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Food additives – risk analysis and legislation

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Abstract

Food additive is any substance not normally consumed as a food, the intentional addition of which to food for a technological purpose results in it or its by-products becoming a component of such foods. The use of each new additive is preceded by a risk analysis consisting of three interrelated components: risk assessment, risk management and risk communication. At the international level in the Codex Alimentarius system, risk assessment is performed by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) and risk management by Codex Alimentarius Commission (CAC) that, based on the results of the risk assessment, prepares international standards and recommendations that Member States incorporate into national regulations. At the level of the European Union (EU), risk assessment is performed by the European Food Safety Authority (EFSA) as a basis for risk management by the European Commission (EC) that prepares food additive legislation, and member states authorities responsible for official control of additives on the market. Risk communication takes place between all stakeholders including academia, food producers and consumers. The regulation on additives in the Republic of Serbia is fully harmonized with the EU legislation in this area.

Key words: food additives, food flavourings, Codex Alimentarius, European Food Safety Authority

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Introduction

All substances that are intentionally added to food, excluding foodstuffs and their characteristic ingredients, are classified into several groups that are separately regulated in the European Union (EU) and national food legislation (1, 2). Two main groups of these substances are substances that are added to food as nutrients (vitamins, minerals, amino acids etc.) (3) or for technological purposes. The second group is further divided into four sub-groups: food additives (4, 5), food flavourings (6, 7), processing aids (8) and food enzymes (9, 10).

According to the definition in the Regulation (EC) No 1333/2008 (4), a food additive is any substance not normally consumed as food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods. On the other hand, processing aids (such as extraction solvents, adsorbents, catalysts, clarifying agents) that are also used for technological purposes, are not becoming a component of foods, may only remain as residues in food and do not have a technological effect in the final product (4, 8).

Food additives have been in use for centuries, such as curing salts to make meat last longer, sulphites to protect wine from oxidation and unwanted bacteria and yeast, caramel and plant extracts as colours or gums and pectins to improve food texture (11, 12). From the middle of 19th century, with the development of food industry and increased use of processed foods, food additives were used more widely, but without adequate control. Cases of adding substances to food to mislead the consumers concerning the nature or quality of foodstuffs have also been reported. The most common falsifications in France in 19th century were adding the lime in flower, colouring the wine with fuchsine, adding strychnine to beer to achieve bitterness, or adding sulphuric acid to vinegar (12, 13). The use of these substances in food had a negative impact on the consumers' health and for these reasons several countries started with the assessment of safety of food additives and with preparation of lists of substances forbidden or approved in food (12).

International standards and evaluations

The evaluation of food additives on the international level started from 1956, when the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) established the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as an international scientific body, initially for evaluating the safety of food additives. JECFA prepares specifications and performs safety assessment of chemicals in foods considering developments in toxicology, food chemistry and other relevant sciences (14). The Codex Alimentarius Commission (CAC) was founded by

FAO and WHO in 1963 as an intergovernmental body for the adoption and implementation of international food standards and recommendations that member states incorporate in the national legislation (15, 16). Codex standards are recognised by the World Trade Organization (WTO) in the international food trade and have become an integral part of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade (TBT) Agreement (15, 17). In the Codex system, standards for food additives are prepared by the Codex Committee on Food Additives (CCFA) (15, 16).

Based on the available data and the extent of evaluation, in the beginning of Codex food additives standardization, all the existing food additives were classified into six following groups (18):

Group A1 - additives that have been fully evaluated for permanent safe use in food,

Group A2 - additives that have been used in technological practice for a long time and have not shown harmful consequences so far, but which have not yet been fully evaluated for permanent safe use in food,

Group B1 - additives used in some countries, but not evaluated by the FAO/WHO Commission,

Group B2 - additives that could potentially be used and have yet to be evaluated by the relevant FAO / WHO Commission,

Group C1 - additives which the FAO / WHO Commission considers, based on their toxicity testing, not to be safe for use in food,

Group C2 - substances considered toxic by the FAO / WHO which should be banned as food additives.

From 1989, when the toxicological databases for food additives became sufficient for safety assessment, this Codex classification of food additives was abolished and for all approved additives from the positive list, on the basis of the JECFA evaluations and intake assessment, CAC adopted the conditions for use and maximum permitted levels in foodstuffs as a part of the Codex General Standard for Food Additives (GSFA).

Risk analysis for food additives

Risk analysis provides a systematic methodology for risk assessment and for the determination of effective actions to protect health. To achieve a high level of protection of human health, the EU General Food Law is based on risk analysis (1), and from 2009 the risk analysis paradigm is also incorporated in the Serbian Food Safety Law (2).

According to the definitions in EU General Food Law, “risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard where “hazard” means a biological, chemical, or physical agent in food or feed with the potential to cause an adverse health effect (1).

Risk analysis is a process consisting of three interconnected components: risk assessment, risk management and risk communication (1, 2).

Risk assessment

Risk assessment is a scientifically based process consisting of the following four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Risk assessment is based on the scientific evidence and should be performed as an independent and transparent process (1, 2). At the international level, risk assessment for food additives is performed by JECFA (14, 15). In the EU, from 1974 to 2002 the safety of food additives was assessed by the Scientific Committee for Food (SCF) (18), until in 2002 the European Food Safety Authority (EFSA) was set up as a source of scientific advice on risks associated with the food (19). The EFSA was legally established under the EU General Food Law (1). As a risk assessor, EFSA produces scientific opinions and advice that form the basis for European food legislation. It consists of ten expert panels covering nutrition, food and feed safety and animal and plant health. Until 2008, the safety of food additives was evaluated by the Scientific Panel for Additives, Flavourings and Contact Materials (AFC Panel). After the EFSA reorganization, from 2008 to 2018, additives were assessed by the Scientific Panel for Additives and Nutrient Sources (ANS Panel), and after the second reorganization, from 2018 until now additives have been evaluated by the Scientific Panel for Food Additives and Flavourings (FAF Panel) (20). All food additives which were permitted before 20 January 2009 are subject to re-evaluation carried out by the EFSA (21). The risk assessment methodology for food additives is further developed in 2012 in the EFSA Guidance for submission for food additive evaluations (22).

Hazard identification

Hazard identification is the first step of risk assessment that aims to identify potential toxicity of substances, including impurities and residuals from the manufacturing process, which are then further characterized via their biological and toxicological dose-response relationships. Food additive specifications are important to confirm that toxicological and other studies are performed with the specified material (22).

Hazard characterisation

In the second step, hazard characterisation, the Panel seeks to define a health-based guidance value such as an Acceptable Daily Intake (ADI) (23) for the general population. The ADI is defined as the amount of a food additive, expressed on a body weight basis, that can be consumed daily over a lifetime without an appreciable health risk. ADI may be established for compounds for which a threshold mechanism of toxicity can be demonstrated or expected. The aim is to identify the most sensitive endpoint from a range

of toxicological hazards also known as a Reference Point (RP) or Point of Departure (POD). Depending on the available toxicological database, PODs usually include the No Observed Adverse Effect Level (NOAEL) or a Lower confidence bound of the Benchmark Dose value (BMDL) (22, 24). EFSA Scientific Committee prepared a Guidance on selected default values to be used by the EFSA Panels for rat and mice studies, such as uncertainty factors for the calculation of ADIs from obtained NOAELs (25). For an additive which is neither carcinogenic nor genotoxic, but for which the available toxicological data are not sufficient for the derivation of POD, the EFSA Panel uses a Margin of Safety (MOS) approach to conclude if there would be a risk at the proposed use and use levels (22).

For the evaluation of the following toxicological endpoints: sub-chronic and chronic toxicity, carcinogenicity, genotoxicity, and reproductive and developmental toxicity, as well as toxicokinetics, the new tiered approach was introduced in 2012 by EFSA. The new approach balances data requirements against the risk and introduces refined animal testing strategies taking into consideration animal welfare. The tiered approach for toxicological studies consists of 3 tiers, presented in Figure 1. A minimal dataset required for all compounds has been developed under Tier 1 and includes absorption, *in vitro* genotoxicity testing and subchronic toxicity. Tier 2 testing is required for substances which are absorbed or demonstrate toxicity in Tier 1 tests and includes absorption, distribution, metabolism and elimination (ADME) of a single dose of the food additive, genotoxicity *in vivo*, chronic toxicity and carcinogenicity testing, extended one-generation reproduction toxicity study (EOGRTS) and prenatal developmental toxicity study. Tier 3 testing is performed on a case-by-case basis to identify specific endpoints needing further investigation of findings in Tier 2 investigations and includes studies such as ADME repeated dose studies, carcinogenicity with the mode of action investigation, more extensive reproductive and developmental studies, and specific studies such as: immunotoxicity, neurotoxicity, endocrine activity, allergenicity and other studies. Food additives are regulated substances and compounds that are genotoxic carcinogens are not approved for intentional use in food. If *in vitro* genotoxicity is demonstrated in Tier 2 tests, no further action is required, and such a substance is prohibited for use as a food additive. In 2007, in the process of re-evaluation of food additives from the Positive list, EFSA noted that food colour Red 2G (disodium 8-acetamido-1-hydroxy-2-phenylazo-naphthalene-3,6-disulphonate) is extensively metabolised to aniline. Both genotoxic and carcinogenic effects have been observed in rodents treated with aniline and based on these considerations, EFSA withdrew the ADI of 0.1 mg/kg bw for Red 2G and the European Commission banned the use of Red 2G as a food additive in the EU (26).

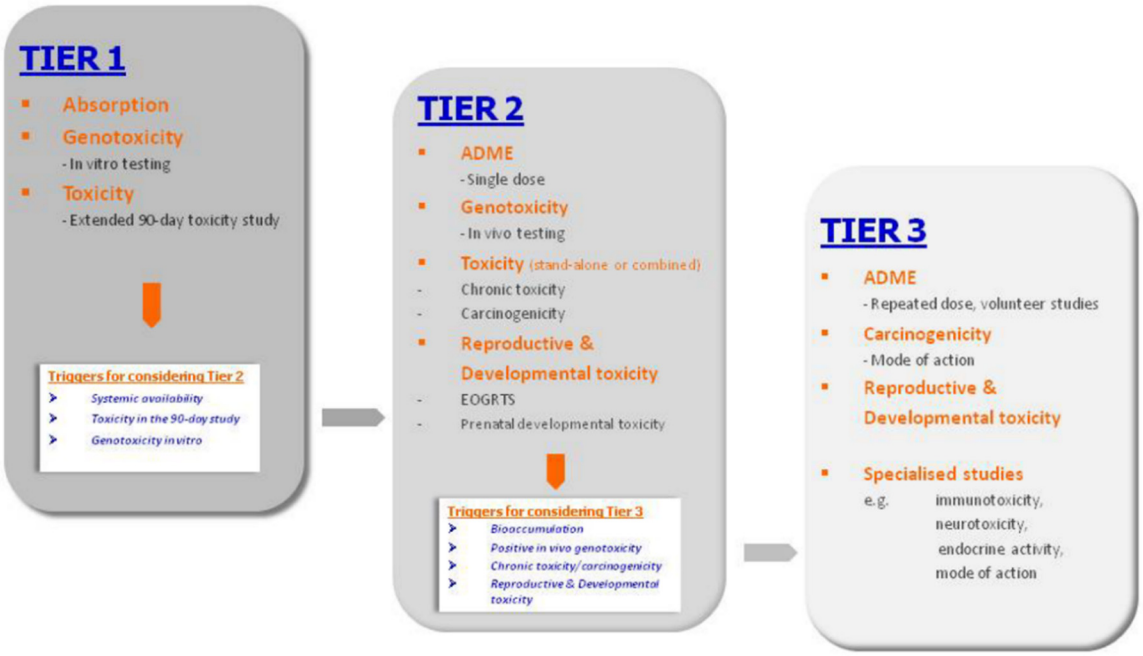

Figure 1. Tiered toxicity testing for food additives (from EFSA guidance for submission for food additive evaluations)

Slika 1. Nivoi toksikoloških ispitivanja prehrambenih aditiva (iz EFSA vodiča za podnošenje zahteva za evaluaciju prehrambenih aditiva)

Exposure assessment

Assessment of the exposure to food additives is the quantitative evaluation of their likely intake by a certain population, taking into account the intake from all dietary and other sources. As the dietary habits are not the same in all parts of the world, e.g. the consumption of bread is not the same in China and in the EU, if the targeted population is more specific, the exposure estimate will be more precise. Usually, to estimate the exposure to the food additive, food consumption data obtained in national and international surveys for various age groups of the population are combined with the intended use levels of the food additive in different foodstuffs. The aim is to ensure that the derived safety levels such as ADI would not be exceeded by the consumers, including high consumers (22).

Risk characterisation

In risk characterization, the calculated human exposure from all sources is compared with the ADI derived from the POD. The EFSA Panel considers each MOS to determine whether the magnitude of the MOS between anticipated exposure and derived

NOAEL or BMDL is sufficient to conclude that there is no safety concern, taking into account the uncertainties from the toxicological database (22).

Risk management

Risk management is the process of weighing policy alternatives, taking into account risk assessment and other legitimate factors, and selecting appropriate prevention and control measures (1).

In the system of Codex Alimentarius the risk manager is CAC that, based on the scientific advice from JECFA, develops international standards and recommendations that are used by member states for national legislation and in international trade.

In the EU, risk managers are the European Commission that, on the basis of evaluations presented by the EFSA, prepare the EU policy and legislation on food additives and relevant member states authorities that have adequate mechanisms, such as inspections and laboratories, to control the use of food additives on national levels. In Serbia, the competent authorities for risk management of food additives are the Ministry of Health and the Ministry of Agriculture. According to the national Food Safety Law (2), the Ministry of Health is responsible for the preparation of legislation and control of food additives on the market, as well as for the control of the use of food additives in dietetic products and food supplements, while the Ministry of Agriculture is responsible for the control of additives in foods of plant and animal origin. Our national regulation on food additives is fully harmonized with the Regulation (EU) 1333/2018 on food additives.

Risk communication

Risk communication is the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors, and risk perceptions, among all interested parties, including the explanation of risk assessment findings and the basis of risk management decisions (1, 2).

Food additive legislation

EU food additive regulation

The regulation of food additives was among the first agreed harmonisations in the European Economic Community (EEC), as the differences in the national food additive regulations of the member states represented a trade barrier in the Community. The framework Directive 89/107/EEC (27) regulated the definitions, rules for labelling food additives, and general criteria for the use of additives in food. The conditions for the use of sweeteners, colours and all other additives were regulated separately in the Directives 94/35/EC (28), 94/36/EC (29) and 95/2/EC (30), respectively, as well as the specifications for their purity in the Directives 95/31/EC (31), 95/45/EC (32) and 96/77/EC (33). Within

the EU, E numbers were introduced as codes for substances approved for use as food additives. The numbering scheme numerically follows that of the International Numbering System (INS), determined by the Codex Alimentarius (34), with the letter "E" in front of the INS number, indicating that the additive is approved for use in the EU. All the existing directives on food additives have now been replaced with the Regulation (EC) No 1333/2008 (4) and Commission Regulation (EU) No 231/2012 (35). In order to regulate the use of food additives in food, all foodstuffs are classified into the following 18 main food categories:

1. Dairy products and analogues
2. Fats and oils and fat and oil emulsions
3. Edible ices
4. Fruit and vegetables
5. Confectionery
6. Cereals and cereal products
7. Bakery wares
8. Meat and meat products
9. Fish and fisheries products
10. Eggs and egg products
11. Sugars, syrups, honey and table-top sweeteners
12. Salts, spices, soups, sauces, salads and protein products
13. Foods intended for particular nutritional uses
14. Beverages
15. Ready-to-eat savouries and snacks
16. Desserts
17. Food supplements
18. Processed foods not covered by categories 1 to 17

Each of these categories is further divided into several sub-categories to form a comprehensive hierarchical system where each sub-category includes all sub-levels under the selected one. This system, based on the Codex food category system from the GSFA standard (36), facilitates the precise setting of maximum permitted levels of food additives in different foods.

For the purpose of labelling, the following 22 functional categories are used: colour, preservative, antioxidant, acid, acidity regulator, bulking agent, anti-caking agent,

emulsifier, emulsifying salts, anti-foaming agent, gelling agent, firming agent, humectant, flavour enhancer, glazing agent, flour treatment agent, raising agent, foaming agent, propellent gas, modified starch, sequestrant, sweetener, thickener and stabiliser. The additives used in foods placed on the EU market in the original packaging should be presented in the list of ingredients by the category and the name or E number of the additive, e. g. preservative (sodium benzoate) or preservative (E 211). If an additive belongs to more than one of the functional categories, the category appropriate to the principal technological function in the certain food should be indicated on the label.

Food additive regulation in Serbia

The first food additive regulation in SFRJ was the Rulebook on quality of additives for food products from 1989 (37). It was based on Codex standards and contained a positive list and short specifications for food additives from the old Codex A1 and A2 lists, with several additives from the B1 list. The conditions for use and maximum permitted levels of food additives in foods were regulated in separate food quality regulations. The Rulebook on quality and other requirements for additives and their mixtures for food products from 2001 (38) that replaced the outdated Rulebook from 1989 was partially harmonised with the EU regulation concerning the positive list, use of E numbers, general requirements and labelling, but the conditions for use in foods still remain regulated in the separate regulations on quality of certain foodstuffs. The Rulebook on quality and conditions for use of food additives from 2004 (39) was the first Serbian horizontal food regulation containing the conditions for use and maximum permitted levels of food additives in all foodstuffs and it was fully harmonised with the 2004 EU food additive legislation. The EU food category system was also implemented. Rulebooks on food additives from 2013 (40) and 2018 (4) were harmonised with the actual Regulation (EC) No 1333/2008 and Commission Regulation (EU) No 231/2012 and all its amendments until 2018. The new amendment to the actual rulebook is in preparation.

Conclusions

Risk analysis for food additives provides a systematic methodology for risk assessment, management and communication in order to achieve a high level of protection of human health. Considering the developments in the relevant sciences such as food chemistry and toxicology, the methodology for evaluation of food additives is constantly being improved. A major update in the assessment of safety of food additives was introduced by the EFSA in 2012, with the new tiered approach for toxicological studies (22).

An international procedure has been established that precedes permits for the use of additives. Their positive list (list of permitted additives), purity, restriction of use,

labelling and other requirements are legally regulated, and Serbia is harmonizing the national food additive regulation with international standards and the EU food additive legislation.

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Prehrambeni aditivi – analiza rizika i regulativa

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Kratak sadržaj

Prehrambeni aditiv je svaka supstanca koja se normalno ne koristi kao sastojak hrane, a koja se iz tehnoloških razloga namerno dodaje hrani u toku proizvodnje, prerade, pripreme, obrade, pakovanja, transporta ili čuvanja, tako da direktno ili indirektno preko svojih međuproizvoda postaje sastojak hrane. Upotrebi svakog aditiva prethodi analiza rizika koja se sastoji od tri međusobno povezane komponente: procene rizika, upravljanja rizikom i komunikacije o riziku. Na međunarodnom nivou u sistemu Codex Alimentarius-a procenu rizika radi Zajednički (FAO/WHO) ekspertski komitet za prehrambene aditive (JECFA) koji priprema hemijske specifikacije, vrši procenu izloženosti i kvantitativnu procenu bezbednosti upotrebe aditiva u hrani, a upravljanje rizikom radi Komisija Codex Alimentarius (CAC) koja na bazi rezultata procene rizika priprema međunarodne standarde i preporuke za upotrebu aditiva koje zemlje članice ugrađuju u nacionalne propise. Na nivou Evropske Unije (EU) procenu rizika radi Evropsko telo za bezbednost hrane (EFSA), a upravljanje rizikom Evropska komisija (EC) koja donosi propise, kao i nadležna ministarstva zemalja članica koja sprovode službenu kontrolu. Komunikacija o riziku odvija se između svih zainteresovanih strana uključujući i akademske krugove, proizvođače i konzumente hrane. Regulativa o aditivima u Republici Srbiji harmonizovana je sa regulativom EU u ovoj oblasti.

Ključne reči: prehrambeni aditivi, prehrambene arome, Codex Alimentarius, Evropsko telo za bezbednost hrane

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