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# THE DEVELOPMENT OF UKRAINE'S SANITARY AND PHYTOSANITARY OFFICIAL CONTROLS LEGISLATION IN LIGHT OF EU LAW

# DESENVOLVIMENTO DA LEGISLAÇÃO UCRANIANA SOBRE CONTROLE SANITÁRIO E FITOSSANITÁRIO DO ESTADO À LUZ DA LEGISLAÇÃO DA UE

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**Abstract:** The study deals with the issues of aligning Ukraine's national legislation on official controls in the field of food safety, animal and health with the recent developments in the relevant EU law. It is argued that according the `farm to fork` approach the scope of Ukraine's legislation on official controls has to be extended along the entire agri-food chain, covering in particular plant health. Since proper risk-assessment is crucial to the planning of official controls, Ukraine needs an IT system similar to that of the EU, integrating data about various factors affecting food safety, animal and plant health and facilitating the collection, processing, exchange and use of data and documents relating to official controls. A wider application of digital technologies might also help prevent corruption that may result from the application of such discretionary concepts as suspicion of non-compliance, which is a legal basis for unscheduled official controls. It is also argued that addressing these issues requires a new of the Law of Ukraine on official controls over the compliance with sanitary and phytosanitary legislation, which has to be in conformity with the relevant EU law.

**Keywords:** official control, food safety, sanitary and phytosanitary measures, legislative alignment, EU law

**Resumo:** O estudo trata das questões de alinhamento da legislação nacional da Ucrânia sobre controles oficiais no campo da segurança alimentar, animal e saúde com os recentes desenvolvimentos na legislação pertinente da UE. Argumenta-se que, de acordo com a abordagem "da fazenda ao garfo", o escopo da legislação ucraniana sobre os controles oficiais deve ser estendido ao longo de toda a cadeia agroalimentar, abrangendo em particular a fitossanidade. Uma vez que uma avaliação de risco adequada é crucial para o planejamento de controles oficiais, a Ucrânia precisa de um sistema de TI semelhante ao da UE, integrando dados sobre vários fatores que afetam a segurança alimentar, saúde animal e vegetal e facilitando a coleta, processamento, troca e uso de dados e documentos relativos aos controlos oficiais. Uma aplicação mais ampla de tecnologias digitais também pode

ajudar a prevenir a corrupção que pode resultar da aplicação de conceitos discricionários como suspeita de não conformidade, que é uma base legal para controles oficiais não programados. Argumenta-se também que abordar essas questões requer uma nova Lei da Ucrânia sobre controles oficiais sobre o cumprimento da legislação sanitária e fitossanitária, que deve estar em conformidade com a legislação pertinente da UE.

**Palavras-chave:** controle oficial, segurança alimentar, medidas sanitárias e fitossanitárias, alinhamento legislativo, direito da UE.

## 1. Introduction

It is common knowledge that sanitary and phytosanitary measures are essential for the protection of human, animal and plant health. Besides, it is also clear that animal and plant health has a significant impact on human health through the food chain. So, ultimately the main focus of sanitary and phytosanitary measures is on the protection of human health. Therefore, sanitary and phytosanitary measures are particularly important for the implementation of some provisions of Ukraine's Constitution, namely the provisions of article 3 recognizing human life and health as the highest social values (Constitution of Ukraine, 1996).

Judging from the analysis of the EU law, the protection of human health is also one of the priorities for the EU. In accordance with article 168 (4) (b) of the Treaty on the functioning of the European Union the European Parliament and the Council are authorized to adopt measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health (the Treaty on the functioning of the European Union, 2012). Acting in conformity with this priority the EU has developed a massive body of law on food safety, animal health and plant health, including a large piece of legislation dedicated to the organization of official controls in this area.

In recent years there has been a significant effort to update the EU legislation in this field. In this regard, it is important to point out that the original Regulations No 854/2004 and No 882/2004 have been replaced by the subsequent EU Regulation No 625/2017 (Pettoello-Mantovani & Olivieri, 2022). The adoption of this new regulation represents a major step forward in the evolution of the EU legislation on official control over the compliance with food safety, animal health and plant health requirements. This latest development in the EU law is particularly important for Ukraine as a country aspiring for membership in the EU. In light of this it is necessary to assess the existing issues of the current legislation of Ukraine governing the performance of official controls in this area and suggest ways of addressing these issues, taking into account recent developments in the EU law.

## 2. Literature Review

Despite the importance of issues concerning the alignment of Ukraine's legislation on official controls in the areas of food safety, animal and plant health with the relevant EU law, they have not been properly addressed by Ukrainian legal scholars. That's why this study is largely based on comparative analysis of the Ukrainian and the EU law as well as relevant scientific findings of European scientists and scholars in the field of food science, food safety, public administration and information technology. In particular, the concept of "farm to fork" underlying the EU food law was explored, taking into account the research carried out by H. Schebesta and J.J.L. Candel (Schebesta, Candel, 2020). Factors relevant to risk-based approach used for planning inspections were examined thanks to the research findings of E.D. van Asselt, Y. Hoffmans, E.F. Hoek- van den Hil, H.J. van der Fels-Klerx (van Asselt, Hoffmans, Hoek-van den Hil, van der Fels-Klerx, 2021). The study of discretionary powers in public administration, carried out by B. Chand (Chand, 1949), was also taken into consideration. The research on the use of digital technologies in combating corruption, carried out by D. Darusalam, M. Janssen, K. Sohag, N. Omar, J. Said, M.I. Merhi, I. Adam, M. Fazekas (Darusalam, Janssen, Sohag, Omar, Said, 2021; Merhi, 2022; Adam, Fazekas, 2021) turned out to be useful as well.

## 3. Methodology

The methodology of this study involves the use of general scientific research methods such as analysis and synthesis as well as well the logical method of research. These methods are applied throughout the whole article for the purpose of identifying the main issues of aligning Ukraine's legislation on sanitary and phytosanitary official controls with the relevant EU legislation and finding solutions to these issues. In addition, the comparative method of research is used for collating the Ukrainian and the EU legislation. Besides, the historical research method is applied for exploring the main stages in the development of Ukraine's legislation on official controls in the field of food safety, animal health and plant health as well as the relevant EU law.

## 4. Results and Discussion

In Ukraine the most fundamental laws in the field of food safety, animal health and plant health were adopted in the first decade of independence. They were the Law of Ukraine "On veterinary medicine" of 25.06.1992, the Law of Ukraine "On the quality and safety of food and food raw materials" of 23.12.1997 and the Law of Ukraine "On the protection of plants" of 14.10.1998 (Law of Ukraine, 1992; Law of Ukraine, 1997; Law of Ukraine, 1998). However, in those days the laws were often the legacy of the former Soviet system of sanitary and phytosanitary measures. This legislation needed an overhaul. The first major wave of amendments came when Ukraine joined the World Trade Organization in 2008.

The second wave of legislation reform in this field is closely intertwined with Ukraine's efforts to join the EU. Ever since the signing of the Association Agreement with the EU in 2014 Ukraine has been trying very hard to bring its legislation in line with the requirements of the EU law. In recent years there have been a lot of major changes in Ukraine's national legislation on food safety and animal health. First of all, the Law of Ukraine "On the quality and safety of food and food raw materials" received a complete overhaul and was set out in a new edition with a new title "On the basic principles and requirements for food safety and quality". This Law of Ukraine was brought in line with the fundamental acts of the EU legislation on food safety, including Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin (the European Parliament and the Council, 2002; the European Parliament and the Council, 2004; the European Parliament and the Council, 2004).

The Law of Ukraine "On veterinary medicine" received its new edition in February, 2021. The new version of this Law of Ukraine is also based on the provisions of the relevant EU legislation, in particular Regulation (EU) No 2016/429 on transmissible animal diseases and Regulation (EU) 2019/6 on veterinary medicinal products (the European Parliament and the Council, 2016; the European Parliament and the Council, 2019).

Another significant milestone in the development of Ukraine's sanitary and phytosanitary legislation was the adoption of the Law of Ukraine "On the safety and hygiene of feed" in December, 2017. This particular law contains important legal provisions for ensuring animal health as well as human health considering the indirect impact of feed on human health through the food chain. This Law of Ukraine incorporates the requirements of the EU feed law, primarily

Regulation (EC) No 183/2005 laying down requirements for feed hygiene, Regulation (EC) No 1831/2003 on additives for use in animal nutrition and Regulation (EC) No 767/2009 on the placing on the market and use of feed (the European Parliament and the Council, 2005; the European Parliament and the Council, 2003; the European Parliament and the Council, 2009).

At present these laws make up Ukraine's primary legislation containing basic rules on ensuring food safety, including the safety of feed, as well as animal health. These rules can be regarded as material law. At the same time the provisions of this legislation cannot be properly enforced without official control on the part of the public authorities. That's why there need to be certain control procedures aimed at the enforcement of this legislation. In other words, in order for the material law to be properly enforced there has be procedural law in place enabling the public authorities to carry out official controls over the compliance with the requirements of the material law in the field of food safety and animal health. The relevant procedural rules are set out in the Law of Ukraine "On the official control over the compliance with the legislation on food, feed, animal by-products, animal health and welfare" of 18.05.2017 No 2042. This Law was also developed on the basis of relevant EU legislation, namely Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (the European Parliament and the Council, 2004).

Many provisions of this Law are quite new and challenging for Ukraine. Therefore, there is a need for in-depth analysis and discussion of the legal issues arising in connection with the implementation of the relevant provisions on official controls. This is particularly important in light of the fact since 2017 the EU has moved forward and enacted new legislation on official controls in this field, namely Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (the European Parliament and the Council, 2017). The adoption of this regulation once again caused the need for Ukraine to update its national legislation on official controls and align it with the new EU legislation.

The official controls legislation reforms taking place in Ukraine at the moment can be better understood if they are examined against the background of the fundamental concepts and approaches underlying the EU agri-food chain legislation.

One of the most important pillars underpinning the agri-food chain legislation is the "farm to fork" approach. As Hanna Schebesta and Jeroen J. L. Candel point out, the 2000 White Paper on Food Safety already coined a 'farm to table' approach, which over time morphed into

'farm to fork' and established a coherent approach to food safety to further the internal market (Schebesta & Candel, 2020). This approach is built on the notion of agri-food chain, which encompasses the individuals and/or businesses involved in the agricultural production and processing of food, encompassing production, processing, storage, trading, distribution and consumption (Future Learn, 2022). In terms of food safety, the 'farm to fork' approach means that the measures aimed at ensuring food safety have to be applied at all stages of the production, processing, distribution and consumption of food. In particular, this concept implies that animal health and plant health are essential for ensuring food safety as they have a great impact on the raw materials and ingredients used in the production of food.

When it comes to the organization of official controls according to the 'farm to fork' approach official controls over the compliance with the legal requirements on food safety, animal and plant health must be implemented along the entire agri-food chain, involving agricultural production, production, processing, storage, distribution and consumption of food. It essentially means that there has to be an integrated approach to the system of official controls based on the application of uniform official control procedures, comprehensive planning and risk-assessment.

However, in recent years the 'farm to fork' approach has evolved into a concept that goes far beyond food safety. According to the Farm to Fork Strategy of 2020 elaborated by the European Commission, apart from ensuring food security and access to safe food this approach is also supposed to help achieve a number of other goals, such as preserving affordability of food, mitigating climate change, reversing the loss of biodiversity and having a neutral or positive impact on the environment etc. (European Commission, 2020). Therefore, this concept is quite likely to influence the trends of law-making in many other areas alongside agri-food chain and food safety.

As for the implementation of 'farm to fork' approach in the EU legislation on official controls, it is very well described in the preamble of Regulation (EU) 2017/625. According to this preamble, Regulation (EC) No 882/2004 established a single legislative framework for the organization of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of the EU agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the EU as well as the level of protection of the environment from risks that might arise from genetically modified organisms and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.

At the same it is emphasized that there are a number of provisions of the EU agri-food chain legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No882/2004. In particular, specific official control rules were kept in place in Regulation (EC) No1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002. Plant health was also outside the scope of Regulation (EC) No882/2004.

Considering the fact that Regulation (EC) No882/2004 only partially covers the agri-food chain, the preamble of Regulation (EU) 2017/625 goes on to explain that it is necessary to integrate the rules applicable to official controls in specific areas into a single legislative framework for official controls. Thus, the case is made for repealing Regulation (EC) No882/2004 and replacing it with Regulation (EU) 2017/625, which is supposed to establish a harmonized legal framework for the organization of official controls and official activities other than official controls along the entire agri-food chain.

As for the current situation in Ukraine, its legislative framework for official controls is still at the level of Regulation (EC) No882/2004. The Law of Ukraine on official controls covers a large part of the agri-food chain leaving out some important bits like plant health. So, it is time for Ukraine to follow the example of the EU and develop the Law of Ukraine on official controls over the compliance with sanitary and phytosanitary legislation that will replace the existing Law of Ukraine on official controls, adopted in 2017. This reform of the legislation on official controls based on the comprehensive implementation 'farm to fork' concept will ultimately help rationalize and simplify the existing system of official control in the field of food safety, animal health and plant health, enhancing its overall efficiency and making a positive impact on the protection of human health.

Along with the 'farm to fork' concept one of the main foundations underlying the organization of official controls in the field of food safety, animal health and plant health is the risk-based approach. According to the Food and Agriculture Organization of the UN, risk analysis is a structured internationally accepted framework that provides national food safety authorities with a systematic and disciplined approach for making evidence-based food safety decisions. It consists of three interactive components, risk assessment, risk management and risk communication, which serve to develop an estimate of the risks to human health and safety, identify and implement appropriate measures to control the risks, and communicate with stakeholders about the risks and the measures applied (Food and Agriculture Organization, 2022).

The risk-based approach is the cornerstone of scheduling the frequency and timing of official controls with regards to various food, feed and animal establishments as well as relevant imports.

Carrying out official controls on a regular basis and a large scale is costly and time-consuming both for the competent authorities performing relevant checks and for the business operators undergoing them. Even though nowadays many food business operators recognize the importance of official controls and realize that actions taken as a result of inspections enhance the safety of their products (Kalenius & Janne, 2013), it is not sensible to check every single business for irregularities due to budgetary constraints. So, there has to be a clear criterion for determining the frequency and timing of official controls. The general criterion is the level of risk, posed by different food, feed and animal establishments as well as relevant imports crossing the border.

Since different categories of such establishments (food and feed businesses, animal holdings etc.) pose different levels of risk to human health as well as animal and plant health, it makes a lot of sense to apply official controls more often to the establishments posing a high risk and reduce the number of official controls applied to establishments posing a low risk. In other words, the risk-based approach comes down a fairly simple formula – the more risk, the more official controls.

Although, at first sight the risk-based approach appears to be pretty straightforward, its correct application depends on the accuracy of risk-assessment, which in turn can be quite complex, as it has to take into account a large amount of data relating to various factors affecting food safety, animal health and plant health. As it can be inferred from the recent scientific studies of factors relevant to the risk-assessment, food business operators can be prioritized for inspection based on the type of food they produce and human health risks related to this. Other factors, which need to be taken into consideration, include the size of the business, past records of non-compliance (historical data), including food fraud, the type of activities and the type of the operator etc. (Van Asselt et al., 2021). The collection, processing and evaluation of these data for the purposes of official control is not easy and requires a lot of technical support such as relevant databases and information systems.

Therefore, the overall effectiveness of the official controls based on the assessment of risk greatly depends on the availability of relevant data and information management systems available to the competent authorities. In part, this is why Regulation (EU) 2017/625 pays a lot of attention to the Information Management System for Official Controls (IMSOC).

In this connection it should be emphasized that according to article 132 of Regulation (EU) 2017/625 the IMSOC is not only expected to provide a mechanism for the exchange of data, information and documents, necessary for or resulting from the performance of official controls, but also to integrate the existing computerized systems managed by the Commission and used for the rapid exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health. The integration of various information systems is very important, as it enables the competent authorities of the EU member-states to improve the planning of official controls in accordance with the risk-based approach.

Currently the IMSOC is composed of such information systems as iRASFF (the system for notifying direct or indirect risk to human health deriving from food, food contact material or feed), ADIS (the system for notifying and reporting information on animal diseases), EUROPHYT (the system for notifying and reporting the presence of pests in plants and plant products), TRACES (the online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products) (Commission, 2019). It is expected that the integration of data from these information systems can significantly improve the assessment of various factors affecting food safety, animal health and plant health in accordance with the risk-based approach.

Despite the fact that Ukraine has some information systems designed to facilitate the performance of official controls, it still has a long way to go, when it comes to the kind of information management system required by Regulation (EU) 2017/625. The development and deployment of such a system in Ukraine may require not only technical assistance in the area of IT, but also amendments to the current legislation on official controls allowing this system to be used as a decision-making platform for the planning of official controls on the basis of risk-assessment.

Apart from scheduled official controls, in some cases official controls are carried out without any prior planning. For example, such unscheduled official controls are performed in cases of non-compliance or suspicion of non-compliance, which obviously cannot be accurately predicted or planned beforehand. The notion of non-compliance as a legal basis for carrying out official controls does not cause much controversy. It is not something new for Ukraine, as it has been in use for decades. At the same time the idea of performing official controls in case of suspicion of non-compliance is relatively new, as it was introduced into the Ukrainian national

legislation on official controls only in 2017 as a result of the legislative alignment with the provisions of Regulation (EC) No882/2004.

The main problem for Ukraine arising in connection with the use of this new concept consists in the lack of legal certainty. The suspicion of non-compliance is a very broad notion, which is prone to ambiguous and arbitrary interpretation. The legal nature of this notion implies a wide discretion on the part of the competent authority and its officials responsible for carrying out official controls. In Ukraine this problem is additionally exacerbated by wide-spread corruption. That's why in recent years the Ukrainian law-making practice has been quite cautious with regards to discretionary powers and any notions creating legal uncertainty.

As for the EU, its legislation has always tended to use discretionary notions. It is necessary to acknowledge the fact that to a large extent discretion is indispensable in public administration. According to Bool Chand no administrative system, however detailed may be the statutory law or the superior rules and regulations governing its work, can be expected to function without recourse to the experience, the opinions, and the commonsense of those who are operating it… it has been shown almost indisputable that a certain amount of discretionary authority has necessarily to be conceded to those, who are actively engaged in government work (Chand, 1949). Therefore, effective public administration is impossible without a certain amount of discretion.

As Ukraine is heading towards further European integration, sooner or later it will have to bring its national legislation on official controls in correspondence with the provisions of Regulation (EU) 2017/625, in particular in full correspondence with the provisions on suspicion of non-compliance. Hence, a certain amount of discretion related to suspicion of non-compliance is inevitable. In theory it cannot be ruled out that this legislative alignment may trigger a wider spread of corruption resulting from the abuse of relevant discretionary powers. So, the question is how to prevent a possible wave of corruption.

According to recent studies many countries around the world rely on digital technologies as effective means of enhancing transparency and fighting corruption in the system of public administration (Darusalam et al., 2021). The results of scientific research show that digital transformation can significantly lower the corruption (Merhi, 2022). In particular, some studies suggest that a 1% increase in the index of e-government can result in a decrease in corruption by 6.7 % for countries entering the EU, and 6.3 for non-EU member (Lupu & Lazăr, 2015). In addition, it should be mentioned that Ukraine has its own positive experience of using digital technologies in the fight against corruption. For instance, Ukraine made digital procurement

mandatory in 2016 and adopted the ProZorro platform to scrutinize its 4500 bids per day. In its first two years of operation, ProZorro saved US$1.9 billion (Santiso, 2021). It shows that technology can be a powerful tool supplementing and improving the operation of public administration mechanisms.

When it comes to the organization of official controls in the field of food safety, animal health and plant health, it should be viewed as part of the overall system of public administration. Therefore, digital technologies can play a positive role in preventing corruption during the performance of official controls in this field as well. However, there needs to be a proper legislative framework allowing digital technologies to be applied as the means of preventing corruption. In this regard, it should be mentioned that Ukraine's legislation already includes some legal provisions relevant to the application of digital technologies.

For example, Ukraine's current legislation on official controls entitles both business operators and official inspectors to make video- and audio- records of the official controls. However, this is only their right. It is not an obligation. So, in most cases official controls are performed without any video or audio recording at all. It cannot be ruled out that in some cases officials and business operators may decide not to have any video and audio records of their interactions in an attempt "to settle their issues on mutually beneficial terms". I light of this, a mandatory legal requirement to make and keep video and audio records of all inspections carried out at the premises of business operators would potentially make a significant difference.

Furthermore, in cases where as a result of official controls a non-compliance is revealed such video and audio records should be made public on the web-site of the competent authority. Alternatively, such records could be made public on transparency portals, if these portals were created in Ukraine. According to Isabelle Adam, Mihály Fazekas transparency portals are online platforms usually run by governments or NGOs that publish information on government operations. Transparency portals can help to tackle corruption by enhancing the information flow from governments to citizens… The existence of such platforms can discourage public officials from engaging in corruption as the risk of punishment increases (Adam & Fazekas, 2021).

Making video and audio records of non-compliances available on official web-sites or transparency portals would serve two purposes. On the one hand, it would work as an additional safeguard measure against corruption. On the other hand, the general public would have more opportunities to know about non-compliances that might threaten human, animal and plant

health. Hence, it would also work as an additional measure aimed at the protection of public health, animal and plant health.

## 5. Conclusion

In recent years the EU legislation on official controls in the field of food safety, animal health and plant health has made a significant progress towards the ultimate implementation of the `farm to fork` principle. Despite the fact that Ukraine has already brought most of its sanitary and phytosanitary legislation in line with the EU law, its national legislation on official controls in this field is lagging behind and needs to be updated in order to harmonize the organization of official controls along the entire agri-food chain, including plant health.

Since the effectiveness of official controls scheduled in accordance with the risk-based approach greatly depends on proper risk-assessment, it is important for Ukraine to be able to collect, process and make use of a large amount of data about various factors affecting food safety, animal health and plant health. Therefore, Ukraine needs an IT system similar to the Information Management System for Official Controls of the EU, which integrates other IT systems related to food safety, animal and plant health, sanitary and phytosanitary certification. The development and deployment of such a system will require certain legislative amendments and will help provide sufficient data for risk-assessment and proper implementation of the risk-based approach to the planning of official controls.

As a legal basis for unscheduled official controls the suspicion of non-compliance is prone to ambiguous and arbitrary interpretation. However, a certain amount of discretion is always inevitable in public administration. So, instead of trying to get rid of the suspicion of non-compliance as a legal basis for official controls, Ukraine should take some measures preventing the its abuse for corrupt goals. In order to prevent corruption, it might make sense to make better use of digital technologies, for instance, introduce a mandatory legal requirement to make and keep video and audio records of all inspections carried out at the premises of business operators and make records of non-compliances public on the official web-site of the competent authority or transparency portals.

In order to address the highlighted issues, the Law of Ukraine on official controls over the compliance with sanitary and phytosanitary legislation has to be developed in conformity with the relevant EU requirements.

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