



UKRAINE AND THE ASSOCIATION AGREEMENT

Implementation monitoring
July 1 — November 1 2016



UKRAINIAN CENTRE
FOR EUROPEAN
POLICY



Konrad
Adenauer
Stiftung

Review



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Methodology

This report presents the results of the research related to the implementation of the Association Agreement with Ukraine, on the one part, and the European Union, the European Atomic Energy Community and their member states, on the other part (hereinafter referred to as the Association Agreement) over the period of July 1 till November 1, 2016.

Integration processes which are taking place in Ukraine progress at a different speed, depth, and complexity. However, all of them are aimed at the approximation of the laws of Ukraine to the European Union legislation. It has become necessary after the Association Agreement was signed.

Today, the Association Agreement exists in the following three “dimensions” related to the its enactment:

- provisions that started to be temporarily applied since November 1, 2014;
- provisions that started to be temporarily applied since January 1, 2016 (free trade zone with the EU);
- provisions that cannot be applied temporarily and can not be applied until the Agreement fully comes into force.

This report focuses on those provisions of the Association Agreement which have already come into force and should have been implemented by November 1, 2016.

The following two aspects have become the focus of attention in the course of assessing the results of implementation of Ukraine’s obligations under the Association Agreement:

- 1) the process of approximation¹ of the Ukrainian legislation to the European Union laws through transposition (the process aimed at reaching of adaptation through transposing the EU’s *acquis* into the national law),
- 2) the process of implementation² of *acquis communautaire*, as provided for by the Association Agreement.

As known, the Association Agreement includes a list of commitments (legislative acts of the EU) that have been formed as of 2012. Since both versions of European legislation and the timing of their implementation undergone some changes, we have

1) **Approximation** - the process of adapting to the changing conditions; in international law, approximation is a process of bringing the national law in line with the regulations and standards of the international law through the improvement of national law (amendments and supplements, adoption of new regulatory acts), conclusion or accession to international treaties.

2) **Implementation** – the process of transposition of legislative acts, including the determination of the order and the procedures of their implementation (in the narrow sense); this process also covers interpretation, the practice of application, ensuring compliance with and enforcement of the law by public authorities (implementation in a broad sense). In the international law, it is the actual fulfillment of international commitments at the national level, as well as one of the ways of incorporating international legal regulations into the national legal system in line with the goal and the international standards.

determined the list of commitments for the assessment including updated versions of EU legislation, but the timing of their implementation are clearly tied to deadlines defined in the annexes of the Association Agreement for the “old” versions. Exceptions from this rule were set as the following when:

- (1) Ukraine’s commitments to the Energy Community in the “Energy” sector have a priority with regard to the period of implementation;
- (2) The deadlines for implementation are determined by the supplementary documents to the Association Agreement (e.g. new lists of EU acts on program commitments under the Association Agreement, decisions of the Association Council, etc.)
- (3) There are general obligations, or when the Agreement leaves the decision on the period of implementation at the discretion of its parties. In this case, we stick to deadlines specified in the relevant implementation plans of the Government of Ukraine.



Note: The information contained in the report has been processed as of December 2, 2016.

Summary

The Association Agreement stipulates that by the end of 2025 Ukraine shall approximate its legislation to that of the EU and implement (transpose) into its legislation the provisions of around 350 directives, regulations, and decisions, as well as develop the order and the procedure of their implementation. It is, definitely, a gradual implementation, as each document has its own terms and requirements as to the form of such implementation.

As of November 1, 2016, Ukraine had to approximate its national legislation in the following seven spheres, which makes a total of 44 commitments regarding approximation of the EU regulatory acts:

- 1) Energy – 13 commitments
- 2) Environment – 15 commitments
- 3) Healthcare – 5 commitments
- 4) Social policy – 2 commitments
- 5) Business activity – 4 commitments
- 6) Taxation – 2 commitments
- 7) Public procurement – 3 commitments

Approximation of the laws on public procurement turned out the most successful. The process of approximation was launched back in 2015 owing to the activity of the Ministry of Economic Development and Trade of Ukraine. As a result, three commitments in the field of public procurement, provided for by the direct requirements of Art. 150-151 of the Association Agreement, have been fully met. In particular, a roadmap on public procurement has been developed in time, the national legislation has set the standards of concluding government contracts, and the public authorities responsible for the public procurement policy and review of customers' decisions were determined.

Owing to a systemic work of the State Agency on Energy Efficiency and Energy Saving of Ukraine and the State Nuclear Regulatory Inspectorate of Ukraine on approximating the energy labeling and nuclear facilities safety standards, which had been launched long before the official start of implementation of commitments under the Association Agreement, the process of approximation in the sphere of energy is also quite successful. The most successful cases were the development of a regulatory framework and a number of energy labeling standards which are actually being used to determine the energy efficiency class of household appliances, as well as implementation of the regulations of the EU framework directive for the safety of nuclear installations, which allowed to introduce more stringent safety standards in the field of nuclear energy which have been introduced in the EU as a result of analysis of the causes and consequences of meltdown at the nuclear power plant in

Fukushima (Japan).

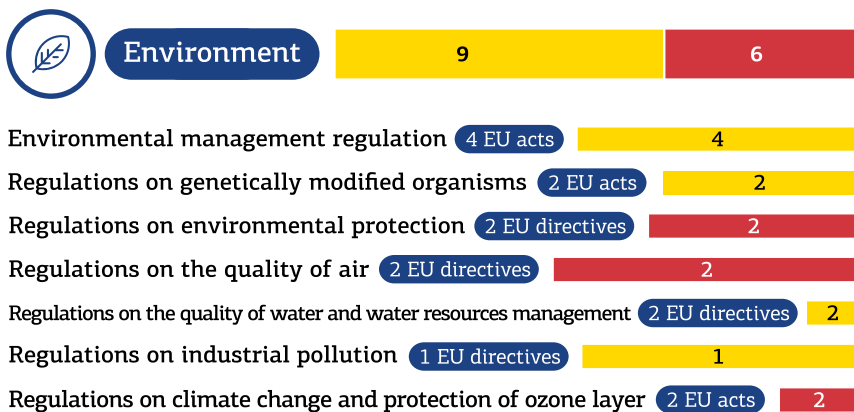
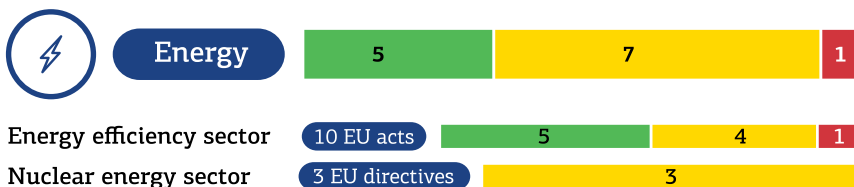
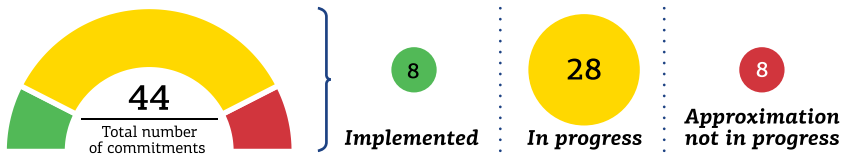
Environment is another sphere which could demonstrate successful results in the process of approximation of legislation. Two systemic laws in the field of environmental management and integration of environmental policy in other sectoral policies – the Law “On environmental impact assessment” and the Law “On strategic environmental assessment” were adopted on October 12, 2016. However, as soon as on October 26, 2016, these laws were vetoed by the President of Ukraine. Thus, these commitments cannot be considered fulfilled. Partial approximation of the Water Directive is the only achievement over the period under analysis.

The commitments in the field of taxation regulating general terms of excise duty administration, the register of excisable goods, and the specific issue of codification of excise duty on tobacco products are also approaching the final stage of implementation – it is necessary to make some technical changes to the Tax Code of Ukraine to fulfill them completely.

The commitments in other areas, such as environmental protection, healthcare, social policy, and business activity, have not been fulfilled in time due to a number of reasons and currently at different stages of approximation of the national legislation to the relevant EU standards.

This report has been written to assess the effectiveness of approximation of the Ukraine legislation to that of the EU, evaluate the progress and identify the problematic areas, as well as verify whether the regulatory acts of Ukraine meet the EU requirements mentioned in the Association Agreement.

The list of commitments for EU legislative acts implementation to Ukrainian law with the period from 07.01.2016 to 01.11.2016





Business activities

3

1

Sector of business establishment 1 EU directives

1

Sector – protection of the rights of participants and creditors 2 EU directives

1

1

Sector – accounting and audit 1 EU regulation

1



Taxation

2

Sector of indirect taxation 2 EU directives

2



Public procurement

3

Development of a policy document 1 commitment

1

Adoption of the Roadmap in the sphere of public procurement

Approximation of Article 151 of the Association Agreement 1 commitment

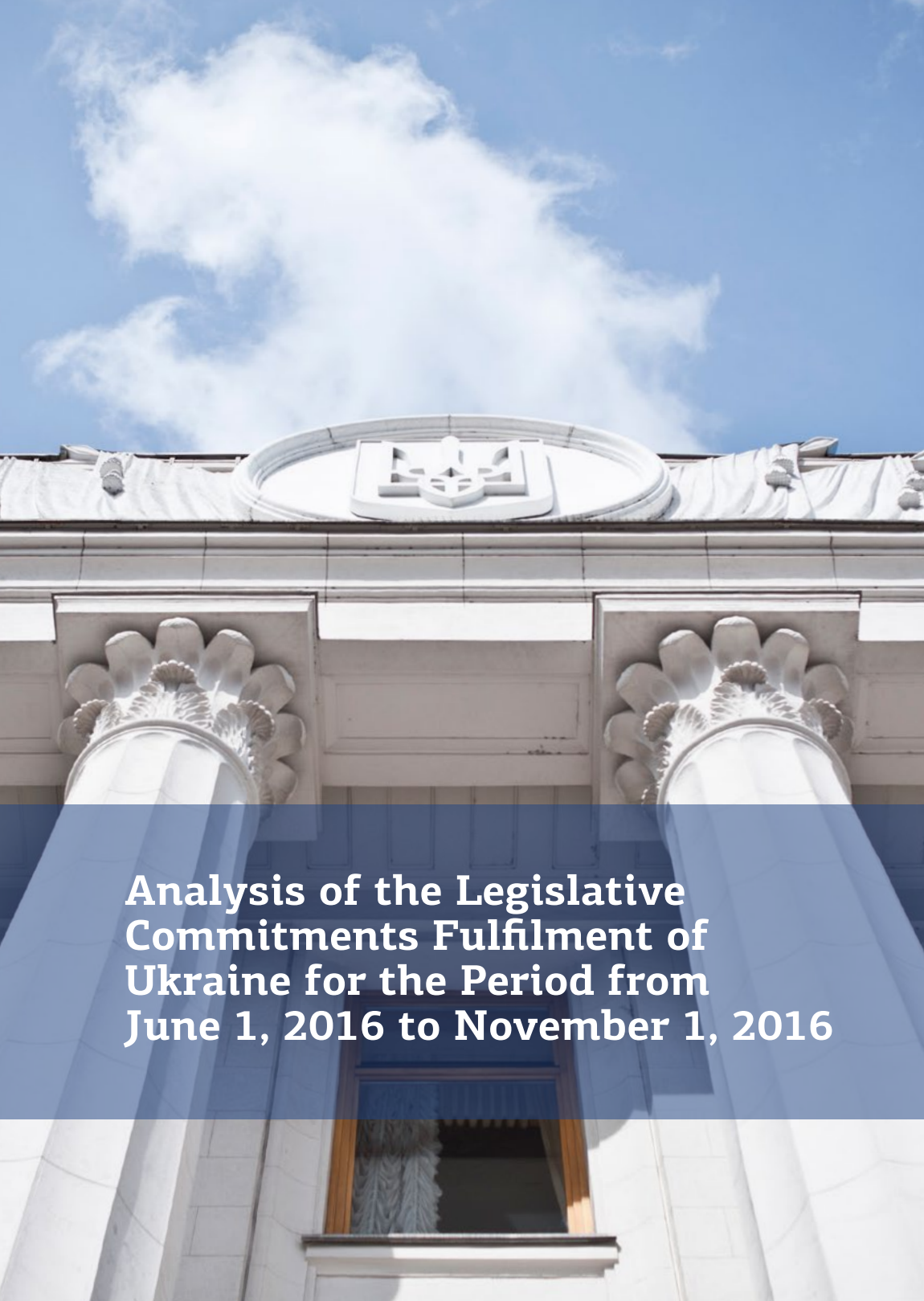
1

To introduce basic standards regulating the process of conclusion of governmental contracts

Approximation of Article 150 of the Association Agreement 1 commitment

1

To determine two governmental authorities responsible for the policy in the field of public procurement and revision of customers' decisions



**Analysis of the Legislative
Commitments Fulfilment of
Ukraine for the Period from
June 1, 2016 to November 1, 2016**



Commitments in the field of public procurement



Expert



Oleksandr
Shatkovskiy

Reform of public procurement is one of the most successful examples of implementation of the Association Agreement: many of Ukraine's commitments in this area have been fulfilled in advance¹.

According to the Association Agreement, in 2016 – specifically **by July 1, 2016** – Ukraine had to fulfil three commitments²:

- 1) Introduce the key standards governing the process of conclusion of state agreements (Art. 151 of the Association Agreement);
- 2) Identify two state government bodies responsible for the policy in the field of public procurement and review of clients' decisions (Part 2 of Art. 150 of the Association Agreement)
- 3) Work out a "Roadmap" in the field of public procurement (Art. 152 of the Association Agreement).

What has been done to fulfil these commitments?

1) Task: Introduction of the key standards governing the process of conclusion of state agreements (Art. 151 of the Association Agreement).

Task execution status: In our opinion, this task has been fulfilled.

The Law of Ukraine "On Public Procurement" (hereinafter – the [Law on Procurement](#)) provides for public procurement procedures, as well as their conclusion procedure and basic requirements for procurement agreements (Art. 36).

2) Task: Identification of two state government bodies responsible for the policy in the field of public procurement and review of clients' decisions (Part 2 of Art. 150 of the Association Agreement).

Task execution status: In our opinion, this task has been fulfilled.

The Law of Ukraine "On Public Procurement" determines the Competent Authority as the central executive body that enforces the state policy in the field of public

1) See UCEP report "[Ukraine and the Association Agreement. Monitoring of Implementation for 2014 – half-year period of 2016](#)".

2) See Annex XXI-A to the Association Agreement.

procurement (Art. 1, Para. 34). Such Competent Authority is the MEDT³.

The law also provides for an opportunity to appeal against the client's decisions via the appeal body (the Antimonopoly Committee of Ukraine - AMC), which has the right to oblige the client to fully or partially revoke their decisions (Art. 1 Para.14, Art. 18 Para. 9).

3) Task: Approval of the "Roadmap".

Task execution status: In our opinion, this task has been fulfilled.

What is the "Roadmap"?

The "Roadmap" is a comprehensive program covering all the reforms in the field of public procurement with timetables and key interim results.

Ukraine approved the "Roadmap" in compliance with the six-month period established by the Agreement (i.e. July 1, 2016): in February 2016, it was approved by the CMU⁴ in two documents - (a) Strategy of Reforming the Public Procurement System, and (b) Action Plan for its implementation. The "Roadmap" implies the transition to electronic procurement on the basis of EU standards, as well as development of relevant institutions, curricula and professionalization of procurement, coordination measures and control over their implementation.

Following the positive estimation of the Committee for Trade⁵, this "Roadmap" shall be viewed as a reference document for the implementation of the Association Agreement with regard to public procurement. Currently the "Roadmap" has not yet been approved by the Committee for Trade⁶, however this regulation is valid and mandatory for ministries in charge.

The Action Plan of the Strategy Implementation specifies the stages of reforms with specific tasks and deadlines for their implementation. It should be noted that the terms specified in the "Roadmap" are more stringent than those set out in the Association Agreement. Thus, if Ukraine complies with the "Roadmap", the approximation of Ukrainian public procurement legislation to that of EU will be implemented faster than required by the Association Agreement.

In particular, the Action Plan includes the assignment of adapting the Ukrainian norms to European legislation with the deadline set by the end of 2016. While the Association Agreement itself stipulates the nearest deadline for adapting the European legislation as **January 1, 2019**⁷.

Besides, the "Roadmap" provides for the adaptation of new EU directives in the field of public procurement, whereas the Association Agreement refers to the old

3) Regulation on MEDT approved by Directive of the CMU No. 459 dated August 20, 2014

4) Directive of the CMU No. 175-p dated February 24, 2016

5) Committee for Trade comes up as one of the formats of work for the Association Committee established in compliance with Article 464(4) of the Association Agreement. It consists of senior officials of Ukraine and the EU in various areas of cooperation and meets at least once a year. The Association Committee in its trade format considers issues related to Chapter IV of the Agreement. It includes high-ranking officials from Ukraine and the European Commission responsible for trade and issues related to trade. See more details [here](#).

6) The "Roadmap" might be approved at the next meeting of the Committee for Trade in December 2016.

7) See. Annex XXI-A to the Association Agreement.

Directives. Thus, by implementing the “Roadmap” Ukrainian legislation will be faster approximated to the effective (rather than the previous one, which is already invalid) EU legislation.

What measures to implement EU legislation are stipulated in the Action Plan for 2016?

According to the Action Plan, currently the reform of public procurement is at the first stage (January 1 – December 31, 2016). Out of the measures planned for 2016, we have identified the steps aimed at the implementation of European legislation. Please note that the deadline for their execution is not over yet as it covers the period by the end of the year:

- 1) Adoption of the regulatory and legal basis for application of electronic means in public procurement procedures in compliance with the EU principles and standards, including establishment of requirements to the information technologies used at e-auctions (Art. 35 of Directive No. 2014/24/EU).

Directive No. 2014/24/EU is a new EU directive in the field of public procurement repealing Directive No. 2004/18/EC – the “old” Directive, which Ukraine must implement under the Association Agreement (the first deadline, as indicated above, is January 1, 2019). The Ukrainian party decided to implement the new Directive in a shorter time by stipulating relevant commitments in the “Roadmap”.

Competent body: Ministry of Economic Development and Trade of Ukraine (hereinafter the MEDT).

What has been done to adapt national legislation?⁸

In December 2015, the Law on Procurement was approved, which incorporates certain provisions of Directive No. 2014/24/EU⁹. In particular, Directive No. 2014/24/EU provides for and specifies the procedure of electronic auctions (Art. 35 of the Directive). The Law on Procurement also regulates the issue of electronic auctions (Art. 29 of the Law), which implements certain aspects of Art. 35 of the Directive.

The measures included in the Plan are aimed at ensuring the technical feasibility of electronic auctions (establishing requirements for computer hardware and software) in accordance with the standards and principles of the EU.

In February 2016, the CMU adopted a Resolution that governs the operation of e-procurement and authorisation of electronic platforms, making it possible to conduct electronic auctions¹⁰ in Ukraine.

According to the Law on Public Procurement, Ukraine has introduced the electronic public procurement system ProZorro, which since August 1, 2016 has been mandatory for all purchasers.

8) It should be noted that the progress in the reform of public procurement in Ukraine took place in many respects due to the technical assistance of the EU. See more details [here](#).

9) [Directive No. 2014/24/EU](#) of March 31, 2014 on the Coordination of Procedures for the Award of Public Works Contracts, public Supply Contracts and Public Service Contracts

10) Resolution of the CMU No. 166 of February 24, 2016.

However, the adaptation of Article 35 of Directive No. 2014/24/EU is still underway, as the final deadline for its implementation is set for as late as 2022.

2) Establishment (identification) of a centralised procurement organisation (organisations) for implementation of the pilot project aimed at determining the mechanism of centralised procurement and legislative regulation of provisions on centralised procurement (Art. 37 and 38 of Directive 2014/24/EU).

Competent body: MEDT.

What has been done to adapt national legislation?

The Law on Procurement provides for the opportunity to implement procurement by centralized purchasing organisations (CPOs). CPOs are specially created organisations that purchase the same product for several different (small) clients based on framework agreements so that clients could save time and resources and reduce the risk of appeal against already concluded agreements¹¹.

However, the procedure of creation and activity of CPOs should be regulated by an Act of the CMU, which is currently pending.

In order to identify the best mechanism of centralised procurement, the CMU will hold a pilot project of centralised procurement. To this end, the MEDT has developed a draft order of the Cabinet of Ministers of Ukraine "[On Implementation of the Pilot Project on Creation and Arrangement of a Centralised Purchase Organisation](#)", which was approved by the CMU on November 23, 2016.

¹¹) [Centralization of purchases – streamlining instead of the “Soviet-type” administration based on the example of EU countries](#), Oleksandr Shatkovskiy, Senior Expert of the Public Procurement Project



Commitments in the field of energy industry



Experts



*Olha
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Naumenko*

The competent bodies responsible for the adaptation of Ukraine's legislation to that of the EU in the energy sector during the period under consideration were the **Ministry of Economic Development and Trade of Ukraine, the State Agency on Energy Efficiency and Energy Saving (SAEE) and the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU).**

The list of commitments undertaken by Ukraine in the power sector is based on the versions of EU directives contained in the relevant implementation schedule acquis communautaire set as a priority by the Protocol on the Accession of Ukraine to the Energy Community (for details see [1 Monitoring Report 'Ukraine and the Association Agreement: Monitoring of Implementation for 2014 – first 6 months of 2016'](#)¹). At the same time, to determine the deadlines for adaptation of provisions of relevant directives and their implementation, we adhered to the schedule determined by the Association Agreement. In cases where the precise deadlines for implementation according to the schedule of the Agreement cannot be established (e.g., where the general articles of the Agreement are referred to), we relied on the deadlines set in the respective implementation plans of the government as benchmarks.

Commitments with the deadlines set by July 1 – November 1, 2016

As of November 1, 2016, there were 13 such commitments, of which 10 are associated with energy efficiency, such as energy labelling of household appliances (competent bodies on the part of Ukraine – the Ministry of Economy and State Agency on Energy Efficiency and Energy Saving of Ukraine (SAEE)), 3 refer to nuclear energy (competent body on the part of Ukraine – the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU)). According to the assessment results, only five of them were transposed into the national legislation of Ukraine.

Energy Labelling of Household Appliances

EU energy labelling regulations that had to be implemented by November 1, 2016:

- **Directive of the European Parliament and EU Council No. 2010/30/EU** on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products

¹) In order to determine the "new" versions of the EU directives taken into account in relevant government implementation plans.

(repealing Directive No. 92/75/EEC), which provides for the implementation of the following delegated (“supplementary”) regulations:

1. **Commission delegated regulation (EU) No. 1060/2010** with regard to energy labelling of household refrigerating appliances (substituting Commission Directive No. 2003/66/EC)
2. **Commission delegated regulation (EU) No. 847/2012** with regard to energy labelling of electrical lamps and luminaires (substituting Commission Directive No. 98/11/EC)
3. **Commission delegated regulation (EU) No. 1059/2010** with regard to energy labelling of household dishwashers (substituting Commission Directive No. 97/17/EC)
4. **Commission delegated regulation (EU) No. 1061/2010** with regard to energy labelling of household washing machines (substituting Commission Directive No. 95/12/EC)
5. **Commission delegated regulation (EU) No. 65/2014** with regard to energy labelling of domestic ovens and range hoods (substituting Commission Directive No. 2002/40/EC)
6. **Commission delegated regulation (EU) No. 626/2011** with regard to energy labelling of household air-conditioner (substituting Commission Directive No. 2002/31/EC)
7. **Commission delegated regulation (EU) No. 392/2012** with regard to energy labelling of household electric tumble driers (substituting Commission Directive No. 95/13/EC)
8. **Directive of the EC No. 96/60/EC** with regard to energy labelling of household combined washer-dryers.

However, it should be noted that the list of EU regulations specified in the Agreement is not complete when it comes to the full set of EU rules governing energy labelling. In particular, the list of delegated regulations today (as of November 2016) consists of 16 Regulations and a Directive², while Ukraine, according to the Association Agreement, has committed to implement only eight of them³.

On the other hand, Ukraine also has a list of commitments on energy labelling to the Energy Community, which almost fully coincides with the list of obligations under the Agreement, except for one delegated regulation that is not included in the Agreement, which also makes it possible for us to include it in the assessment list, namely:

9. **Commission delegated regulation (EU) No. 1062/2010** with regard

2) For the complete list, please, follow the [link](#).

3) On the other hand, another three Commission Delegated EC Regulations with regard to energy labelling of vacuum cleaners, heaters and water heaters are contained in the [Strategy for Development of the Technical Regulation System for the Period by 2020](#), approved by the CMU Resolution No. 844-p dated August 19, 2015, approved by the Cabinet of Ministers No. 844-p of August 19, 2015. However, as these regulations are not included in the assessment list, they are not included in the official schedule of the government implementation plans for the Agreement.

to energy labelling of televisions.

Therefore, in this section we will assess one framework regulation and nine implementing delegated regulations.

How do we benefit from the relevant EU regulations?

Directive of the European Parliament and EU Council No. 2010/30/EU is one of the so called “framework” directives on energy efficiency. Together with another Directive No. 2009/125/EC, which sets requirements for ecodesign of energy-related products⁴, they make up the basis for establishing specific rules and standards for energy labelling and design for all household appliances that consume energy, encouraging both producers and consumers of such devices to manufacture and use devices with lower power consumption rates.

The main purpose of these directives in the EU is to increase energy efficiency in the use of household appliances and by so doing to stimulate domestic consumers to contribute to the reduction of the total energy consumption.

Accordingly, the aforementioned Directives are aimed at achieving the following goals⁵:

1. Increasing energy-efficiency of household energy consuming appliances and improving the level of environment protection;
2. Free circulation of energy consuming products in the EU;
3. Providing consumers with information that allows them to choose more energy efficient household appliances;
4. Obliging public procurement bodies to purchase only the energy consuming appliances of the highest energy efficiency class (as indicated in the delegated regulations) or even higher (which should be specified in tender conditions).

Cutting energy consumption of household appliances is an important contribution to achieving the objectives of EU climate policy, one of which is to reduce energy consumption by 20% by 2020, as in 2014 domestic consumers consumed about 25% of the total energy in the EU-28⁶. The results of ex-post evaluation of the efficiency of policy measures on energy labelling and design made by the European Commission in 2015, showed that it had resulted in a rapid transformation of the market of household appliances towards better energy efficiency. According to the Commission, the full implementation of the two directives will achieve 19% savings in energy consumption in the sector of domestic energy consuming devices in 2020, compared to the “business-as-usual” scenario, besides it will help households to save about 100 billion euros a year by 2020 (or 400-500 euros a year per household).

4) According to Annex XXVII to the Association Agreement, the relevant Ukrainian laws should be adapted to the requirements of Directive No. 2009/125/EC by November 1, 2017.

5) [REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Review of Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication of labelling and standard product information of the consumption of energy and other resources by energy-related products.](#)

6) [EU Energy in figure. Statistical Pocketbook 2016.](#)

Delegated Regulations (see above) specify the requirements of Directive 2010/30/EU with regard to energy labelling standards for certain types of household appliances that have the greatest potential to reduce energy consumption. In particular, they identify the ways of measuring (and parameters to be measured) the energy efficiency class (A+++ to D) for each type of appliances following the Energy Efficiency Index calculated based on the deviation of the actual rate of energy consumption for a specific appliance from the standardised energy consumption indicator, which, in fact, sets the “minimum standard” for power consumption. It also sets requirements for the label model, which should always be placed on the device, the types of information it must include, requirements for design etc. Besides, it stipulates the inspection procedures to check the accuracy of these data (just like any other certification in the EU, energy labelling of household appliances belongs to the exclusive area of responsibility of the manufacturer).

Overall, the delegated regulations establish a clear and standardised labelling system, which is supposed to influence consumer choice (the consumer will be more likely to choose appliances that consume less energy) and encourage the manufacturers of home appliances to use better production technologies that make it possible to reduce energy consumption.

What has been done to adapt national legislation?

SAEE. Work on the adaptation of the national legislation of Ukraine to the requirements of Directive No. 2010/30/EU officially began in November 2014, when the Cabinet of Ministers [ordered](#)⁷ the Ministry of Economic Development and Trade to undertake the [implementation](#) of this framework Directive.

In particular, it was resolved that Ukraine should review the existing technical standards and add new ones (or update the existing ones) in order to introduce new technical regulations with regard to labelling energy consuming products and legislatively specify the requirements for placing such labelling on household appliances, its circulation, the rules of sale, preparation of relevant technical documentation, etc., as well as ensure the state supervision over the circulation of devices that consume energy.

The State Agency for Energy Efficiency and Energy Saving (SAEE) was identified as the Competent Body, while the Ministry of Economy was tasked to introduce new technical regulations in the system of national technical standards.

In fact, the adaptation of national legislation to Directive No. 2010/30/EU started in August 2013 after the approval of [Resolution of the CMU No. 702 dated August 7, 2013 on Approval of Technical Regulations on Energy Labelling](#), and completed in May 2015, when the resolution underwent final amendments.

This very detailed document contains three revised technical regulations (replacing the previous versions adopted in January and February 2011 to fulfil the requirements of the “old” Directive 92/75/EEC), almost literally transposing EU regulations concerning the following to the national legislation:

- Creating a system of energy labelling of energy-related products (Directive

7) Resolution of the Cabinet of Ministers No. 1150-p dated November 26, 2014.

No. 2010/30/EU;

— Energy labelling of household electric refrigerators (Commission Delegated Regulation (EU) No. 1060/2010);

— Energy labelling of household washing machines (Commission Delegated Regulation (EU) No. 1061/2010).

The only exceptions to the provisions of Directive No. 2010/30/EU is the absence of a number of requirements that do not apply to Ukraine as it is not a Member State, as well as incentives for the purchase of energy efficient appliances in public procurement.

However, in developing technical standards for adaptation of Ukrainian legislation to the requirements of supplementing delegated EU regulations only partial progress has been made; for of the seven technical regulations to be adapted only two have been approved, while the others have been drafted but so far they are pending approval, specifically:

A. The following regulatory legal acts have been approved:

1. [Technical Regulation on Energy Labelling of Electrical Lamps and Luminaires](#)⁸ (requirements of Delegated Regulation No. 847/2012);

2. [Technical Regulation on Energy Labelling of Household Dish-Washers](#)⁹ (requirements of Delegated Regulation No. 1059/2010);

B. Draft regulatory legal acts that have been developed but have not been approved¹⁰:

3. [Draft resolution of the CMU On Approving the Technical Regulation on Energy Labelling of Domestic Ovens and Range Hoods](#) (requirements of Delegated Regulation No. 65/2014);

4. [Draft resolution of the CMU on Approving the Technical Regulation on Energy Labelling of Air-Conditioners](#) (requirements of Delegated Regulation No. 626/2011);

5. [Draft resolution of the CMU on Approving the Technical Regulation on Energy Labelling of Household Electric Tumble Driers](#) (requirements of Delegated Regulation No. 392/2012);

6. [Draft resolution of the CMU On Approving the Technical Regulation on Energy Labelling of Televisions](#) (requirements of Delegated Regulation No.1062/2010).

C. Regulatory legal acts being drafted:

7. Draft regulatory legal act in execution of the requirements of Commission Directive No. 96/60/EC still is to be developed in cooperation with technical

8) Resolution of the CMU No. 340 dated May 27, 2015.

9) Resolution of the CMU No. 514 dated June 17, 2015.

10) As of October 2016, all the below projects were pending approval in the Ministry for Regional Development to be further submitted for consideration in the CMU.

assistance project INOGATE, as the above Directive itself does not comply with the requirements of the updated EU legislation and is being reviewed by the European Commission.

One of the main reasons why so many draft technical regulations were developed by the SAEE but have not been approved was the excessively bureaucratic procedure for coordination of draft regulatory legal acts within the hierarchy of the Cabinet of Ministers, resulting from the insufficiently high status of the SAEE in the system of central executive bodies.

In particular, according to the [Regulation on the SAEE](#), the agency is subordinate to the Ministry for Regional Development and Building, hence all draft legal regulatory acts developed by the SAEE are subject to complex coordination procedures, which significantly slows down their process of approval. Moreover, if the government changes, all draft regulatory legal acts have to undergo another coordination round, which inhibited the process even more in 2014–2016 (two governments changed).

Thus, the progress in the development and approval of amendments to national legislation on energy labelling greatly slowed down due to the complicated and long procedure for approval of draft legal regulatory acts at the level of the Cabinet of Ministers.

What has been done to implement the EU regulations?

By implementing the above EU regulations in national legislation, Ukraine aims to create a system of energy labelling similar to the one currently operating in the EU. The actual introduction of these standards will mean, first of all, additional obligations for producers and importers of household energy consuming devices to apply appropriate labelling of their products, without which their sale in Ukraine will be impossible.

Implementation of national standards for energy labelling of household appliances harmonised with the requirements of the relevant delegated EU regulations should be considered in the context of the reform of technical regulation as a whole.

On the one hand, from the perspective of consumers and importers, the European system of energy labelling of household appliances is not new, since today a fairly large share of household appliances in Ukraine is imported from the EU and already has proper energy labels.

On the other hand, full harmonisation of Ukrainian technical standards in the field of energy labelling with the European ones has not yet taken place, because it depends on the reform of the technical regulation system in general, specifically with regard to the mutual recognition of technical standards of the EU and Ukraine. Thus, both Ukrainian and European manufacturers so far have to adhere to the national labelling standards and accordingly follow them when selling products in the markets of the EU and Ukraine. However, the undoubted advantage of approximating our labelling standards to those established in the EU is their identical methodology of measuring the energy efficiency class, and consequently they actually differ only in the emblem and flag on label, which greatly facilitates mutual export of the products subject to such labelling.

When it comes to the application of new technical standards for labelling, as of

November 2016 manufacturers and importers of household appliances started applying a new type (national) of labelling for refrigerators, washing machines and dishwashers, as well as electric lamps and luminaires, which are identical to the European labels. However, the issue of controlling manufacturers with regard to the accuracy of the information on the energy efficiency class still remains problematic. One of the reasons is the lack of authority of the SAEE to check the progress of implementation of the requirements of the new technical regulations, as well as the current moratorium on inspections for the key supervisory authority in this system – the State Service of Ukraine on Food Safety and Consumer Protection – which makes it impossible to fully control the accuracy of energy labelling¹¹.

Nuclear Power Sector

Regulatory legal acts of the EU in the field of nuclear energy that had to be implemented by November 1, 2016:

- **Council Directive No. 2014/87/Euratom** establishing a Community framework for the nuclear safety of nuclear installations (substituting Directive 2009/71/Euratom).
- **Council Directive No. 2013/59/Euratom** laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (repealing the following Directives of Euratom – 89/618, 90/641, 96/29, 97/43, 2003/122).
- **Council Directive No. 2006/117/Euratom** on the supervision and control of shipments of radioactive waste and spent fuel.

The inclusion of Directive No. 2014/87/Euratom in the list of assessment objects for the “Nuclear Power Sector” gave rise to a legal conflict, since initially this Directive (as well as its “predecessor” – Directive 2009/71/Euratom) was not included in the list of Ukraine’s commitments, despite the fact that it is the key regulatory legal document of the EU concerning safety standards for nuclear power plants.

Accordingly, in the implementation plan of the State Nuclear Regulatory Inspectorate of Ukraine - SNRIU (identified as the competent body in the field of safety of nuclear installations)¹², new Directive No. 2014/87/Euratom was bound to the implementation of Art. 342 of the Association Agreement that defines rather general terms of cooperation between Ukraine and the EU¹³. The situation is even more uncertain due to the fact that Art. 342 of the Agreement is not subject to provisional application in accordance with the decisions of the European Council of 23.06.2014 No. 2014/668/EU, i.e. it has to be delayed until the full ratification of the Agreement. However, given the great importance of this Directive in improving the regulation in the field of safety of nuclear installations, as well as the fact that the SNRIU has carried out substantial work to adapt national legislation to its requirements, we also decided to include it in

11) However, even despite this, there has been a number of lawsuits against manufacturers of household appliances related to the inaccuracy of their labelling on the part of the State Service on Consumer Protection.

12) The Implementation Plan approved by [Decree of the CMU No.110-p dated February 18, 2015](#).

13) In particular, in our opinion, the obligation to implement Directive No. 2014/87/Euratom may have been encouraged by the following sentence in paragraph 2 of Art. 342 “...cooperation will also include the further development of policies and legal and regulatory frameworks based on EU legislation and practices, as well as on International Atomic Energy Agency (IAEA) standards”.

the assessment list; since, according to the government implementation plan, certain provisions of Directive 2014/87 were already introduced in the legislation of Ukraine by November 2016 inclusive¹⁴.

How do we benefit from the relevant EU regulations?

Council Directive No. 2014/87/Euratom is one of the so-called “framework” EU directives in the field of nuclear energy, establishing common rules for the safe operation of nuclear installations. This regulation was adopted in the EU in order to establish and ensure functioning of a sustainable unified system of nuclear safety standards, as well as to implement the key international instruments in the field of nuclear safety (such as the Convention on Nuclear Safety and the IAEA Safety Fundamentals) in EU legislation.

It was the accident at the nuclear power plant in the Japanese city of Fukushima in 2011 that gave impetus to adopting new Directive No. 2014/87/Euratom, for it became apparent that the existing regulations could not cover all risks that threaten the safe operation of nuclear facilities. Accordingly, it was decided to update the existing EU regulations, namely to set higher safety standards in order to eliminate the risks revealed in the stress tests at European nuclear power plants. The updated Directive is also supposed to greatly enhance the powers and institutional capacity of regulators on nuclear safety in the EU member states.

Council Directive No. 2013/59/Euratom and No. 2006/117/Euratom supplement framework Directive No. 2014/87/Euratom and detail its general provisions with regard to the standards of radiation protection as well as control and supervision of shipments of radioactive waste and spent nuclear fuel.

What has been done to adapt national legislation?

SNRIU. With a view to fulfilling the above Implementation Plan, the SNRIU developed the Timeline of Measures to Implement Council Directive 2014/87/Euratom¹⁵. Besides, national and international legislation in the field of nuclear and radiation safety were thoroughly analysed and resulting data were used to develop the Concept on Improving Regulatory and Legal Framework on Nuclear and Radiation Safety of Nuclear Installations¹⁶.

Directive No. 2014/87/Euratom

As of now, the key regulation aimed at meeting the requirements of Art. 5, Ch. 2 and 3 of Council Directive 2014/87/Euratom involving commitments of states to grant institutional independence, financial and professional capacity to the national agency for nuclear and radiation safety has not been adopted.

To implement these standards, the SNRIU developed a draft law on the State

14) Moreover, according to the Final Provision of Directive No. 2014/87/Euratom, Member States shall implement its provisions into national law by August 15, 2017. Ukraine too is focused on this deadline, having set it in the relevant Implementation Plan (see above).

15) The full title: [“Timeline of Measures to Implement Council Directive 2014/87/Euratom dated June 8, 2014, repealing Directive 2009/71/Euratom, establishing a Community framework for the nuclear safety of nuclear installations”](#), approved by Order of the SNRIU No. 54 dated 24.03.2015

16) Put into effect by [Order of the SNRIU No. 52](#) dated 24.03.2015

Regulation of Nuclear Safety – the National Commission for Regulation of Nuclear and Radiation Safety, which has not yet been submitted to the CMU. The authors of the draft law were waiting for the Law On the National Energy and Public Utilities Regulatory Commission (NEPURC) to pass through the Verkhovna Rada, as it is similar and was blocked for a long time due to a legal conflict arising out of the fact that such Commissions are not executive power bodies and are not provided for in the Constitution.

The law on the NEPURC was finally passed and enacted during September-November 2016, which allowed to remove the uncertainty regarding the status of such commissions. Currently the preparation of the draft law has been completed; its latest version takes into account the aspects of the above law on the NEPURC concerning its constitutional status¹⁷. The SNRIU intends to soon send it for approval to the concerned ministries and submit to it the CMU by 1 January 2017. Amendments to other laws are being prepared – they will be possible after the adoption of this draft law. Work is underway to clarify the activities covered by the state regulation of nuclear energy and functions of the Commission.

Adaptation of other more specialised regulatory legal acts has been advancing more rapidly:

1. **Resolution of the Cabinet of Ministers of Ukraine No. 89 dated 27.01.2016 [On Introducing Amendments to the Procedure of Development and Approval of Regulations, Rules and Standards of Nuclear and Radiation Safety](#)** approved the amendments developed by the SNRIU to The Procedure of Development and Approval and Regulations, Rules and Standards of Nuclear and Radiation Safety¹⁸.

To develop this resolution of the CMU, the SNRIU has prepared the draft order “On Approval of the Procedure of Development and Publication of Rules and Regulations on Nuclear and Radiation Safety by the State Nuclear Regulatory Inspectorate of Ukraine”, which is currently undergoing internal approval.

2. Adoption of the **Requirements for Emergency Cooling of Nuclear Fuel and Heat Removal and Transfer to the Ultimate Heat Sink**¹⁹.

This document establishes requirements for elements of emergency cooling of nuclear fuel in the reactor core and spent fuel pool, as well as heat removal and transfer to the ultimate heat sink. It meets the standards of modern approaches to the safety of nuclear power plants, taking into account international requirements and experience.

3. Adoption of **[Requirements of the Power Supply Systems Important for the Safety of Nuclear Power Plants](#)**.^{20, 21}

17) However, the final text of the draft law so far is not in public access.

18) Approved by Resolution of the Cabinet of Ministers of Ukraine No. 163 dated 08.02.1997.

19) Adopted by [Order of the SNRIU No. 233](#) dated 24.12.2015 and registered in the Ministry of Justice No. 77/28207 dated 16.01.2016

20) Adopted by [Order of the State Nuclear Regulatory Inspectorate of Ukraine \(SNRIU\) No. 234](#) dated 24.12.2015

21) Amendments 3 – 6 introduced to comply with Art. 8a – 8d of the Directive.

This document establishes requirements for power supply systems that are important for the safety of nuclear power plants. Compliance with these requirements will ensure the capacity of power supply systems to duly perform all their necessary functions that are important for NRS at all stages of the life cycle of a nuclear installation.

4. Adoption of the **Requirements for Nuclear and Radiation Safety for Information and Control Systems Important to the Safety of Nuclear Power Plants**²².

The requirements apply to the information and control systems that are important to the safety of nuclear power plants and their components: software and hardware sets that are part of the information and control systems, including operational autonomous components of these software and hardware sets; operational autonomous automation hardware that makes up part of the information and control systems; software for information and control systems, software and hardware sets, and automation hardware, if any.

5. Adoption of the [Requirements for Seismic Design and Evaluation of the Seismic Safety of Generator Units at Nuclear Power Plants](#)²³.

This document sets more stringent requirements to ensure the earthquake-resistance of nuclear installations of at least 0.1 g taking into account the lessons learned from the Fukushima accident.

6. [The Requirements to Assessment of Nuclear Power Station Safety](#)²⁴ have been amended to establish a methodology for evaluation of risks for NPP work based on results of stress tests.

When applied, these standards will enhance the level of safety substantiation of nuclear power plants and harmonise the rules, regulations and standards of the NRS in the field of safety assessment of nuclear power plants with the WENRA reference levels of the reactor safety and, accordingly, with the regulatory requirements of the European countries. In particular, the additional requirements concern the need to take into account combinations of internal and external extreme impacts when analysing the safety of nuclear power stations, and also taking into account worst-case scenarios of safety system operation when substantiating the safety design fundamentals of nuclear power stations.

Apart from that, Order of the SNRIU No. 33 dated 03.03.2016 rendered the [following regulations](#) of the former Soviet Union non-applicable in the territory of Ukraine:

- PNAE G-5-020-90, Design and Operation Rules for Emergency Core Cooling System and the System of Heat Removal from Nuclear Reactor to the Ultimate Heat Sink, approved by Resolution of the USSR Committee for Supervision of the Safe Conduct of Work in Industry and Atomic Energy

22) Adopted by [Order of the SNRIU No. 140](#) dated 22.07.2015.

23) Adopted by [Order of the SNRIU No. 175](#) dated 17.10.2016.

24) Approved by [Order of the SNRIU No. 15](#) dated 11.02.2016.

(Gospromatomnadzor) No. 3 dated 05.04.1990;

— PNAE G-9-026-90, General provisions for the design and operation of emergency power supply systems of nuclear power plants, approved by Resolution of the USSR Committee for Supervision of the Safe Conduct of Work in Industry and Atomic Energy (Gospromatomnadzor) No. 2 dated;

— PNAE G-9-027-91, Design rules of emergency power supply systems of nuclear power plants, approved by Resolution of the USSR Committee for Supervision of the Safe Conduct of Work in Industry and Atomic Energy (Gospromatomnadzor) No. 11 dated 28.10.1991.

7. Adopted Action Plan to implement the [Concept on Improving Regulatory and Legal Framework on Nuclear and Radiation Safety of Nuclear Installations](#), based on which the SNRIU have developed the following documents:

— The List of Legal Regulatory Acts Approved by the Body for State Regulation of Nuclear and Radiation Safety, and

— The List of Legal Regulatory Acts of the former USSR that are Used in the Field of Nuclear Energy.

The above documents were posted on the [official website](#) of the SNRIU on 12.30.2015.

8. Besides, to standardise the definitions of terms of the Directive, IAEA standards and conventions in the field of nuclear and radiation safety deposited by the IAEA, a [unified glossary of terms related to nuclear safety of nuclear installations](#) has been developed. The list of terms was posted on the official web-site of the SNRIU on 30.12.2015 to be used by operators and licensees.

All these regulatory legal acts have come into force and are binding upon operators of nuclear installations in Ukraine, which include nuclear power plants, research nuclear installations, and spent fuel storage facilities.

Directive No. 2013/59/Euratom

Based on the Implementation Plan, the SNRIU prepared the draft law of Ukraine "On Amending Certain Laws of Ukraine in the Field of Nuclear Energy". The draft law was registered in the Verkhovna Rada of Ukraine on 01.02.2016 under No. [3858](#). However, due to the government changes, the draft law was withdrawn, underwent a re-approval process in the relevant ministries and is currently undergoing legal expert review in the Ministry of Justice.

In addition, the SNRIU drafted the CMU Resolution [On Approval of the Procedure of Establishment of the Unified State System for Control and Recording Individual Doses of Occupational Exposure](#), that underwent coordination with the Ministry of Healthcare of Ukraine, Ministry of Economic Development and Trade of Ukraine, and the State Employment Service of Ukraine. Currently, the document is being finalised in accordance with the proposals of the State Employment Service of Ukraine.

Besides, other regulatory legal acts have been drafted, currently undergoing the

process of coordination with the relevant ministries:

- [General Radiation Safety Provisions with Regard to the Mining and/or Processing of Uranium Ore](#);
- Requirements for Administrative Supervision of Uranium Facilities within the Framework of the Limited Exemption from Regulatory Control (undergoing the process of internal coordination);
- [General Safety Rules for Ionising Radiation Sources in Medicine](#);
- The rules of radiation safety of ionising radiation sources in brachytherapy (undergoing the process of internal approval).

Due to delayed adoption of amendments to the Law on Human Protection from Effects of Ionising Radiation, there is a delay in the development of the National Action Plan (state target program) to Reduce the Risks of Long-Term Exposure of Products of Radon. Accordingly, it will affect the implementation of the Directive through organisational measures, specifically the terms of creating a database of radon exposure in representative groups as part of the national system of registration and control of radiation doses for the population of Ukraine.

Regulatory legal acts regulating the handling of materials containing naturally occurring radionuclides, as well as acts that regulate standards for medical exposure are now at the stage of development. The development of legislation aimed at resolving the situation of existing, planned and emergency exposure has not even started.

Directive No. 2006/117/Euratom

The SNRIU developed a draft resolution of the Cabinet of Ministers of Ukraine on Amendments to the Procedure for Issuing Permits for International Shipment of Radioactive Materials, which is currently stuck at the stage of the coordination procedures with the central executive authorities.

In particular, the State Regulatory Service (SRS) has refused to approve the draft resolution on the grounds that the SRS will review the matter after the adoption of the Law of Ukraine [on Licensing in the Sphere of Nuclear Energy Use](#) No. 1370-XIV dated 11.01.2000 in accordance with the requirements of the Law of Ukraine [on Administrative Services](#) No. 5203-VI dated 06.09.2012, which has to take place after the adoption of draft law No. [3858](#) (see above).

What has been done to implement the EU regulations?

A. Raising the safety of nuclear power stations in Ukraine

The operator of nuclear power plants in Ukraine Energoatom implements the [Complex \(Consolidated\) Programme for Increasing the Safety of Generator Units of Nuclear Power Stations \(KzPPB\)](#)²⁵. In 2012, the KZPPB was supplemented with additional measures based on the findings of the National Report of Ukraine on the Results of Targeted Reassessment of the Safety of Nuclear Installations Located on NPP Sites ("stress tests"), taking into account the lessons learnt from the accident

25) Adopted by Resolution of the Cabinet of Ministers of Ukraine No. 1270 dated 07.12.2011.

at the Fukushima-Daichi plant in Japan, which occurred in March 2011. Full scope implementation of the KzPPB, in fact, means implementation in practice of the provision of the Directive on the Safety of Nuclear Power Reactors.

In the framework of the international project UK/TS/47 during 2016, the information system for storing data on the status of implementation of each KzPPB action was developed, as well as on the organisation of access to technical documentation related to the process of implementation of KzPPB actions at generator units of NPP of Ukraine. The information system is operating in the experimental mode. Access to the system is organised via the official website of the IAEA for representatives of the companies Riskaudit, SNRIU and SSTC NRS that are involved in this project. In the third quarter of 2016, a detailed specification of the system was developed, involving works to determine the need to make additional changes to the system interface.

Besides, there was an in-depth evaluation of selected KzPPB activities, general monitoring of the KzPPB implementation, gathering and updating information on the implemented KzPPB actions at generator units.

As part of the international project UK/TS/50, the condition of the control system and safety culture in Ukraine was examined in the context of supervision and evaluation of nuclear safety and support of the regulatory body with regard to the analysis of human, organisational and technical factors.

The implementation of measures under the revised National Action Plan for Ukraine continued based on the results of "stress tests", as approved in April 2015. Most of the activities are included in the current KzPPB for NPP of Ukraine.

In the third quarter of 2016, attention was focused on the implementation of measures to improve safety determined based on the results of stress tests for the generator units with lifetime extended beyond the design lifetime (units No. 1 and 2 of the Zaporizhzhya NPP). Decisions of the Board of the State Nuclear Regulatory Inspectorate of Ukraine extended the lifetime of units No. 1 and No. 2 of the Zaporizhzhya NPP by 2025. When taking the decision, among other factors the state of implementation of measures based on the results of stress tests was taken into account.

Apart from that, in 2016, state expert evaluation was held with regard to the nuclear and radiation safety of the set of documents on the modifications to improve nuclear power plant safety, particularly in terms of equipment qualification for seismic impacts. There were works concerning the equipment qualification for seismic impacts, implementing measures to improve security in conditions of a complete blackout of nuclear power plants, management of severe accidents and so on.

Representatives of the SNRIU, together with other European regulatory authorities on nuclear safety, took part in the peer review of the national self-assessment of the regulatory framework for nuclear safety with regard to its compliance with the WENRA reference levels for reactor safety and decommissioning of nuclear power plants.

B. Construction of a storage facility for spent nuclear fuel

Work continues on the construction of storage facilities for dry type spent nuclear fuel in the zone of the Chernobyl nuclear power plant (ISF-2) under Grant Agreement

007 (Project of Chernobyl NPP Nuclear Safety) between the European Bank for Reconstruction and Development (as the administrator of the Grant of the Nuclear Safety Account) Cabinet of Ministers of Ukraine and the State Nuclear Regulatory Inspectorate of Ukraine (as the Receiver)²⁶. Works are carried out under SNRIU No. 001002 Construction and Commissioning of a Nuclear Facility (ISF-2)", issued on 20.02.2013 to the Chernobyl NPP.

During 2016, the SNRIU carried out review of sets of technical specifications (TS) for systems and equipment that are important to the safety of ISF-2, as well as testing programmes for these systems and components. In particular, there has been preliminary approval of 7 TSs for systems that are important to safety out of the 7 developed under the project; 41 TSs for equipment that is important to safety out of the 41 developed under the project; 1 TS for equipment with uncertain impact on security (table for handling damaged nuclear fuel). Besides, 32 testing programmes have been approved for equipment that is important to safety out of the 33 scheduled; and 2 TSs for equipment that is important to safety out of the 41 developed under the project. In addition, there have been 30 factory acceptance tests of equipment that is important to safety out of the 33 planned.

Currently, the SNRIU involving SSTC NRS carries out state expert examination of the nuclear and radiation safety out of the 4 technical documents developed under the project ISF-2.

Summing up, it can be concluded that the implementation of Council Directive 2014/87/Euratom is being successfully implemented in national legislation in compliance with the planned terms, and its new standards are already applied in practice during reevaluation of the safety of nuclear reactors and other nuclear installations and for extension of their lifetime beyond the design lifetime.

Implementation of the provisions of Directives No. 2013/59/Euratom and No. 2006/117/Euratom has not taken off yet because of the delay with amendments to the relevant laws of Ukraine.

26) Signed on 08.07.2009 and ratified by Law of Ukraine No. 1813-VI dated January 20, 2010.



Adjusted
Gross
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Enclose, but do not attach, any payment. Also, Form 1040-V. If you did not get a W-2, see instruction W-2 he attach! W-2s are 1099-R if was with

Refund
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and Tax

Amount
You Owe
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Form
1040EZ
Your first name and initial

Income Tax Return for
Joint Filers with Equal
9292
Department of the Treasury—Internal Revenue Service

10
U.S. Individual Income Tax Return
Department of the Treasury—Internal Revenue Service
Jan. 1-Dec. 31, 2012, or other tax year beginning

22222
b Employer identification number

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CORRECTED

2012
OMB No. 1545-01

Form 1099-INT
2012
Credits and Taxes, obligations

Commitments in the Field of Taxation



Expert



Viacheslav
Cherkashyn

The competent body responsible for the approximation of the Ukrainian legislation to the EU legislation in the field of taxation during the specified period is the **Ministry of Finance of Ukraine (MFU)**.

Assessment of the range and period of implementation of the commitments undertaken by Ukraine in the energy sector was grounded on the versions of EU directives contained in Annex 28 (XXVIII) to Chapter 4 “Taxation” of Chapter V “The Economic and Sector Cooperation” of the Association Agreement¹, whereby the deadline for their transposition into Ukrainian legislation is set for November 1, 2016.

Commitments with deadlines set for June 1 – November 1, 2016

As of November 1, 2016, there were two such commitments, both of which are related to the EU regulation in the field of indirect taxation, such as rules governing excise duty. Specifically, one of them is related to the general conditions of levying excise duty and has to coordinate it with the wording prescribed in the relevant EU legislation; another one regulates the rates and structure of excise duty on tobacco (codification). Based on the results of our evaluation, both of these commitments were not timely fulfilled by Ukraine and, in fact, are currently under implementation.

As of November 1, 2016, Ukraine had to adapt national legislation to the requirements of the following EU regulations:

- **Council Directive No. 2008/118/EC** of December 16, 2008 concerning the general arrangements for excise duty and repealing Directive No. 92/12/EEC.
- **Council Directive No. 2011/64/EU** of June 21, 2011 on the structure and rates of excise duty applied to manufactured tobacco (codification), except Articles 7 (2), 8, 9, 10, 11, 12, 14 (1), 14 (2), 14 (4), 18 and 19 – the schedule of implementation for the latter Articles will be established by the Association Council.

Thus, the object of evaluation in this section includes two EU Directives.

How do we benefit from the relevant EU regulations?

Excise duties are indirect taxes on the consumption or use of certain goods. Unlike the VAT, they are mainly specific taxes, which essentially consist in collecting a certain

¹) Which, in turn, is stipulated in Art. 353 of the Association Agreement.

amount of money for a certain quantity of goods. The most common subjects to the excise tax include alcohol, tobacco and energy products (motor fuels and heating fuels, such as petrol and gasoline, electricity, natural gas, coal and coke).

All EU member countries apply excise taxes to these three product categories. Revenues from excise taxes are directed entirely to the EU member states. EU legislation on excise tax was adopted mainly on January 1, 1993 in the context of the internal market, which implied the abolition of fiscal controls at internal borders between the EU member states.

This legislation, which was further improved, falls into three major categories:

- **structure of taxation** applied to some product groups. The structure of taxation implies determining the categories of products, the method of excise tax calculation (e.g., per hectolitre, per ABV, per 1,000 pieces, etc.), the scope of potential exemption and so on.
- **minimum tax rates** to be adhered to by each member state with regard to each product type. Member states are free to establish their own rates if these are higher than the minimal ones.
- **general provisions applicable to all categories of goods.** These provisions refer to the production, storage and transportation of excisable products among the member states.

The basic regulation in the field of excise duties is **Council Directive 2008/118/EC of 16.12.2008 concerning the general arrangements for excise duty and repealing Directive No. 92/12/EEC** (came into force on April 1, 2010). The document identifies:

- the general mechanism for establishing excise duties;
- the list of goods covered as excisable goods;
- conditions for exemption from excise duties;
- excise duties refund mechanism;
- the basic elements of administration (identification of the taxpayer, conditions of accrual and payment, procedure and specific features of the movement of excise goods before and after their release for consumption),
- procedures of labelling or national identification of excisable goods.

Apart from the general legislation, each group of excisable goods is governed by relevant Directives. Thus, tobacco is covered by **Council Directive No. 2011/64/EU of June 21, 2011 on the structure and rates of excise duty applied to manufactured tobacco**, which stipulates:

- names, types and requirements for tobacco products;
- special features of taxation of tobacco products (ad valorem and specific component of excise duty, the maximum retail price);
- fixing minimum and maximum sizes of excise duty;

— establishment of the phases of increasing tax rates by 2020.

What has been done to adapt national legislation?

Directive No. 2008/118/EC

As it was specified in Art. 211 of the [Action Plan for Implementation of the Association Agreement for 2014-2017](#)², the competent body responsible for the implementation of Directive No. 2008/118/EC is the Ministry of Finance, which had to complete the process by July 2015. The main task of the Ministry of Finance with regard to this Directive was the harmonisation of the list of goods, consumption or use of which is subject to excise tax in accordance with the relevant EU standards.

What has been done?

In late 2014, the Law of Ukraine No. 71 [On Amendments to the Tax Code of Ukraine and Certain Legislative Acts of Ukraine with Regard to Tax Reform](#) dated 28.12.2014 expanded the list of excisable goods to include the category of “electricity” and amended paragraph 215.1 of the Tax Code of Ukraine (hereinafter – the TCU). The other categories of excisable goods stipulated in EU legislation, but not included in the legislation of Ukraine have not been encompassed.

What has been done to implement the EU regulations?

Article 1 of Directive 2008/118/EC clearly outlines the list of products to be classified as excisable goods, namely alcohol and alcoholic beverages, tobacco products, energy products and electricity. However, while alcoholic beverages, tobacco and “classic” types of energy (oil and gas) have been traditionally subject to excise duty in national legislation (e.g. pursuant to Resolution of the Verkhovna Rada of Ukraine No. 1997-XII of December 18, 1991 [On the Procedure of Entry into Force of the Law of Ukraine ‘On Excise Tax’](#)), many alternative energy products, including biofuels and its biological components, have never become fully subject to excise tax (see Annex 1 for details concerning individual products).

The list of energy products in the EU acquis regulated by Directive 2003/96/EC³, which provides for the taxation of energy, electricity and any products used as fuel for vehicles or as an additive or filler for fuel. Ukrainian tax legislation (paragraph 215.3.4. of the Tax Code of Ukraine) contains the term “fuel”, which is essentially similar, but much narrower in scope. By comparing these categories⁴ it is possible to determine the list of excisable goods in accordance with the EU acquis, which Ukraine failed to implement in its national legislation as of 01.11.2016 (see Annex 2 for details concerning individual products).

Based on the monitoring results, we must report that Ukraine, unfortunately, failed to fully unify the list of goods, consumption or use of which is subject to excise tax, in accordance with the EU legislation. In particular, these products include: coal; coal,

2) Order of the Cabinet of Ministers of Ukraine No. 847-p dated September 17, 2014

3) Council Directive 2003/96/EC of October 27, 2003 on restructuring the Community framework for the taxation of energy products and electricity.

4) The Combined Nomenclature of the European Union and the Ukrainian Classification of Goods for Foreign Economic Activity (UKTZED) are based on the Harmonised System (HS) – the international nomenclature of products developed by the World Customs Organisation.

water or gas; resins, mineral and vegetable oils (soybean, peanut, olive, palm and other oils); animal or vegetable oils; petrolatum, paraffin, coke and bitumen.

Council Directive N°2011/64/EU

The main purpose of adaptation of the national legislation of Ukraine to the requirements of this Directive is the harmonisation of the excise structure and gradual approximation to the excise tax rates levied on tobacco products in the EU.

The adaptation process is developing in accordance with the provisions of the Law of Ukraine [On the National Programme of Adaptation of Ukrainian Legislation to EU Legislation](#) and in accordance with paragraph 210 of the Action Plan for the implementation of the Association Agreement for 2014-2017.

What has been done?

Back in 2012, the rate of excise duty on tobacco products was significantly increased with a view to approximating it to EU standards, which was implemented through the Law of Ukraine No. 5503 [On Amending the Tax Code of Ukraine with Regard to Revision of the Rates of Certain Taxes](#).

During the evaluation period, the Law of Ukraine No. 909-VIII of 24.12.2015 [On Amending the Tax Code of Ukraine and Certain Legislative Acts of Ukraine to Ensure the Balance of Revenues to the Budget in 2016](#), which increased the specific excise duty rate on tobacco products by 40%; clarified the notion of "excise warehouse" and "excise warehouse manager" (paragraphs 14.1.6 and 14.1.224 of the TCU); and provided the definition of "manufacture of excisable goods (products)" (paragraph 14.1.28-1 of the TCU).

Besides, Order of the State Fiscal Service of Ukraine No. 401 dated 09.06.2015 [On Adopting Explanations to the Ukrainian Classification of Goods for Foreign Economic Activity](#) was adopted. It takes into account the requirements of Council Directive No. 2011/64/EU:

- taxation of products consisting in whole or in part of substances other than tobacco;
- exclusion from the list of products containing no tobacco and used exclusively for medical purposes;
- compliance with the criteria for definition of cigarettes, cigars and cigarillos and of other smoking tobacco.

Currently, the only pending issue is implementing regulations for custom size cigarettes (the requirements of paragraph 2, Article 3 of Directive No. 2011/64/EU have not been taken into account), which are not included in the corresponding Ukrainian legislation. It is necessary to bring Para. 215.3.3, Art. 215 of the Tax Code of Ukraine in line with the Directive provisions.

What has been done to implement the EU regulations?

The majority of the standards of Council Directive No. 2011/64/EU have been implemented in the practice of excise duty in Ukraine, since a large number of

European rules on tobacco taxation have already been included in earlier versions of the Tax Code of Ukraine. Currently, the implementation process is virtually complete, except for the implementation of the rules on the collection of excise duty on custom size cigarettes, which that should be implemented at the level of subordinate regulatory legal acts after appropriate amendments to the Tax Code of Ukraine.



Commitments in the environmental field



Experts



*Andriy
Andrusevych*



*Natalia
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The main performer responsible for approximation of Ukrainian legislation to the EU law on environment is the **Ministry of Ecology and Natural Resources¹ (the Ministry of Nature)**.

Ukraine must gradually approximate its legislation to the EU law on environment under article 363 of Title V (Economic and Sector Cooperation) of the Association Agreement. Approximation proceeds under the terms and according to the list of the EU acts indicated in Annex XXX (30) to the Association Agreement.

Commitments with the fulfillment deadline November 1, 2016, and what they envisage

In general, one may point out **15 commitments** for the given period relating to environmental impact assessment and strategic environmental assessment, public access to environmental information, conservation of wild flora and fauna, creation of the state bio-safety system, control over emissions of volatile organic compounds, marine environmental policy, environmental policy on industrial emission, greenhouse gas emission allowance trading, substances that deplete the ozone layer, assessment and management of flood risks. Regulatory documents have been adopted to fulfill the last of the above commitments. As far as other 14 commitments are concerned, eight of them are under implementation, while no approximation is generally taking place on six other commitments.

Some of the below Directives have got two implementation deadlines: one – under the Energy Community Treaty, another one – under the Association Agreement. Implementation deadlines for fulfillment of the Energy Community's commitments precede the implementation deadlines under the Association Agreement. However, the present Report considers timeliness of legislation approximation in compliance with the implementation deadlines under the Association Agreement only.

EU regulations on environmental governance and integration of environment into other policy areas:

Directive No. 2011/92/EU on the assessment of the effects on the environment (partially²) presupposes:

1) In the context of the acts that must be implemented as of November 1, 2016.

2) General commitments of Ukraine stemming from the content of the EU act and envisaged by the Association Agreement (under Annex XXX to Chapter 6 'Environment' of Title V 'Economic and Sector Cooperation' articles 4, 5, 6, 7 and 9 of Directive No. 2011/92/EU should be approximated according to the Association Agreement.

- Establishment of clear requirements for the procedure of assessing the effects of public and private commercial projects on the environment, including transboundary effect cases;
- Determination of a procedure for consultation with environmental authorities and a public consultation procedure;
- Determination of the scope of information to be provided by the project developer for assessing the possible effects on the environment.

Directive No. 2003/4/EC on public access to environmental information presupposes:

- A detailed determination of environmental information;
- Establishment of the procedures of public access to environmental information in practice, including upon public request;
- The grounds for refusing to provide information upon the request for environmental information provision;
- The possibilities for appealing illegal refusal to provide environmental information;
- Requirements to the quality of information provided on the environmental condition.

Directive No. 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment presupposes:

- Establishment of the mechanisms for providing the public with information and for public consultation as well as the mechanism for public proposals to be taken into account in the process of preparing plans and programmes relating to the environment;
- Public participation in the adoption of plans and programmes developed within the framework of the requirements of Directives on waste, hazardous waste, batteries and accumulators containing certain dangerous chemical substances, on packaging and packaging waste, concerning the protection of waters against pollution caused by nitrates from agricultural sources as well as on ambient air quality assessment and management.

Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer, presupposes:

- Establishment of bans for production and use of controlled substances (cooling agents, solvents, fire-fighting agents), including phasing out of hydrochlorofluorocarbons by 2025³;
- Determination of a set of commitments relating to recovery, processing, regeneration and destruction of used controlled substances;

³) Art. 3(3)e) of Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer.

- Setting procedures for monitoring and checking water quality.

EU regulations on genetically modified organisms

Directive No. 2001/18/EC on the release into the environment of genetically modified organisms presupposes:

- The system of assessment of environmental risks related to release of genetically modified organisms;
- Introduction of a public register and establishment of the procedure for public consultation;
- Establishment of the requirements for the report on GMOs, safety criteria, disclosure deadlines.

Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms presupposes:

- Criteria for differentiating between the GMOs designed for deliberate release into the environment (that is field testing or cultivated one, import or transformation of GMOs in industrial products) and the GMOs designed for producing food-stuffs, or forage, or for processing;
- Exporters of the GMOs designed for deliberate release into the environment shall notify the competent national body thereof. The exporter shall keep this notice and receipt confirmation for 5 years;
- Establishment of the system for notification and exchange of information on GMO export in the countries for the sake of ensuring adequate protection level.

EU regulations on environmental protection

Directive No. 92/43/EEC on habitats (partially)⁴ presupposes:

- Steps aimed at preservation or recovery of proper nature conservation status of natural habitats and species of wild flora and fauna;
- Conservation regime for about 1,200 species of wild flora and fauna;
- Establishment of the mechanism for development and functioning of the environmental network of nature conservation territories;
- Criteria for developing the environmental network, determination and preservation of habitats, their management.

Directive No. 2009/147/EC on the conservation of wild birds (partially)⁵ presupposes:

- The mechanism for conservation of wild birds that presupposes the measures

4) The general commitments of Ukraine stemming from the content of the EU act and envisaged by the Association Agreement (under Annex XXX to Chapter 6 'Environment' of Title V 'Economic and Sector Cooperation' articles 11, 12 and 22 of Directive No. 92/43/EEC on habitats must be approximated according to the Association Agreement.

5) The general commitments of Ukraine stemming from the content of the EU act and envisaged by the Association Agreement.

to protect, manage and control wild birds as well as requirements for their use;

- Measures aimed to protect habitats of birds;
- Requirements for conservation and use of birds;
- Preventing damages caused by invasive species;
- Studies and reports.

EU regulation on the ambient air quality

Directive No. 1999/32/EC on reduction of sulphur content of certain liquid fuels (partially) (as amended by Directive No. 2005/33/EC) presupposes:

- Establishment of an efficient sampling system and appropriate analytical methods of sulphur content analysis;
- Prohibition of use of marine fuel, heavy fuel oils, marine gasoils, diesel fuel and boiler fuel with the content of sulphur greater than established limit values.

Directive No. 94/63/EC on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations (partially)⁶ presupposes:

- Registration of all oil terminals designed for storing, loading and discharging oil products, setting of technical means on them to reduce VOC emissions from oil product storage tanks;
- Bringing of all stationary storage tanks, railway, marine, road tankers as well as devices for loading and discharging oil products in conformity with the requirements set.

EU regulation on the quality of water and water resources management

Directive No. 2007/60/EC on the assessment and management of flood risks (partially) presupposes:

- Performing preliminary assessment of flood-related risks in the region;
- Preparation of flood hazards maps and flood risks maps, with indication of the areas subject to this risk;
- Development of flood risk management plans.

Directive No. 2008/56/EC on marine environmental policy (partially) presupposes:

- Establishment of the minimum requirements for development of the strategy aimed at marine eco-system protection;
- Cooperation in marine areas (norh-east Atlantic Ocean, Baltic, Mediterranean and Black Seas) through transboundary programme development. The

⁶ The general commitments of Ukraine stemming from the content of the EU act and envisaged by the Association Agreement

programmes include actions aimed at meeting coordinated targets set to ensure 'good environmental condition' by 2020;

- Promotion of the establishment of the global network of marine protected areas.

EU regulation on industrial pollution

Directive No. 2010/75/EU on industrial emissions (partially)⁷ presupposes:

- The use of the system of integrated permission for certain types of activity;
- All installations should prevent or reduce pollution through usage of the best available technologies, efficient energy use, prevention of waste appearance and waste management;
- Transparency of the integrated permission issuance procedure shall be ensured through public participation.

EU regulation on climate change and ozone layer protection

Directive No. 2003/87/EC on a scheme for greenhouse gas emission allowance trading presupposes:

- Development of the national plan of allowance distribution between plants/complexes;
- Introduction of permission system for greenhouse gas emission and for allowances to be sold at the national level to plants/industrial complexes in Ukraine;
- Development of the monitoring, reporting, checking and proper implementation system as well as the procedure for public consultations.

Regulation (EC) No. 842/2006 on certain fluorinated greenhouse gases presupposes:

- Proper storage of such gases (prevention of leakage, inspections, accounting);
- Limitations imposed on the sale of some substances;
- Marking and attestation systems;
- All people responsible for the emissions shall take all possible steps which are expedient from the technical and economic point of view for preventing and minimizing leakages;
- Inspection for refrigerating equipment, conditioning and heat pumps, fire-prevention equipment and systems at least once a year (the frequency of inspections depends on the amount of fluorinated gas available in the equipment).

What has been done to approximate national legislation?

⁷⁾ The general commitments of Ukraine stemming from the content of the EU act and envisaged by the Association Agreement.

- In the field of environmental governance and integration of environment into;
- other policy areas.

To fulfil international commitments under the Association Agreement and implement provisions of Directive 2011/92/EU there has been developed draft law No. 2009 а-д⁸, presupposing introduction of the EU legislation norms of environmental impact assessment (EIA) in Ukraine. Under part I, of article 2 of Directive (2011/92/EU), the country has to take all measures necessary to ensure assessment of projects likely to have significant effects on the environment, with due account of their nature, size and location, before consent to the implementation of such project is granted.

In general, the draft law implements the model of environmental impact assessment envisaged by Directive 2011/92, it reflects sufficient and detailed requirements for its main stages. The draft law suggests a regulatory approval procedure for environmental impact assessment.

Draft law No. 2009 а-д presupposes:

- Environmental impact assessment shall be applied to activities and facilities set by the draft law;
- Periods for the necessary actions and steps at each EIA stage are set;
- Transparency of the procedure and publicity of decisions is ensured through making information public in the Environmental Impact Assessment Register open to the public;
- The environmental impact assessment procedure is envisaged in regulatory approval procedures (for instance, procedure of granting a permission for construction performance);
- Environmental impact assessment is included into the permission granting procedure for using natural resources (forest cutting on significant areas, mineral extraction, etc).

Quite a number of provisions of draft law No. 2009 а-д take into account requirements of Directive No. 2011/92/EU, which fact may prove commitment performance.

A drawback of the draft law is the fact that it contains not only the provisions of the Directive, but also provisions of recommendations for the EU countries which are not mandatory for approximating to the Directive within the framework of the Association Agreement implementation. Another drawback is that the approximated norms of the draft law are not well-coordinated with the applicable Ukrainian legislation on environmental protection, construction and energy. For instance, the transitional provisions of draft law No. 2009 а-д indicate that the results of environmental impact assessment shall be attached to project documentation for construction of facilities subject to environmental impact assessment. It is not clear from such wording whether the environmental impact assessment constitutes a part of project documentation, or not. In case the results of environmental impact assessment are not a part of project documentation, the question arises: at which out of the three

8) Draft law No. 2009 а-д "[On environmental impact assessment](#)" dated 22.02.2016

designing stages (feasibility studies; draft; working draft) should such procedure be conducted and whether it should be conducted prior to the beginning of designing.

In case the given draft law is approved, for it to 'function' it is necessary to pass a whole range of by-laws for actual implementation of provisions of Directive No. 2011/92/EU.

At the same time, the environmental impact assessment facility list includes some facilities which are generally not there in the Directive, like cinemas and parking lots for up to 100 cars. All those facilities, as European practice shows, may be subject to environmental impact assessment, but it depends on the special features of the project in each state and these are not commitments under the given Directive. Also, another problematic provision is the one about facilities in relation to which the country is free to choose the threshold starting with which the facility shall be subject to environmental impact assessment (the list of Annex II to the Directive). The Law contains some facilities with very low thresholds. For instance, the facilities for which the lowest thresholds have been chosen are tanks for surface and underground liquid fuel storage. Inclusion of such provisions into Ukrainian legislation may cause rise of corruption and limitation of SMEs development.

On October 4, 2016 draft law No. 2009 а-д was passed, and on October 12, 2016 it was signed by the Chairman of the Verkhovna Rada. Already on October 13 the Law was submitted to the President for signing. But, contrary to expectations, on October 28, 2016 the President sent the Law back to the Verkhovna Rada for being amended, with some proposals, on vetoing it. The reasons indicated include drawbacks in law-making techniques, too wide a field of application, corruption risks and ungrounded obstacles for economic development. Currently, the Law has not yet been adopted.

To fulfill international commitments under the Association Agreement and implement provisions of **Directive No. 2003/4/EC** draft law "On Amending Some Legislative Acts of Ukraine as to Access to Environmental Information" is being developed, but its draft has not been made public yet.

At the same time, draft law No. 2009 а-д, developed to fulfill provisions of Directive No. 2011/92/EU, contains provisions on public access to information on the environmental impact assessment process and its participation in it. These are the requirements of provisions of Directive No. 2003/4/EC and Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters.

On the whole, draft law No. 2009 а-д suggests sufficient and detailed requirements concerning providing information to the public and public debate holding, though it presupposes the need to pass additional by-laws in the field. The main positive factor here is that the duty to hold a public debate lies with the state authorities.

Among the drawbacks of the draft law there may also be pointed out the fact that article 7 'Public Debate', in spite of a detailed regulation of those issues, does not suggest any comprehensive procedure for holding a public debate. For example, the article provides for a clear procedure for discussing the activity planned only on the basis of the results of the environmental impact assessment report. At the same time, this very article presupposes public debates and proposals as to the activity planned, which is much wider than discussion of the results of the environmental impact

assessment report only. And the clear procedure for public debate on the activity planned is not determined, as well as it is not determined what elements of it are subject to the public debate procedure.

Also, the draft law does not clearly determine what constitutes the object of public debate: planned activity (that is just a type of economic activity, and not certain materials under the draft law), or environmental impact assessment report.

At the same time, the draft law suggests establishing the register on environmental impact assessment matters, which fact may be pointed out as a positive element.

On the whole, it may be said that the draft law, if it considered through the prism of its correspondence to the requirements of Directive 2003/4/EC, meets its basic requirements, but at the same time contains a wide range of conflicts which require adoption of additional regulatory legal acts for them to be resolved.

To fulfill international commitments under the Association Agreement and implement provisions of **Directive No. 2003/35/EC** there has been developed the draft law (SEA). On the whole, the draft law meets the Directive's requirements as to performance of a strategic environmental assessment of plans and programmes. The drawback of the draft law is the standards which, in fact, take urban planning documents (like, master plans of cities) out of the mandate of the law. About 90% of all SEAs in the EU countries are performed in relation to territory planning documents. Obviously, the principles and the main requirements to strategic environmental assessment should be the same for all the facilities subject to SEA under Directive 2001/42 and Protocol on SEA, and their unification was one of the goals of this Law⁹.

Draft law No. 3259 was passed on October 4, 2016. Already on October 12, 2016 the Law was signed by the Chairman of the Verkhovna Rada, and on October 13 the Law was sent to the President to be signed. But, contrary to expectations, on October 28, 2016 the President sent the Law back to the Verkhovna Rada for being amended, with some proposals, on vetoing it. Currently, the Law has not been introduced. As it is indicated in the President's proposals, different approaches to determining the field and the object of legal regulation make the process of state planning complicated, and this will have an adverse effect on the establishment of the integral system of forecast and programme documents in economic and social development of Ukraine, some economy branches and some administrative territorial units. It is also indicated that the majority of provisions of the Law are declarative, unclear, with inner contradictions, and do not fully consistent with other legislative acts, thus this will not contribute to efficient implementation of the state policy on strategic environmental assessment.

Draft law No. 3259 aimed to regulate relations in the field of strategic environmental assessment of draft documents in state planning and supplements the procedures of state planning document development and approval. Under the draft law, SEA shall be performed in relation to strategies, plans, schemes, urban planning documents, general state programmes, state special-purpose programmes. An exception here are draft state planning documents the only goal of which is to serve the needs relating to defense and emergency situations as well as financial or budget state planning documents.

9) [Comments and suggestions](#) of Resource & Analysis Center "Society and Environment" to the draft law of Ukraine "On Strategic Environmental Assessment".

In case the President of Ukraine signs draft law No. 3259, one might consider that the majority of provisions of Directive No. 2003/35/EC have been approximated.

To fulfil international commitments under the Association Agreement and implement provisions of **Regulation (EC) No. 2037/2000** back in 2013 draft law "On Ozone Layer Protection" was developed, it envisaging establishment of legal and organizational principles of regulating relations in the field of handling ozone-depleting substances and goods containing or using ozone-depleting substances. The draft law sets legal and organizational principles of regulating relations in the field of handling of ozone-depleting substances, mechanisms of their consumption cuts. Important is the fact that this year at the 28th Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer which took place in the city of Kigali (the Republic of Rwanda) an amendment to the Montreal Protocol was adopted, which, for Ukraine as for a participant of the Protocol since 1998, means continuation of development and implementation of a comprehensive climate policy in the context of our commitments envisaged by the Association Agreement.

As of today, the Law has not been adopted. In general, it meets the requirements of the Regulation, but it has not been approved due to remarks on corruption-causing factors and lack of coordination of the mandate of the central executive authorities in relation to its implementation.

• ***In the field of genetically modified organisms***

To fulfil international commitments under the Association Agreement and implement provisions of Directive No. 2001/18/EC and Regulation (EC) No. 1946/2003, according to the information obtained from the Ministry of Ecology and Natural Resources, there has been developed a draft law. Now the revised version of the Law of Ukraine "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms" is now being under interdepartmental coordination. This draft law has not been made public, thus it is impossible to make an assessment of the correspondence of its provisions to the requirements of Directive No. 2001/18/EC and Regulation No. 1946/2003.

• ***In the field of nature conservation***

To fulfil international commitments under the Association Agreement and implement provisions of Directive No. 92/43/EEC through the order of the Ministry of Nature there has been set up a task force working at the development of the draft law that would meet the Directive's requirements. The main goal of approximating Ukrainian legislation to Directive No. 92/43/EU on habitats must be to promote biodiversity conservation through conservation of natural habitats (hereinafter referred to as habitats) and species of natural flora and fauna which are of importance for the society. It is difficult to say to what extent the given draft law corresponds to the requirements of the Directive, since the text is not in open access.

As far as Directive No. 2009/147/EC¹⁰ is concerned, its approximation should have started back on January 1, 2015, and to be ongoing as of November 1, 2016, however that is not what happened. As of today, provisions of this Directive remain absolutely

¹⁰) [Policy paper](#): "Implementation of the EU Directive on the Conservation of Wild Birds in Ukraine" by Resource Analysis Center "Society and Environment" (2016)

unattended by the authorities. This Directive is important since it refers to two important components. The first one is creation of special nature conservation territories (SCT). The second one is introduction of birds' conservation regime. SCT establishment must be arranged only on the basis of ornithological criteria and presupposes establishment of separate 'reserves for birds' which will then automatically be included into the European NATURA 2000 network. It provides for protection of natural species of birds from uncontrolled shooting, capturing or killing in other ways as well as their conservation within the areas of their living and habitats (in particular, that refers to endangered and migrating species).

At the current stage the Ministry of Ecology and Natural Resources of Ukraine takes steps to develop an Emerald Network¹¹ in the territory of the already functioning nature conservation fund. From a scientific point of view, those two systems are very much alike, but officially, from a legal point of view, the Emerald Network is in no way related to the Directive, it refers to the Bern Convention. This Convention was developed for the non-EU Member States having no commitment to perform the Directive on the Conservation of Wild Birds. One more important point is that the Directive presupposes establishment of separate SCTs for birds, with a special regime, and not just their establishment exclusively on the basis of the available nature conservation fund, in which a different protection regime is applied. That is particularly important due to low level of reserves in Ukraine (about 6% of the territory against 15% in the EU)¹².

The organizational form the Ministry will choose for the SCT creation will affect further legislative decisions: it will either be necessary to introduce amendments in the effective Law "On Nature Conservation Fund of Ukraine", or develop a separate law on SCT.

• *In the field of ambient air quality*

To fulfil international commitments under the Association Agreement and implement provisions of **Directive No. 1999/32/EC on sulphur in fuel (partially)** the Ministry of Energy and Coal Industry has made public the draft resolution of the Cabinet of Ministers of Ukraine "On Amending Resolutions of the Cabinet of Ministers of Ukraine of June 1, 2011 No. 573 and August 1, 2013 No. 927." The draft resolution has been developed for the sake of removing problematic issues identified during the application of the [Technical Regulation on Requirements to Motor Petrol, Diesel, Marine and Boiler Fuel](#). Besides, for the sake controlling the quality of oil products sold via the car fuelling stations network, the draft resolution envisages designating a market supervision body. On the whole, the draft resolution settles the problems with correspondence of legislation to the Directive's requirements. At the same time, this issue is being considered by the Energy Community within a [special proceeding](#).

As far as Directive No. 94/63/EC is concerned, no regulatory legal act has either been developed or adopted to fulfil those commitments.

11) Territories of special importance for biological diversity preservation. While assessing the territories to be included to the Emerald Network, it is taken into account whether there are species of plants and animals that are under the threat of extinction here, whether it is an important stopping point along the migration routes of animals or birds, whether it stands out for a high biodiversity level.

12) "Na Shliakhu do Zelenoho Zrostantnia: Monitorynh Prohresu v Ukrayini." / Panel of authors: Andrusevych A., Andrusevych N., Kozak Z., Khomiakova O. — Lviv. — 2014.

• ***In the field of water quality and water resources management***

To fulfil international commitments under the Association Agreement and implement provisions of Directive No. 2007/60/EC there has been passed Order of the Cabinet of Ministers of Ukraine (CMU) as of March 25, 2015 No. 419-p “On Approval of the Action Plan on Implementation of the Concept of Managing the Risks of Appearance of Emergency Situations of Technogenic and Natural Origin for the Years 2015-2020”. Also, Order of the State Emergency Service as of July 05, 2016 No. 317 “On Establishment of the Interdepartmental Commission and Approval of the Plan of Implementation of Measures as to Implement the Implementation Plan for Directive No. 2007/60/EC of the European Parliament and Council as of October 23, 2007 on the Assessment and Management of Flood Risks for the Years 2016 – 2017.” As of November 1, 2016 this is the only Directive the respective provision of which has been approximated with due regard of the deadlines.

One more positive element is adoption of the Law “On Amending Some Legislative Acts of Ukraine as to Introduction of Integrated Approaches to Water Resources Management Following the Basin Principle” taking into account not only provisions of Directive No. 2007/60/EC on establishment of the framework for the Community’s activity in the field of water policy, but also Directive No. 2000/60/EU, commitments under which are envisaged by the Association Agreement for 2018, 2021 and 2025.

To fulfil international commitments under the Association Agreement and implement provisions of **Directive No. 2008/56/EC** no single regulatory legal act has been either developed, or adopted.

• ***In the field of industrial pollution***

To fulfil international commitments under the Association Agreement and implement provisions of Directive No. 2010/75/EU there has been developed and passed in the first reading draft law “On Amending Some Legislative Acts of Ukraine Regulating Relations Connected with Obtaining Documents of Licensing Nature (as to Special Water Use)” No. 3323. However, this draft law is one of the steps on the way towards approximation of the given Directive. A significant point is development of the National Plan of Reducing Emissions Produced by Large Burning Installations by the Ministry of Energy and Coal Industry. Implementation of this Directive will lead to a considerable reduction of regulatory load on companies. That will enable the companies to get one integrated permission instead of a whole range of permissions (for discharge of polluting substances, special water use, etc.). At the same time, the Central Scientific Experts Office provides its remarks as to the draft in question, and after considering draft law No. 3323 for the second reading points out a number of problem points as well as claims that the submitted draft law does not meet the rule of law principle and the requirements to legal determination of legislative norms since a number of its provisions are not based on the laws of Ukraine¹³.

• ***In the field of climate change and ozone layer protection***

To fulfil international commitments under the Association Agreement and implement provisions of **Directive No. 2003/87/EC and Regulation (EC) No. 842/2006** no single regulatory legal act has been developed or adopted.

¹³) Draft law No. 3445 On [Amending Some Legislative Acts of Ukraine](#) (as to Protection of Fauna and Flora in Accordance with International Agreements) dated 10.11.2015.



Commitments in the field of social policy



Expert



Zoriana
Kozak

The main performer responsible for approximation of Ukrainian legislation on health and safety is the **State Labour Service of Ukraine** (hereinafter referred to as the State Labour Service).

The EU-Ukraine Association Agreement (hereinafter referred to as the Association Agreement) determines that Ukraine must fulfil a number of commitments aimed to improve the level of ensuring occupational health and safe working conditions, in particular, to promote preventive measures implementation, to prevent major accident hazards and manage toxic chemicals, trainings in health and safety and experience exchange. (article 420). Also, according to article 424 of Title V (Economic and Sector Cooperation), according to the timetable set in Annex XL (40), Ukraine must approximate to the EU legislation in the field of employment, social policy, equal opportunities and health and safety.

In spite of the fact that so far the EU-Ukraine Association Agreement has not come into effect due to unfinished process of its ratification, some of its provisions are applied on a provisional basis¹. Provisional application embraces the parts of the Agreement that are within the EU competence. Such provisions include Ukraine's commitments to approximate legislation in the field of social policy, including the ones relating to the field of occupational health and safety². In particular, Annex XL (40) to the Association Agreement that sets the list of Directives in the field of occupational health and safety that need to be approximated as well as time frame for their approximation is subject to provisional application.

On November 1, 2016 there expired the deadline for the implementation of two directives in the field of occupational health and safety, but these commitments have not been fulfilled by Ukraine.

Commitments had to be implemented by November 1, 2016

Field: occupational health and safety

- Directive of the Council No. 92/91/EEC concerning the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries through drilling (hereinafter referred to as Directive No. 92/91/EEC) (partially)³;

1) See article 486 of the Association Agreement.

2) Annex XL to the Association Agreement has been applied provisionally since November 1, 2014.

3) The deadline for approximating to the norms of the Directive as to workplaces which already exist makes up 5 years from the date the Agreement comes into effect, while approximation to all other norms of the Directive makes up 2 years.

- Directive of the Council No. 92/104/EEC on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (hereinafter referred to as Directive No. 92/104/EEC) (partially)⁴.

What do the respective EU norms provide us with?

Directive No. 92/91/EEC sets the following:

- a detailed description of the minimum requirements to safety of working areas and health protection of workers in the mineral-extracting industries through drilling (through wells), as well as activity related to extracted minerals processing;
- the duty of the employer to maintain safety in working areas, in particular, to prepare a document on health and safety which determines the risks the workers run at workplaces as well as the measures aimed to eliminate them prior to the work commencement;
- establishment of the systems of communication, warning and emergency alarm aimed at efficient rescuing and evacuation of workers by employers;
- the right of worker to preventive medical examination prior to work commencement and to regular and repeated examination;
- the right of workers to be informed about all available health and safety measures in the way understandable for them;
- sets specific requirements to health and safety, viz. common and special requirements to performance of works in the surface and performance of underground works.

Directive No. 92/104/EEC sets:

- a detailed description of the minimum requirements to safety of working areas and health protection of workers in surface and underground mineral-extracting industries (but for extraction of minerals through drilling regulated by Directive No. 92/91/EEC).
- the employer's duties and the rights of employees similar to the requirements set by Directive No. 92/91/EEC described above.

What has been done to adapt national legislation?

The 'internal deadline' for approximation to Directive No. 92/91/EEC was set back in October 2015⁵. Under the implementation plan developed by the State Labour Service⁶, by the end of the above period it was necessary to develop a regulatory legal act on the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries through drilling.

Along with that, according to information obtained from the State Labour Service and the Ministry of Social Policy, the developed draft regulatory legal act implementing

4) The deadline for approximation to the norms of the Directive as to workplaces which already exist makes up 9 years from the date the Agreement comes into effect.

5) P. 393 of the Action Plan on implementation of the Association Agreement between the European Union, the European Atomic Energy Community and its Member States, of the one part and Ukraine, of the other part, for the years 2014-2017, approved by Order of the Cabinet of Ministers of Ukraine No. 847-p as of September 17, 2014.

6) The implementation plan approved by Order of the Cabinet of Ministers of Ukraine No. 745-p as of July 17, 2015.

Directive No. 92/91/EEC⁷ — draft order of the Ministry of Social Policy “On Approval of the Minimum Requirements for Improving the Safety and Health of Workers in the Mineral-Extracting Industries through Drilling”, — is still being under development with the structural units of the State Labour Service. Taking into account the fact that the above document has not been published, we cannot assess to what extent it corresponds to the Directive’s requirements.

Also, we assume that the State Labour Service has faced a problem of approximation to the above Directive, since according to the notice of the Ministry of Social Policy, the State Labour Service has addressed the Ministry of Social Policy and the Government Office with the request to postpone the deadline for the Directive implementation till October 2017⁸. In the Action Plan on implementation of the Association Agreement for the years 2014-2017 and in [Order of the Cabinet of Ministers of Ukraine No. 745-p](#) as of July 17, 2015 which approved the plans of implementation of both Directives, no changes in relation to the deadlines of implementation of this Directive have been made (Order No. 745-p functions in its initial version as of July 17, 2015).

It should be noted that the issue of health and safety of workers of mineral-extracting industries through drilling are also regulated in the General Health and Safety Requirements for Workers of Mineral-Extracting Companies⁹ (hereinafter referred to as the General Requirements). This regulatory act contains provisions corresponding to the provisions of the Directive (for instance, regular medical examinations, supervision over working areas performed by qualified staff, requirements for sanitary working conditions, etc). Along with that, the General Requirements do not contain any detailed requirements for health and safety in minerals extraction specifically through drilling of wells, the way it is envisaged by Directive No. 92/91/EEC.

Along with that, the Plan of Implementation of Directive No. 92/104/EEC presupposes having a separate act on the minimum requirements for improving health and safety of workers in surface and underground mineral-extracting industries developed by May 2016. As of November 11, 2016 such document has not yet been adopted.

According to information obtained from the main performers¹⁰, there has been developed draft order of the Ministry of Social Policy “On Approval of the Minimum Requirements for Improving Health and Safety of Workers in Surface and Underground Mineral-Extracting Industries” which is under development with the State Labour Service and the National Research Institute of Industrial Health and Safety. The same as in the case with Directive No. 92/91/EEC, this draft act is not in public access, thus we cannot assess to what extent it corresponds to the Directive’s requirements.

And the State Labour Service has also addressed the Ministry of Social Policy and the Government Office with the request to postpone the deadline for adoption of the act developed for the sake of Directive implementation to May 2018. It is also not known which decision has been passed on postponement of the deadline for adoption of this draft Order.

7) Response of the State Labour Service to the request for public information provision as of October 04, 2016 No. 2068/1/15-38-16.

8) The response of the Ministry of Social Policy to the request for public information provision as of October 20, 2016 No. 602/8/1/87-16.

9) NPAOP (Regulatory Legal Acts on Health and Safety) 14.3-7.02-06 approved by Order of the Ministry of Ukraine on Emergencies and Affairs of Population Protection from the Consequences of Chernobyl Catastrophe as of July 19, 2006 No. 459.

10) The response of the State Labour Service to the request for public information provision as of October 04, 2016 No. 2068/1/15-38-16; The response of the Ministry of Social Policy to the request for public information provision as of October 20, 2016 No. 602/8/1/87-16.



Commitments in the field of company operation



Expert



Iryna
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The main performers responsible for approximation of Ukrainian legislation to the EU legislation are the **Ministry of Justice of Ukraine (MinJust)**, the **Ministry of Finance of Ukraine (MinFin)** and the **Ukrainian National Securities and Stock Market Commission (NSSMC)**¹.

Ukraine must adjust the EU legislation in the field of establishment and operation of companies, corporate governance as well as accounting and audit under article 387 of Title V (Economic and Sector Cooperation) of the Association Agreement. Approximation shall take place in compliance with the deadlines and list of the EU acts determined in Annexes XXXIV (34) – XXXVI (36) of the Association Agreement, in particular:

- Annex XXXIV (34): acts in the field of protection of the rights of shareholders, creditors and other stakeholders;
- Annex XXXV (35): acts relating to accounting and audit;
- Annex XXXVI (36): acts in the field of corporate policy².

Commitments with the deadline November 1, 2016.

On the whole, one may point out 4 EU acts (3 Directives envisaged by Annex XXXIV (34) and 1 Regulation envisaged by Annex XXXV (35)³, the period of implementation of which is November 1, 2016. Out of them, 2 Directives refer to making information about company operation public, 1 Directive – to requirements for capital. In its turn, the Regulation regulates the issues of international financial reporting standards application.

EU regulation on company operation:

- The First Council Directive No. 68/151/EEC as of March 09, 1968, as amended by Directive No. 2003/58, on co-ordination of safeguards which, for

1) In the context of the acts that must be implemented as of November 1, 2016.

2) Article 387 of the Association Agreement is not embraced with provisional application, while Annexes 34-36 apply on a provisional basis since November 1, 2014.

3) The difference between the Directive and the Regulation lies in the need for their implementation (introduction) into national legislation. Under article 288 of the Treaty on the Functioning of the EU, the Regulation shall be mandatory, shall be applied directly and in full scope (without the need to pass any additional acts transferring the Regulation into national legislation). The Directive shall be binding only as to its result, and the state itself settles what forms and means are to be used to fulfill the goal set by the Directive.

the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, with a view to making such safeguards equivalent throughout the Community (hereinafter referred to as the First Directive).

The First Directive was cancelled by Directive No. 2009/101/EC of the European Parliament and the Council as of September 16, 2009. It was Directive No. 2009/101/EC that is currently under approximation in Ukraine.

The main competent body is the **Ministry of Justice**.

- The Second Council Directive No. 77/91/EEC as of December 13, 1976, as amended by Directives No. 92/101/EEC and No. 2006/68/EU, on coordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, in respect of the formation of public limited liability companies and the maintenance and alteration of their capital, with a view to making such safeguards equivalent (hereinafter referred to as the Second Directive).

The Second Directive was cancelled by Directive No. 2012/30/EU of the European Parliament and the Council as of October 25, 2012. Along with that, the main performer – the Ukrainian National Securities and Stock Market Commission – is working at the implementation of the Second Directive in the version set by the Association Agreement (indicated above). According to the latest information, the Ukrainian National Securities and Stock Market Commission also takes into account the requirements of Directive No. 2012/30/EU in its work at draft regulatory acts, but no separate implementation plan for the new Directive has been developed.

- The Eleventh Council Directive No. 89/666/EEC as of December 21, 1989 concerning disclosure requirements in respect of branches opened in a Member State by certain types of company governed by the law of another State (hereinafter referred to as the Eleventh Directive).

The Eleventh Directive was partially cancelled by Directive No. 2013/34/EU of the European Parliament and the EU Council as of June 26, 2013.

The main competent body has not been designated⁴.

- Regulation (EC) No. 1606/2002 of the European Parliament and the Council as of July 19, 2002 on the application of international accounting standards.

What do the respective EU norms provide us with?

[Directive No. 2009/101/EC](#) refers to (i) disclosure of the company's documents, (ii) validity of commitments undertaken by companies, as well as (iii) recognition of state registration of such companies. It applies to economic entities in which responsibility of their participants to the third parties is limited. Article 1 of Directive No. 2009/101/

4) In Order of the Cabinet of Ministers of Ukraine as of September 17, 2014 No. 847-p On Implementation of the Association Agreement between the European Union, the European Atomic Energy Community and its Member States, of the one part and Ukraine, of the other part.

EC directly indicates to what types of economic entities in each specific Member State the Directive⁵ is applied. For Ukraine no specific list of economic entities is determined. Analysis of applicable Ukrainian legislation in the field enables to assume that such Directive must be applied, as a minimum, to joint-stock companies (public and private) as well as to limited liability companies.

Information disclosure: The Directive sets the minimum list of documents and data subject to disclosure by the company⁶. Disclosure presupposes transfer of those documents and data to the central state register where there is a separate registration file for each company, documents in which are kept in paper or electronic format. Any person may get access to the registration file of the company and get copies of documents kept there on making a request to the register for a certain fee that may not exceed the administrative costs of processing of such request⁷. Disclosure is also made through publication of the documents submitted to the register or the information on their inclusion into the registration file in a specially selected national newspaper. In case the documents and the data on the company are not made public, punitive measures must be taken against the company.

In particular, such documents include the following: constituent documents and articles of association, any amendments made in them, annual financial reporting, information on individuals authorized to represent the company in relations with the third parties as well as the ones exercising supervision and control over its activity, court decision on the liquidation of the company, data about liquidators and the date of termination of liquidation procedures, etc.

Another important issue regulated by the Directive is validity of the company's commitments, in particular, in cases when the commitments go beyond the frame of the company operation goals or in case the bodies authorized to represent the company were appointed with violations⁸.

Also, Directive No. 2009/101/EU sets an exhaustive list of grounds when companies embraced by the Directive may be acknowledged to be 'invalid'. Such grounds include, in particular, the cases when the company's operation goals are illegal, run counter to the state policy, when the company, contrary to national legislation, was founded by one person⁹.

What has been done to approximate national legislation?

The first question that arises in relation to approximation of Ukrainian legislation to this Directive is absence of the guidance in the implementation plan developed by the Ministry of Justice as to what types of economic entities implementation will be applied.

5) For instance, in case of Poland that is limited liability company, limited joint-stock company, joint-stock company. For Great Britain – these are limited liability companies, and for Germany – joint-stock companies, limited liability companies and limited companies.

6) Art. 2 Directive 2009/101/EC.

7) Art. 3 of Directive 2009/101/EC.

8) Art. 9, 10 of Directive 2009/101/EC.

9) Art. 12 of Directive 2009/101/EC. That is, a company may be founded by one person, but such possibility must be provided by national legislation of the EU Member State.

Here we will consider what has been done specifically for the Directive implementation.

1) Making information about companies public.

In Ukraine the issue of economic entity registration and making the data about its business public is regulated by the Law of Ukraine “[On State Registration of Legal Entities, Natural Persons-Entrepreneurs and Public Formations](#)” as of May 15, 2003 No. 755-IV (hereinafter referred to as the Law “On State Registration”). Under that Law, in Ukraine there functions the Unified State Register (hereinafter referred to as the USR), registration in which constitutes a mandatory condition for the establishment of an economic entity¹⁰. The Law “On State Registration” sets the requirements for the information to be provided by the economic entity to the USR¹¹.

Under the plan of implementation of Directive No. 2009/101/EU the Law On State Registration in general corresponds to this Directive. But, on contrasting those acts, one may draw a conclusion that the Law does not fully reflect the goal of the Directive, viz.:

- According to the Law “On State Registration”, access is guaranteed to the data available in the Unified State Register (for instance, data on the type of constituent document (articles of association, model articles of association, constituent act). Information may be obtained from the register on a free-of-charge basis in the form of an electronic request or on a paid basis in the form of an excerpt.
- Instead, the Directive presupposes access not only to the data, but also to documents submitted by the company (that is the possibility to obtain information not only about the type of document, but to get a copy of the articles of association, financial reporting, etc.)¹². That is, there must be ensured access to the very registration file. Under the Law “On State Registration”, courts and some state authorities¹³ have such access.

The plan of implementation of Directive No. 2009/101/EC presupposes that implementation of the Directive requires amending the Law “On State Registration.”

Over the years 2014-2016, numerous amendments have been made in the Law. In particular, in 2014 Law of Ukraine as of April 15, 2014 No. 1206-VII “[On Amending Some Legislative Acts of Ukraine as to Simplification of Business Opening Procedure](#)” was passed, it ensuring a free-of-charge access of citizens to the data the USR contains.

However, until access of the third parties to the documents available in the registration file is ensured, one may not speak about complete implementation of this EU act. So far we know of no developed draft laws that would consider that issue.

2) The grounds for validity of commitments and company invalidity.

The plan of implementation of Directive No. 2009/101/EC does not embrace this part of the Directive, focusing only on the issues of making information public.

¹⁰) Art. 80 of the Civil Code of Ukraine (hereinafter referred to as the CC of Ukraine).

¹¹) Part 2 of art. 9 of the Law On State Registration.

¹²) See part 4 of article 3 of Directive No. 2009/101/EC.

¹³) See art. 30 of the Law On State Registration.

Along with that, the issue of validity of commitments undertaken by economic entities to which Directive No. 2009/101/EC refers, is regulated in Ukraine by the [Civil Code of Ukraine](#), the Law of Ukraine “[On Economic Entities](#)” and the Law of Ukraine “[On Joint-Stock Companies](#)” (hereinafter referred to as the Law “On JSC”).

Also, in Ukrainian legislation there is no notion of ‘invalidity of economic entity’, that may be established only by court decision, while instead there are grounds for termination of operation of economic entity (through re-organization or liquidation) that are of a different legal nature.

Also, Ukrainian legislation envisages the grounds for refusing to carry out state registration of an economic entity¹⁴ and the case when a joint-stock company is considered not to have been founded (in case of incomplete payment of the authorized capital stock of the joint-stock company)¹⁵.

However, as it has been mentioned above, the Directive’s requirement is that ‘invalidity’ may be acknowledged only on the basis of court decision¹⁶. In Ukraine decision to refuse to carry out state registration is passed by the state registrar. As far as compulsory liquidation of an economic entity under court decision is concerned, unlike the Directive, the laws of Ukraine do not contain any exhaustive list of the grounds for which court may pass a decision on invalidity of the company’s registration.

Thus, in spite of the fact that recently Ukrainian legislation has undergone significant changes in the field of making information about companies public, it may not be stated that there is complete correspondence to Directive No. 2009/101/EC. Also, it may not be stated that the measures selected by the Ministry of Justice in the implementation plan are sufficient for complete implementation of Directive No. 2009/101/EC.

The Second Directive in the version of 2006 refers to the requirements for forming and changing the authorized capital stock of joint-stock companies¹⁷, which may not be less than 25,000 Euros. Also, the Second Directive sets the requirements for the information indicated in the articles of association or constituent documents subject to being made public under the First Directive. Besides, the Directive envisages:

- Mandatory valuation of the property with which the shares have been paid for (in case payment has been made not in a monetary form), and exceptions when such valuation is not performed;
- The company’s profit distribution among the shareholders (in particular, dividend payment);
- Conditions of redemption of owned shares by the company;
- Protection of the rights of the company’s creditors in case of reduction of subscription capital¹⁸;

14) Art. 28 of the Law On State Registration.

15) P. 3 of art. 11 of the Law of Ukraine On Joint-Stock Companies.

16) Art. 12 of Directive No. 2009/101/EC.

17) Art. 1 of the Second Directive.

18) Art. 32 of the Second Directive.

- The principle of equality of same-class shareholders¹⁹.

What has been done to approximate national legislation?

The Ukrainian National Securities and Stock Market Commission (NSSMC). Under the [plan of implementation of the Second Directive](#) developed by the NSSMC²⁰, the majority of its provisions have been reflected in the Law of Ukraine “On Joint-Stock Companies.” To ‘finally bring Ukrainian legislation in conformity’ with the Directive, the implementation plan presupposes development of several regulatory acts, among which:

- The Law of Ukraine “On Amending Some Legislative Acts of Ukraine for the Purposes of the EU Legislation Implementation in the Field of Corporate Governance”, which, in particular, will bring in conformity with the Second Directive the data publicized by a joint-stock company; publicizing of property appraisal report in cases payment for the shares is made in other than monetary form.

Analysis. According to information obtained from the NSSMC, the draft law of Ukraine “On Amending Some Legislative Acts of Ukraine for the Purposes of the EU Legislation Implementation in the Field of Corporate Governance” was developed and made public on the [site of the NSSMC back](#) on December 25, 2015. Also, in its response the NSSMC indicates that so far the draft law is under development with a view to taking into account provisions of Directive No. 2012/30/EU which cancelled the Second Directive. So far this revised draft is not in public access (judging by the analysis of the NSSMC’s site), that is why the final conclusion as to how much it corresponds to Directive No. 2012/30/EU can be made after it is made public.

- Development of the NSSMC’s regulatory legal act which presupposes ‘inclusion of information about redemption of its own shares by the joint-stock company in the joint-stock company’s annual report’ and ‘setting the requirements for the annual report of the supervisory board’.

Analysis. The NSSMC has adopted amendments in the Regulation “On Information Disclosure by Securities Issuers”²¹, which introduce the below changes:

- The joint-stock company shall report on redemption of its own shares, including on the grounds for the redemption, overall cost of the redeemed shares²², – in general, the provision corresponds to p. 2, art. 22 of the Second Directive.
- ‘establishment of the requirements for the annual report of the supervisory board’ – fulfilment of the requirements of the Recommendations of the

¹⁹) Art. 42 of the Second Directive.

²⁰) It is also worth noting that the NSSMC has developed one implementation plan for several Directives in the field of corporate governance with different implementation deadlines, viz.: the Second Directive (November 1, 2016), Directive No. 2007/36/EU (November 1, 2017) as well as Recommendations of the European Commission 2005/162/EC, 2004/913/EU and the OECD principles as to implementation of standards in the field of corporate governance and operation of joint-stock companies, for which no deadline is set.

²¹) Approved by decision of the NSSMC as of December 03, 2013 No. 2826. Amendments made by Decision of the NKTS PFT as of September 01, 2015 No. 1348.

²²) See subparagraph 13 of paragraph 1 of section 4 of chapter III of Decision No. 2826.

European Commission No. 2005/162/EU, with no implementation deadline.

All in all, a conclusion can be drawn that the NSSMC at least tries to perform the tasks set in the implementation plan, but without the respective Law being passed by the Parliament complete implementation of the Second Directive will not take place.

The Eleventh Directive was adopted in the EU since the requirements for making the data about the company public as set by the First Directive were not valid for its branches in other states. The general rule set by the Eleventh Directive is as follows: in case the company is subject to the First Directive (that is, as a rule, a limited liability company or a joint-stock company that should make certain information public in the state register), then its branch established in a different EU Member State also makes the information the list of which is set by the Eleventh Directive public. The requirements for information disclosure shall also be applied to the company's branches in the third countries (that is the ones established in the states that are non-EU countries).

Such documents and data include: address and types of the branch's activity, information about the constituent company (articles of association, financial reporting, excerpt from the register in which the company's registration file is available, information on liquidation of the company, etc.), authorized persons representing the branch, the data about its closure, etc.

In general, the Eleventh Directive is aimed to protect people starting relations with the company's branch established in a different state and, correspondingly, requiring to check how much the branch (and the company) is legally capable and solvent.

Connection of the Eleventh Directive to Directive No. 2013/34/EU.

Problem: The Eleventh Directive is not reflected in Order of the Cabinet of Ministers of Ukraine No. 847-p setting the action plan on implementation of the Association Agreement for the years 2014-2017. Also, there is no Eleventh Directive implementation plan in public access. Hence, a conclusion can be drawn that no work at the implementation of the Eleventh Directive is being done.

- Along with that, Directive No. 2013/34/EU that partially cancels the Eleventh Directive²³ is valid in Ukraine. There arises a logical question as to whether implementation of Directive No. 2013/34/EU will at the same time lead to implementation of the Eleventh Directive in Ukrainian legislation (at least partially)? In case of a positive answer, that could explain the 'silence' of the Cabinet of Ministers on the Eleventh Directive.

However, analysis of both directives enables to state that the answer is negative: implementation of Directive No. 2013/34/EU does not mean automatic implementation of the Eleventh Directive.

Primarily that is because those Directives have a different object of regulation. The Eleventh Directive, as it has been numerously mentioned above, refers to publicizing of information about the branches of some types of foreign companies. In its turn, Directive No. 2013/34/EU regulates the issues of annual financial reporting,

23) See reference about the Eleventh Directive in the [EuroLex base](#)

consolidated financial reporting and related reporting of certain types of companies. That is a new Directive which is not envisaged by the Association Agreement.

What has been done to approximate national legislation?

The Directive is not being implemented:

- The Directive is not available in the action plan on implementation of the Association Agreement for the years 2014-2017 (approved by Order of the CMU No. 847-p) – the main document, which, besides measures proper, sets ‘internal’, national implementation deadlines and determines the main performers developing implementation plan for this or that Directive. Obviously, the implementation plan for the Eleventh Directive is also not available.
- Under the Law “On State Registration”, the USR provides information on the branches of Ukrainian legal entities, but there are no requirements for publicizing information on the branches set up by foreign companies in Ukraine.
- That is related to the fact that in Ukraine registration of ‘foreign representative offices’ (a special term used in Ukrainian legislation to denote separate units of foreign companies) is done following a different procedure than [registration of a Ukrainian company](#)²⁴. Foreign representative offices get registered with the Ministry of Economic Development and Commerce (MERT) in a special register of representative offices, public access to which is not provided.

Regulation (EC) No. 1606/2002 is aimed to standardize financial reporting submitted by companies functioning in the EU. With this in view, while preparing their reporting, companies should use International Financial Reporting Standards (IFRS)²⁵. This rule, however, has got some limitations – it refers only to consolidated reporting²⁶ of companies the securities of which are quoted on the regulated EU market. The Member State may, upon its own discretion, make the use of the [IFRS](#) valid for annual reporting of the company (that is, not only consolidated), or make their use valid for companies that do not undergo the listing procedure (that is, the shares of which are not allowed to participate in the bidding on the securities market).

What does Ukrainian legislation envisage?

In Ukraine the issue of using the IFRS while compiling financial reporting is regulated by the Law of Ukraine “[On Accounting and Financial Reporting](#)”.

24) Guidance on the procedure of registration of representative offices of foreign economic entities in Ukraine approved by order of the Ministry of Foreign Contacts and Commerce of Ukraine as of January 18, 1996 No. 30.

25) The IFRS are developed by the International Accounting Standards Board (IASB). IASB is an independent body of a non-commercial international organization, the IFRS Foundation, and consists of experts in the field of accounting. The IFRS Fund is a separate independent organization that has got no relation to the EU bodies. The IFRS are not binding. However, governments of states may, upon their discretion, make it binding for the companies functioning in their territory to use the IFRS while preparing financial reporting. Thus, the IFRS become binding under national legislation.

26) Consolidated financial reporting is united reporting of the whole group of companies, that is a parent company and its subsidiaries.

According to this Law:

- The IFRS are binding for joint-stock companies as well as banks, insurers and other companies determined by a special list of the CMU²⁷. The CMU has approved such list, making it binding for companies providing financial service, carrying out non-state pension provision or carrying out auxiliary activity in the fields of financial services and insurance, to use the IFRS while compiling financial reporting²⁸.
- Other companies may choose, upon their discretion, to use the IFRS while compiling their annual reporting.

In Ukraine the requirement for using the IFRS is somewhat narrower than it is envisaged by Regulation No. 1606/2002. Unlike Ukrainian legislation, the Regulation requires a wider application of the IFRS for all companies the securities of which are allowed to be traded on securities exchanges (that may include both shares, and debt securities). Other companies, that is not only the ones set by the Law and the CMU's list may be the issuers of such securities.

27) See art. 12-1 of this Law.

28) See Resolution of the CMU as of November 30, 2011 No. 1223 On Amending the Procedure for Financial Reporting Submission.



Commitments in the field of public health



Experts



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The main performer responsible for approximation of Ukrainian legislation to the EU legislation in the field of public health is the **Ministry of Healthcare (MOH)**¹.

Ukraine must gradually approximate its legislation to the EU acquis legislation in the field of tobacco, tissue and cell transplantation under article 428 of Chapter 22 of Title V (Economic and Sector Cooperation) of the Association Agreement. Approximation proceeds within the deadlines and according to the list of the EU acts set in Annex XLI (41) to the Association Agreement².

On the whole, five commitments for November 1, 2016 refer to manufacture, presentation and sales of tobacco goods, tobacco advertising as well as tissue and cell transplantation. To fulfil those commitments, draft laws have been developed. Among the acts that require implementation there are two EU acts relating to tobacco and three EU acts relating to tissue and cell transplantation. According to our assessment, none of those acts has been fully implemented into Ukrainian legislation³.

Commitments with the deadline November 1, 2016

On the whole, there may be pointed out 3 EU acts relating to tissue and cell transplantation, the implementation deadline of which is November 1, 2016. According to our assessment, none of these acts has been fully implemented into Ukrainian legislation⁴.

EU regulation on tissue and cell transplantation:

- Directive No. 2004/23/EC of the European Parliament and of the Council as of March 31, 2004 on setting standards of quality and safety for the donation,

1) In the context of the acts that must be implemented as of November 1, 2016 see also p. 418 of Order of the CMU as of September 17, 2014 No. 847-p On Implementation of the Association Agreement between the European Union, the European Atomic Energy Community and its Member States, of the one part and Ukraine, of the other part.

2) [Article 428 and Annex XLI](#) are subject to provisional application since November 1, 2014 under Decision of the EU Council № 2014/668/EU.

3) On September 29, 2016 the Ukrainian Centre for European Policy (UCEP) sent a request for public information provision to the Ministry of Healthcare. As of November 14, 2016 the Ministry has not provided any response. Thus, our conclusion is based on the fulfillment of the implementation plan developed by the Ministry of Healthcare, which is in [public access](#).

4) On September 29, 2016 UCEP sent a request for public information provision to the Ministry of Healthcare, and the Ministry provided a response with its letter No. 06.23-17/1328/3ПІ/1624/29884 as of November 18, 2016. Thus, our conclusion is based on the fulfillment of the implementation plan developed by the Ministry of Healthcare, which is in [public access](#), as well as response to the request

procurement, testing, processing, preservation, storage and distribution of human tissues and cells (hereinafter referred to as Directive No. 2004/23/EC);

- Commission Directive No. 2006/17/EC as of February 8, 2007 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (hereinafter referred to as Commission Directive No. 2006/17/EC);
- Commission Directive No. 2006/86/EC as of October 24, 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (hereinafter referred to as Commission Directive No. 2006/86/EC).

All the three Directives are applicable and have not been cancelled or amended by any other Directives. And Directive No. 2004/23/EC is 'basic', while the two others have been adopted by the European Commission for its implementation⁵.

What do the EU norms provide us with?

Directive No. 2004/23/EC sets a unified framework for ensuring high standards of quality and safety for the donation of tissues and cells in their procurement, testing, processing, preservation, storage and distribution. The aim of the Directive is to apply all possible means of protection in those processes in order to avoid transmitting infectious diseases during donation. In general, the Directive sets the minimum standards, that is the EU Member States may introduce more rigid requirements.

Directive No. 2004/23/EC has a limited scope of regulation:

- It refers only to human tissues and cells (including, those of peripheral blood, stem cells, reproductive cells, umbilical blood) and refers to their application to humans only;
- It does not apply to blood and blood products (except for the above), transplantation of human organs or their parts as well as the use of animal organs and cells.

The Directive is aimed to encourage free-of-charge and voluntary donation and introduction of transparent standards of access to tissues and cells⁶. In particular, donation should not aim at profit gaining, and any compensation for provision of cells or tissues shall be paid on clearly set terms and may cover only the costs relating to the donation. The Directive also sets rigid requirements for data confidentiality – thus, for the donor and the recipient not to be identified. The secrecy of donation may be

5) Sometimes the European Commission may also pass general binding Directives (the so-called 'delegated' acts) in case such authorities have been delegated to it. In particular, when there is a need to supplement or change non-basic elements of the 'basic' directive – but in the 'basic' directive there should be indicated the goal, scope and content of the delegated act, beyond which the European Commission may not go (so far, delegation is envisaged by article 288 of the Treaty on the Functioning of the European Union).

6) Article 13 of Directive 2004/23/EC.

disclosed only in relation to donors of reproductive cells⁷.

Also, donor or other persons giving consent on his/her behalf (for instance, relatives), before tissues or cells are taken, should necessarily be informed about the aim of the donation, the related risks, data confidentiality and other important aspects the list of which is set by the Annex to the Directive.

Also, the Directive presupposes creation of the so-called 'tissue establishments', the systems of accrediting and licensing which as well as the systems of notification about serious adverse events and reactions⁸ in procurement, testing, processing, preservation, storage and distribution of tissues or cells, in particular:

- 'Tissue establishments' are allowed to carry out the above procedures only if they have been accredited, have received a permission or license from a competent authority⁹;
- A competent authority conducts regular inspections of 'tissue establishments' at least once in two years, as well as in case there appears a serious adverse event or reaction¹⁰.
- 'Tissue establishment' should preserve all the data about the tissues and cells within 30 years after their clinical use, for the sake of ensuring the possibility of tracing the path from the donor to the recipient at all stages¹¹;
- Import/export of human tissues and cells is possible only in case the 'tissue establishment' has got the respective license or accreditation.
- Annually, the 'tissue establishment' should prepare its activity report which is submitted to the competent authority. This report should also be in public access. In its turn, the competent authority should keep the register of 'tissue establishments', in which licensed (permitted, accredited) types of activity of each establishment¹² are indicated.
- In case of appearance of a serious adverse event or reaction, investigation should necessarily be conducted and a report on their causes and consequences should be compiled, and the competent authority¹³ is also informed thereof.
- The 'tissue establishment' introduces and permanently upgrades the rigid quality system which, as a minimum, includes the following documents: 'standard operating procedures' (see explanation below), guidances, manuals,

7) Article 14 of Directive No. 2004/23/EC.

8) Article 3 of Directive No. 2004/23/EC. A serious adverse event appears when any of the above procedures has led to disease transmission, death or a threat to the life, disability of patients, that causes or prolongs their hospitalization or the state of disease. A serious adverse reaction stands for an unexpected response of the organism, including appearance of an infectious disease, with the donor or with the recipient, that is connected to the transfer or application of tissues and cells, which is lethal, constitutes a threat to the life, causes disability or prolongs hospitalization or the disease.

9) Article 6 of Directive No. 2004/23/EC.

10) Article 7 of Directive No. 2004/23/EC.

11) Article 8 of Directive No. 2004/23/EC.

12) The idea is to unite all such EU registers and to create a network of such registers. Article 10 of Directive No. 2004/23/EC.

13) Article 11 of Directive No. 2004/23/EC.

reporting forms, records on donors, information about the point of tissue and cell destination, etc.¹⁴ The staff of such establishment should be duly qualified¹⁵, and a competent person should be designated to ensure implementation of the Directive and to communicate with the competent body¹⁶.

The last important aspect implemented by the Directive is establishment of a system for identifying human tissues and cells for their further detection, with assignment of identification codes to the donor material, as well as of the unified European Coding System that will enable to trace tissues and cells within the EU and preserve information on the main characteristics and properties of tissues and cells¹⁷.

Along with that, Directive No. 2004/23/EC sets the duty of the European Commission to develop a range of technical standards for its implementation: for instance, as far as the quality system of 'tissue establishments', donor selection criteria, procedures of procurement, processing and testing of tissues and cells, etc.¹⁸ are concerned. It is for the sake of fulfilment of this requirement that Commission Directive No. 2006/17/EC and Commission Directive No. 2006/86/EC have been adopted.

Commission Directive No. 2006/17/EC sets the technical standards for the procurement of human tissues and cells, donor selection criteria, laboratory tests donors have to take, procedures of accepting the acquired tissues and cells by the 'tissue establishment', requirements for direct provision of specific tissues and cells to the recipient.

The Directive implements international documents in the field – the 1997 Convention on Human Rights and Biomedicine, additional protocols to it and the WHO recommendations.

For the majority of the above processes there must be developed 'standard operating procedures, SOPs¹⁹, that is a detailed step-by-step guidance with the description of the methods and materials used and the expected final product that should be applied by 'tissue establishments' in their operation. SOPs should not run counter to the Directive. In particular, the Annexes to the Directive set detailed requirements for the persons who may become donors, including donors of reproductive cells, as well as the rules of taking donor material, documents on the donor, packaging and marking of the tissues and cells taken as well as transportation containers, getting of tissues and cells by the 'tissue establishment' and data registration.

Commission Directive No. 2006/86/EC sets detailed requirements for accreditation, designation, provision of permissions or licensing of 'tissue establishments', in particular, as to their organization and management, staff, devices and materials used, equipment and premises, documentation and data registration as well as quality and safety audit system.

14) Article 16 of Directive No. 2004/23/EC.

15) Article 18 of Directive No. 2004/23/EC.

16) Article 17 of Directive No. 2004/23/EC.

17) Article 25 of Directive No. 2004/23/EC.

18) Article 28 of Directive No. 2004/23/EC.

19) Direct provision of tissues and cells to the recipient for immediate transplantation shall be made under the decision of the competent authority. Article 6 of Directive 2006/17/EC.

Also, the Commission Directives sets the requirements for quality and safety of human tissues and cells during their coding, processing, preservation, storage and distribution between health institutions where they will be applied to human body.

Besides that, the Directive sets the forms of reporting and urgent notification of serious adverse events and reactions and lays out detailed information available in the European Coding System.

What has been done to approximate national legislation?

Currently, Ukrainian legislation in the field of transplantation is regulated by the following:

- The Law of Ukraine “Fundamentals of the Ukrainian Healthcare Legislation” as of November 19, 1992 No.2801-XII
- The Law of Ukraine “[On Transplantation of Organs and Other Anatomic Materials to Humans](#)” as of July 16, 1999 No. 1007-14 (hereinafter referred to as the Law On Transplantation).
- **Resolutions of the CMU:**
 - “[Some Issues of the Implementation of the Law of Ukraine On Transplantation of Organs and Other Anatomic Materials to Humans](#)” as of April 24, 2000 No. 695, which sets the list of health care institutions and research institutions that may do transplantation in Ukraine.
 - “[On the Measures Aimed at Organizing Activity of Health Care Institutions and Scientific Institutions Relating to Transplantation of Organs, Tissues and Cells](#)” as of September 05, 2007 No. 1100. Under this resolution, the main institution carrying out clinical testing of tissue and cells transplants shall be the Coordination Centre for Organ, Tissue and Cell Transplantation.
 - “[On Approval of Licensing Provisions for Carrying Out Economic Activity of Banks of Umbilical Blood, Other Human Tissues and Cells according to the List Approved by the Ministry of Healthcare](#)” as of March 02, 2016 No.286.
 - “On Approval of Licensing Provisions for Carrying Out Economic Activity in Medical Practice” as of March 02, 2016 No.285, setting organizational, staff and technological requirements for the material and technical base of the licensee, which are binding for the economic activity in medical practice, including the one relating to transplantation of organs, tissues and cells.
- **Orders of the Ministry of Healthcare:**
 - “[On Provision of Live Family Donors with a Homotransplant for Transplantation](#)” as of April 10, 2012 No. 250.
 - “The Procedure of Carrying Out Clinical Testing of Tissue and Cell Transplants and Examination of the Clinical Testing Materials” as of October 10, 2007 No. 630.
 - “[On Approval of Regulatory Legal Documents on Transplantation](#)” as of September 25, 2000 No. 226, which approves a whole range of acts regulating

transplantation:

1. Guidance on Human Organ Removal from the Donor Corpse;
 2. Guidance on Removal of Anatomic Formations, Tissues, Their Components and Fragments from the Donor Corpse
 3. The List of Human Organs Allowed to Be Removed from the Donor Corpse;
 4. The List of Anatomic Formations, Tissues, Their Components and Fragments and Fetal Materials Allowed to Be Removed from the Donor Corpse and Dead Human Fetus.
 5. Guidance on Bioimplant Production;
 6. Conditions for Ensuring Preservation of Anatomic Materials during Transportation.
- [On Approval of the Procedure of Taking and Temporary Preservation of Umbilical \(Placental\) Blood and/or Placenta](#) as of July 10, 2014 No. 481.
- [On Approval of Licensing Provisions for Carrying Out Economic Activity of Banks of Umbilical Blood, Other Human Tissues and Cells](#) as of February 10, 2012 No. 251.

Analysis of the above regulatory documents shows that in the course of approximation to the European Directives no changes have been made in the applicable legislation, which fact causes norm duplication. Such is the situation with Resolution of the CMU No. 286 “On Approval of Licensing Provisions for Carrying Out Economic Activity of Banks of Umbilical Blood, Other Human Tissues and Cells according to the List Approved by the Ministry of Healthcare” as of March 02, 2016.

Old order of the Ministry of Healthcare No. 251 “On Approval of Licensing Provisions for Carrying Out Economic Activity of Banks of Umbilical Blood, Other Human Tissues and Cells” as of February 10, 2012, regulating the same issue, has not been cancelled yet. We assume that this conflict is caused by the adoption of the Law of Ukraine “On Licensing Types of Economic Activity”, whereby it is the Cabinet of Ministers of Ukraine that shall approve licensing provisions²⁰. To fulfil this regulation, the licensing provisions were adopted by the Resolution of the CMU, but the old order of the Ministry of Healthcare has not been cancelled. As the official response of the Ministry of Healthcare which we have received says, so far in June 2016 the Ministry set up a task force that must bring the resolution into conformity with the European Directives. The question arises why the resolution was not immediately brought into conformity with the European Directives at the project development stage, since any draft resolution of the CMU must undergo obligatory processing in terms of its correspondence to Ukraine’s commitments in the field of European integration²¹.

Analysis of the above regulatory legal acts as well as the implementation plan for the Directives enables us to state that Ukrainian legislation reflects just occasional requirements of those Directives. In particular, the applicable regulatory legal base

20) See part two of art. 9 of the Law of Ukraine On Licensing Types of Economic Activity

21) See paragraph 1 § 35 of the Regulation of the CMU.

in the issues of cell and tissue transplantation allows using a whole spectrum of anatomic material, both of autological, and of allogenic origin, in the clinical practice²². Clinical use of cell and tissue transplants obtained from anatomic material is allowed only after clinical testing is carried out, the requirements for which are clearly set in [Order of the Ministry of Health No. 630](#).

At the same time, a whole range of issues remain not implemented in Ukrainian legislation. In particular, that refers to confidentiality issues: art. 17 of the applicable Law “[On Transplantation](#)” indicates that the data about the recipients as well as about the persons who have declared their consent or disagreement to become donors in case of their death is confidential. However, in our opinion, this is insufficient since the Law “[On Transplantation](#)” does not determine: (1) the procedure ensuring compliance with the confidentiality requirements, (2) the process of information coding, and (3) the procedure for donor register compilation.

This problem could be solved through simple implementation of [Order of the Ministry of Healthcare as of November 29, 2002 No.432](#), which approves the Regulation on the Unified State Transplantation Information System. However, no funding has been provided for the measures aimed at the development of the Unified State Transplantation Information System. The above system was to develop data bases and registers of organs, anatomic materials, bioimplants, which would partially correspond to the requirements of the European legislation on development of the coding system which would enable to trace tissues and cells at all transplantation stages.

Also, Ukrainian legislation needs to be brought into conformity with the Directive in what concerns introduction of the quality system in the institutions working with human tissues and cells, including staff training, procedures of notifying of serious adverse events and reactions, provision of donors with information and their examination before tissues or cells are taken. Besides that, it is necessary to supplement donor selection criteria, additionally develop standards of tissue and cell preparation, their processing and distribution of direct supply of some tissues and cells to recipients²³, as well as to ensure compliance with the European requirements for the tissue and cell quality and safety.

Under the implementation plan, the main regulatory legal steps towards the implementation of the Directives in Ukrainian legislation must be amending the Law “[On Transplantation](#)” (the main performer – the Ministry of Healthcare). However, as of the date the present report is being prepared, no amendments have been made in the Law “[On Transplantation](#).” We draw attention to the fact that art. 3 of the Law “[On Transplantation](#)” excludes the issues of transplantation of reproductive cells, autotransplantation and activity of umbilical blood banks from its field of regulation, though these issues are also within the scope of the Directive’s regulation (though some of those issues are regulated by the acts of the Ministry of Healthcare).

Along with that, on April 21, 2016 in the first reading as the basis there was passed

22) Autological origin appears in case tissues and cells are transplanted to the same person (the donor is the recipient), allogenic origin – tissues and cells taken from one person (donor) are transplanted to the other person (recipient).

23) See the implementation plan for the Directives.

draft law “[On Amending Some Legislative Acts of Ukraine on Health Care and Transplantation of Organs and Other Anatomic Materials to Humans](#)”, developed by the MPs of Ukraine (registration No. 2386a-1). The explanatory document to this draft law indicates that Directive of the EC No. 2010/45/EC on the Standard of Quality and Safety of Human Organs Intended for Transplantation constitutes the basis for it. Let us remind that Directive No. 2004/23/EC refers to transplantation of tissues and cells, and does not include transplantation of organs in the field of its regulation. At the same time, the task force set up in affiliation with the Committee on Health Matters of the Verkhovna Rada of Ukraine headed by the MP O. M. Kyrychenko, which deals with preparation of the draft law for the second reading, has suggested a number of amendments to draft law No. 2386a-1, which enable to approximate to Directive No. 2004/23/EC.

Also, the Committee on Health Matters of the Verkhovna Rada of Ukraine has set up a task force to develop draft law of Ukraine “On Assisted Reproductive Technologies.” This draft law aims to regulate the issues of transplantation of sexual glands, reproductive cells and live embryos, which are currently out of the field of regulation of the Law “On Transplantation” and are regulated by the Order of the Ministry of Healthcare. Namely, the procedure of application of assisted reproductive technologies in Ukraine is regulated by order of the Ministry of Healthcare of Ukraine as of September 09, 2013 No. 787.

EU regulation on tobacco

- Directive No. 2001/37/EC²⁴ on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products
- Directive No. 2003/33/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

What do the respective EU norms provide us with?

Directive No. 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

- regulates the maximum permitted level of tar, nicotine and carbon monoxide and the way of testing their content as well as makes it binding to place this information on the cigarette packaging;
- introduces a ban on oral tobacco consumption;

24) On April 3, 2014 this Directive was cancelled, and to replace it Directive 2014/40/EU of the European Parliament and of the EC Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and accompanying goods and cancellation of Directive 2001/37/EC was adopted. Article 31 of Directive 2014/40/EU indicates that ‘Directive 2001/37/EC is cancelled since May 20, 2016... Reference to the cancelled Directive should be interpreted as reference to this Directive. Since the text of the EU-Ukraine Association Agreement in Ukrainian was published on the official site of the Committee for European Integration of the VRU on June 20, 2013, and the Agreement was initiated in Brussels by heads of negotiation delegations on March 30, 2012, the above Directive 2014/40/EU as of April 3, 2014 technically could not be a part of the official text of the Agreement. Thus, commitments under Annex XLI to the Agreement should be interpreted as Ukraine’s commitments to introduce provisions of Directive 2014/40/EU into national legislation.

- regulates marking of tobacco products through a ban on using terms, inscriptions, trade marks, images, symbolic or any others signs that may be deceptive or create a wrong impression as to the characteristics of the tobacco products on their packaging (the norm is available in Ukrainian legislation)

What has been done to approximate national legislation?

2 draft laws have been registered in the Verkhovna Rada of Ukraine (VRU):

1) draft law “On Amending Some Laws of Ukraine as to Performance of Ukraine’s Commitments under the Association Agreement between the European Union, the European Atomic Energy Community and its Member States, of the one part and Ukraine, of the other part (concerning Manufacture, Presentation and Sale of Tobacco Products, Their Advertising and Sponsorship)”, registration No. 2430-1 as of April 03, 2015, developed to fulfil Directive No. 2001/37/EC available directly in the Association Agreement.

2) Draft law “On Amending Some Laws of Ukraine on Public Health Protection against Harmful Tobacco Impact”, registration No. 2820 as of May 13, 2015, developed to fulfil Directive No. 2014/40/EC, which cancels and replaces Directive No. 2001/37/EC.

Directive No. 2001/37/EC was amended by Directive No. 2014/40/EC, that is its provisions lost effect and implementation of such provisions may seem to be absurd. At the same time, the Association Agreement makes it binding for Ukraine to approximate its legislation to it. Directive No. 2014/40/EC took effect in 2016, and its provisions, as compared to Directive No. 2001/37/EC, are more comprehensive and progressive. Therefore, opinions of law-makers split as to provisions of what Directive need to be implemented. There are advocates of legislation approximation to Directive No. 2001/37/EC, which presupposes basic requirements to the tobacco industry in the country. But at the same time there are people considering approximation to Directive No. 2014/40/EC as the one setting much higher standards of public health and protection against tobacco expedient and logical.

Draft law No. 2430-1 (to fulfil Directive No. 2001/37/EC) presupposes the minimum changes and the maximum deadlines:

- 3 years of transitional period
- regulates the rates of nicotine and tar in cigarettes
- introduces definition of tobacco for oral use.

Respectively, provisions of this draft law may be considered to be the ones that take into account the main requirements of Directive No. 2001/37/EC.

At the same time, draft law No. 2820 (to fulfil Directive No. 2014/40/EC), but for the provisions on the minimum content of tar, nicotine and carbon monoxide in cigarettes and a ban on tobacco for oral use, available in draft law No. 2430-1, sets new and more rigid requirements and standards of protecting residents against tobacco, viz.:

- bans using flavours in cigarettes;

- introduces annual reporting of the tobacco industry to the Ministry of Healthcare as to the composition of tobacco products;
- introduces lower permitted norms of ingredients and secretory products of tobacco products, including the maximum levels of tar, nicotine and carbon monoxide in the cigarette smoke;
- introduces new marking for the packaging of tobacco products, including combined medical cautions that have to be placed on the packs of tobacco products on the 65% of the package area, with annual rotation;
- bans placement of tobacco for oral use on the market;
- regulates sale and presentation of electronic systems of nicotine supply (electronic cigarettes) and their fuelling containers as well as herbal products designed for smoking;
- regulates marking of tobacco products through a ban on using terms, inscriptions, trade marks, images, symbolic or any others signs that may be deceptive or create a wrong impression as to the characteristics of the tobacco products on their packaging (the norm is available in Ukrainian legislation);
- introduces rules of selling and marking herbal smoking mixes;
- bans advertising and promotion of electronic cigarettes;
- introduces requirements for the content of substances and ingredients harmful for human health, that are within tobacco products and are emitted with tobacco smoke during smoking as well as the mechanisms of controlling them
- 2 months of the transitional period²⁵.

It may be stated that the above project contains provisions meeting the requirements of Directive No. 2014/40/EU. Also, a positive thing is that the project has been assessed positively by international partners like the World Health Organization, the World Bank in Ukraine, Smoke Free Partnership, European Network for Smoking and Tobacco Prevention (ENSP) as well as has been supported by the Cabinet of Ministers, the Committee on Health Matters of the VRU, the Committee for European Integration of the VRU.

Among the problems that do not allow law-makers to pass any of the drafts, there may be pointed out availability of transitional period: in draft law No. 2820 that is May 2016, and in draft law No. 2430-1 it makes up three years. Obviously, there is no transitional period envisaged for this period in draft law 2820, and it should be determined in the course of preparation for the second reading, and two months are not enough, since, for example, the EU countries had two years for that. Thus, the EU Member States, while implementing Directive No. 2014/40/EU had some time between the date when it was adopted (April 13, 2014) and the date when it took effect (May 20, 2016). Also, it should be taken into account that the Ukrainian side did not raise the issue of the Directive replacement, therefore, it has not got the official

²⁵) The issue of transitional period must be settled between the first and the second reading in the VRU

consent of the EU thereto, though there is no ban either. If the consent was available, Ukraine would be entitled to approximate to Directive No. 2014/40/EU without any additional approvals.

What do the respective EU norms provide us with?

Directive No. 2003/33/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

- sets a ban on advertising and sponsorship of cigarettes and other tobacco products in printed mass media, during provision of information services and radio broadcasting.

What has been done to approximate national legislation?

The applicable Ukrainian legislation meets almost all provisions of Directive No. 2003/33/EC in relation to advertising and sponsorship of tobacco products, besides that, the Law of Ukraine "On Advertising", viz. article 22, sets that advertising of tobacco products shall be banned on the Internet, but for web sites designed for people of majority age, an obligatory condition of accessing which is preliminary identification of the user age²⁶. While the EU norms envisage a ban without any exceptions relating to the age of the user of information services (advertising). Respectively, Ukraine must fully ban advertising of tobacco products on the Internet.

Draft law No. 2820 "On Amending Some Laws of Ukraine on Public Health Protection against Harmful Tobacco Impact", developed to approximate Ukrainian legislation to Directive No. 2014/40/EU, envisages amendments in the Law of Ukraine "On Advertising", which eliminate from the text of the Law provisions on permitting advertising for people of majority age. In this version the Law will fully meet the requirements of Directive No. 2003/33/EC.

26) Explanatory note to draft law No. 2820 On Amending Some Laws of Ukraine on Public Health Protection against Harmful Tobacco Impact*



Conclusions

The analysis of the implementation of the Association Agreement as to legislation approximation as of November 1, 2016 has revealed the following trends. The legislation approximation is most successful in the field of public procurement and energy. One of the reasons influencing this success is active standpoint of the main responsible institutions as well as the fact that the approximation process was launched 2 years ago. Also, the field of taxation is rather a success since the applicable Ukrainian legislation is mostly already approximated to the European Directives. In other fields like environment, public health, social policy and company operation, legislation approximation is slow. The factors curbing the process include the following:

- insufficient staff capacity of the responsible institutions to ensure the process of legislation approximation. In some fields like environment there are a great number of commitments, and to perform all of them in time it is necessary to involve a great number of environmental experts.
- lack of attention to the norms of the applicable legislation in the course of legislation approximation that causes norm duplication;
- the EU acts regulate very many fields and affect the interests of different stakeholders for which approximation of the European norms is an expensive process. Respectively, quite often the above stakeholders resist the process of Ukrainian legislation approximation to the EU requirements.

Also, in each field there have been traced special features of Ukrainian legislation approximation to the EU legislation.

Public procurement

- Ukraine has performed its commitments in the field of public procurement under the Association Agreement, the deadline for which was 2016:
 - it has designated the Ministry of Economic Development and Commerce as the authorized body carrying out the policy in the field of public procurement, and the Antimonopoly Committee of Ukraine – as the body that may revise decisions of customers;
 - the Law “On Procurement” sets the requirements for the process of procurement agreement conclusion;
 - it has adopted the ‘Roadmap’ aimed at stage-by-stage reform of public procurement.
- Ukraine is, in fact, successfully completing the first stage of public procurement reform in accordance with the ‘Roadmap’ as to approximation to some provisions of Directive No. 2014/24/EU.

Energy

Energy marking of household appliances

- Currently, development of the national system of energy marking of energy-absorbing products in Ukraine is within the responsibility of the State Agency for Energy Efficiency and Energy Saving, which must adopt the respective technical standards.
- In 2013 Ukraine approximated its legislation to the requirements of the Framework Directive No. 2010/30/EU, laying down the general principles of the system of energy marking in the country as well as started development and approval of detailed technical regulations for the set types of energy-absorbing products. As of November 01, 2016 four such regulations were adopted and came into effect (for refrigerators, washing machines, dish-washers as well as electric lamps and lights), 5 draft regulations are pending adoption.
- The main problem today, impeding completion of adoption of a full package of technical regulations on energy marking is a complex and slow system of approving such draft regulations along the vertical of the Cabinet of Ministers.
- As far as implementation of the already adopted regulations is concerned, for 4 types of household appliances it has become binding and is followed by producers and importers of such technology, but institutional capacity of the state to control reliability of the information provided still remains weak.

Nuclear energy

- As of November 01, 2016 Ukraine was still implementing the norms of 3 EU Directives in the field of nuclear energy regulating the basics of nuclear safety of nuclear installations, standards of protection from radiation as well as supervision and control over transportation of radioactive waste and spent nuclear fuel. The norms of those Directives set the task for Ukraine to meet still more rigid safety standards in the field of nuclear energy that have been introduced in the EU (as well as at the level of IAEA in general) after the accident in the Nuclear Power Station in the city of Fukushima (Japan).
- From the point of view of approximation of national legislation to the EU norms, the most serious progress has been made in the development of by-laws to fulfil the requirements of Directive No. 2014/87/Euroatom, but the changes requiring amending the laws or acts of the Cabinet of Ministers (for instance, establishment of a new regulator in the field of nuclear safety, amending the standards of protection against radiation, etc.) are, in fact, blocked because of unsatisfactory work of the Parliament and delayed procedure of draft approval at the level of the Cabinet of Ministers.
- The implementation of the already accepted changes is successful, including within the projects of IAEA and other international organizations, with the focus on the measures aimed to improve safety of nuclear installations in Ukraine and perform the project of construction of spent nuclear fuel storage in the area of the Chernobyl Nuclear Power Station.

Taxation

- In spite of a considerable progress achieved, Ukraine has failed to fully approximate national legislation to the requirements of two EU Directives regulating the issues of excise duty.
- Unification of the list of goods, consumption or use of which is subject to taxation with excise duties, set by the norms of Directive No. 2008/118/EC, is still ongoing. Most goods subject to excise duty payment in Ukraine meets the EU norms, and the list of goods subject to excise duty payment has been expanded due to inclusion of electric power into it. But the logic of the European Directive requires also inclusion of other alternative energy products to this list, in particular, those of biological origin, as well as a wide range of other mineral products.
- Unification of the structure and rates of excise duty applied in Ukraine, in accordance with the requirements of Directive No. 2011/64/EU, is almost over. The only aspect left is approximation of Ukrainian legislation to the European norm relating to non-standard size cigarettes, which is set by p.2 of art. 3 of the Directive, and its implementation at the level of by-laws.

Environment

- The field of environment is one of the field with a considerable number of commitments, and possibly that has become one of the factors that impedes the approximation process. Besides that, environment is not a priority on the national reform agenda, which fact also influences the speed of the EU environmental legislation implementation.
- A correct step was the fact that the Ministry of Nature started legislation approximation with the most systemic directions, like development of draft laws on environmental impact assessment and strategic environmental assessment. But, possibly because during draft law development the interests of all stakeholders were not taken into account and no sufficient and active clarifications on the social and environmental importance were provided, that the draft laws have been vetoed.
- With quite a number of commitments, a positive step has been made only towards the approximation to the Water Directive, but even adoption of the Law cannot be considered to be a complete approximation to the Directive's provisions. Such a result testifies to possible available problems that are not voiced.
- In each of the eight fields in which approximation is under development, there are directives and regulations approximation of which takes more time than the law-making activity requires. These are Directives on the environmental impact assessment and strategic environmental assessment, on public access to information, the GMOs, habitats, sulphur and industrial waste.
- Special attention is paid to directives and regulations approximation to which has not been started for unknown reasons, viz. Directive on habitat protection, bird protection, control of emissions of volatile compounds, marine environment and greenhouse gas emission trading.

Social policy

- The period of implementation of both Directives in the field of health and safety which is set by the Association Agreement has already expired. The applicable legislation of Ukraine contains some norms that meet the main provisions of the Directive relating to the requirements for health and safety of workers of mineral-extracting industries. However, for complete approximation to the Directives it is necessary to pass draft Order of the Ministry of Social Policy “On Approval of the Minimum Requirements for Improving Health and Safety of Workers in Mineral-Extracting Industries through Drilling” and draft Order of the Ministry of Social Policy “On Approval of the Minimum Requirements for Improving Health and Safety of Workers in Surface and Underground Mineral-Extracting Industries.”
- So far no conclusion can be made about the correspondence of the developed draft regulatory legal acts to the requirements of Directives since they have not been made public.

Company operation

Approximation work is under developed:

- In the field of making information on companies public there is already certain progress achieved, in particular, in the aspect of access to data in the USR. While access to registration files of companies is still not provided.
- In the field of corporate governance work is being done on the implementation of a whole range of the EU acts, but it is not known what the approximate periods of this implementation will be. In any case, the deadline for complete implementation of the Second Directive has already expired.
- No work is being done on implementation of the requirements for making information about the branches of foreign companies public.
- In Ukraine the IFRS are used in a narrower sense than the one envisaged by Regulation No. 1606/2002.

Public health

Field: tissues, cells and organs

- As of November 1 Directive No. 2004/23/EC, Directive No. 2006/17/EC and Directive No. 2006/86/EC were not adapted.
- The applicable legislation only partially meets the requirements of directives on transplantation as to the possibility of using a whole spectrum of anatomic materials in clinical practice: both autological, and allogenic one; clinical use of cell and tissue transplants is allowed only after clinical testing. However, so far confidentiality provision is not yet fully approximated, the quality system in the institutions working with human tissues and cells has not been introduced, the standards of tissue and cell preparation have not been finalized.
- Adoption of the draft law “[On Amending Some Legislative Acts of Ukraine](#)”

[on Health Care and Transplantation of Organs and Other Anatomic Materials to Humans](#)” developed by the MPs of Ukraine (registration No.2386a-1) with amendments suggested by the task force and draft law of Ukraine “On Assisted Reproductive Technologies” will enable to adapt Directive No. 2004/23/EC, Commission Directive No. 2006/17/EC and Commission Directive No. 2006/86/EC as well as to start development of regulatory legal acts that will regulate activity in the field of transplantation.

Field: Tobacco

- Already for more than a year approximation of Ukrainian legislation to the European standards in the field of tobacco has been put off.
- Draft laws No. 2430-1 and No. 2820 are with different committees, which, according to the Regulation of the VRU, cannot make them alternative ones, but such was the conclusion of the Regulation Committee. Such status leads to the situation when the above draft laws must be considered only simultaneously. Consideration of draft law No. 2430-1 is put off, which, respectively, makes it impossible to consider draft law No. 2820, and which, in its turn, violates the approximation periods set by the Association Agreement.
- Due to delays in the consideration of draft law No. 2820, which has mainly been developed in accordance with the provisions of Directive No. 2014/40/EC, fulfilment of commitments under Directive No. 2003/33/EC that are prescribed in the above draft law may be at risk, though partially Ukraine fulfilled those commitments in 2012 when it amended article 22 of the Law of Ukraine “On Advertising.”

Recommendations

For the sake of efficient implementation of the Association Agreement and approximation of national legislation to the EU legislation it is necessary to involve the responsible institutions, specialty experts in the EU law in the work. Also, there should be developed the mechanism for accelerated approval of draft laws aimed to implement the Association Agreement. For instance, some hours may be set for the European integration draft laws on each day of sessions.

Public procurement

- In future, to fully harmonize the Law “On Procurement” with Directive No. 2014/24/EU.

Energy

Recommendations on legislation approximation

Energy marking:

- To raise the status of the State Agency for Energy Efficiency and Energy Saving of Ukraine as compared to other executive authorities, providing it with the authorities of the central body responsible for implementation of the policy in the field of energy efficiency. This, in turn, will facilitate the process of development and approval of the necessary regulatory acts.
- To approve four already developed technical regulations on conventional ovens and kitchen hoods, air conditioners, drying machines and TV sets.
- After Directive No. 96/60/EC is updated in the EU, to develop and adopt technical regulation on household combined washer-dryer.

Nuclear energy:

- To add to the official list of Ukraine’s commitments under the Association Agreement Council Directive No. 2014/87/Euroatom establishing a Community framework for the nuclear safety of nuclear installations (amending Directive No. 2009/71/Euroatom).
- To approve and adopt in the Parliament the draft law on the body of state regulation of the safety of nuclear energy use – the National Commission for Nuclear and Radiation Safety Regulation.
- To adopt draft law [No. 3858](#) that has been re-agreed by the related ministries and is currently with the Ministry of Justice for the legal examination purposes.
- To adopt a number of draft regulatory acts of the State Inspection for Nuclear Regulation of Ukraine which are under agreement by the related ministries (see above).
- To develop the National Action Plan (state target-oriented program) on

Reduction of the Risks of Long-Term Irradiation with Radon Products.

- To adopt draft resolution of the Cabinet of Ministers of Ukraine “On Amending the Procedure of Granting Permission for Carrying Out International Transportation of Radioactive Materials.”

Recommendations on implementation:

Energy marking:

- To create an efficient system of state control over compliance with energy marking standards by producers and importers of household appliances.
- To complete the reform of the technical regulation system that will enable to determine Ukrainian energy marking standards in the EU and vice versa.

Nuclear energy:

- Additional implementation steps will be necessary after a package of amendments in the legislation is adopted.

Taxation

Recommendations on legislation approximation

- To complete the process of unification of Ukrainian national legislation as to alternative energy products, in particular, biofuel and its biological components, as well as coal; coal, water or generator gas; resins, mineral and vegetable oils (soy, peanut, olive, palm and other oils); animal and vegetable fats; vaseline, paraffin, coke and bitumen (to take into account the requirements of Directive No. 2008/118/EC).
- To introduce to national legislation on the norm on non-standard size cigarettes (to take into account the requirements of paragraph 2 of article 3 of Directive No. 2011/64/EU).

Recommendations on implementation:

- All amendments relating to excise duties do not require any significant additional implementation steps at the current stage since the respective legislation has been implemented in Ukraine and has been in effect for already quite a long time.

Environment

- For successful completion of approximation of environmental legislation, viz. Adoption of the Laws “On Environmental Impact Assessment and On Strategic Environmental Assessment”, it is necessary either to give the draft laws back for additional development (as the President of Ukraine requests), and then this will testify to the repetition of the law adoption procedure, or it is necessary to overcome the veto which seems to be hardly realistic, due to lack of agreement with the President, and, therefore, his faction.
- For the approximation to take place within the periods set by the Association Agreement, it is worth accelerating the process of regulatory acts development

and conduct the approval procedure with due account of all the stakeholders at once.

- During the implementation of the respective directives or regulations it is necessary to provide for a wide public dialogue as well as for multilateral consultations with stakeholders at the stage of conceptual decisions development, and not in the ready draft regulatory acts phase.

Social policy

- To make draft Orders of the Ministry of Social Policy on approval of the minimum requirements for improving health and safety of workers of mineral-extracting industries through drilling and workers in surface and underground mineral-extracting industries public.

Company operation

- Within the framework of approximation to Directive No. 2009/101/EC to ensure access to registration files of companies (at least limited liability companies and joint-stock companies).
- The Cabinet of Ministers of Ukraine should appoint the responsible performer of the Eleventh Directive that will develop its implementation plan.
- To consider expediency of expanding the scope of the IFRS application in Ukraine under the basic rule of Regulation 1606/2002.

Public health

Field: tissues, cells and organs

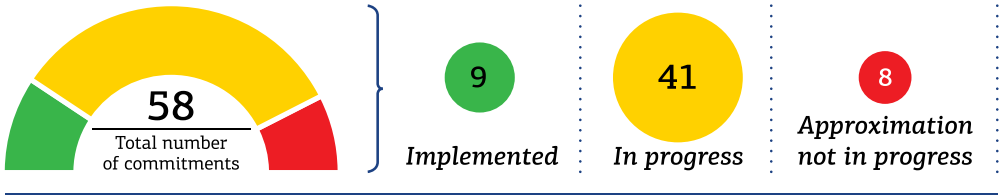
- To adopt the draft law “On Amending Some Legislative Acts of Ukraine on Health Care and Transplantation of Organs and Other Anatomic Materials to Humans”, registration No. 2386a-1
- To accelerate development of the draft law “On Assisted Reproductive Technologies”
- To remove duplications in the applicable regulatory acts regulating the field of cell and tissue transplantation in Ukraine.

Field: Tobacco

- Primarily, it is worth coordinating it with the EU side to what Directive Ukraine should approximate its legislation, to avoid future misunderstanding on fulfillment of commitments within the framework of the Association Agreement implementation.
- It is worth considering draft laws No. 2430-1 and No. 2820 not as alternative ones, but considering them as separate ones, that will help speed up their consideration and approval, on the one hand, and will enable to consciously fulfill commitments within the Association Agreement as well as to improve standards in the field of public health, on the other hand. That will be an additional bonus for Ukraine to the EU.

ANNEX 'A'

The list of commitments in approximation of Ukrainian legislation within the framework of the previous and current reports within the Association Agreement (2014 – 2016)

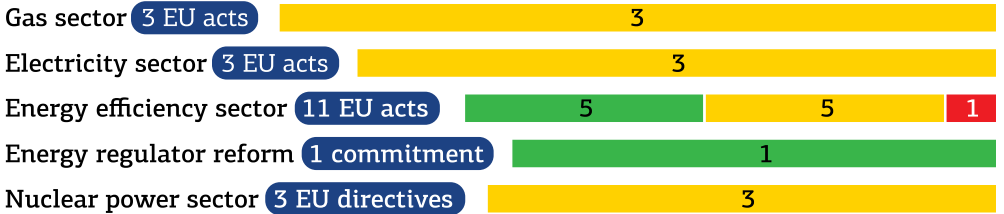


Energy

6

14

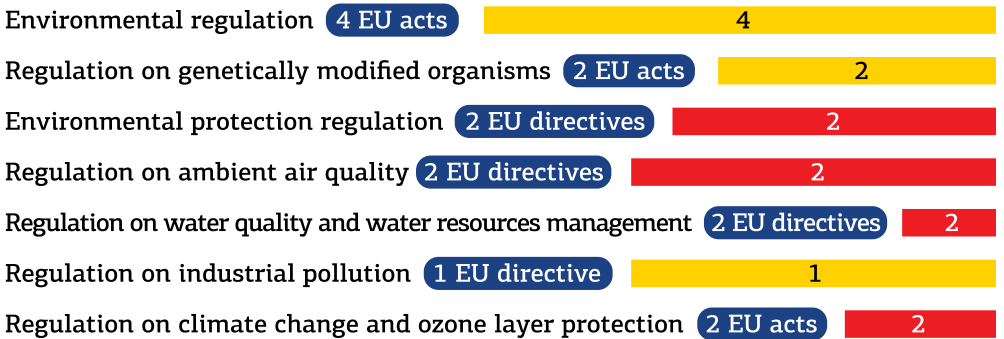
1



Environment

9

6



Transport

3





Public health

8

Infectious diseases sector **3 EU decisions**

3

Tobacco sector **2 EU directives**

2

Sector of tissues, cells and organs **3 EU directives**

3



Social policy

2

Health and safety sector **2 EU directives**

2



Company operation

3

1

Company establishment sector **1 EU directive**

1

Sector – protection of the rights of shareholders and creditors **2 EU directives**

1

1

Sector – accounting and audit **1 EU regulation**

1



Taxation

2

Indirect taxation section **2 EU directives**

2



Sanitary and phytosanitary measures

1

1

Program document development **1 assignment**

1

Adoption of the Strategy for the implementation of Chapter IV (Sanitary and Phytosanitary Measures)

Sector of basic legislation in the field of public health **1 EU regulation**

1



Public procurement

3

Program document development **1 commitment**

1

Adoption of the 'Roadmap' in the field of public procurement

Approximation of art. 151 of the Association Agreement **1 commitment**

1

To introduce the main standards regulating the procedure for concluding public contracts

Approximation of art. 150 of the Association Agreement **1 commitment**

1

To designate two state authorities responsible for the policy in the field of public procurement and customer decision revision

ANNEX 1

The status of implementation of the requirements of Directive 2008/118/EC concerning alternative energy products, in particular, biofuel and its biological components

Provisions of the EU act subject to implementation	Norms of the Ukrainian legislation regulating the respective subject of commitments	Status of implementation and specific comments.
<p>1. This Directive lays down general arrangements in relation to excise duty which is levied directly or indirectly on the consumption of the following goods (hereinafter – ‘excise goods’):</p> <p>a) energy products and electricity covered by Directive 2003/96/EC;</p> <p>b) alcohol and alcoholic beverages covered by Directives 92/83/EEC and 92/84/EEC;</p> <p>c) manufactured tobacco covered by Directives 95/59/EC, 92/79/EEC and 92/80/EEC</p>	<p>14.1.145. Excise goods (products) are the goods with codes under the UKT ZED (Ukrainian Classifier of Goods for Foreign Economic Activity), for which the present Code sets excise tax rates;</p> <p>Article 215. Excise goods and tax rates</p> <p>215.1. Excise goods include:</p> <ul style="list-style-type: none"> - ethyl alcohol and other alcohol distillates, alcoholic beverages, beer; - tobacco products, tobacco and commercial tobacco substitutes; - fuel; - motor cars, auto bodies to them, trailers and semi-trailers, motorcycles, means of transport designed for transportation of 10 and more persons, means of transport for freight transportation; - electric power. 	<p>Partly implemented.</p> <p>The list of excisable goods under national law is incomplete.</p>
<p>2. Member States may levy other indirect taxes on excise goods for specific purposes, provided that those taxes comply with the Community tax rules applicable for excise duty or value added tax as far as determination of the tax base, calculation of the tax, chargeability and monitoring of the tax are concerned, but not including the provisions on exemptions.</p>	<p>1.1. The Tax Code of Ukraine sets an exhaustive list of taxes and duties to be paid in Ukraine as well as the procedure of their administration, as well as responsibility for violation of tax legislation.</p>	<p>Provisions of a general nature</p>
<p>3. Member States may levy taxes on:</p> <p>a) products other than excise goods; the supply of services, including those relating to excise goods, which cannot be characterised as turnover taxes.</p> <p>However, the levying of such taxes may not, in trade between Member States, give rise to formalities connected with the crossing of frontiers.</p>	<p>215.1. Excise duties include:</p> <ul style="list-style-type: none"> - motor cars, auto bodies to them, trailers and semi-trailers, motorcycles, means of transport designed for transportation of 10 and more persons, means of transport for freight transportation; <p>215.3.4. ‘fuel’</p> <p>2901 10 00 00 Hydrocarbons acyclic saturated</p> <p>2905 11 00 00 Methanol technical (methyl alcohol)</p> <p>2909 Other simple ethers, ethereal alcohols, ether phenols, ether alcohol phenols</p> <p>3811 Antidetonation agents</p> <p>3826 Biodiesel and its mixtures</p> <p>3824 90 97 10 Fuel motor alternative</p>	<p>Fully implemented.</p> <p>National legislation provides features excise tax other than that specified list of common goods.</p>

ANNEX 2

The status of implementation of the requirements of Directive 2008/118/EC on taxation of energy carriers, electricity and any product used as fuel for means of transport, or as an admixture, or as a filler for fuel

Provisions of the EU legislative act subject to implementation	The list of excise goods in the EU falling within the definition 'energy products'	The list of Ukrainian excise goods falling under the definition 'fuel'
Paragraphs 2 and 3 of article 2 Directive 2003/96/EC	Combined EU nomenclature	Article 215, paragraph 215.3.4. 'fuel' of the Tax Code of Ukraine (according to codes under the UKT ZED (Ukrainian Classifier of Goods for Foreign Economic Activity))
<p>2. For the purposes of this Directive, the term 'energy products' shall apply to products:</p> <p>(a) falling within CN codes 1507 to 1518, if these are intended for use as heating fuel or motor fuel;</p> <p>(b) falling within CN codes 2701, 2702 and 2704 to 2715;</p> <p>(c) falling within CN codes 2901 and 2902;</p> <p>(d) falling within CN code 2905 11 00, which are not of synthetic origin, if these are intended for use as heating fuel or motor fuel;</p> <p>(e) falling within CN code 3403;</p> <p>(f) falling within CN code 3811;</p> <p>(g) falling within CN code 3817;</p> <p>(h) falling within CN code 3824 90 99 if these are intended for use as heating fuel or motor fuel.</p> <p>3. This Directive shall also apply to Electricity falling within CN code 2716.</p>	<p>1507 Soya oil and its fractions, regardless of refining, but not chemically modified</p> <p>1508 Groundnut oil and its fractions, regardless of refining, but not chemically modified</p> <p>1509 Olive oil and its fractions, regardless of refining, but not chemically modified</p> <p>1510 Other oils and their fractions obtained exclusively from olives, regardless of refining, but not chemically modified, in particular mixtures of such oils or fractions with oils or fractions under code 1509</p> <p>1511 Palm oil and its fractions, regardless of refining, but not chemically modified</p> <p>1512 Sunflower oil, safflower, cotton oils, regardless of refining, but not chemically modified</p> <p>1513 Coconut (copra) oil, palm kernel oil or babasu oil and their fractions, regardless of refining, but not chemically modified</p> <p>1514 Rape, rabsen-seed, or mustard oil and their fractions, regardless of refining, but not chemically modified</p> <p>1515 Other solid vegetable fats and oils (in particular, jojoba oil) and their fractions, regardless of refining, but not chemically modified</p> <p>1516 Animal or vegetable fats and oils and their fractions, partially or fully hydrated, etherified, re-etherified or elaidyled, regardless of refining, but not chemically modified</p> <p>1517 Margarine; edible mixtures or semi-finished products of vegetable or animal fats or fractions of different fats or oils of this section, other than edible fats, or oils, or their fractions</p> <p>1518 Animal or vegetable fats and oils and their fractions, boiled, oxidized, dehydrated, sulphur-processed, oxygenized, polymerized thermally in vacuum or in inert gas or otherwise chemically modified, but for the ones indicated in line 1516; non-edible mixtures or materials of animal or vegetable fats or of fractions of different fats or oils of this section, which have not been indicated or included</p> <p>2701 Coal; briquette, ovoid and similar solid fuel made of coal</p>	<p>Goods under codes 1507-1518 are not considered excise goods</p> <p>Goods under codes 2701, 2702, 2704, 2705, 2706 are not considered excise goods</p>

	<p>2702 Brown coal (lignite), regardless of concentration, but for dark brown coal</p> <p>2704 Coke and semi-coke of coal, lignite or peat, regardless of concentration</p> <p>2705 Coal gas, water gas, generator gas and similar gases, other than oil gases and other gaseous hydrocarbons</p> <p>2706 Pitch, distilled from coal, lignite or peat and other mineral pitches, regardless of dehydration or partial refining, in particular, diluted pitches</p> <p>2707 Oils and other products of coal pitch distillation at high temperature; similar products, in which the shares of ethereal-oil components exceeds the share of other components</p> <p>2708 Petroleum pitch and pitch coke obtained from coal pitch or other mineral pitches</p> <p>2709 Mineral oils and oils obtained from raw bituminous minerals</p> <p>2710 Mineral oils and oils obtained from bituminous minerals, other than raw ones; materials not indicated in other places, containing in their weight 70% or more of mineral oils, or oils obtained from bituminous minerals, where such oils constitute a component of such semi-finished products; spent oils</p> <p>2711 Oil gases and other gaseous hydrocarbons</p> <p>2712 Vaseline, solid paraffin, microcrystal paraffin, ozokerit, mineral wax, peat wax, other mineral waxes and similar products obtained through synthesis or other processes, regardless of enrichment</p> <p>2713 Oil coke, oil bitumen and other remains of mineral oils and oils obtained from bituminous minerals</p> <p>2714 Bitumen and natural asphalt, bituminous or oil shale and bituminous sand, asphaltite and asphalt natural bitumen</p> <p>2715 Bituminous mixtures based on natural asphalt, natural bitumen, oil bitumen, semi-liquid natural bitumen or pitch of the latter (for instance, bituminous lubrications, diluted products)</p>	<p>2707 aromatic mixtures of hydrocarbons, benzene, toluene, xylene</p> <p>goods under codes 2708 and 2709 are not considered excise goods</p> <p>2710 distillates (light, medium and heavy), gasolines, kerosene, separate fuel types</p> <p>2711 liquefied gas natural and other gases</p> <p>goods under codes 2711-2715 are not considered excise goods</p>
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