreement provides for the gradual achievement by Ukraine of conformity with EU technical regulations, standardization, metrology, accreditation, conformity assessment procedures and market surveillance systems (with the relevant list and schedule (Annex III)). Ukraine is also progressively introducing the corpus of European standards (EN) as national standards (paragraph 8 of Article 56).
- Just as in Articles 10-11 of the TBT Agreement, so in paragraphs 3-6 of Article 56 of the Association Agreement, reporting information about the status and changes in the field of technical regulations, standards and conformity assessment procedures is envisaged; it should be noted that the provisions of the TBT Agreement clearly state this procedure.
- Paragraph 5 of Article 57 of the Association Agreement provides for the direct link of the TBT with the potential Agreement on Conformity Assessment and Acceptance of Industrial Products (the ACAA Agreement), before signing of which Ukraine and the EU must take into account the provisions of the TBT Agreement in their relationship.
- The Association Agreement (Article 58), as well as some provisions of the TBT Agreement (for example, Annex I), also pays attention to the technical requirements for marking and labeling.

Thus, the EU-Ukraine Deep and Comprehensive Free Trade Area involves, *inter alia*, the cooperation at the international regional level with regard to technical barriers, their unification and harmonization. This cooperation should be conducted in order not to create additional non-tariff barriers, on the one hand, to international trade in the performance by States of their protective/security functions in respect of their own (national) interests, and on the other hand, to national commodity producers and consumers. By comparing the TBT Agreement and Association Agreement, one can argue about their interrelation and interdependence, due to the impact of the TBT Agreement provisions on the content of the Association Agreement and its participants, as well as about the relevance of their core provisions. The EU and Ukraine, while drafting the Association Agreement, adhered to their own international commitments as a result of their WTO membership, and in general, without repeating, supplemented and specified the provisions of the TBT Agreement in the international regional agreement.



### **3. Some aspects of technical regulations, standardization, accreditation, conformity assessment procedures and market surveillance systems of products/goods in the EU**

The introduction/application of technical barriers (including technical regulations, standardization, certification, conformity assessment, etc.) in the EU was regulated and is being regulated by specific statutory acts: – directives and decisions of the European Parliament and of the EU Council (formerly the EEC), in particular: by the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, and of rules on Information Society services<sup>27</sup>, and the Decision 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardization<sup>28</sup>, and the Council Decision No. 87/95/EEC of 22 December 1986 on the standardization in the field of information technology and telecommunications<sup>29</sup>. However, the Regulation of the European Parliament and of the Council 1025/2012 of 25 October 2012 recognized the inconsistency of the above-mentioned legal framework with changes in EU standardization over the last decades. Accordingly, the Regulation makes amendments in the Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council, and repeals the Council Decision 87/95/EEC, and the Decision of the European Parliament and of the Council 1673/2006/EC<sup>30</sup>.

<sup>27</sup> *Laying down a procedure for the provision of information in the field of technical standards and regulations: Directive of the European Parliament and of the Council of 22 June 1998 № 98/34/EC. No longer in force. Date of end of validity: 06.10.2015. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31998L0034>*

<sup>28</sup> *On the financing of European standardisation: Decision of the European Parliament and of the Council of 24 October 2006 № 1673/2006/EC. No longer in force. Date of end of validity: 31.12.2012. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006D1673>*

<sup>29</sup> *On standardization in the field of information technology and telecommunications: Council Decision of 22 December 1986 № 87/95/EEC. No longer in force. Date of end of validity: 31.12.2012. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31987D0095>*

<sup>30</sup> *On European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the*

The technical regulation system established in the European Union is recognized as the most effective model for international cooperation in the world<sup>31</sup>. The large number of the agreements concluded on the mutual recognition of conformity assessment results with many countries attests to the high efficiency of the European approach in the field of technical regulations<sup>32</sup>. One has to agree that the free movement of products/goods in the EU is based on a new approach to technical harmonization and standardization, and on a global approach in the area of conformity assessment<sup>33</sup>.

Thus, by the Decision of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01), the EEC Council<sup>34</sup>:

- emphasized the need to resolve the situation as regards technical barriers to trade;
- stated its importance and necessity for reference, primarily, to European standards in order to define the technical characteristics of products;
- determined the principles of European standardization policies (for example, revising applicable technical regulations to eliminate obsolete or unnecessary ones; ensuring the mutual recognition of test results and creating the agreed rules for functioning of certification bodies; expanding practices to define the technical characteristics of products in accordance with European standards).

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Council: Regulation (EU) of the European Parliament and of the Council of 25 October 2012 № 1025/2012. In force. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R1025>

<sup>31</sup> See: BRENTON P., SHEEHY J., VANCAUTEREN M. *Technical Barriers to Trade in the European Union: Importance for Accession Countries*. CEPS: Working Document No. 144. April 2000, 27 p.; CHEVASSUS-LOZZA E., MAJKOVIČ D., PERSILLET V., UNGURU M. *Technical barriers to Trade in the European Union: Importance for the new EU members. An assessment for agricultural and food products*. Paper prepared for presentation at the 11th congress of the EAAE (European Association of Agricultural Economists), The Future of Rural Europe in the Global Agri-Food System Copenhagen, Denmark, August 24–27, 2005 etc.

<sup>32</sup> To study an example of the practical use of provisions of the WTO's Agreement on Technical Barriers to Trade (TBT) and various EU's regulations in this sphere we may attend to: C-147/96, *Netherlands v Commission* case, [2000] ECR I-4723; C-27/00 & 122/00, *Omega Air* case, [2002] ECR I-2569; C-377/98, *Netherlands v Parliament and Council (Biotech)* case, [2001] ECR I-7079; C-100/96, *The Queen v MAFF, ex parte British Agrochemicals Association Ltd* case, [1999] ECR I-1499; C-149/96, *Portugal v Council (Portuguese Textiles)* case, [1999] ECR I-8395 etc.

<sup>33</sup> KRYVOSHEIA, S. O., DIADIURA, K. O. Obgruntuvannia natsionalnoi systemy tekhnichnoho rehuliuвання ta yii transformatsiia do zahalnoievropeiskoi. *Tekhnolohycheskyi audyt y rezervy proyzvodstva*, 2015, vol. 2/3 (22), p. 58. (in Ukrainian).

<sup>34</sup> *On a new approach to technical harmonization and standards: Council Resolution* of 7 May 1985 № 85/C 136/01. In force. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31985Y0604%2801%29>

The guidelines for a new approach to technical harmonization and standards (Annex II<sup>35</sup>) include the following principles among basic ones:

- legislative harmonization is limited to the adoption of directives;
- the task of drawing up the technical specifications is entrusted to bodies competent in the standardization area;
- technical characteristics are not mandatory and maintain their status of voluntary standards;
- the producer has the choice of not manufacturing in conformity with the standards, but in this event he has an obligation to prove that his products conform to the essential regulatory requirements.

In 1989-1990s, the EEC Council adopted the Resolution on a global approach and Decision 90/683/EEC, which determined the general guidelines and detailed conformity assessment procedures<sup>36</sup>. As of today, “the relevant EU decisions and regulations”, on “technical regulations and standardization, metrology, accreditation, conformity assessment procedures and market surveillance systems” (paragraph 1 of Article 56<sup>37</sup>) are the Regulation of the European Parliament and of the Council No. 765/2008/EC of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing the Regulation (EEC) No. 339/93<sup>38</sup> (hereinafter – the Regulation No. 765/2008/EC), and the Decision of the European Parliament and of the Council No. 768/2008/EC of 9 July 2008 on a common framework for the marketing of products, and repealing the Council Decision 93/465/EEC<sup>39</sup> (hereinafter – Decision No. 768/2008/EC) and its Annexes (Annex I. Reference Provisions For Community Harmonization Legislation For Products; Annex II. Conformity

<sup>35</sup> *On a new approach to technical harmonization and standards: Council Resolution of 7 May 1985 № 85/C 136/01. In force. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31985Y0604%2801%29>*

<sup>36</sup> *Concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives: Council Decision of 13 December 1990 № 90/683/EEC. No longer in force. Date of end of validity: 22.07.1993. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1533063499296&uri=CELEX:31990D0683>*

<sup>37</sup> *Uhoda pro asotsiatsiiu mizh Ukrainoiu, z odnii storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony vid 27.06.2014 r. [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/984\\_a11](http://zakon2.rada.gov.ua/laws/show/984_a11). (in Ukrainian).*

<sup>38</sup> *Pro vstanovlennia vymoh do akredytatsii ta rynkovoho nahliadu, poviazanykh z realizatsiieiu produktiv, ta pro skasuvannia Rehlementu (IeES) № 339/93: Rehlement Yevropeiskoho Parlamentu i Rady (IeS) vid 09.07.2008 r. № 765/2008. [online]. Available at: [http://zakon5.rada.gov.ua/laws/show/994\\_938](http://zakon5.rada.gov.ua/laws/show/994_938). (in Ukrainian).*

<sup>39</sup> *Pro spilni ramky dlia realizatsii produktiv ta pro skasuvannia Rishennia Rady 93/465/IeES: Rishennia Yevropeiskoho Parlamentu i Rady vid 09.07.2008 r. № 768/2008/IeS. [online]. Available at: [https://zakon.rada.gov.ua/laws/show/994\\_b42](https://zakon.rada.gov.ua/laws/show/994_b42). (in Ukrainian).*

Assessment Procedures). Let us consider some of the provisions of these regulatory legal acts.

The Regulation No. 765/2008/EC provides for the recognition of a single accreditation organization at the regional level (the European Accreditation Organization (EA)), whose task is to promote a transparent, quality-led system for the evaluation of the competence of conformity assessment bodies throughout Europe (paragraph 23 of the Preamble of the Regulation No. 765/2008/EC).

Paragraph 2 of the Preamble and Article 2 of the Decision No. 768/2008/EC lay down common principles and definitions required for the adoption of sectoral regulatory acts; and define the structure of a future unified legislation on procedures for trade in products/goods. These are principles and rules for the organization and accreditation of conformity assessment bodies, according to which a Member-State shall appoint only a single national accreditation body operating on a non-for-profit basis, having financial and personnel resources for the performance of tasks, not providing consultancy services, not owning shares nor otherwise having a financial or managerial interest in a conformity assessment body (Article 4), i.e. is independent, objective and impartial, and upon that, it shall publish audited annual accounts and ensure confidentiality of information (Article 8 of the Regulation No. 765/2008/EC, Article R17 of Annex II to the Decision No. 768/2008/EC).

Paragraph 17 of the Preamble and Article 1 of the Decision No. 768/2008/EC declare the position that the quality of products placed on the EU market shall comply with the requirements of the European legislation. The general principles of the CE marking and the obligation of Member-States to ensure the correct implementation of the regime governing in this field and to take appropriate measures (sanctions) for the improper use of the marking are contained in Article 30 of the Regulation No. 765/2008/EC, and upon that the following has been entrenched: – the CE marking right belongs to the manufacturer or his authorized representative, who thereby assumes responsibility for the conformity of a product with all applicable requirements; – the CE marking shall be affixed only to products, to which its affixing is provided for by the specific harmonized legislation; – the affixing to a product of markings, symbols, or inscriptions, which are likely to mislead third parties regarding their meaning or form shall be prohibited. The Decision No. 768/2008/EC, however, contains the provision on the CE marking, which indicates the conformity of a product quality with the requirements established (paragraph 29), and is applied only for that purpose (paragraph 30). Article R12 of Annex I to the Decision No. 768/2008/EC substantially supplements the general principles of the CE marking set out in Article 30 of the Regulation 765/2008/EC<sup>40</sup>, with the

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<sup>40</sup> *Pro vstanovlennia vymoh do akredytatsii ta rynkovoho nahliadu, poviazanykh z realizatsiieiu produktiv, ta pro skasuvannia Rehlamentu (IeES) № 339/93: Rehlament Yevropeiskoho*

rules for its affixing. Thus, the CE marking applied to products or their label shall be legible and visible; it shall be affixed to products before they are placed on the market; it may contain the identification number of the conformity assessment body, where that body has carried out the conformity assessment at the manufacturing stage. The EU Member-States are under the obligation to develop a legal mechanism to regulate public relations in the field of marking, as well as to bring business entities to responsibility, up to criminal one, for committing infringements in the field of marking products<sup>41</sup>.

Paragraphs 20-27 of the Decision No. 768/2008/EC identify the participants in the process of distributing goods on the market, namely: – the manufacturer's sole responsibility is to carry out the conformity assessment procedure (paragraph 21); – importers must guarantee that conformity assessment procedures of products supplied by them have been fully implemented, products have been labeled, and documentation drawn up by manufacturers is suitable for inspection by the supervisory public authorities (paragraph 22); – the distributor of products must monitor that during their sale or other handling of them, their quality characteristics are not adversely affected (paragraph 23), as well as should be involved in control and supervisory measures, and provide the specially authorized state authorities with all necessary information about products/goods (paragraph 27).

Article R2 of Annex I to the Decision No. 768/2008/EC contains the obligations of the manufacturer, who shall: – ensure that products are manufactured in accordance with the requirements of a specific regulatory act; – draw up the technical documentation, carry out the conformity assessment procedure of products/goods, and deliver goods already assessed for the conformity; – draw up the EU declaration of conformity, and affix the marking of products/goods, etc. The requirements for products are: – availability of a serial number, indications on belonging to the series of goods, other designations and elements allowing them to be identified; – providing each product with instructions and safety information on precautionary measures when using it (set out in a language, which can be easily understood by consumers of a country, on whose market it is sold). The manufacturer is also obliged, further to a reasoned request from government authorities, to provide with information and documentation regarding the conformity of the product in a language they understand. According to Article R10 of Annex I, it is the obligation of the manufacturer to draw up and regularly update

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*Parlamentu i Rady (IeS)* vid 09.07.2008 r. № 765/2008. [online]. Available at: [http://zakon5.rada.gov.ua/laws/show/994\\_938](http://zakon5.rada.gov.ua/laws/show/994_938). (in Ukrainian).

<sup>41</sup> *Pro spilni ramky dlia realizatsii produktiv ta pro skasuvannia Rishennia Rady 93/465/IeES: Rishennia Yevropeiskoho Parlamentu i Rady vid 09.07.2008 r. № 768/2008/IeS.* [online]. Available at: [https://zakon.rada.gov.ua/laws/show/994\\_b42](https://zakon.rada.gov.ua/laws/show/994_b42). (in Ukrainian).

the EU Declaration of conformity (of a standard form (Annex III), with modular elements (Annex II)), indicating the conformity in the manufacture of products with all the requirements established by regulatory legal acts<sup>42</sup>.

The obligations of the importer according to Article R4 of Annex I to the Decision No. 768/2008/EC include placing only compliant products on the EU market of goods. The importer shall ensure that the manufacturer of products has carried out the conformity assessment procedures, drawn up the technical documentation, and affixed the marking; the necessary documents are attached to products/goods; goods are provided with instructions and documents containing the information about its safe use in a language, which can be easily understood for the consumer. The importer shall indicate their name and trademark, as well as contact information. Further to a request from public authorities, the importer shall provide with the information and documentation regarding the conformity of products/goods. When placing goods on the market, in accordance with the provisions of Article R5 of Annex I to the Decision No. 768/2008/EC, the distributor shall take into account all the requirements established by law: shall verify the marking available on goods, and be convinced that goods are accompanied by the required documentation, instructions and safety information in a language, which can be easily understood. In the event of uncertainty as to the fact that a product is in conformity, it shall not make products available on the market until they have been brought into conformity with the requirements established. If products/goods pose a threat, the distributor is obliged to provide the manufacturer or importer with all necessary information, as well as to report this fact to the market surveillance authorities. Further to a request from public authorities, the distributor shall provide with the information and documentation regarding the conformity of products/goods. Article 4 of the Decision No. 768/2008/EC establishes the conformity assessment procedures to be applied when the EU legislation imposes the specific conformity requirements for certain products. The procedures shall be chosen from among the determined modules (Annex II to the Decision No. 768/2008/EC), taking into account a number of the following criteria: – the module shall be appropriate to the category of goods in terms of its characteristics; – the conformity assessment shall be determined by the degree of risk and the type of threat inherent in it; – there is a need to avoid imposing modules that may lead to appearance of artificial obstacles to the conformity assessment of products/goods. Annex II to the Decision 768/2008/EC contains the description of the conformity assessment procedure of products/goods by modules: Module A “Internal Production Control”; Module B

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<sup>42</sup> See: C-149/96, *Portugal v Council (Portuguese Textiles)* case, [1999] ECR I-8395; C-147/96, *Netherlands v Commission* case, [2000] ECR I-4723.

“EC-type Examination”; Module C “Conformity to Type Based on Internal Production Control”; Module D “Conformity to Type Based on Quality Assurance of the Production Process”; Module E “Conformity to Type Based on Product Quality Assurance”; Module F “Conformity to Type Based on Product Verification”; Module G “Conformity Based on Unit Verification”; and Module H “Conformity Based on Full Quality Assurance”.

The market surveillance mechanisms for goods (including products originating from third countries) are a guarantee of their compliance with the safety requirements (including protection of the consumers’ rights, and the environment). The Member-States are obliged to set up market surveillance authorities with the relevant competence, powers, and resources, as well as communication and coordination between them (Articles 17, and 18 of the Regulation No. 765/2008/EC). The important aspect of activities in this matter is the procedures for tracking complaints, and reports on risks that arise in relation to products/goods subject to the harmonized EU legislation; monitoring accidents and health damages caused by such products. The market surveillance measures determined by the Regulation include the checks of product characteristics according to the appropriate scale (document verification, physical and laboratory checks of samples). According to Article 19 of the Regulation No. 765/2008/EC, market surveillance authorities shall be empowered not only to require business entities to provide with the necessary documentation, but also, if needed, to enter premises of such entities, take samples of products, destroy or otherwise dispose of products that present a serious risk. Other duties of market surveillance authorities include the prevention and reduction of risks identified for any product; independence, impartiality and objectivity of activities. The concept of “products presenting a serious risk” is enshrined in Article 20 and stipulates the duty of the Member-State to guarantee that such products will be promptly withdrawn or removed, or their placement on the market will be prohibited. In this case, the clear criteria are set for decisions on qualifying products as those presenting a serious risk: they must be based on a risk assessment that takes into account the nature of the hazard and the likelihood of its occurrence.

As defined by the ‘Blue Guide’<sup>43</sup> on the implementation of EU products rules, the Decision No. 768/2008/EC updated, harmonized and consolidated the various technical tools: terms, criteria for the designation and notification of conformity assessment bodies, rules for the notification procedure, conformity assessment procedures (modules) and rules for their use, mechanisms of interim measures,

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<sup>43</sup> The ‘Blue Guide’ on the implementation of EU products rules 2016: Commission Notice, C/2016/1958. [online]. Available at: <https://op.europa.eu/en/publication-detail/-/publication/ca3224fa-5303-11e6-89bd-01aa75ed71a1>

business entities' duties and traceability requirements. Therefore, the Regulation (EC) No. 765/2008 and the Decision No. 768/2008/EC contain all the necessary elements of the comprehensive regulatory framework for the effective work on safety and conformity of products/goods with the requirements adopted for the protection of different public interests and proper functioning of the single market, which is particularly important for Ukraine in view of paragraph 1 of Article 56 of the Association Agreement.

#### **4. Current state and prospects of the performance by Ukraine of its commitments on national technical barriers to trade in the context of the EU-Ukraine Association Agreement**

The EU-Ukraine Association Agreement<sup>44</sup> has been already in force for five years, including its full effect since September 1, 2017<sup>45,46</sup>. The Provisions of the Agreement envisage the freedom for the movement of goods (Article 26 and certain provisions of Chapter 2), with the exception of agricultural ones (Article 40, Chapter 17 “Agriculture and Rural Development” (Articles 403-406). The signing of the Association Agreement, as well as creation within this Agreement of the deep and comprehensive free trade area between Ukraine and the European Union have a serious impact on the development of foreign trade, because: – Ukrainian commodity producers have acquired certain improved opportunities to enter the EU market, which envisages the connection with improving the level of quality, safety and the environmental profile of Ukrainian goods; – the increase of competition on the domestic market; – more opportunities to share experience and technology; – implementation of more modern tools for the non-tariff regulation (including technical regulations, standardization, metrology, accreditation, conformity assessment procedures systems, sanitary and phytosanitary measures,

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<sup>44</sup> *Uhoda pro asotsiatsiiu mizh Ukrainoiu, z odniiei storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony vid 27.06.2014 r.* [online]. Available at: [http://zakon2.rada.gov.ua/laws/show/984\\_a11](http://zakon2.rada.gov.ua/laws/show/984_a11). (in Ukrainian).

<sup>45</sup> *Pro ratyfikatsiiu Uhody pro asotsiatsiiu mizh Ukrainoiu, z odniiei storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony: Zakon Ukrainy vid 16.09.2014 r. №1678-VII.* [online]. Available at: <https://zakon.rada.gov.ua/laws/show/1678-18>. (in Ukrainian).

<sup>46</sup> *Shchodo nabrannia chynnosti Uhodoiu: Lyst Ministerstva zakordonnykh sprav Ukrainy vid 20.07.2017 r. № 72/14-612/1-1713.* [online]. Available at: <http://zakon5.rada.gov.ua/rada/show/v1713321-17>. (in Ukrainian).