Food Additives, between Necessity and Normative Restriction

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Abstract: - Food additives were for the first time defined by the Codex Alimentarius Commission, a FAO-WHO mixed organism, which does not have mandatory legal force. The Codex Alimentarius principles were adopted in the European Union legislation, through several directives and regulations regarding colorings, sweeteners and other food additives, and the E.U. member states have rendered the community directives in the internal law, the regulations being enforced directly. As for the banning of food additives, the positive list principle is applied, according to which the use of a food product or other additives in the manufacturing process is forbidden except for those whose use is legal. According to the quantum satis principle, additives should be used in food products according to the good practices of productions. Otherwise, a higher level of additives than necessary must not be used in order to reach a certain goal and mislead the consumer.

Key-words: - food additives, food quality control, food safety, authorization, comparative legislation

1. Introduction

Ever since the nineteenth century, once processed foods started being used more and more, food additives started being used more frequently, at different security levels. Significant controversies have emerged regarding the risks and benefits of food additives, and the research on their toxicity led many to believe that only the safe additives should be used in food products. This led to the legalization of their use in many countries. With time, some artificial additives were linked to cancer, digestive, neurological problems, heart diseases or obesity, but it has been proved that natural additives can be just as harmful or cause allergic reactions in some people [1]. For instance, in 2007, a research financed by Britain's Food Standards Agency and posted online the British medical magazine The Lancet, has revealed that a mix of additives usually found in children’s food increases the level of hyperacidity [2]. The team of researchers has concluded that the finding lends strong support for the case that food additives exacerbate hyperactive behaviors (inattention, impulsivity and overactivity) at least into middle childhood.

Lately, several international health organisms have drawn the signals regarding these synthetic additives, saying they were toxic. According to the reports of international organizations, mortality caused by the consumption of foods enriched with artificial chemical substances is on the fourth place after cardiovascular diseases, traffic accidents and substance and pill abuse.

According to several opinions, food additives become dangerous only when they are added in large quantities in certain product. It is worth knowing that consuming such foods can have a negative effect on the consumer’s health in the long run. Furthermore, long or improper use can lead, with time, to the onset of serious diseases.

Food additives have several definitions at an international level.

FAO/WHO has defined the food through the Codex Alimentarius Commission as any substance not normally consumed as a food by 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 [4].

In other words, a food additive is any substance of a chemical or microbiological nature not consumed naturally as a food, not used as a typical ingredient of foods, with no nutritional value, and by adding it in food products it modifies the product organoleptically, shortens the processing period, it is better packaged and stored for longer periods of time, the product does not contaminate, and the nutritional qualities of foods are maintained and improved.

We can extract the following ideas from these definitions:

• the additive is intentionally added, in a certain quantity, has an intentional character and substances added accidentally are excluded, such as: chemical substances used for treating plant and animal diseases; chemical substances which stimulate plant and animal growth that are chemical contaminants of foods;
• the additive is added with a well-determined purpose: to improve the physical properties, thickness, aspects, emulsifiers, colouring agents; to improve taste and smell, sweetening agents, acidity regulators, salt; improving storage properties, preservatives and antioxidants;
• the added additive excludes the contaminants and adding some substances to improve the nutritional value, vitamins, amino acids etc.

In the food industry, using food additives favors:

• the preservation of the nutritional value of a food product;
• better preservation quality and stability of a food product;
• the improvement of production, packaging, storing and transportation of food products;
• the improvement of sensorial characteristics of food products.

The use of additives is not justified when the quantity used jeopardizes consumer health, reduces the nutritional value of the food, masks some major hidden defects of the food product, misleads the consumer.

The conditions of use of additives refer to additive safety in itself and the absence of dangers related to dosage and effect in time. The use must be necessary and approved by FAO/WHO. With regard to the purity of additives, such impurities come from substances used in their processing, from solvents used for crystallization, from by-products formed when processing and storing the finished product due to oxidation, hydrolysis, polymerization.

2. General standards for food additives

In 1963, the Codex Alimentarius Commission, created as a mixed FAO (Food and Agriculture Organization of the United Nations) - WHO (World Health Organization) working group, set the international food standards, the guiding lines and practice codes to protect consumers in the food trade. It also encourages the coordination of all works referring to food norms undertaken by governmental and non-governmental organizations.

The population’s concerns regarding food security issues often places the Codex in the middle of the global debate. Biotechnologies, pesticides, food additives and the presence of contaminants in food are some of the topics discussed during the Codex meetings. The two international organizations - FAO and WHO - claim that Codex standards are based on the latest scientific research with international organizations and independent competition risk assessment or on the spot consultations organized by FAO and WHO. The scientific organizations by the three FAO/WHO expert committees: the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA).

Codex Alimentarius is the reference authority regarding the development of quality standards, standards of health, safety, nutrition standards, uniform standardization methods.

Even if the recommendations are not binding on member states, the Codex standards serve in many cases as a basis for national legislation elaboration. Furthermore, Codex members cover 99% of the world population and more and more developing countries are actively participating in the Codex activities.

General Standard for Food Additives (GFSA) was adopted in March 1995 by the member governments of the Codex, so food producers could use them, accord to standard manufacturing practice. In July 1989, the Codex Alimentarius Commission had already adopted the Numbering System for Food Additives (INS), intending to harmonize the names of food additives as a long-term alternative to the use of specific names. INS is an open list subject to the inclusion of additional
additives or the elimination of existing ones on a common basis [5]. At the European level it was decided that each authorized additive should be marked on the label or packaging by an alphanumeric code consisting of the letter E (from Europe) followed by a number of 3 or 4 digits, the same as the INS ones.

3. Regulations at the European Union Level
EU legislation on food additives consists of a framework directive and three special directives regarding colors, sweeteners and the rest of food additives.

The entire community legislation is based on the principle that only additives authorized explicitly can be used, according to the "positive list" principle. In other words, what is not expressly authorized is prohibited.

Most food additives may only be used in limited quantities in certain foodstuffs. If quantitative limits are not set for the use of a food additive, it should be used in accordance with good manufacturing practices, i.e. only enough to achieve the desired technological outcome.

- a technological necessity imposes that, and the objective set cannot be achieved through other economic methods and technologies used;
- they are not dangerous in the established dose, and the existing scientific do not prove that;
- they do not mislead the consumer.

Before authorizing them, food additives are assessed regarding their safety by the European Food Safety Authority.

The Directive 89/107/CEE states that all food additives must be under constant supervision and to be reassessed whenever necessary in the light of changes regarding their use and in the light of new available scientific information.

The consolidated community legislation regarding food additives is completed by:
- European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners, amended by Directives 96/85/EC, 98/72/EC, 2001/5/EC, 2003/52/EC, 2003/114/EC and 2006/52/EC. Directive 95/2/CE regarding additives contains a list of authorized food additives (the so called E-s), the foods that can be used for and conditions of use. The directive has to be adapted in the light of recent technical and scientific progress. So, the changes refer to:
  - the revision of some authorizations (nitrites and nitrates; food supplements and foods for specific medical purposes; p-hydroxybenzoates etc.)
  - the authorizing of new food additives (for instances eritritol, 4-hexylresorcinol, soy hemicellulose, ethyl cellulose etc);
  - the authorizing for extension of use of some authorized food additives (sodium carbohydrate for cheeses, sorbates and benzoates for crustaceans, silicon dioxide as support, additives for traditional foods).

Furthermore, all authorized food additives must correspond with the purity criteria in the Commission’s three directives:
concerning colours for use in foodstuffs (Codified version).

In December 2008, a new legislative package was adopted on food improvement agents, which amended and supplemented the current legislation. The package consists of:

- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. The Regulation states that these substances be assessed regarding their safety by the European Food Safety Authority (EFSA) before being authorized for use in the European Union.

According to the current legislation [6], food additives which were allowed before January 20, 2009 will be reassessed until December 2020 by EFSA (The European Food Safety Authority), in the following way:

(a) review of all authorized food colors in Directive 94/36/EC shall be completed no later than December 31, 2015;
(b) review of all authorized food additives other than colors and sweeteners in Directive 95/2/EC shall be completed no later than December 31, 2018;
(c) review of all authorized food sweeteners in Directive 94/35/EC shall be completed no later than December 31, 2020.

Regarding the list of allowed additives, except where reference is made to a special European directive on nutrition, many types of additives have not been defined precisely to allow a certain degree of flexibility to harmonize the differences between types of foods eaten in different Member States. However, because the three Directives were negotiated separately, without a common categorization, the categories of foods are not always directly comparable. When categories are mostly explicit, there may be cases where a classification of the position of a particular food is necessary. For instance, some foods can fit into the description of more than one category. Categories of food were distributed only to control the use of food additives and have no impact on food labeling.

4. Regulations at the member states level

It is common knowledge that food additives are authorized for member states at the European Union level. Before 1988, the Community regulation on food additives was limited to directives which set the lists of additives, member states stating their conditions of use (field and doses).

A change of this approach took place on December 21, 1988 with the publication of Directive 89/107/EEC concerning additives that may be used in products intended for human consumption.

This directive was transposed into French law by Decree no.89-674 of September 18 1989 regarding food additives which may be used in products intended for human consumption. According to it, the term "food additive" means any substance not normally consumed as a food in itself and not normally used as a regular ingredient, with or without nutritional value and whose intentional addition to foods for a technological purpose in the production, processing, conditioning, transport or warehousing stage has or might have the effect, directly or indirectly, that it could become a compound of these food products.

Food additives could not be used in foodstuffs except under conditions established by norms drawn up by ministries of consumption, agriculture, health and industry. These norms established the list of authorized food additives, the foodstuffs they could be added to, the conditions of incorporation, substances used for product support or dilution,
conditions referring to sale to the final consumer, etc.

Article 4 of the decree stipulated that the quantum satis principle applies, according to which there is no fixed maximum amount of the food additive in food. Additives must be used according to good manufacturing practices, the allocated dose not exceeding the amount strictly necessary to achieve the desired effect and provided that the consumer was not misled.

The institution responsible for the selling of foods containing additives, whose quantity is governed by this principle, must be able to provide evidence to justify the amount used. Control agents may require such evidence.

Some traditional products must not have additives in them. In France, any traditional French bread, traditional French truffle, French snail cans etc. In other European countries, some products also have special status.

French rules require the use of food additives to be labeled on food packaging by category (antioxidant, preservative, colorant, etc.) together with the name or E number. The ways of labeling additives in foods and additives sold as such to food manufacturers and consumers are set by the Community legislation.


The lists of additives and colorants that can be used in the manufacture of foodstuffs for human consumption, as well as the requirements that apply to them are found in the Consumer Code and other normative uncoded texts, such as decisions, decrees and even newer laws. For example, Law no.2012-1442 from December 24, 2012 regarding the suspension of the manufacture, import, export and marketing of food products containing bisphenol A shall apply from January 1, 2015, but pregnant women and children younger than 3 years should be warned from 1 January 2013.

As a general methodology, a new additive cannot be used only after a decision signed by the ministers of economy, health, agriculture and industry, which specifies how to use it (dose and products that it can be introduced in). The development of such a decision is made only after the pronouncement of the National Security Agency of Sanitary Food, Environment and Labor, and the Scientific Committee on Food.

In conclusion, according to the French legislation, food additives must:
- be on a positive list;
- be allowed to use in foodstuffs;
- have some identity and purity criteria;
- be mentioned on the product label.

In Germany, the legal provisions are in the Ordinance on admission of additives in foodstuff from January 29, 1998, as subsequently amended, as well as in the Ordinance on requirements for and marketing of additives for technological purposes from January 29, 1998, as subsequently amended.

The ordinance authorizing food additives, consists of 10 articles and 7 annexes, contains definitions of terms and treats problems such as coloring agents, sweetening substances, other additives, feed additives for infants, the maximum of additives, packaging and labeling. Article 10 provides penalties for violations.

The ordinance on the marketing of additives consists of 7 articles and 4 annexes, it does not apply to additives used in the preparation of drinking water. Article 6 deals with packaging and labeling, which must clearly show all the ingredients. Annex 1 lists the equivalent additive substances, Annex 2 states purity of additives in accordance with the European Union guidelines.

In Italy, with time, a number of decrees of the Ministry of Health have implemented the European directives regarding food additives. The most recent one is the Decree from April 7, 2011 implementing Directives 2010/67/EU and 2011/3/EU concerning specific purity criteria for food additives. Besides the Community regulations which Italian authorities are constantly implementing, the Ministry of Health adopts normative acts in the field on its own, such as the one in which it bans the use of chemical additives and liquid nitrogen in restaurant kitchens. This has been enforced since the end of 2010, the ministry pointing that, in order to protect its citizens, Italy wishes to ban from restaurants the use of some additives, still used in industrial processing.

Great Britain has implemented the European directives in its internal law through various Regulations which came into force on January 1, 1996:
- The Colors in Food Regulations 1995 No 3124 with subsequent amendments;
- The Sweeteners in Food Regulations 1995 No 3123 with subsequent amendments;
- Miscellaneous Food Additives Regulations 1995 No 3187 with subsequent amendments.
Each of these implements a European Union Directive, which established the list of authorized food additives and conditions of use.

All these acts specify that terms not defined in Regulations have the same meaning as in the corresponding Directive. When terms are not found in the relevant Directive, they will automatically have the same meaning as in the 1990 British Law on Food Safety, the framework in which regulations are adopted.

Regulations specify the maximum number for using an additive, because it is necessary for safety reasons to establish a maximum level. In this case the quantum satis principle is applied, as defined in the Regulations, which means that food additives must be used in accordance with good manufacturing practice. This means that one must not use a higher additive level than necessary to achieve its purpose and they should not be used so as to mislead the consumer.

A number of food categories exist in the three regulations. Since food categories are not clearly defined in the European legislation, there will always be a need for interpretation, which the Guide of Food Standards Agency does in the UK regarding the interpretation of categories of food for each regulation.

All three normative acts restrict the level of additives present in foodstuffs. The level is called „maximum level” or, in the case of Regulation no.3123/1995, „the maximum dose” and has two meanings:

a) the level of the food when ready for consumption, taking into account the instructions of use. This rule applies to Regulations no.3123/1995 and no.3124/1995, as well as for three programs in Regulation no.3187/1995. For instance, the quantity of an authorized sweetener in a concentrated juice bottle might have a higher level than specified in Regulation no.3123/1995. This is acceptable, if there are dilution instructions, for, when it is ready to be consumed, the level of the authorized sweetener is not higher than the maximum level allowed by the Regulations. Cooking in Great Britain, when it applies, it not a considered an additional instruction of use. The cooking effect on the level of additives in a product differs according to a number of variables. Thus, it fit had been considered an additional instruction of use, the observance and uniform enforcement of Regulations.

b) in all the other instances from Regulation no.3187/1995, the level refers to the sold foodstuff. The level of food additives in the production of a foodstuff can slightly differ between individual products. When a certain variation is known to occur in a group, producers must make sure that maximum additive levels are respected for each of the individual products.

In Romania, specialized literature defines food additives as substances which are not originally part of the food, but which are added to change – favorably – the organoleptic traits or as a direct need for certain technological processes.

Article 3, letter g) of the Emergency Ordinance no.97/2001 [7] defines food additives as any substance not normally consumed as a food in itself and not used as a characteristic ingredient of food, whether or not having a value nutrition, which intentionally added to foods for technological purposes during manufacture, processing, preparation, treatment, packaging, transport or storage of such food, is or may become itself or by its derivatives, directly or indirectly, a part of the foods.

The legislation in force in Romania set the allowed dose in a particular food for each food additive. In the list of ingredients, food additives fall within the category name followed by their specific name or code E.

In the process of accession to the European Union until 2007, Romania has implemented EU directives on food additives into its national legislation. As a result, the food industry in Romania may use food additives included in European Directives.

Order no.438/295 from 2002 of the Ministry of Health and Family, Minister of Agriculture, Food and Forestry came into force on October 3, 2003 for approval of food additives for use in foods for human consumption [8], as amended and supplemented many times representing Romanian alignment to the accepted EU norms. Thus, this order transposes Directive 94/35/EC, Directive 95/2/EC.

These norms apply to food additives whose categories are in the annex, which are used or meant for use as ingredients for manufacturing of a foodstuff and which are present in the finite product as such or in a changed form. The order specifies that these norms do not apply in the case of technological auxiliaries; substances used for the protection of plants and plant products in conformity with the national regulation in the phytosanitary field; the flavors used in foods according to the national regulation in the field; substances added in foodstuffs as nutrients: minerals, vitamins and others.

The order also issues lists with categories of food additives which can be used to manufacture or
prepare foods in certain conditions. One can include food additives in one of the categories from the annex only based on the main function usually associated with the food additive. Including the additive in a specific category does not exclude the possibility that the additive will be authorized for other purposes.

In case new information surfaces or existing information is reassessed and using additives is considered detrimental to public health, though it fits the norms, the Ministry of Health can revoke or temporarily suspend the use of such additives.

The monitoring report of the European Commission from May 16, 2006 showed at chapter 4.1.1 – Free movement of goods that: „Foodstuffs are added. These substances are generically called energetic or nutritional value of foods in which they foodstuff and which do not have or enrich the composition different from that of the respective contain a series of substance with a chemical besides the basic components, most products

5. Conclusions

Besides the basic components, most products contain a series of substance with a chemical composition different from that of the respective foodstuff and which do not have or enrich the energetic or nutritional value of foods in which they are added. These substances are generically called food additives and they are added to foods for a variety of technical reasons, such as preserving, stabilizing, coloring, sweetening. Since hyperacidity in children’s cases, allergies, asthma and migraines are considered adverse reactions of some additives, the European Union and the United States of America have banned and restricting the use of some existing E-s.

In the European Union, the general conditions of use of some food additives were set by the European Parliament and the Council through directives, starting with Directive 89/107/EEC which sets the general framework, principles and objects the entire additive-specific legislation refers to. Thus, the use of additives must be sure, justified from a technological point of view, it must not mislead the consumer and should have advantages and benefits for the consumers.

The adapting of E.U. member states’ legislation has been done constantly till 2008, when the most EU regulations regarding food improvement agents were adopted. Since then, those acts with subsequent amendments are applied directly in member states. It is common knowledge that a regulation generates dispositions which are immediately enforced in all member states, like the national legislation, without an intervention from national authorities. The directives adopted after this year have continued to be transposed in member states.

What member states can do now is to ask the European Commission to adapt the food additive list, thus to change the conditions of use of some additives so as the use of those additives be allowed, in specific cases, for the preparation of various products.

Since the effects of food additives on the consumers’ health are not fully known, especially regarding the consequences in time, lengthy studies are required and experiences on a major number of subjects which would bring precise data. Saying that all additives are dangerous would generate panic and it would be untrue. That is why their use has been with time regulated by the law. Thus, any safe additive may be included on the food additives „positive list”.

References

[8] Published in the Official Gazette no.722 from October 3, 2002
[9] Published in the Romanian Official Gazette, Part I, no.236 from April 14, 2010