EU legislation in the field of additives in the diet: category sweeteners-aspartame

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POSTGRADUATE SPECIALISATION EXECUTIVE MBA PROGRAMME IN AGRIBUSINESS AND COMMERCE

UNIVERSITY OF ZAGREB FACULTY OF AGRICULTURE

FINAL THESIS PROJECT

THESIS: EU LEGISLATION IN THE FIELD OF ADDITIVES IN THE DIET:

CATEGORY SWEETENERS-ASPARTAME

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Zagreb, November 2017.

LIST OF ABBREVIATIONS

A

ADI-Acceptable Daily Intake

ANS-The Panel on Food Additives and Nutrient Sources

C

CAC-Codex Alimentarius Commission

CFA-Croatian Food Agency

CSI-Croatian Standards Institute

D

DG (SANCO) SANTE- European Commission's Directorate-General for Health and Food Safety

E

EC-European Commission

EFSA-European Food Safety Authority

ERF-European Ramazzini Foundation

ESA-EFTA Surveillance Authority

EU-European Union

F

FAO-Food and Agriculture Organization

FDA-The US Food and Drug Administration

G

GM-Genetic Modification

GMP-Good Manufacturing Practice

I

IPCS-International Programme on Chemical Safety

J

JECFA-Joint FAO/WHO Expert Committee on Food Additives

L

LOAEL-Lowest Observed Advance Effect

M

MOA-Ministry of Agriculture

MoA-Mode of Action

NOAEL-No Observed Adverse Effect Level

O

OG-Official Gazette

OJ-Official Journal

P

PAFF-Standing Committee on Plants, Animals, Food and Feed

PAH-Phenylalanine Hydroxylase

PKU-Phenylketonuria

PRC-People's Republic of China

R

RASFF-Rapid Alert System for Food anf Feed

RC-Republic of Croatia

S

SCF-Scientific Committee on Food

T

TARIC- TARif Intégré Communautaire; Integrated Tariff of the European Communities

U

US-United States

W

WHO-World Health Organization

TASK

The task of final work is an extensive overview of a large number of the current Regulations and the Acts governing the area of food additives, especially the sweetener category. The work reviews the EU legislation and its compliance with the legislation of the Republic of Croatia (RC). Particular attention is placed on the aspartame from the sweetener category, one of the most explored and most controversial sweeteners in history of food industy.

SUMMARY

’Food additive‘ mean any substance not normally consumed as a 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.[1]

Food additives are substances that are not normally consumed as food itself but are intentionally added to food for a technological purpose described in Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, such as the preservation of food.[2]

The adjective of food suggests that additives are used exclusively in food production unlike other additives used in the manufacture of plastic masses, cosmetic products, washing and cleaning agents, lubricants for the automotive industry and similar.

According to Article 4 of the Ordinance on Food Additives (Official Gazette 62/10), the following substances are not considered as additives:

a) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties,

b) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect,

c) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods,

[1] Ordinance on Food Additives (Official Gazette 62/10), Article. 3, Paragraph 2., Indent a)
[2] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L354, 31.12.2008), Point (5)

d) products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin),

e) chewing gum bases,

f) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes,

g) ammonium chloride,

h) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten,

i) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function,

j) caseinates and casein,

j) inulin.

The use of additives in the Republic of Croatia is regulated by the Act on Food Additives, Flavorings and Food Enzymes (Official Gazette No. 39/13) issued on March 27, 2013, the Ordinance on Food Additives (Official Gazette 62/10) of 1 March 2010 with Amendments to the Ordinance on Food Additives (Official Gazette No 79/2012), adopted on 20 June 2012, by which the provisions of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008), were adopted and which replaces and puts in force many acts including the Ordinance on sweeteners for use in foodstuffs (94/35/EC), Ordinance on colors for use in foodstuffs (94/36 / EC) and Ordinance on food additives other than colours and sweeteners (95/2/EC).

If a substance is planned to be included in a food additive, it is necessary to perform a toxicological evaluation or an evaluation of the additive. They are labeled with E number that is a confirmation of toxicological evaluation.

Additives categories include colours, sweeteners and other additives, and a great attention is devoted to aspartame from the sweetener category which is one of the most tested food additives in history.

CONTENTS

1. INTRODUCTION.....1

2. HISTORICAL REVIEW.....2

3. GENERAL FOOD LAW.....4

3.1. European Food Law.....4

3.1.1. General Food Law Principles.....5

3.1.2. General Food Law Requirements.....7

3.1.3. General Food Law Procedures.....8

3.2. Food Law in the Republic of Croatia.....10

3.2.1. The Croatian Food Agency (CFA).....11

3.3. EU Rules.....13

3.3.1. Safe Food Additives.....14

4. LEGISLATION ON FOOD ADDITIVES.....16

4.1. Legislation on Food Additives in the Republic of Croatia.....16

4.1.1. Act on Food Additives, Flavorings and Food Enzymes.....16

4.1.2. Ordinance on Food Additives.....17

4.1.3. Ordinance on Food Additives on Amendments to the Ordinance on Food Additives.....18

5. USE OF ADDITIVES.....20

5.1. Toxicological evaluation of Additives.....21

5.2. Additive Lists.....22

5.3. Institutions responsible for additives.....23

6. CATEGORIES AND LABELLING ADDITIVES.....24

6.1. Additive categories according to tehnological and functional properties.....24

6.2. Labelling additives.....26

6.2.1. Labelling additives not intended for sale to the final consumer.....27

6.2.2. Labelling additives intended for sale to the final consumer.....28

7. SWEETENERS.....29

7.1. Specific name and E number of sweeteners.....29

7.2. Classification of table-top sweeteners.....30

7.3. Approved sweeteners and conditions of use in Food categories.....31

7.4. Informing consumers about food containing sweeteners.....31

8. ASPARTAME.....33

8.1. EFSA Scientific opinion on aspartame.....35

8.1.1. What is aspartame?.....36

8.1.2. What happens after ingestion of aspartame?.....36

8.1.3. Is aspartame safe?.....36

8.1.3.1. DNA damage and cancer.....37

8.1.3.2. Brain damage and behavioural consequences.....37

8.1.3.3. Reproductive and developmental effects 37

8.1.3.4. Effects of methanol, aspartame's metabolite.....39

8.1.4. Acceptable Daily Intake.....39

8.1.5. Review of literature.....40

8.1.6. What happens next?.....40

8.2. EFSA's recent activities.....40

8.3. Conclusions of conducted research.....41

8.4. Protection against dumping import of aspartame originating in the PRC.....44

9. CONCLUSION.....46

REFERENCES.....48

1. INTRODUCTION

Even before massive industrial production people used in the process of preparing food some of the substances that are added to the additives today. Our grandmothers used, for example, pectin of immature apples for gelling jam or baking powder (sodium bicarbonate and sodium acid phosphate). In households, we are still preserving food today with salt, vinegar, honey, sugar and lemon juice which contains citric and ascorbic acid (vitamin C) preventing fresh peeled fruit and vegetables from being brown.

By adding additives to industrial production some food properties are changed. Additives achieve a consistent product quality, making the supply of seasonal products independent of the season, and therefore allow for cheaper food production and its long-term storage. Preservatives, for example, prevent or slow down the reproduction of microorganisms that can cause food spoilage. The ever-diversified supply of food products is based on the development of food production technology, as well as on the use of additives. Without sweeteners and emulsifiers there would not be modern "light" products, melted cheese can not be produced without emulsifying salts, half-foods and ready-made meals without flavor enhancing substances, depending on the nature of food and preservatives, antioxidants, stabilizers and other additives.

One of the categories of additives are sweeteners that give a sweet taste to food, and we share them with those that have calorific value (sugar substitutes) and those that have a negligible calorific value (artificial sweeteners) that are obtained chemically. Sugar substitutes include glucose, fructose, sucrose and sugar alcohols: sorbitol (E420), mannitol (E421), isomalt (E953), neotame (E961), maltitol (E965), lactitol (E966), xylitol (E967) artificial sweeteners acesulfame-K (E950), aspartam (E951), cyclamic acid (E952), saharone (E954), taumatin (E957) and neohesperidin DC (E959). Artificial sweeteners are often not used alone, but in mixtures, to give a more natural flavor.

2. HISTORICAL REVIEW

The first written traces of the substances that today we call food additives originate in Egypt 3,500 years ago. Then colorants were used for coloring a stick candy called "khad". Khad came to Europe thanks to Alexander the Great. The chemical composition and the origin of the dyestuff are unknown, but it is certain that the original coloring raw material was natural origin. This multi-century tradition of dyeing has continued to this day. Only in 1856 when Perkins synthesized aniline violet-colored dyestuff, the way for the synthesis of persistent organic synthetic dyes opened from which only some of them can be used in the diet. Much before the development of food technology and chemistry as exact science, empirically the food state and various food supplements were linked to the health of humans. So already in 300 BC, in India, a law prohibiting the sale of foods and herbal preparations that were unacceptable for consumption was adopted. Also in England (1215- 1597) there was a law protecting consumers from food that could have a harmful effect on consumer health. The British, Germans and Swedes accept the General Food Act between 1860 and 1870 but only a more precise Regulation on the sale of food and medicines in England in 1875 gave better results in market control of these products.

The consequences for human health, uncontrolled food technology and the addition of various substances to food have been the result of the need for more stringent legislation. In the United States in 1906, the Decree on Food and Drugs was issued. That same year the Congress approved the funds for creating food standards, and accepted the Veterinary Inspection Decree.

Additives are added to food:

- in the production process
- during preparation
- during processing
- during treatment
- during forming
- during packing
- transport and
- storage

Modern food production can not be imagined without adding additives under well-defined conditions with a well-established reason. Quantities used to achieve the technological effect are measured in milligrams, and only a few additives are added to the food in grams. Additives that achieved technological or sensory effect after the addition and did not degrade become one of the components of that food. Additives and their mixtures may be added to foods under the following conditions: they are toxicologically evaluated; their use is technologically justified unless the final effect can not be achieved by means which are economically and technically more applicable; they are added to food in quantities permitted by special regulations; that by adding them the consumer does not mislead the true nature, the ingredients or the nutritional value of the food; that it does not substantially affect the natural taste and the smell of the food to which it is added, unless it is a special purpose that by mixing and adding them to the food they do not create toxic substances during processing, storage and use.

3. FOOD LAW

3.1. European General Food Law

Citizens of the European Union need to have access to safe and wholesome food of the highest standard. A series of food incidents that happened in late 1990s draw attention to the need of establishing general principles and requirements concerning food and feed law at Union level. Accordingly, the European Commission (EC) developed an integrated approach to food safety 'from farm to table', primarily set out in its White Paper on Food Safety which was issued on January 12, 2000. It covers all sectors of the food chain, including food production, primary production, food processing, storage, transport and retail. Chapter 7 in The White Paper refers to consumer information where, among other things, labeling and advertising are listed in such a way that consumers must have access to relevant and accurate information to make decisions. Since consumers show a growing interest in the nutritional value of the food they buy, there is an increasing need for the right information about the foods they consume. Labeling and providing the correct data is very important for specific groups of population.

The European Parliament and the Council adopted Regulation (EC) No 178/2002 on January 28, 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 safety.

The purpose of Regulation (EC) 178/2002 is to ensure safety of all food placed on the European Union market. Sine flavorings are used in foods they are also covered by this legislation.

The General Food Law Regulation is the basis of food and feed law. It sets outs an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. For that purpose, it lays down general principles, requirements and procedures that support decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

The Regulation (EC) 178/2002 also established an independent agency responsible for scientific advice and support, the European Food Safety Authority (EFSA) and it creates the

main procedures and tools for the management of emergencies and crises as well as the Rapid Alert System for Food and Feed (RASFF).

The General Food Law Regulation ensures a high level of protection of human life and consumers' interests in relation to food, while ensuring the effective functioning of the internal market.

According to the European Commission (2014), the EU Food Law is based on the following common principles that must be implemented by all EU member states:[3]

- protection of public health, plant health and animal health and welfare
- risk analysis and independent scientific advice
- precaution
- possibility to trace the origin of all products
- transparency and clear, unambiguous information on food and feed
- clearly defined responsibilities for all actors in the agro-food chain. It is the prime responsibility of all actors along the food chain to put safe food on the market
- strict controls and regular checks
- training and education

3.1.1. Food Law general principles[4]

The general principles of food and feed law are outlined in the General Food Law Regulation (Articles 5 to 10). They form a horizontal framework underpinning all Union and national measures relating to food and feed. They cover all stages of the production, processing and distribution of food as well as feed.

General objectives of food and feed law:

- Guarantee a high level of protection of human life and health and the protection of consumers' interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment

[3] European Commission (2014.), From Farm to Fork: Safe and healthy food for everyone (p.5), https://europa.eu/european-union/topics/food-safety_en

[4] European Commission Food Law General Principles, https://ec.europa.eu/food/safety/general_food_law/principles_en

- Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation
- Facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union.

Risk analysis principle

The General Food Law Regulation determines the principle of risk analysis in relation to food and feed and establishes the structures and mechanisms for the scientific and technical evaluations, which are undertaken by the European Food Safety Authority (EFSA).

Depending on the nature of the measure tha must be used, Food Law, and in particular measures relating to food safety must be supported by strong science. The Union has been at the forefront of the development of risk analysis principles and their subsequent international acceptance. Food law is based on the three inter-related components of risk analysis:

- risk assessment
- risk management
- risk communication.

Risk assessment must be undertaken in an independent, objective and transparent manner based on the best available science.

Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk. In the risk management phase, the decision makers need to consider a range of other information besides the scientific risk assessment. These include, for example:

- most effective risk reduction actions depending on the part of the food supply chain where the problem occurs
- feasibility of controlling a risk
- socio-economic effects
- environmental impact
- a wide range of other factors legitimate to the matter under consideration.

Risk communication is the interactive exchange of information and opinion throughout the risk analysis process among risk assessors, risk managers, consumers, feed and food businesses, academics, other interested parties.

Precautionary principle

The precautionary principle (Article 7 of the General Food Law) refers to specific situations where:

- there are reasonable grounds for concern that an unacceptable level of risk to health exists
- the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment

Transparency

Food safety and protection of consumer interests are of great concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. Therefore, decision-making transparency is of the greatest importance. The General Food Law Regulation provides for the mechanisms necessary to increase consumer confidence in food law:

- Effective public consultations during the preparation, evaluation and revision of food and feed law
- Obligation on public authorities to inform the general public, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health.

3.1.2. Food Law general requirements[5]

Safety requirements

The safety of food is of critical importance. Consumers must have confidence and assurance that the food they buy will not harm them or have an adverse effect.

[5]European Commission Food Law General Requirements
https://ec.europa.eu/food/safety/general_food_law/general_requirements_en

The General Food Law Regulation establishes that only safe food and feed can be placed on the market of the European Union. It also establishes basic criteria for establishing whether a food or feed is safe.

Traceability

Tracing food and feed throughout the food chain is very important for the protection of consumers, particularly when food and feed are found to be faulty. The General Food Law Regulation defines traceability as the ability to trace and follow food, feed, and ingredients through all stages of production, processing and distribution.

Food operator's responsibilities

Primary responsibility for ensuring compliance with food law - and in particular the safety of the food - rests with the food business operators. To complement and support this principle, the competent authorities of the Member States must assure adequate and effective controls.
When food or feed is unsafe, business operators are obliged to withdraw or recall it. They are also obliged to notify the competent national authorities so as to be able to monitor whether the appropriate measures have been taken or require that additional measures be taken for reducing or eliminating a food safety risk.

Implementation guidance

A guidance document on the implementation of the General Food Law aims to assist all players in the food chain to better understand the Regulation and to apply it correctly and in a uniform way. It provides guidance on main food law requirements.

3.1.3. Food Law procedures

The General Food Law Regulation provides certain procedures relating to food safety. Specifically, it provides 4 measures:[6]

- the establishment of the Rapid Alert System for Food and Feed (RASFF)
- the establishment of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee)
- the adoption of emergency measures

[6]Europska komisija Food Law Procedures, https://ec.europa.eu/food/safety/general_food_law/procedures_en

- the establishment of a general plan for crisis management.

Rapid Alert System for Food and Feed

The primary focus of the European Union is maintaining a high level of safety and ensuring quick responses to any threats that arise. One of the key tools used to react rapidly to food and feed safety emergencies and incidents is the Rapid Alert System for Food and Feed (RASFF). RASFF enables efficiently sharing of information between its members (EU-28 national food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland). RASFF members have to notify the RASFF if they take such measures as withdrawing or recalling food or feed products from the market in order to protect consumers' health and if rapid action is required.

Standing Committee on Plants, Animals, Food and Feed

The Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) plays a key role in ensuring that measures of the European Union on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt.

The PAFF Committee is composed by representatives of all Member States and it is presided by a European Commission representative.

The PAFF Committee's mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumer's table - helping the EU in effectively solving with health risks at every stage of the production chain.

Emergency measures

If food or feed, including those imported from a non-EU country, presents a serious and uncontainable risk to human health, animal health or the environment, the Commission can establish protective measures, based on an opinion from the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) and:

- suspend the placing on the market or use of products originating from the EU
- suspend imports of products originating from non-EU countries.

Such action can be initiated by the Commission itself, or it can be requested by a Member State. However, if the Commission does not act after after being notified of the existence of a risk, the EU country concerned may take temporary protective measures. Within a period of

10 working days, the Commission must refer the matter to the Standing Committee on Plants, Animals, Food and Feed with a view to extending, amending or revoking the national measures.

Crisis management

Sometimes incidents related to food or feed that pose serious risks to human health cannot be properly managed in routine procedures. In such cases, the Commission, European Food Safety Authority (EFSA) and the affected Union countries are required to follow the general crisis-management plan as adopted by Decision 2004/478/EC.

In the case of a serious risk, the Commission must immediately set up a crisis unit, which EFSA supports by providing scientific and technical support. The crisis unit is responsible for collecting and evaluating all relevant information and identifying the options available for preventing, eliminating or reducing the risk to human health.

3.2. Food Law in the Republic of Croatia

Regulation (EC) 178/2002 is applicable directly but has been formally taken over by the new Food Law (Official Gazette No. 81/2013) adopted on June 28, 2013 and published on June 29, 2013, which is in compliance with the regulations and regulations within the boundaries European Union.

The Act on Food (Official Gazette No. 81/2013) determines competences, controls, misdemeanor measures and a number of other provisions. The competent bodies for the implementation of this Act are the Ministry of Agriculture (MOA) and the Ministry of Health. The Ministry of Agriculture is responsible for the coordination of official controls and at the same time the contact point (contact point with the European Commission), while the Ministry of Health is responsible for establishing and implementing the food safety policy.

The Act lays down the competent bodies and tasks of the competent authorities, the obligations of food business operators and official controls, and prescribes administrative measures and misdemeanor provisions for the implementation of Regulation (EC) No. 178/2002 (OG 81/13). The law covers all phases of production, processing and distribution of food and feed except primary production, preparation, handling and storage of food and feed intended for use and personal consumption in the household. The concept of food and basic principles of food regulations has been defined: risk analysis, precautionary principle,

transparency and consumer protection principle based on the establishment of a food safety system.

Furthermore, basic rules for import and export, placing of food and feed on the market are laid down, a system for placing new food on the market, genetically modified food and genetically modified feed is set up.

Food business operators and feeders had to comply with the provisions relating to hygiene requirements, registration or approval of the facility, establishment and conduct of self-control, establishment of traceability and the obligation to withdraw or recall food or feed from the market if there is a reasonable doubt in her health correctness.

According to the Food Act (OG 81/13) a series of regulations concerning health, quality, labeling of food and feed have been adopted, a fast alert system for food and feed - RASFF), crisis management and emergency cases has been arranged. The law also clearly defines which food is not safe, health improper, or foods that are harmful to human health.

3.2.1. The Croatian Food Agency (CFA)

The Croatian Food Agency (CFA) is legal entity which role, organization and modus operandi are regulated by the Food Act (Official Gazette No. 81/13, 14/14 and 30/15), the Statute of Croatian Food Agency and other legal acts of Croatian Food Agency. The founder of the Croatian Food Agency is the Government of the Republic of Croatia. CFA was established by the Food Act from 2003, and officially has started with its work in January 2005. It is seated in Osijek. Director is the legal representative of CFA and is responsible for all operational and legal matters. CFA is funded by the state budget of the Republic of Croatia (RC).

CFA performs scientific and technical tasks in the field of food and feed safety and is national referent point for risk assessment in food and feed safety area. In performing its duties CFA is guided by principles of independence, transparency and confidentiality.

Activities of Croatian Food Agency are following jobs and tasks:[7]

- scientific risk assessment in the field of food and feed safety
- to provide scientific studies in the field of food and feed safety
- to provide scientific opinions at the request of the competent authorities, ex officio, or at the request of third parties for their needs,

[7] Croatian Food Agency, https://www.hah.hr/

- to provide technical opinions and scientific and technical support to the competent authorities in the areas of food and feed safety, food and feed quality, human nutrition, animal health and welfare, plant health,novel food, nutrient enriched food, food and feed for particular nutritional uses and GM food and feed,
- to provide initial risk assessment (as RASFF contact point in the Republic of Croatia),
- to collect and analyse data from official controls and other relevant data for characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety,
- to identify and characterize risks and emerging risks,
- to establish and coordinate national institution network in the field of food and feed safety in the Republic of Croatia,
- to develop and apply risk assessment methodologies in the field,
- to educate interested parties and publish educative materials about food and feed related risks,
- to inform public about matters within its field of work,
- to express independent conclusions and views on matters within its field of work and to provide rapid, reliable, objective and understanable information to the public and interested parties,
- to promote the effective coherence between risk management, risk assessment and risk communication.

CFA cooperates closely with competent institutes, academic society, laboratories and other legal entities in food and feed safety system in the Republic of Croatia. CFA also cooperates with other EU member states and competent international institutions and organizations in the field of food and feed safety.

CFA is Focal Point for cooperation with European Food Safety Authority (EFSA). CFA delivers information and data received from EFSA to the competent authorities in the Republic of Croatia (the Ministry of Agriculture and the Ministry of Health) and vice versa.

CFA has the task of evaluating the risk based on the research (scientific, professional) and notifying the results of risk assessment related to the health and hygiene of food and feed. The Ministry of Agriculture and the Ministry of Health, along with the State Inspectorate, are the

bodies responsible for the implementation of official controls over the implementation of this Act (Official Gazette No. 81/13).

3.3. EU rules on additives

All additives in the EU must be authorised and listed under the terms of use in the EU's positive list based on:

- Safety assessment
- The technological need
- Ensuring that use of the additive will not mislead consumers

Regulation (EC) 1333/2008 sets the rules on food additives: definitions, conditions of use, labelling and procedures and contains:

- Technological functions of food additives: Annex I
- Union list of food additives approved for use in food additives and conditions of use: Annex II
- Union list of food additives approved for use in food additives, food enzymes and food flavourings, and their conditions of use.: Annex III
- Traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives: Annex IV
- Additives labelling information for certain food colours: Annex V

Commission procedure

The Commission will change the EU lists of food additives with regulations through regulatory procedure with scrutiny (Decision 1999/468/EC). Producers must inform the Commission of new information which may affect the safety assessment of the food additive.

Rules for use in additives in food additives, food enzymes, food flavourings and nutrients

The list of authorised food additives approved for use in food additives, enzymes and flavourings can be found in the Annex of Commission Regulation (EU) No 1130/2011 which amends Annex III to Regulation (EC) No 1333/2008. The additives approved for use in flavourings can be found in part 4 of this Annex.

Specifications

Food additives must comply with specifications which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity.

Regulation (EU) No 231/2012 laid down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

Guidance documents

- Guidance notes on the classification of food extracts with colouring properties - On the 29th November 2013 the Standing Committee on the Food Chain and Animal Health approved the Guidance notes providing a tool for classification when considering whether a substance is a colour (i.e. a food additive) or not.
- Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives - The guidance document describing the food categories was elaborated by Commission services after consultation with the Member States' experts on food additives and the relevant stakeholders. The descriptions of the categories can be useful for Member State control authorities and food industry to assure correct implementation of the food additives legislation.

3.3.1. Safe food additives

Regulation (EC) No 1333/2008 of the European Parliament and Council of 16 December 2008 on food additives aims to replace previous European Union legislation by bringing all types of food additives under one legal act.

It provides list of:

- approved additives
- conditions on their use and labelling.

It also simplifies the authorisation procedure. Only EU-approved additives may be sold and used in food. To be approved, a food additive must not pose any health risks or mislead consumers. It must meet a reasonable need that cannot be achieved in any other way. An additive must provide benefits for consumers and these include: preserving food's nutritional quality; helping in its manufacture, processing, preparation, treatment, packing, transport or storage; meeting special dietary needs. Specific conditions apply to sweeteners and colourings. Additives should be used at the lowest level needed to achieve

the desired effect. This level must take account of an acceptable daily intake and the needs of special groups of consumers (e.g. people with allergies).
Additives as a rule should not be used in:

- unprocessed foods;
- foods for infants and young children.

Additives, whether for sale to the final consumer or not, must meet clear labelling requirements, such as providing the name and/or E-number (for instance, sunset yellow colouring is E 110). The legislation does not apply to the following substances, unless they are used as food additives which is mentioned in Article 2 (2) of Regulation (EC) No. 1333/2008 of the European Parliament and the Council of 16 December 2008 on nutritional additives:

a) processing aids, i.e. a substance used to process raw materials;
b) substances used to protect plants and plant products;
c) nutrients added to food;
d) water treatment substances.

Regulation has been applied since 20 January 2010. Most evaluations of additives date back to the 1980s and 1990s. They are now being re-evaluated and this process should be completed by 2020. After that, the European Commission may suggest changes to the current usage conditions, or remove some additives from the approved list. The safety of all food additives that are currently authorised has been assessed by the Scientific Committee on Food (SCF) and/or the European Food Safety Authority (EFSA). Only the additives considered to be safe for the intended use are listed on the EU list.

Regulation (EC) No. 1333/2008 on food additives has established a list of permitted food additives, fully published in Commission Regulation (EU) No. 1129/2011 of November 11, 2011.

4. LEGISLATION ON FOOD ADDITIVES

4.1. Legislation on food additives in the Republic of Croatia

The field of food additives in the Republic of Croatia is governed by the following regulations:

- Act on Food Additives, Flavorings and Food Enzymes (Official Gazette No. 39/2013) adopted on March 27, 2013.
- Ordinance on food additives (OG 62/2010), Amendments to the Ordinance (Official Gazette 62/2011, 135/2011 and 79/2012) which were made on the basis of Article 15, paragraph 2, subparagraph 4 of the Food Act (Official Gazette number 46/07 and 55/11).

The listed regulations are fully harmonized with EU regulations regulating the field of food additives, flavors, enzymes and nutrients in the European Union.

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4.1.1. Act on Food Additives, Flavorings and Food Enzymes

Act on Food Additives, Flavorings and Food Enzymes (Official Gazette No. 39/2013) was adopted on March 27, 2013.

The Act establishes the competent bodies, their duties, official controls and procedures, and the reporting of the competent authorities and the European Commission, as well as the obligations of the official laboratories and food business operators, for the implementation of the EU Regulation relating to additives and other substances to be added foods (enzymes, flavorings and the like).

Regulations regulating the field of food additives, enzymes and food flavorings in the European Union, which are implemented in the Republic of Croatia by this Act are:

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008),
- Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012),
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008),

- Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008),
- Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 168, 28.6.2012),
- Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003),
- Commission Regulation (EC) No 627/2006 of 21 April 2006 implementing Regulation (EC) No 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products

The competent authorities for the implementation of the Law on Food Additives, Flavorings and Food Enzymes in the Republic of Croatia are the Ministry of Agriculture and the Ministry of Health.[8]

4.1.2. Ordinance on Food Additives

The Ordinance on Food Additives (Official Gazette 62/10) was adopted on 1 March 2010. It prescribes the permissibility of use and other requirements for food additives used in food with a view to ensuring the efficient functioning of the market, the high level of human health protection, the interests of consumers, as appropriate environmental protection and fair trade behavior in food.

The provisions of this Ordinance apply to the additives.

This Ordinance takes over provisions in accordance with the following acts of the European Union:

[8] Act on Food Additives, Flavorings and Food Enzymes (Official Gazette No. 39/2013), Article. 3, Paragraph 1

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
- Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs
- Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners
- Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs
- Commission Directive 2009/163/EU of 22 December 2009 amending Directive 94/35/EC of the European Parliament and of the Council on sweeteners for use in foodstuffs with regard to neotame

4.1.3. Ordinance on Food Additives on Amendments to the Ordinance on Food Additives

The Ordinance on Food Additives on Amendments to the Ordinance on Food Additives (Official Gazette No. 79/2012) was issued on 20 June 2012.

The Ordinance contains provisions in accordance with the following acts of the European Union:

- Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (OJ L 295, 12.11.2011.);
- Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (OJ L 295, 12.11.2011.);
- Commission Regulation (EU) No 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides (OJ L 295, 12.11.2011.);
- Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) (OJ L 78, 17.3.2012.);

- Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012.)

In Annex II of the Ordinance on substances that may be added to the food and used in the manufacture of food and substances whose use is prohibited or restricted (Official Gazette No 160/13) includes *OTHER SUBSTANCES PERMITTED FOR USE*, including amino acid L-aspartic acid which is one of the ingredients of aspartame.

5. USE OF ADDITIVES

The use of additives is directly related to their basic functional, technological properties, and they are now divided into 26 categories: sweeteners, colours, preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti foaming agents, bulking agents, emulsifiers, emulsifying salts, firming agents, flavour enhancers, foaming agents, gelling agents, glazing agents, humectants, modified starches, packaging gases, propellants, raising agents, sequestrants, stabilisers, thickeners, flour treatment agents. The list of food additives, the method of use and the quantities permitted for food additions are established in a series of basic regulations, both in the European Union, in Regulation (EC) No. 1333/2008 on food additives from 16 December 2008 (OJ L354, 31.12.2008), as well as in Republic of Croatia.

Additives are labeled as E-number as a confirmation of the toxicological evaluation and classification of an individual additive. Substances similar to additives which also have a technological role in production, have no E-number and are differently marked (aromas and enzymes), while the auxiliary substances in the production process due to a mode of action that differs from the action of a true additive in food production, do not to have to be labeled although some of them have an E-number. When added to food, additives on the product declaration must be labeled with the category name, which is also the technological purpose of the additive use, followed by their specific chemical name or E-number.
If the additive has more than one technological function in the production of a foodstuff, it is necessary to state the technological effect that additive is added to the food, which in this case becomes the category of additive.[9]

Before being allowed to use additives in a particular food category, food additives must be estimated (tested and evaluated).

The Ordinance on Food Additives in the Republic of Croatia follows the Regulation (EU) No. 234/2011 laying down a common procedure for the approval of food additives, food enzymes and food flavorings.

[9] Ordinance on Food Additives (Official Gazette 62/10), Article. 3, Paragraph 2, Indent c) and Appendix I.

5.1. Toxicological evaluation of additives

Before placing the chemical compound on the food additive list, it is preceded by a long process of toxicological testing and evaluation, followed by recommendations on the amount and mode of use. The application for the use of the "new" additive is submitted to the Commission for Additives on the basis of the scientific opinion of the Croatian Food Agency (CFA) and it gives an opinion on the use of this additive. The final permit is issued when health determinants are assessed by estimating the intake of all foods in which the additive may be used. Toxicological, physiological and scientific data are monitored and evaluated so that there is constant monitoring of the effects of dietary additives on human health. Interaction of additives with food ingredients and the effect on human metabolism is particulary examined. Also, interactions of additives with other food ingredients and medicines are being examined. After thorough testing, the maximum amount of additive that does not cause any toxic effects or "No observed adverse affect level" (NOAEL) is determined. If several studies show different but similar results, the lowest value for determining NOAEL is taken. Minimum determined amount of a compound and also additives that can adversely affect human health are the "Lowest observed advance effect level" (LOAEL). For each additive for which it has been specifically determined, the largest quantity of no observed toxicological effects on health (NOAEL) is usually divided by the safety factor 100 taking into account the possible extrapolation differences with respect to the individual parts of the population with special attention to the population of children and the elderly person as a risk group. After previous tests and calculations using a safety factor, the obtained values serve as the basis for determining acceptable daily intake (ADI), which is defined as the amount of additive that can be consumed on a daily basis as an integral part of the food for a lifetime without any risk for health. The acceptable daily intake for each additive is individually expressed in mg/kg of human body mass. Based on the determination of the daily intake of foodstuffs and the amount of additives in these foods, actual daily intake for each additive can be determined and assess whether acceptable daily intake for each individual additive is exceeded. Like all tests and conclusions concerning human health, additives and their established acceptable daily intake (ADI) remain permanently under control so that at the time of new findings or better analytical methods are revised.

After testing the additives, the maximum allowable amounts that may be applied are determined. The maximum allowable quantities are determined at the lowest possible level

necessary to achieve the desired effect of the additive. The quantitative limit is expressed numerically as the maximum quantity allowed or by the "quantum satis" principle. Quantum satis means that the additives are used in accordance with Good Manufacturing Practice (GMP) in an amount not higher than necessary to achieve the purpose, provided that the consumer does not mislead.[10]

5.2. Additive lists

Based on data obtained from the toxicological assessment, the list of additives are compiled including the carriers approved for use in additives, food enzymes and flavorings, nutrients and conditions of their use.

Approved additives must comply with the additive specifications (criteria of purity) prescribed by Regulation EU 231/2012. Article 7 of the Ordinance on nutritional additives in Official Gazette No. 62/10 lists the conditions that the additive must meet in order to be included in the List of Ordinance on Nutritional Additives:

- not to endanger the health of consumers
- to be used in accordance with the permitted use
- that the use is technologically justified
- the use of additives does not mislead the consumer

Except for the above mentioned conditions, the additive must preserve the nutritional value of the food and provide the necessary ingredients of food produced for groups of consumers with special nutritional needs.

An additive may not be used to conceal effects by using poor quality raw materials or unauthorized procedures or methods, including non-hygienic procedures or methods.

An additive that meets these conditions is included in the List of Additives approved for use in food or on the List of Additives approved for use in additives, enzymes, flavorings and nutrients.

According to Article 8, paragraph 2 of the Ordinance on food additives (Official Gazette 62/10), the following information should be provided for inclusion of the additive on the List:

- the specific name of the additive and its E - number,
- the specific name of the additive and its E - number,

[10] Ordinance on Food Additives (Official Gazette 62/10), Article. 3, Paragraph 2. Indent h)

- the food to which the additive may be added
- conditions of use of additives
- limitation of use of additives

5.3. Institutions responsible for additives

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international scientific committee of experts of United Nations FAO/WHO. Until today more than 1,500 chemical compounds have been evaluated. It gives proposals to members to incorporate scientific opinions into their legislation on a particular additive. Opinions include toxicological evaluation, ADI, quantity suggestion and type of food to be used, as well as data that will determine the health of the additives. The start of work is 1955.

DG SANCO - Directorate General for Health and Consumers is responsible for the drafting of legislation on food, food safety and consumer rights, while the European Food Safety Agency (EFSA) has a scientific risk assessment, Scientific Committee on Food Additives and Nutrient Sources of Nutrient Supplements - The Panel on Food Additives and Nutrient Sources Added to Food (ANS) which under that name was formed on July 10, 2008 year.

The basic directive on additives came out in 1989. In Croatia, the Food Safety Authority is in the Ministry of Agriculture, while the risk assessment is carried out by the Croatian Food Agency (CFA), the Scientific Committee for Food Additives, Flavorings, auxiliary substances in the process of production and objects that come in direct contact with food. The Croatian Food Agency (CFA) was established in 2003 and the Food Safety Authority in July 2008. Analytical support is made by a number of laboratories of the Public Health Institute and the Veterinary Institute. All these bodies were preceded by national organizations that took care of additives, and they worked on the basis of recommendations of the Codex Alimentarius (Food Law Book), the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The Republic of Croatia is a member of the (CAC) of the Codex Alimentarius Commission since 1994, and the Codex Contact Point for the Republic of Croatia is the Croatian Standards Institute (CSI).

6. CATEGORIES AND LABELLING ADDITIVES

The European Union has established an E-numbering system, which was soon accepted by the Codex Alimentarius Commission, and was subsequently adopted by most countries of the world. The E-number is a certificate of toxicological evaluation, identification and classification of an individual additive.

6.1. Additive Categories according to tehnological and functional properties

Annex I of the Ordinance on food additives (Official Gazette 62/10) lists categories of additives, i.e. functional classes of food additives in food and nutritional additives in food additives and food enzymes[11]:

1. *'sweeteners'* are substances used to impart a sweet taste to foods or in table-top sweeteners
2. *'colours'* are substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours;
3. *'preservatives'* are substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms;
4. *'antioxidants'* are substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;
5. *'carriers'* are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;
6. *'acids'* are substances which increase the acidity of a foodstuff and/or impart a sour taste to it;

[11] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L354, 31.12.2008), Appendix I

7.*'acidity regulators'* are substances which alter or control the acidity or alkalinity of a foodstuff;

8. *'anti-caking agents'* are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

9. *'anti-foaming agents'* are substances which prevent or reduce foaming;

10. *'bulking agents'* are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

11. '*emulsifiers*' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

12. . *'emulsifying salts'* are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

13. '*firming agents'* are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel;

14. *'flavour enhancers'* are substances which enhance the existing taste and/or odour of a foodstuff;

15. *'foaming agents'* are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

16. *'gelling agents'* are substances which give a foodstuff texture through formation of a gel;

17. *'glazing agents'* (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating:

18. *'humectants'* are substances which prevent foods from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

19. *'modified starches'* are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

20. *'packaging gases'* are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

21. *'propellants'* are gases other than air which expel a foodstuff from a container;

22. *'raising agents'* are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

23. *'sequestrants'* are substances which form chemical complexes with metallic ions;

24. *'stabilisers'* are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food;
25. *'thickeners'* are substances which increase the viscosity of a foodstuff;
26. *'flour treatment agents'* are substances, other than emulsifiers, which are added to flour or dough to improve its baking.

6.2. Labelling additives

All food additives in the European Union are identified by an E number. Food additives are always included in the ingredient lists of foods in which they are used. Product labels must identify both the function of the additive in the finished food (e.g. colour, preservative) and the specific substance used either by referring to the appropriate E number or its name (e.g. E 415 or Xanthan gum). The most common additives to appear on food labels are antioxidants (to prevent deterioration caused by oxidation), colours, emulsifiers, stabilisers, gelling agents and thickeners, preservatives and sweeteners. According to action and purpose additives are designated by the E numbers in the ranges shown in the table below. The E-numbering system was introduced to rationalize the range of additives already in use and to make the additive identification easier. Prefix E denotes additives that are applicable in Europe.

Table 1: Review of labelling additives

Activity	Range of E numbers
Colours	100-181
Preservatives	200-285 i 1105
Antioxidants	300-340
Acidity regulators	Different numbers
Thickeners/emulsifiers	322, 400-499 i 1400-1451
Anti-caking agents	550-572
Flavor enhancers	600-650
Glazing agents	900-910
Sweeteners	420, 421, 950-970

Source: Katalenić M., Additives, food and consumer, Zagreb, March 2005, p. 9

Depending on the intended use, the additives are divided into:

- additives not intended for sale to the final consumer
- additives intended for sale to the final consumer

6.2.1. Labelling additives not intended for sale to the final consumer

Article 21 of the Ordinance on food additives (Official Gazette 62/10) lays down the information to be contained on the packaging or containers and is clearly visible, clearly readable and indelible in the case where additives not intended for sale to the ultimate consumer are sold individually or in interchange mixed with other food ingredients:

- the name and/or E-number laid down in this Ordinance in respect of each food additive or a sales description which includes the name and/or E-number of each food additive;
- the statement ‘for food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use;
- if necessary, the special conditions of storage and/or use;
- a mark identifying the batch or lot;

- instructions for use, if the omission thereof would preclude appropriate use of the food additive;
- the name or business name and address of the manufacturer, packager or seller;
- an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Ordinance or other relevant food regulations; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle;
- the net quantity;
- the date of minimum durability or use-by-date;
- where relevant, information on a food additive or other substances.

6.2.2. Labelling additives intended for sale to the final consumer

According to Article 22 of the Ordinance on food additives (Official Gazette 62/10) additives sold individually or in a mixture and/or other food ingredients intended for sale to the final consumer may only be placed on the market if their packaging contains the following information:

a) the name and E-number laid down in Regulation (EC) No. 1333/2008 in respect of each food additive or a sales description which includes the name and E-number of each food additive

b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use

The labelling of a table-top sweetener containing polyols and/or aspartame and/or aspartame-acesulfame salt shall bear the following warnings:

(a) polyols: 'excessive consumption may induce laxative effects';

(b) aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'[12].

[12] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L354, 31.12.2008), Article. 23, Paragraph 3.

7. SWEETENERS

According to the definition of category of additives sweeteners are substances used to impart a sweet taste to foods or in table-top sweeteners.

'Table-top sweeteners' shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugars.[13]

A food additive may be included in the List for the functional class of sweetener only if it serves one or more of the following purposes:
a) replacing sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars, or
b) replacing sugars where this permits an increase in the shelf-life of the food; or
c) producing food intended for particular nutritional uses in accordance with the provisions of the Ordinance on food for special nutritional uses (Official Gazette 78/08) which is harmonized with the provisions of Directive 89/398/EEC of 3 May 1988 on the harmonization of Member States legislation concerning food for particular nutritional needs.[14]

7.1. Specific name and E number of sweeteners

Annex II Part B 2. *Sweeteners* of the Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette 79/12) specifies the specific name and E number of sweeteners

[13] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L354, 31.12.2008), Article.3, Paragraph g)
[14] Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette No. 79/2012), Article 7a

Table 2: E number and specific name of sweeteners

E number	*Specific name*
E 420	Sorbitols
E 421	Mannitol
E 950	Acesulfame K
E 951	Aspartame
E 952	Cyclamates
E 953	Isomalt
E 954	Saccharines
E 955	Sucralose
E 957	Thaumatin
E 959	Neohesperidine DC
E 960	Steviol glycosides
E 961	Neotame
E 962	Salt of aspartame-acesulfame
E 965	Maltitols
E 966	Lactitol
E 967	Xyilitol
E 968	Erythritol

Source: Annex II Part B 2. *Sweeteners* of the Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette 79/12)

7.2. Classification of table-top sweeteners

The Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette 79/12) in *PART D* of the *FOOD CATEGORIES* lists the division of table-top sweeteners

Table 3: Classification of table-top sweeteners

11.4	**Table-top sweeteners**
11.4.1	Table-top sweeteners in liquid form
11.4.2	Table-top sweeteners in powder form
11.4.3	Table-top sweeteners in tablets

Source: *PART D* of the *FOOD CATEGORIES* the Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette 79/12)

7.3. Approved sweeteners and conditions of use in Food categories

Within Part B of the Ordinance on Amendments to the Ordinance on Food Additives (Official Gazette No. 79/12), among others, sweeteners and maximum permitted quantities are stated. Table one of the Codex Alimentarius also lists the food category number, the notes and the year of adoption.

7.4. Informing consumers about food containing sweeteners

Annex III of the Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, mentions *FOODS FOR WHICH THE LABELLING MUST INCLUDE ONE OR MORE ADDITIONAL PARTICULARS*, where besides other type/category of food, under item 2. **Foods containing sweeteners** is defined what must be stated on the label.

Table 4: Labelling food containing sweeteners

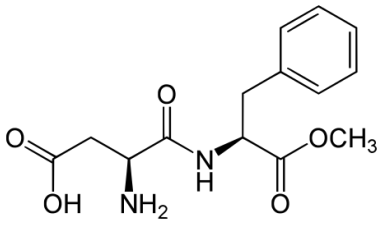
TYPE OR CATEGORY OF FOOD	PARTICULARS
2. Foods containing sweeteners	
2.1. Foods containing a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008.	'with sweetener(s)' this statement shall accompany the name of the food.
2.2. Foods containing both an added sugar or sugars and a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008.	'with sugar(s) and sweetener(s)' this statement shall accompany the name of the food.
2.3. Foods containing aspartame/aspartame-acesulfame salt authorised pursuant to Regulation EC) No 1333/2008.	'contains aspartame (a source of phenylalanine)' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E number. 'contains a source of phenylalanine' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients by its specific name.
2.4. Foods containing more than 10 % added polyols authorised pursuant to Regulation (EC) No 1333/2008.	'excessive consumption may produce laxative effects'.

Source: Annex III of the Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011

8. ASPARTAME

Aspartam is the name for a non-energetic, synthetic highly intensive sweetener N- (L-α-aspartyl) -L-phenylalanine 1-methyl ester. It is added to about 6,000 food items, especially in non-alcoholic beverages.

Picture 1: Molecular formula of aspartame



Source: https://en.wikipedia.org/wiki/Aspartame

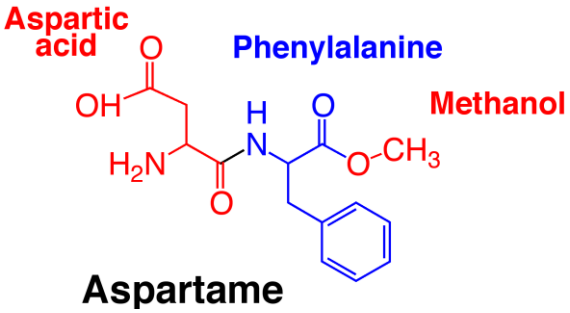
Synonyms: NutraSweet, Equal, Sugar Twin
Molecular formula: C14H18N2O5
Molar mass: 294,301 g/mol
Appearance: White crystalline powder having a sweet taste and no smell
CAS number (Chemical Abstract Service): 22839-47-0
Density and phase: 1.347 g/cm3
Water solubility: 10 g/100 ml pri 25 °C
Melting point: 246-247 °C
Boiling point: Decomposes
The main danger: Toxicity

In 1965, American chemist James M. Schlatter, working on a project to discover new gastric ulcer treatments by chance, discovered as a byproduct aspartyl-phenylalanine methyl ester-ASPARTAM. Aspartam has a sweet taste with minimal bitterness. Its calorific value is 4 kcal/g, and sweetness about 180 times larger than the sucrose, so its energy value added to food is negligible. In the body is metabolized to its components:

- Aspartic acid-aspartate: a natural amino acid that is a constituent part of a protein. It is not an essential acid, so if it is not introduced into the organism through food, the organism itself synthesizes it.

- Phenylalanine: an essential amino acid. People lacking an enzyme converting phenylalanine into tyrosine can not metabolize phenylalanine. This is called phenylketonuria because then the excess phenylalanine turns into phenylketones and if such condition is not treated it can lead to mental retardation. Therefore on products containing aspartame, it should be noted - 'contains the source of phenylalanine'.
- Methanol: alcohol that is poisoned in large quantities.

Picture 2: Degradation products of aspartame



Source: http://www.sweetenerbook.com/aspartame_2.html

Over the past decades, many studies have investigated the impact of aspartame on human health, with two contradictory opinions: on one hand, it tried to prove the toxic effects of aspartame and attribute its carcinogenic properties while on the other hand (primarily the food industry or the artificial sweetener industry) demonstrated the absolute non-toxicity of aspartame when used in approved doses. In rats research, aspartame has been shown to be a carcinogen with carcinogenic effects occurring at a daily dose of 20 mg/kg body weight. This value is lower than the daily admissible dose currently available for people that amounts 50 mg/kg in America and 40 mg/kg in the EU. However, it is important to note here that the aggressive promotion of large producers (including products containing aspartame) the intake of aspartame is increasing, especially in adolescents and young people who consume large amounts of non-alcoholic refreshing drinks sweetened by artificial sweeteners.

Table 5: Aspartame brief timeline

1974	The FDA decided to reconsider the approval of aspartame
1980	The FDA Public Board submitted a written inquiryfor the safety of NutraSweet
1981-1983	Aspartame was once again approved as a food additive in dry foods and carbonated beverages
1984	CDC (Center for Disease Control) published the first customer complaint list associated with aspartame use
1992	The FDA releases a list containing a total of about 8000 complaints against aspartame
2004-2007	Animal studies performed in Europe suggested that aspartame could disrupt human health by causing cancer
2010	Italian study indicates leukemia and lymphoma are linked to Aspartame usage. Another study linked risk of premature delivery in pregnant women
2011	The European Food Safety Authority notes previous studies did not give enough cause for reconsideration of aspartame
2013	Aspartame was finally approved considered safe to be consumed at the current levels of exposure

Source: *http://www.thenutritionalsource.com/aspartame-acesulfame-potassium-not-healthy-cause-cancer-with-no-calories/*

8.1. EFSA scientific opinion on aspartame[15]

All food additives authorised in the European Union (EU) pass a thorough safety assessment. Since January 2002, the European Food Safety Authority (EFSA) provides independent scientific advice and communication on risks associated with the food chain. As prescribed by EU legislation, EFSA has started up a programme for the re-evaluation of the safety of all previously authorised food additives. Besides the re-evaluation of aspartame as part in this programme, it is also the first time that EFSA has carried out a full assessment of the substance.

[15] EFSA Scientific Opinion on Aspartame http://www.efsa.europa.eu/en/corporate/pub/factsheetaspartame

8.1.1. What is aspartame?

Aspartame is a low-calorie food additive, artificial sweetener - approximately 200 times sweeter than sugar and contains 4 calories per gram. It is approved world-wide, including the European Union.

The use od aspartame as sweetener has been approved for a whole range of food products and beverages and has been used in drinks, desserts, sweets, dairy products, chewing gums, energy-reduced and weight control products, and as a table-top sweetener.

8.1.2. What happens after ingestion of aspartame?

Aspartame consists of the two naturally amino acids, phenylalanine and aspartic acid, which are also components of proteins in our body and in food. The phenylalanine in aspartame has been slightly modified by adding a methyl group which gives aspartame its sweet taste.

Proteins in our foods are digested in the intestines. Enzymes break the ingested proteins into smaller molecules (peptides) and the individual amino acids that are then absorbed by the body where they can then together produce new proteins or body energy. The same process happens with aspartame.

Aspartame is completely broken down in the intestines to aspartic acid and phenylalanine, which are absorbed and enter our body. In addition, the methyl group from the modified phenylalanine is released in the intestines to form methanol. Methanol is also absorbed by the body and most of it used to produce energy.

All the scientific studies to date in animals and human volunteers have shown that the degradation of aspartame in the intestine is very fast and complete. Aspartame has never been found in the blood or any other organ after ingestion. This discovery has important implications on how scientists assess the safety of aspartame. Any reported effect occuring in the body after ingestion of aspartame will be caused by one of more of the three components, aspartic acid, phenylalanine or methanol.

8.1.3. Is aspartame safe?

Aspartame safety has been tested in hundreds of different studies. Leading scientists from all over Europe examined all these studies, which have looked at the short-term and long-term

effects of aspartame on experimental animals, including the potential of aspartame to cause cancer or neurotoxicity and the effects of aspartame on the reproductive function, on fetal development and on its potential to cause damage to our genes.

One of the challenges faced by EFSA was that many of the studies were old, dating back to the 1970s. This is not unusual for long established food additives. While standards in the design and implementation of studies have significantly developed since then through the introduction of standardised protocols, the consensus opinion of EFSA's experts was that the quality and number of animal studies available was enough high to allow conclusions.

8.1.3.1. DNA damage and cancer

EFSA's experts could exclude a potential risk that aspartame causes damage to genes and induce cancer. Recently conducted animal studies were included in the risk assessment (including the studies performed by the ERF European Ramazzini Foundation), which did not produce any scientific evidence supporting a carcinogenic effect of aspartame.

Furthermore, there is no evidence that aspartame causes cancer according to existing studies of large human population.

8.1.3.2. Brain damage and behavioural consequences

EFSA's scientific experts also concluded that aspartame does not cause any damage to the brain or induce behavioural consequences, such as hyperactivity.

8.1.3.3. Reproductive and developmental effects

Studies conducted in rabbits to identify all the possible effects of aspartame on the development of the unborn organism (fetus) showed that the pups were born with smaller weights and in smaller numbers. This is the result of an increased number of abortions in mothers who have received very high doses of aspartame. In the same studies, high doses of the amino acid phenylalanine induced similar effects on pup weight and abortions. This similarity suggests that the effects of high doses of aspartame on rabbit development were mediated by phenylalanine. Therefore, experts decided that it was more appropriate to use the available body of experimental and medical human data on phenylalanine for the risk assessment of aspartame. EFSA used the "mode of action" to assess the effects of aspartame on reproductive toxicity.

The Mode of Action (MoA) was developed by the World Health Organisation's International Programme on Chemical Safety (IPCS) to provide a structured approach to assess the importance for humans of experimental observations in animals. The MoA requires an understanding of how and why a chemical is toxic in experimental animals. Moreover, it takes into account anatomical, physiological, and biochemical differences between species. This information can be used to estimate how the chemical could be poisonous in humans.

Adverse effects of excessive phenylalanine levels on pregnancy are not unique to animals but also occur in humans with reduced metabolism of phenylalanine. This disease is called phenylketonuria (PKU) and causes an increased level of phenylalanine in blood which is toxic to the brain. If not treated, it can affect fetal and brain development and cause mental retardation, mood disorders and behavioural problems.

Phenylketonuria (PKU) is the most common inherited disorder of amino acid metabolism. Due to a functional lack of the enzyme phenylalanine hydroxylase (PAH), phenylalanine cannot be metabolised and accumulates in body fluids. In Phenylketonuria, both copies of the phenylalanine hydroxylase (PAH) gene are mutated to produce an inactive enzyme of phenylalanine hydroxylase. In patients with this disease, plasma phenylalanine levels exceed 20 mg/dl without treatment. Increased levels of phenylalanine in the blood can lead to brain damage and affect cognitive function. If phenylalanine levels are not controlled through dietary or pharmacological treatment, Phenylketonuria patients almost always suffer from intellectual disabilities. The overall birth prevalence of Phenylketonuria in the European population is approximately 1/10,000 although its frequency varies between different ethnic groups and geographical areas. Phenylketonuria is usually diagnosed through newborn screening testing that is performed shortly after birth on a blood sample (heel prick test, sometimes known as a Guthrie test). The blood sample is sent to a laboratory where the level of phenylalanine is measured. Individuals with Phenylketonuria diagnose require a strict adherence to a low phenylalanine diet and medications. In Phenylketonuria patients, a limitation of foods rich in protein (meat, fish, eggs, bread, dairy products, nuts and seeds), as well as avoidance of drinks containing aspartame help control the level of phenylalanine in the blood. The development of fetuses of women suffering from Phenylketonuria is particularly sensitive to the levels of mother's phenylalanine. Experts compared blood levels of phenylalanine in humans after consuming aspartame, with blood phenylalanine levels associated with developmental effects in children born from mothers suffering from

Phenylketonuria. To avoid child developing risks, current clinical guidelines recommend that levels of phenylalanine in the mother's blood should be maintained below 6 mg/dl. Mild effects were associated with levels of phenylalanine in the mother's blood of 10-13 mg/dl, while significant adverse effects were 18-20 mg/dl.

In calculating a safe level of exposure to aspartame (based on concentraction of phenylalanine in the blood), the scientific experts assumed a scenario that intake of aspartame occurs in combination with a meal (containing natural sources of phenylalanine), and estimated a worst-case scenario contribution to phenylalanine levels from that meal. They also included many additional conservative assumptions.

Experts modelled the effects of consuming aspartame doses exceeding several times current Acceptable Daily Intake using data on phenylalanine concentrations in the blood after aspartame ingestion. The results of the analysis showed that an adult weighing 60 kg drinking 12 (330ml) cans of a diet soft drink (containing aspartame at the maximum permitted levels of use), every hour would still have a blood phenylalanine concentration below 6 mg/dl as recommended by current clinical guidelines without reported health effects.

8.1.3.4. Effects of methanol, aspartame's metabolite

Experts have included methanol in their risk assessment of aspartame. Like aspartic acid and phenylalanine, methanol is also naturally present in foods including fruits and vegetables. Far the largest quantity of methanol in humans (some 90% on average) is naturally produced by the body from the consumption of pectin-containing fruits such apples and citrus fruits.

Methanol is a safety concern when exposure is extremely high, as in the case with the consumption of some home-distilled alcoholic spirits.

Based on the available scientific evidence, EFSA's experts concluded that dietary exposure to methanol including from aspartame would not cause adverse effects since it only make a small part compared to the natural production by the body. They also concluded that methanol from aspartame is processed by the body in the same way as methanol derived from other dietary sources.

8.1.4. Acceptable Daily Intake

The first safety assessment of aspartame conducted out in Europe was published by the Scientific Committee on Food (SCF) in 1984 and an Acceptable Daily Intake (ADI) for aspartame of 40 mg/kg body weight was set up.

In carrying out the present reassessment of the safety of aspartame, EFSA's experts concluded that the Acceptable Daily Intake for aspartame set by the Scientific Committee on Food is safe for the population (except Phenylketonuria patients) and that exposure of consumers to this sweetener is below the Acceptable Daily Intake. Phenylketonuria patients are excluded from this evaluation. Labelling of aspartame in order to inform this population of the presence of phenylalanine in aspartame is obligatory.

8.1.5. Review of literature

The comprehensive overview was provided following two public calls for data which made it possible disposition a large number of scientific information, including both published and previously unpublished data and studies, and exhaustive literature searches. This included the 112 original documents on aspartame that were submitted to support the request for authorisation of aspartame in the early 1980s. In the interests of transparency, EFSA published the full list of these studies and allowed availability of previously unpublished data.

8.1.6. What happens next?

The re-evaluation of aspartame is part of a systematic review of all food additives authorised in the EU before 20 January 2009.

Food additives approved until January 2009 are subject to the new risk assessment carried out by the Authority.[16]

8.2. EFSA's recent activities

Since 2002, EFSA regularly monitors the safety of aspartame and its Scientific Panels have issued several opinions on studies related to this sweetener. Currently, this work is carried out by the Panel on Food Additives and Nutrient Sources Added to Food (ANS).

EFSA's expert Panel on Food Additives and Nutrient Sources Added to Food (ANS) carries out its safety evaluations of food additives. It reviews all available, relevant scientific data, including information on chemical and biological properties, potential toxicity and estimates of human dietary exposure. Based on these data, the Panel draws conclusions on the safety of the intended uses of the food additive for the consumers.

[16] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L354, 31.12.2008), Article 32

The ANS Panel evaluates the safety of new food additives and new uses of permitted food additives. Since 2009 the Panel has also been re-evaluating all then permitted food additives, with completion by 2020.

The assessment is part of systematic revaluation of all food additives authorised in the EU by 20 January 2009, as provided by Commission Regulation (EU) No. 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

In December 2013 EFSA published its first full risk assessment of aspartame. The opinion concludes that aspartame and its degradation products are safe for general population (including infants, children and pregnant women).

On 24 November 2017, EFSA will host one-day workshops on the status of the EU Food additives Re-Evaluation Program. The day before, 23 November 2017, observers will have the opportunity to attend the open plenary session of the EFSA's Panel on Food Additives and Nutrient Sources Added to Food (ANS).

8.3. Conclusions of conducted research

Many independent scientists proved that aspartame causes a large number of different disorders and adverse side effects in humans including headache, memory loss, mood swings, nerve seizures similar to epilepsy, multiple sclerosis, Parkinson's disease-like symptoms, tumors, and even sudden death.

The US Food and Drug Administration (FDA), based on numerous evidence presented by many eminent scientists, attorneys and consumer associations, confirmed that aspartame causes significant and serious damage to the central nervous system, and has been proven to cause cancer in the animal, and has for a full eight years refused approval for aspartame use in the food and pharmaceutical industry.

In the fall of 1967, a scientist-biochemist, Dr. Harry Waisman, Director of Wisconsin University Joseph P. Kennedy Jr., a Memorable Laboratory for Mental Retardation Research and a well-known phenylalanin toxicity expert (which makes up 50% of aspartame composition) conducted a research on the effects of aspartame in humanoid monkeys. Seven monkeys were fed with milk in which aspartame was added, of whom one ape died while others had very severe seizures similar to epilepsy.

In the spring of 1971 Dr. John Olney, a professor of neuropathology and psychiatry at the University of Washington, responsible for banning the neurotoxic food additive monosodium-glutamate in the production of pediatric food, conducted a study of the effect of aspartic acid, one of the major ingredients of aspartame, and discovered that it was causing holes in the brain in newborn mice.

Ann Reynolds, one of GD Searle's company scientists, conducted a similar research and confirmed Dr Olne's findings. The medical journal Medical World News published information in 1978 that the content of methanol in aspartame was 1000 times larger than allowed. It is well known that high methanol concentration is deadly poison. However, political powers who resisted scientific evidence have contributed to the approval of aspartame in 1981 since it was on the market. For aspartame approval, most respected was Donald Rumsfeld, General Manager of Searle Company.

On May 30, 1984 the FDA approved the use of aspartame in multivitamin products. Already in July of the same year, the results of the research carried out in Arizona, relating to aspartame, were published in a specialized food Journal of Applied Nutrition. Research has shown that in non-alcoholic beverages held at increased temperature aspartame is much more rapidly disintegrated into poisonous methanol. In 1989, the FDA received more than 4,000 complaints from consumers on side effects caused by artificial sweeteners aspartame. In October 1989, Dr. H. J. Roberts, director of the Palm Beach Institute for Medical Research, claimed that several recent aircraft crashes were caused by deviant disturbance of the pilot and confusion resulting from the consumption of aspartame products. The British National Institute of Health published in 1991 Adverse Effects of Aspartame From January 1986 to December 1990, which included 167 studies that documented the adverse side effects caused by aspartame.

Despite the already known side effects when consuming aspartame, on 19 April 1993 the FDA approved the use of aspartame in hard and soft candies, soft drinks, ice teas, fruit juices, bakery products, bakery mixes, glazes, toppings and supplements for bakery products.

In April 1995, an association of consumers and activists gathered at Mission Possible - an association against aspartame based on the legal right to information was forced by the FDA

to publish official information on harmful side effects of aspartame, most of which related to impairment of neurological function. Harmful side effects include: headache, dizziness or balance problems, vomiting, convulsion and nerve attacks, memory loss, tremor, muscle weakness, abdominal pain and cramps, changes of vision, diarrhea, tiredness, exhaustion and weakness, skin redness, weakness of vision, pain in the muscles and joints.
In spite of all the published data on the adverse effects of aspartame on human health, on June 27, 1996, the FDA removed any restrictions on the use of aspartame, so it was approved as a "general-purpose sweetener", meaning that it could be used in any food product and drinks. In November 1996, Dr. John Olney proved that the incidence of brain tumors is constantly increasing and that their occurrence is associated with the consumption of aspartame and there has been a significant change in the type of tumor - fewer lethal brain tumors have been replaced by high deadly brain tumors, he published that in the journal "Neuropathology and Experimental Neurology".

Dr. Ralph G. Walton, Professor of Clinical Psychology from Northeastern Ohio Universities, published in December 1996 the results of the study, which cast a new light on the absurdity of the conducted studies on aspartame health safety. Walton carefully examined and studied 165 separate studies in the last 20 years that were published in well-known medical journals. Of the above mentioned number of studies, 74 funded the industry, and out of the remaining 91 studies that did not finance the industry, 84 showed a negative effect of aspartame on human health.

Independent scientists at the University of Barcelona published in May 1998 research results on rats that clearly demonstrated the conversion of aspartame to formaldehyde in a living organism that then spread to vital organs including the liver, kidneys, eyes and brain.
The results of this study are immediately presented to the aspartame manufacturer who claims that aspartame in the body does not break into formaldehyde and have also confirmed claims of aspartame's critics that many of the symptoms associated with the adverse effect of aspartame are actually a consequence of the harmful and toxic activity caused by the cumulative effect of formaldehyde.

The Institute of Ramazzini in Bologna, a private non-profit institution investigating the causes of cancer, published in July 2005 the results of extensive and long-term research into animals

that took aspartame in the body by ingestion. This study showed that aspartam causes lymphoma and leukemia in females fed aspartame at a dose of about 20 milligrams/kg of body weight, or about half the daily dose recommended for humans.

8.4. Protection against damping import of aspartame originating in the People's Republic of China (PRC)

In order to protect the industry of the European Union from further material damage caused by Chinese damping import of aspartame, on 30 May 2015, the European Commission initiated an anti-dumping investigation with regard to imports into the Union of aspartame originating in the People's Republic of China following a complaint submitted on April 16, 2015 by Ajinomoto Sweeteners Europe SAS ('ASE'). On 15 October 2015 ASE was purchased by Hyet Holding BV and the name of the producer has changed to Hyet Sweet SAS ('Hyet'). The complainant is the sole producer of aspartame in the Union and therefore represents 100% Union production of aspartame. The complaint contained evidence of dumping and of resulting material injury that was sufficient to justify the initiation of the investigation. Commission implementing Regulation (EU) 2016/262 of 25 February 2016 imposed a provisional anti-dumping duty on imports of aspartame originating in the People's Republic of China.

The investigation of dumping and injury covered the period from 1 April 2014 to 31 March 2015 ('the investigation period'). The examination of trends relevant for the assessment of injury covered the period from January 2011 to the end of the investigation period ('the period considered').[17]

Six exporting producers in the People's Republic of China concerned provided the requested information and agreed to be included in a sample. The three sampled Chinese exporting producers or groups that agreed to cooperate represent about 90 % of the total imports of aspartame originating in the PRC.

Product concerned is referring only to aspartame (N-L-α-Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester), CAS RN 22839-47-0, originating in the PRC, currently falling within CN code ex 2924 29 98 ('the product concerned', or 'aspartame').

[17] Commission implementing Regulation (EU) 2016/262 of 25 February 2016 imposed a provisional anti-dumping duty on imports of aspartame originating in the People's Republic of China (OJ L50, 26.2.2016), point 1.8.

Consumption in the Union was based on the sales of the Union producer and imports from the PRC. Aspartame is except from the Union, the PRC and Japan currently only produced in South Korea. The only producer in the US withdrew from the aspartame market in 2014. Based on the available data there were no or only insignificant imports of aspartame into the Union market from Japan, Korea or the US throughout the period considered.

The investigation showed that practically all economic indicators deteriorated during the period considered, except for the market share which remained stable.

Therefore Commission concluded that due to the Chinese damping imports, the Union industry suffered material injury and that no other factor broke the casual link between the Chinese imports and the injury suffered by the Union industry.

The continuous and aggressive price pressure of the PRC forced the Union industry to reduce its prices below total cost of production and suffer significant losses, in particular during the investigation period.

Almost all injury indicators showed negative trends over the period considered, especially production volume, sales volume, sales prices and employment. A downward trend was also established for indicators related to the financial performance, such as profitability, cash flow and return on investments. The Commission concluded that the imposition of anti-dumping duties would be in the interest of the Union industry. Provisional anti-dumping duties for 6 Chinese exporting producers of aspartame into the Union range from 55,4% to 59,4%.

Commission implementing Regulation (EU) 2016/1247 of 28 July 2016 introduced a definitive anti-dumping duty on imports of aspartame originating in the People's Republic of China. This regulation includes aspartame (N-L-α-Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester), CAS RN 22839-47-0, originating in the People's Republic of China, currently classified within CN code ex 2924 29 98 (TARIC code 2924 29 98 05).

Article 2 of Regulation 2016/1247 imposes a final charge on amounts secured by provisional anti-dumping duties on the basis of Commission Implementing Regulation (EU) 2016/262.

9. CONCLUSION

Due to the rapid increase in the use of additives in the food industry in the second half of the 20th century, the interest of science has increased for the safety of their application. By intensifying the research it has been shown that some additives, especially aspartame, if consumed in larger quantities, may have a harmful effect on health or in certain populations cause hypersensitivity and allergic reactions. All this has led to increased awareness and even excessive consumer concern about the use of additives.

Aspartame is one of the most thoroughly studied and most controversial food ingredients ever which the US Food and Drugs Administration declared safe for use in 1981, although, based on numerous research and evidence presented by many scientists and consumer associations, for a full eight years the FDA refused approval for its use in the food and pharmaceutical industries.

Many studies have concluded that phenylalanine, one of the aspartame degradation products, has a harmful effect on persons suffering from phenylketonuria and that aspartame is unsafe for these people, as confirmed by the scientific opinion of the European Food Safety Agency (EFSA). Therefore, foods containing aspartame must have a well-noticeable text on the label 'containing a source of phenylalanine'.

Besides phenylalanine, studies have shown harmful effects and the other two ingredients of aspartame: methanol and aspartic acid.

Research results ordered and funded by manufacturers were in favor of aspartame, while the results of other independent studies prove its harmfulness.

The research conducted by the Ramazzini Institute had many criticism because the results were not validated and EFSA concluded that there is no evidence for aspartame carcinogenicity.

Therefore, it is certainly difficult for consumers to trust the safety of substance that have been approved and refused so many times and is subject to numerous complaints.

EFSA regularly monitors aspartame safety since 2002 and re-evaluates all then authorised food additives, with the completion by 2020. At the end of 2013, it published its first full risk assessment of aspartame in which it concluded that aspartame and its degradation products are safe.

However, the recommendation of independent experts is to avoid aspartame at all cost and to replace it with a healthier alternative such as Stevia, honey or raw sugar.

In order to reduce the material damage caused to the European Union due to the increasing Chinese dumping imports of aspartame, anti-dumping duties have been introduced to help the recovery of the industry.

The Croatian legislation on food additives is fully aligned with the EU regulations which regulate the field of food additives, flavors, enzymes and nutrients.

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives replaces previous European Union (EU) legislation by bringing all types of food additives under one legal act and includes a list of approved additives and the conditions for their use and labelling.

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32. Commission Implementing Regulation (EU) 2016/262 of 25 February 2016 imposing a provisional anti-dumping duty on imports of aspartame originating in the People's Republic of China http://eur-lex.europa.eu/legal-content/HR/TXT/?uri=CELEX:32016R0262
33. Commission Implementing Regulation (EU) 2016/1247 of 28 July 2016 Imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of aspartame originating in the People's Republic of China http://eur-lex.europa.eu/legal-content/HR/TXT/PDF/?uri=CELEX:32016R1247&rid=1