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Analysis of the implementation of the european and national legislation in the feed manufacturing

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Abstract
Over the last years worldwide, at the level of the European Union and in Bulgaria, large-scale studies on the quality and safety of animal feed have been carried out. Through the food chain, harmful substances contained in animal feed can fall into their production and thus affect human health. The present work analyses the international, European and national documents concerning the quality and safety of feed and animal feed.
The aim is to study and analyse the legislative processes and procedures related to the implementation of the European legislation in the feed production sector, as well as to give some recommendations on the implementation of the European legislation into the national feed sector.

Keywords: European legislation, feed production, regulations and normative acts

Introduction
A safe feed for animals is important not only for the animal health and the environment, but also for the safety of the animal production. There are many examples of a close link between the feed safety and the animal feed and human consumption. For example, in 2001, the meat and meat-and-bone meal from mammals was banned by the European Commission (EC) for all the farm animals due to the spread of Bovine Spongiform Encephalopathy (BSE) and the infected meat was associated with the Creutzfeldt-Jakob Disease vCJD) in humans.
How farmers feed their animals depends on a number of factors, the most important of which are: the type and age of the animals, the type of the produce - meat, milk or eggs, price, nutritional value and available feed, the geographic factors, soil and the climate.
Depending on the type of animals, different feeds may be used, such as, for example, (hay, straw, silage, haylage and maize) and cereal feeds that can be fed on their own or in the form of compound feeds - a mix of cereal and protein raw materials and additives.

Material and Methods
We set out to investigate and analyse the legislative processes and the procedures related to the implementation of the European legislation in the feed industry, and to make some recommendations on the implementation of EU legislation in the national feed sector. 4 international law, 17 EU regulations, 5 EU directives, 1 EU decisions, 12 other EU documents, 13 BG national laws, 4 BG ordinances, 1 other BG documents have been used for analysis. This could be present graphically as follows:

Results and Discussion
The 2000 White Paper on Food Safety introduces a new European Union (EU) concept for effective and comprehensive consumer protection associated with their health. In its view, this is achieved as a result of the measures to be taken at all stages of the food chain - a 'farm to table' approach. By publishing the White Paper on Food Safety, the EC sets out a radical overhaul of existing hygiene legislation, according to which the feed business operators bear the primary responsibility for the feed safety. The food chain legislation is harmonized at EU level and requires Member States to develop national enforcement measures. At the same time, this legislation is constantly being updated and it is therefore necessary to be constantly reviewed to the extent to which the necessary changes to the national legislation on its

implementation are made. The main EU rules on food law are laid down in Regulation (EC) №178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food and feed safety, the so-called General Food Law (GFL) of the EU. Under Article 17, paragraph 1 of the GFL, the feed business operators (FBO) are responsible for ensuring that the feed meets the requirements of the legislation, that are relevant to their activity, and they verify whether these requirements are met:

"Food and feed business operators at all stages of production, processing and distribution within the undertakings controlled by them shall ensure that the food and feed concerned meets the requirements of the food law that relate to their activities and verifies whether these requirements are met. "

Ideally, the feed requirements should be formulated in such a way that the FBO can decide how to achieve the feed safety objectives. They can then be controlled by auditing feed safety management systems covering prerequisite programs (PRPs) and HACCP-based procedures and inspections in feed businesses. As Bernd M. van der Meulen (2018) emphasizes, in the conformity assessment, the official inspector must consider the measures taken by the undertaking to carry out its duties. This finding is crucial. In this situation of imposed self-regulation under the law on feed hygiene, the self-imposed requirements are those against which the compliance has to be assessed. The inspectors cannot simply reverse the self-regulatory system by self-assessing the hygiene situation. Regulation (EC) №882/2004 on official controls introduces a legislative framework for the organization of the official control over a part of the food chain including feed production. By analysing this framework, Kostov I. (2018) stressed that it significantly improved the effectiveness of the official controls and the level of protection against the risks to human, animal and plant health and animal welfare in the Union as well as the level of protection the environment from risks that could arise from GMOs and plant protection products. However, some of the tools or enforcement mechanisms are missing and do not provide for official controls throughout the food chain. In order to achieve the objective of strengthening, modernizing and rationalizing the current legal environment and ensuring a high level of protection of human, animal and plant health, the Commission proposed in 2013 a package of five proposals for the revision of EU agri-food chain laying down animal health requirements (animal health legislation), pest protection measures(plant health legislation), production and marketing of plant reproductive material(legislation on plant propagation material), official controls and other official activities carried out to ensure compliance with the whole set of rules in the agri-food chain, including the above-mentioned rules(Official Control Regulation) and management of EU spending in the main areas of the agri-food chain. The package of measures presents a modernized, simplified and risk-based approach to protect human and animal health and introduces more effective control tools. Its main objective is to ensure the effective implementation of the regulatory framework for the functioning of the food chain, to support productivity, the efficient functioning and accessibility of the internal market and to strengthen the EU's global competitiveness. Concerning the feed safety, from the point of view of the official control a major role has the published in 2017 Regulation (EU) 2017/625 on official controls and other official activities carried out in order to ensure the enforcement of food and feed law, animal health and animal welfare rules, plant health and plant protection products, so called the Regulation on official controls (OCR). Major changes in official feed control include: simplifying and clarifying the legal framework applicable to official control activities; consolidation of the integrated approach covering the entire agro-food chain in the broadest sense: food, feed, plant health and plant reproductive material, animal health, animal welfare and provision and pre-provision of adequate funding for Member States' control bodies through the collection of fees by business operators. The Regulation covers the entire agri-food chain, unlike Regulation №882/2004. The new sectors included in the Regulation are those dealing with official controls on animal by-products, residues of VMP, and all official control activities (compliance check). The new requirements of the OCR will replace the requirements of Regulation (EC) No 882/2004 on official controls as well as the other food chain control legislation.

The "One Health" strategy defines human and animal health as related: explicitly highlights the link between the health and the state of the environment, such as air quality, safety indicators for soil and water assessment; the link between animal and human health because of the likelihood of transmission of zoonotic agents; compliance with withdrawal times of the veterinary medical products(VMPs); the risk of transferring resistance genes to antibacterial substances, including cross-resistance; negative human health effects due to exceeding the maximum permissible concentrations of VMPs' residues and other chemical pollutants also in feed. The strategy identifies the dependence of the health status on the degree of the implementation and control of the legislation applicable to the individual sectors. The emphasis is on the prevention and prophylactics, but not on dealing with the negative consequences due to realized risks, which is always a more difficult task, especially when it is likely to be transformed into crises.

Another important strategy is the strategy for limiting the risk of antimicrobial resistance (AMP), where the risk is defined as high. An element of the strategy is linked to the measures that likely to reduce the new antibacterial resistant bacteria and the search for alternatives to overcome the problem. The issue of AMR is related to the health, social, economic, but also to the ethical aspects, which makes the implementation of timely and adequate measures mandatory and urgent. Preventing unwanted scenarios requires particular attention and persistence in the implementation of the measures consistent with the European strategy by the responsible institutions, which also applies to the production of medicated feed. Because of the high risk and the undoubtedly high risk of adverse health effects for humans and animals, the AMR problem requires measures to be taken not only at the institutional level but also by creating conditions for systematic change of the attitudes of the people, which is sometimes difficult and slow process.

A Basic Regulation introducing requirements for the hygiene of feed production is Regulation №183/2005. This Regulation ensures that the feed safety is addressed at all stages that may have an impact on the safety of feed and food, including primary production. In particular, it introduces the following main elements: mandatory registration of all feed business operators by the competent authority; approval of feed businesses carrying out operations involving more sensitive substances, such as certain feed additives, premixes and compound feeds; introducing HACCP concept for feed business operators other than primary production;

development of the Community and the national guides to good hygiene practice in the production of feed and introduction of the mandatory requirements for the production of feed at farm level, to provide the European Union framework for guides to good practice in the production of feed.The rules on the marketing of the feed materials and compound feed are laid down in Regulation (EC) №767/2009 on the placing on the market and use of feed. Together with it, the Commission adopted several implementing acts for this Regulation: Fodder Catalogue; Revision of the tolerances for analytical constituents and provisions on the labelling of feed additives; Guidelines for distinguishing between feed materials, feed additives, biocidal products and veterinary medical products and Guidelines for nutrition of foods no longer intended for human consumption. A basic Community act on the use of additives in animal nutrition is also Regulation (EC) №1831/2003. The Regulation establishes Community procedures for the authorization of the feed additives and lays down rules for their placing on the market, labelling and use. It applies to all feed additives and premixes. Outside of its scope are the processing aids and veterinary medicinal products defined in Directive 2001/82/EC. According to it, only additives that have undergone an authorization procedure may be placed on the market and used. The authorizations are granted for use in the feed intended for specific species or categories and for specific conditions of use. The additives can be classified into the following categories: technological additives (e.g., preservatives, antioxidants, emulsifiers, stabilizing agents, acidity regulators, silage additives); sensory additives (for example, flavourings, colouring agents); food supplements (eg. vitamins, minerals, amino acids, trace elements); zootechnical additives (for example, digestibility enhancers, gut flora stabilizers) and coccidiostatics and histomonostatics. These categories are divided into functional groups according to the main functions of the additives. It should be noted that the antibiotics other than the coccidiostats or histomonostats are not feed additives.

The new Medicines Feed Regulation (EU) 2019/4 repeals the outdated Directive(90/167/EEC) and introduces the following changes EU action to combat antimicrobial resistance through a ban on the use of antimicrobials in medicated feeding stuffs for the prevention and growth promotion.

At national level is the main law in the Bulgarian legislation that governs feed requirements, measures and conditions to ensure feed hygiene and their safety, packaging, labelling, presentation, including advertising; conditions and procedures, as well as requirements for all stages of production, processing, storage, transport, placing on the market, including use of feed, rights and obligations of feed business operators; the rules for carrying out official controls, including verification of compliance with the regulatory requirements, the powers of the official control authorities; the functions and powers of the professional organizations of the feed business operators assigned to them by this Act; the competent authority for the implementation of the EU feed regulations; the control of the quality composition and the completeness of the feed. The law applies to the feed and the conditions under which it is produced and processed by the feed business operators and for the control of the feed at all stages of production, processing, storage, transport, placing on the market, including use. It shall not apply to primary production for personal use and in domestic preparation, processing or storage of feed intended for animals the production of which is not intended to be placed on the market. The Minister of Agriculture, Food and Forestry, with a regulation on the requirements for direct delivery of small quantities of primary production of feed at local level from producer to private farms to be used in these farms according to Article 2 (2)(d) of Regulation (EC) №183/2005.

It is noteworthy that the Feed law has been amended many times since 2006. The latest update of the texts of the Act came into force on 23.02.2018. The Law also lacks an analysis of the provisions of the new Regulation on medicated feeding stuffs applicable to feed business operators working in a feed business, vehicle or on-farm premises as well as for feed business operators who store, transport or place on the market medicated feed and intermediate products. For the FBO who will produce medicated feed, the new Regulation has been granted approval under Regulation (EC) №183/2005 on feed hygiene (under Article 10 of this Regulation). Instead, the current feed law provides for applicants wishing to produce medicated feeds before being entered in the register of approved manufacturers of compound feed (first approval, for which they owe 2,000 leva) , after which they have the right to declare an intention to produce medicated feed (second approval, for which they owe another BGN 2,000).

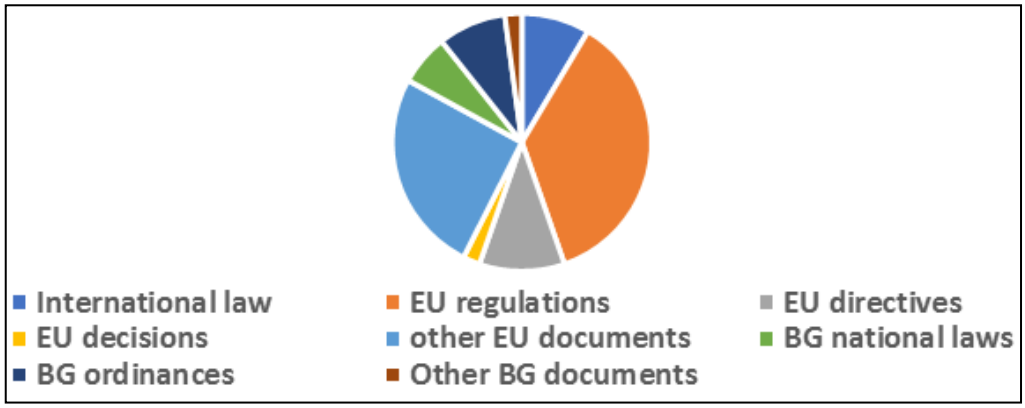

Fig 1: Percentage of different documents used in the analysis

Conclusions

As a result of the analysis we can summarize that many of the texts in national legislation are duplicated by similar or identical to those of the EU regulations. All these changes in the laws and regulations over the years have been made chaotic, "*in a piece*", without seeking the integrity and hierarchy of the tests, as well as the interrelationship between the different sectors of the food chain. Some of the texts of the laws and regulations introduce texts from the European legislation (regulations and directives) that are amended or

repealed. As a major problem at present is that there is no normative act - a legal framework that brings together all the activity in the food chain, clearly indicating its individual elements in their entirety as a continuous process, distinguishing the competences of the authorities, implementing the risk assessment of the food chain, the policy and control over them and the related activities.

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