

LEGISLATION AND RISKS OF USE OF NUTRITIONAL FEED SUPPLEMENTS*

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ABSTRACT: The use of feed supplements' in the European positive law is a process that is not left to the discretion of the feed producers, but there are differences in the application of feed supplements on the national level in countries outside the EU. Those differences necessitate a change in professional approach, raising awareness of feed manufacturers aimed at greater competitiveness and effectiveness, as well as faster discovery of all possible risks of uncontrolled feed supplementation. Increasing level of responsibility of feed manufacturers in countries outside the EU is generated from the demands of EU for harmonization of national legislation with European legislation. Changes in regulations related to the use of feed supplements are in the process of being prepared within the regulatory structures of the European Union. They are based on the results of monitoring and review of documentation during the renewal of registration of feed supplements in the process of which it can be expected that the licenses to use some, until now essential supplements to be revoked. By monitoring the impact of feed on the safety and quality of food of animal origin, certain parameters are obtained which are used as the basis for defining the standards of the international programme for food safety (Codex Alimentarius). By accepting the rules, guidelines and recommendations of the European law, the area of nutritional feed supplementation will be more precisely defined. The aim is to be involved in risk assessment of feed supplements as well as in the consideration of all possible problems that may arise, depending on the process including which the supplements are used in the production process. This will decrease the adverse effect of this production process on the environment and overall food safety.

Key words: *feed, nutritional supplements, legislation*

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INTRODUCTION

Livestock production occupies a very important position in agriculture. Satisfactory results in terms of farming animals and financial gain in livestock as well as public and animal health, animal welfare and environment, depend largely the use of appropriate quality and safe animal feed (1). From the market perspective, more attention is being paid to processes with a goal of livestock development with Euro-

pean Union. Therefore, there is a need for the review, that is a "rebalancing", of Common Agricultural Policy that benefits livestock, towards the improvement of production technologies for balanced and precise animal nutrition which promotes intensive livestock production. The Code of Good manufacturing practice in addition to implementation of HACCP principles when used in the production of specific

feed supplements and components of animal origin, must provide higher level of sustainable livestock production and total agricultural productivity. Therefore, there is an increasing change in the opinions of individual producers and farmers even when they are not involved in commercial production. Analogous to the definition of food from EU regulations, the feed is defined as any substance or product that will be consumed by animals. Therefore, feed supplements are also considered as feed.

Feed supplements are substances, micro-organisms or preparations, together with finished products of animal feed and pre-mixes, which are intentionally added to animal feed or drinking water for animals with the aim of conducting one or multiple functions (2). They are also used for more efficient technology production process in preparation of the mixture, the improvement of the characteristics of products of animal origin, as well as increasing the efficiency of environmental protection. What may be the greatest problem during technically incorrect use of feed supplements, is the fact that in practice all categories of feed additives are called the same - nutritional supplements. Nutritional supplements in feed, whose specific effects on the animal organism are dose-dependent, are the chemicals necessary for life and growth of organisms. Many ingredients in food naturally contain in themselves certain nutritional values (they are rich in specific vitamins, minerals...). With regard to supplements used in feed, it is important to exclude „natural ingredients“ and mention that the nutritional supplements are added afterwards in order to achieve a specific effect.

Legislation, EU-Serbia

The use of feed supplements in European Union member countries is a process that is not left to the discretion of feed producers. The division of supplements on positive lists (lists of authorized and permitted supplements), manufacturing (with essential specificity of organization, calibration of equipment and conditions for storage and transport of supplements), trade, the quality (purity), method and limitations on usage, marking of supplements in feed and premixes, as well as other

requirements (templates for lists of products for feed supplements and pre-mixes, templates for labels recommended for use...) are regulated by ordinances and codex.

The basis of the European legislation in this area is Regulation EC 1831/2003 which includes a list of approved, authorized feed supplements and which is in line with the technological development of feed production (2). Feed supplements, production of supplements and premixes are based on this Regulation. New guidelines relating to animal feed supplements, in line with the Regulation which entered into force in 2004 were as follows: replacement of Directive 70/524/EEC, inclusion of amino acids and equipment for conservation of silage, introduction of compulsory registration for coccidiostatic, as feed supplements, provision for withdrawal of agents that promote growth, that is antibiotic as of 1 January 2006, introduction of five categories of feed supplements, determination of MRL's (maximum residue level) and the period of retreat, entry of existing animal feed supplements and the basis for the procedures for reevaluation of all feed supplements (every 10 years). In addition to a separate category, which includes coccidiostatic and histomonostatic, another four categories with the functional subgroups for each, include: technological supplements, sensory supplements, nutritional supplements and zoo-technical supplements. It should be stressed that the Regulation on additives (initially with the pharmaceutical industry, 1930 – Food and Drug Administration or FDA, and later as a separate codex within World Trade Organisation, 1964 - Codex Committee on Food Additives and Contaminants, CCFAC) is the first harmonized regulation related to food in the EU, and it has introduced the concept of E numbers that are used for marking of additives. In the 1990's the difference and separation of supplements for human consumption and feed supplements was made, so that are E-labels from 1-99 were assigned to feed supplements. Today, the Register of Records of EU includes around 2800 supplements that are used in animal feed, from which 2711 undergo re-evaluation (data from year 2008) which is conducted in line

with the guidelines of the EU Commission (7). Nutritional supplements or "food supplements" include the following functional sub-groups: vitamins, pro-vitamin and chemical substances that have a similar effect to them, compounds of trace elements, amino acids (salts and their analogs), and urea and its derivatives. In line with Annex III of EC Regulation 1831/2003, the trade in nutritional supplements requires declaration of the level of active ingredients and its expiration date, as well as the storage time limit of a given level of active ingredients up until date of manufacturing (3). Organizational position or a special Section relate to nutrition of animals within EU, belongs to the Standing Committee for the feed chain and animal health in European Commission (Committee on the Food Chain and Animal Health, Section: Animal Nutrition).

Based on the opinion of the European Association of manufacturers of feed supplements and premixes (FEFANA), in the area of feed, it is necessary for all participants in the food chain to demonstrate a transparent, solid, steady and clear system for support of producers of feed supplements and manufacturers of animal feed in solving their concerns in the market. First of all, problems arise because of different official requirements relating to definitions according to which substances or products (additives, production and products of feed with supplements, premixtures, dietary and mineral nutrients, medicated feed, veterinary products or substances...) are classified. Also, there are different requirements for labeling and declaration of these products, making it necessary to give support to producers of feed and define the criteria based on which the classification of products will be performed. This will prevent and avoid any misunderstandings that may arise in the market. According to the available information, in recent years a joint team of experts from relevant European organizations (EMFEMA/ FEFAC/ FEFANA) has aimed to provide support to producers of these products through a code of practice for labeling of supplements of feed and premixes. The Code of Practice will be used in preparing product markings, but also as a guide for the relevant authorities

of Member Countries during the control of objects of producers who manufacture feed supplements and premixes. The newest approach is the division of the Code of practice into four main parts which will be actively updated with new requirements, new technological solutions or items faced by producers and relevant authorities. They include the following: Code of Practice for Labeling Feed Additives, Code of Practice for Labeling Pre-mixtures, Templates for Product Specification Sheets for feed additives and pre-mixtures, Label Templates taking into account different options recommended in the Code (5).

In the national legislation, the area of feed supplements is not accurately or comprehensively defined, but is partly covered by legal provisions in various laws and regulations. Legislation on drugs defines concepts of veterinary drug and premixes. A part of the definition for veterinary drug includes the following: "the premix is a pharmaceutical form of veterinary medicinal products intended to be mixed with feed". In addition, on the basis of the same Act, "the premix for medicated feed is a special pharmaceutical form of veterinary medicinal products, manufactured exclusively for the production of medicated feed" (6). Based on regulations in the area of veterinary medicine, a series of legislative acts has been passed that regulate the area the supplements in feed. So on the basis of general and special conditions of feed hygiene, "feed additives are substances or microorganisms that are in accordance with special regulations approved for use in feed", while pre-mixtures are "products with high content of vitamins, minerals, amino acids and feed supplements which are homogeneously mixed with the carrier and are used for feed in combination with feedstuffs or processing of mixtures" (14) (15). The rules regarding the quality of feed cover this, far more demanding, area of feed supplements (13) (16). Classification of supplements and their division into official categories which are in accordance with the EU law is within the framework of planned activities during the process of harmonization of legislation. It is known that the quality of supplements (cleanliness, etc...), the efficacy and safety of use and their contents in products of

feed must be controlled. Control is carried out by relevant inspection services and accredited laboratories for quality control and safety of supplements as well as the finished feed product. It is performed according to the rules of determining the Program of systematic monitoring of residues of biological, hormonal and other adverse substances in animals, animal products and feed (17). In practice we can see some problems regarding the implementation of control of supplements and products of feed. This is due to lack of precise definition of methods of sampling and number of samples required for implementing residue control. The control is implemented based on instructions sent to area laboratories where the current standard of feed is recommended (JUS: ISO standard - taking seven samples per 2.5 tons of feed).

Problems exist also due to the lack of uniform methodology. Difficulties also occur due to analytical problems and outdated analytical techniques in investigations of certain supplements.

Health aspect

Nutritional supplements in feed are, due to the adverse effects and the possibility of endangering the health of animals as well as an increased risk and adverse effects to human health (through products from animal origin) and the environment, in constant international procedures to determine their efficacy and safety. It is not possible to prove absolute safety of nutritional supplements although the degree of their harmfulness may be discussed because, according to French psychologist and pharmacist Claude Bernard (Claude Bernard, 1813-1878), "nothing is toxic and everything is toxic" depending on the amount that is used. For that reason, nutritional supplements are characterized as having a dose - dependent effect. During the process of checking and reevaluation of feed additives, the results of which we expect later this year, in addition to the assessment of the safety of each supplement and preceded by a large number of tests, the following is determined: acute and chronic toxicity, mutagenicity, carcinogenicity, teratogenicity, allergenic,

accumulation, metabolism, interactions with other components of animal feed. Also other studies and evaluation of the effectiveness of supplements are determined and are based on the common agricultural practices in the EU. On the basis of pharmacological and toxicological testing of set level of supplement that is used, any possible consequences or detrimental effect (NOAEL - No Observed Adverse Effect Levels) is determined, which is the basis for calculating the acceptable daily intake (mg per kg of animal weight) (8). Also, the same procedures are used to determine the limitations on the use of certain supplements for certain types of animals in certain feed products. The use of nutritional supplement – urea is well known. This is a source protein for ruminants, although it does not have any nutritional value for monogastric animals. Furthermore, proteins are the main ingredients of dry matter and only some of the proteins contain all of the amino acids that animals need for all processes in the body. The use of animal waste, eg. feathers (for pigs and poultry) is prescribed by the Regulations regarding the quality of feed (14). It is proven that microbial keratinase or their purified enzymes in biotechnological application improved nutritional value of meals from feathers with the energy savings related to the hydrothermal processing of animal feed products (16).

Based on the information of tests in 2009 performed by Mr Petera Fiderra (Quality Assurance & Feed Safety Manager at Trouw Nutrition International BV), when nutritional supplements in the EU are re-evaluated, the results for most vitamins provide a place on the green list. Still, the confirmations regarding the use of taurine, a p-amino benzoic acid (PABA), betaine HCL, betaine monohydrate (Request N° EFSA-Q-2004-090) are unclear. The safety requirements of betaine for proposed use by the applicant were rejected as unfounded (10). Currently, some traces of elements are have not been sorted into a positive list of supplements used in feed. Also, opinions withing FEFANA and other professional committees cover the majority of amino acids (regardless of whether they are on the list of nutritional supplements),

except for certain exotic derivatives which are in the process of examination (9).

Observing the impact of feed products on food of animal origin (products from livestock) generates results that are used for evaluating the quality and safety that are used as the basis for establishing standards for the Code of Nutrition of the International Programme for Food Safety.

For each supplement which is used in feed, there must be a study that determines the effect on the health of animals, as well as a study and evaluation of safety of workers who may be potentially exposed when handling supplements during production or directly through inhalation (eg, allergic rhinitis or asthma). Based on EC Regulation 1272/2008 regarding classification, labeling and transportation of dangerous substances and mixtures, 2010th cobalt salts will be removed from the list of permitted feed supplements as from December 1 (11). Clear risks that animals are exposed to via feed, analogous to the risks to public health, can be classified according to the degree of danger into: microbial agents, hazards due to improper diet, environmental contaminants, natural toxic ingredients in feed, pesticide residues and risks from nutritional supplements which are used.

CONCLUSION

Within the EU organisation, there are relevant authorized body or consortia that are divided according to categories of supplements which regulate their use in feed. The aim of such an organization is establishing cooperation among stakeholders, involvement in the process of authorization of supplements, recording and categorizing of manufacturers for specific supplements, as well as internal rules for the groups themselves which are based on detailed criteria. Setting up of the Commission for feed supplements aims to protect the public health of each country primarily from the misuse of supplements, but it is also a body that provides accurate information regarding the use of supplements and their safety to all interested parties in the food chain.

Within the reform process of the national legislation during the harmonization with

international standards, the Stabilisation and Association Agreement Serbia and the European Union is important. Based on its provisions, the Serbian legislation is required to supplement and amend a number of existing regulations which will in, the area of agriculture, enable the domestic manufacturers to be more aggressive and get faster access to an agricultural market. By accepting the rules, guidelines and recommendations of European law, the field of nutritional feed supplements will be more precisely defined. The goal is to engage in risk assessment of feed supplements and consideration of all the possible problems that arise, depending on the way in which the supplements are used in the production process.

The development of feed technology and regulating the use of nutritional supplements in feed will result in reducing the harmful effects of production on the environment and food safety in general. In the end, increasing attention is being paid to the strategy for sustainable development through the resolution of the greenhouse gas emissions and contribution to the mitigation of climate changes.

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ЗАКОНСКА РЕГУЛАТИВА И РИЗИЦИ ОД УПОТРЕБЕ НУТРИТИВНИХ ДОДАТАКА ХРАНИ ЗА ЖИВОТИЊЕ

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Сажетак: Употреба додатака у храни за животиње у складу са европским позитивним правом је процес који се не препушта слободној вољи произвођача, али и поред тога постоје разлике у примени додатака у земљама ван ЕУ. Због тага су неопходне промене у приступу с аспекта струке, али и свести самих произвођача у правцу постизања већег степена конкурентности, као и брзине уочавања могућег ризика од неконтролисане употребе додатака. Све већи степен одговорности произвођача хране за животиње у земаљама ван ЕУ произилази и из захтева који су постављени у процесу приступања ЕУ, а односе се на преузимање и усклађивање националног с европским законодавством. У одговарајућим законодавним структурама Европске уније се припремају промене уредби које се односе на додатке храни за животиње и њихову употребу. Оне се базирају на резултатима мониторинга и разматрању документације приликом обнове регистрације додатака, када је могуће очекивати и укидање дозвола за употребу појединих, до сада битних, додатака. Праћењем утицаја хране за животиње на безбедност и квалитет хране животињског порекла, добијају се резултати, који представљају основу за утврђивање стандарда Међународног програма за исправност и безбедност хране (Codex Alimentarius). Прихватањем правила, смерница и препорука европског права и област нутритивних додатака храни за животиње биће прецизније дефинисана. Циљ је укључити се у процене ризика додатака храни за животиње, као и сагледавања свих могућих проблема који настају у зависности од начина употребе додатака у производном процесу. На тај начин би се обезбедило смањење штетног утицаја ове производње на животну средину и безбедност хране, уопште.

Кључне речи: *храна за животиње, нутритивни додаци, законска регулатива*

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