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EVALUATION OF FOOD SAFETY

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In evaluation of food safety, microbiological and physico-chemical requirements are taken into consideration. Food safety assurance is carried out attained by toxicological evaluation of substances present in food, determination of its acceptable (ADI) or tolerable (PTWI or PMTDI) levels for human and adequate legal regulations.

The development of various branches of industry, power plants and chemical organic synthesis, as well as intensyfications of agrotechnical and zoohygienic methods and food technology leads to the appearance in food products of various chemical compounds harmful to human health. The poor quality of raw materials obtained without maintaining of the principles of good agricultural and farming practice, errors of technological processes, faulty methods of packing, transport and storage are the causes of chemical and microbiological contamination of food as a result of the activities of man of environmental presence of contaminants. Food safety depends on the microbiological quality and presence of chemical substances in food which are not nutrients. Safe food should have a proper nutritive value and possibly low degree of microbiological and chemical contaminants.

The advances in food technology and better knowledge of hygiene principles in the populations have contributed greatly to significant improvement of the microbiological quality of food. The use modern, automated, closed production lines with computer control has limited considerably the direct contacts of workers with food products and has contributed to improvement of their quality and prolongation of the time of their suitability for consumption, even despite reduced utilization of preserving agents.

However, the occurrence of diseases and food poisonings following the consumption of food excessively contaminated by microorganisms, especially pathogenic ones, is still observed in highly developed as well as in developing countries [5].

Acute food poisonings, even those with milder course, can lead, especially in children to malnutrition, similar to that developing in cases of food deficiencies (Fig 1).

Poisonings with chemical substances present in food are rare. They are found there usually in low amounts, or even in trace amounts and can contribute to late adverse effects of their action. For this reason it is very important to assess foreign substances in the discussion on food safety, that is substances added purposefully as well as chemical and biological contaminants.

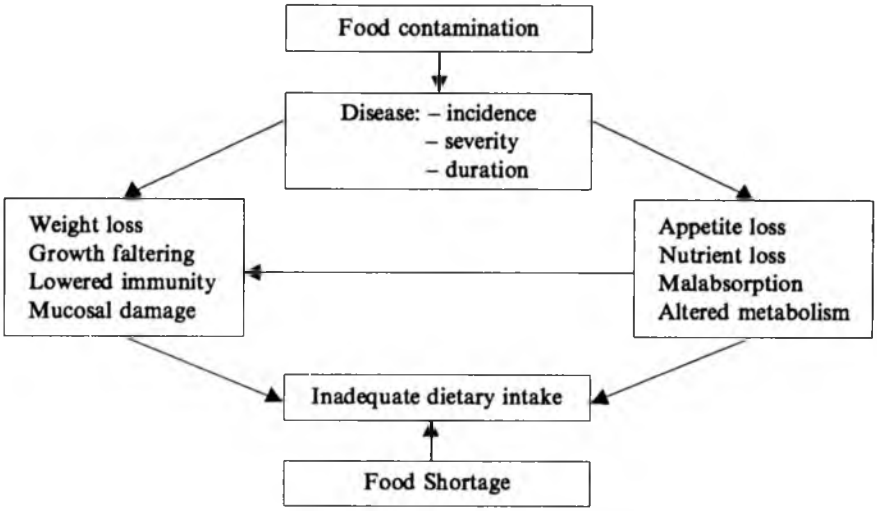

Fig. 1. Malnutrition and infection cycle [5]

According to Codex Alimentarius Commission "Food additive" means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, wheather or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may reasonably be expected to result (directly on indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristic of such food. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

While "Contaminant" means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry and veterinary medicine), manufacture, processing, transport or holding of such food or as a results of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter [2].

The Committees: on Food Additives and Contaminants, Veterinary Drug Residues, Pesticide Residues and Food Hygiene within the Codex Alimentarius Commission FAO/WHO are obliged to present the principles of "risk assessment" in the prepared standards and suggestions related to these substances. These assessment include:

* Hazard identification
* Exposure assessment
* Dose-response assessment
* Risk characterization

The assessment of health risk is nothing more than the study of the probability of development of harmful effects on health following the exposure to risk factors. These factors are broadly understood foreign substances [1].

In the assessment of health risk connected with food and chemical substances present in them, the exposure level is determined. For most chemical substances in

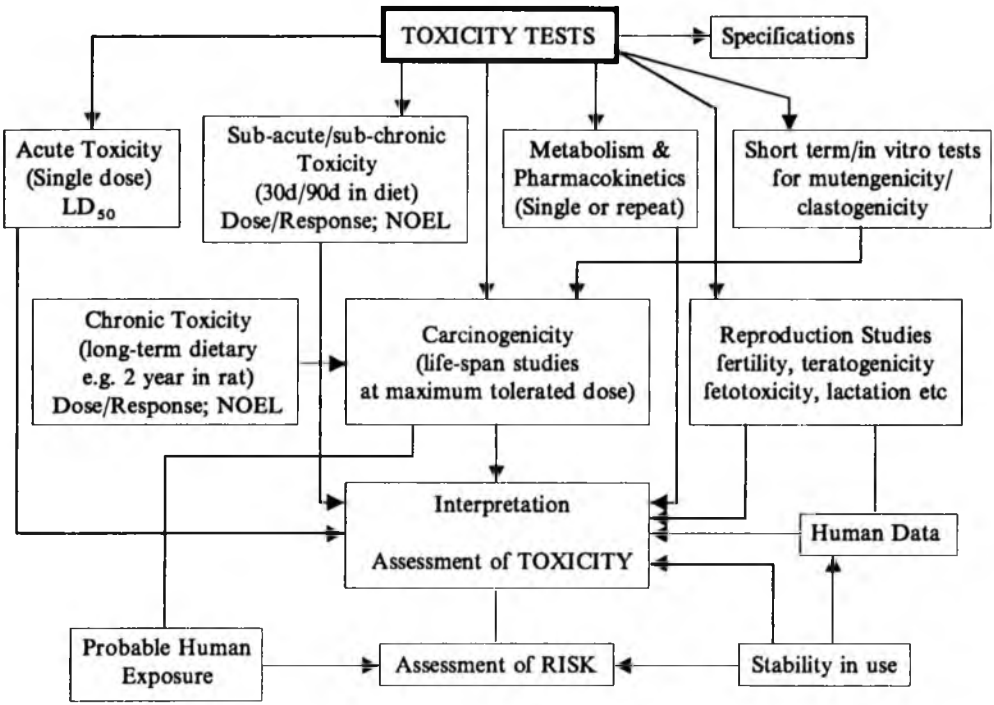

Fig. 2. Assessment of risk from chemicals in food [8]

food, with the exception of genotoxic carcinogens, threshold dose is established which is not a health risk, considering also the safety factors.

Quantitative assessment of health risk is not easy. The most probable assessment should be based on epidemiological studies, especially if the magnitude of the exposure or a given population is known. Such information is rarely available. Thus animal experiments remain as the only practical way of approaching this problem – although this approach is controversial.

Safety assessment of food additives and contaminants is based on the results of toxicological animal studies (Fig. 2).

Toxicological assessment is the first step in the 3-step procedure aiming at ensuring the safety of chemical substances present in food [8] – Fig. 3.

× TOXICOLOGICAL EVALUATION	NOEL
× × SAFETY EVALUATION	ADI
	PTWI
	PMTDI
× × × RISK MANAGEMENT	LEGISLATION
	– PERMITTED LISTS
	– PERMITTED USES
	– MAXIMUM USE LEVELS
	– MAXIMUM RESIDUE LEVELS
	– HYGENIC STANDARDS

Fig. 3. Stages in assuring the safety of chemicals in food [8]

Since the results of studies are transposed to the human populations it is necessary to consider not only prenatal exposure but also the time of production and maturation of gametes (it is the 3-generation test). The time of ageing of the organism is considered also.

The required toxicity tests of all food additives should not be the same. The following factors should be taken into account:

- expected toxicity
- expected exposure levels
- natural occurrence in food
- use in traditional food products
- knowledge of effects in man.

The second step in safety assessment is establishing of exposure levels which can be regarded as safe, that is quantitative values should be established of:

- accepted substances added to food and having definite technological roles – that is ADI,
- tolerable amounts of contaminants – TDI – tolerated daily or weekly intake.

Acceptable daily intake (ADI) an estimate by Joint FAO/WHO Expert Committee on Food Additives (JECFA) means the amount of a food additive expressed on a body weight basis that can be ingested daily over a life time without appreciable health risk.

Tabela I. Provisional doses (FAO/WHO) [3, 4]

	Tolerable Weekly Intake			Torelable Daily Intake	
	mg/kg b.w.	mg/man (60 kg)		mg/kg b.w.	mg/man (60 kg)
Pb	0,025	1,5	Cu	0,5	30,0
Cd	0,007	0,42	Zn	1,0	60,0
Hg	0,005 in it: 0,0033 m – Hg	0,3 in it: 0,2 m – Hg	Fe	0,8	48,0
As	0,015	0,90	I	0,017	1,02
Al	7,0	420,0			
Sn	14,0	840,0			

The term "Provisional maximum tolerable daily intake" (PMTDI) is used for contaminants with no cumulative properties. Its value represents permissible human exposure as a results of the natural occurrence of the substance in food and in drinking water.

"Provisional tolerable weekly intake" (PTWI) is used for contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to the contaminants unavoidable associated with the consumption of otherwise whole some and nutritious foods [2].

The basis for determination of ADI or TDI in man, after consideration given to the safety factor, is the "no observed (adverse) effect level" (NOEL) established on the basis of correctly obtained assessed and interpreted results of toxicological studies. NOEL means the greatest concentration or amount of agent, found by study or observation, that causes no detectable, usually adverse, alteration of morphology, functional capacity, growth, development or lifespan of the target [2].

The last step is risk management which leads to legal regulations. In national as well as international legislations the so called possitive food additives lists are established, which are confirmations of the acceptance of food additives with determining of their maximal accepted levels in food products. Maximal levels are established also for the residues of veterinary drugs or pesticides and permmisible levels of contaminants. This is reflected in national and international standards for various food products.

ADI and TDI values are, in a way, quantitative measures of the accepted risk, and they arouse no reservations from the scientific point of view. Possible doubts may be aroused concerning the choice of an adequate safety index. These doubts are connected with the extrapolation of the results of animal studies to man. The dosage used in animal experiments expressed in the generally accepted way as mg/kg body weight cannot be a counterpart of the constant exposure of man and the level of the exposure resulting in harmful effects. Besides that, there are species-specific and strain-specific differences in the absorption, tissue distribution, biotransformation processes and elimination rates, and also special factors which cannot be considered in animal experiments, that is dietary habits, drinking of alcohol and coffee, cigarette smoking, and stresses. Most frequently the safety index is 100 since it is believed that man is about tenfold as sensitive to these effects, as the experimental animals, besides that about tenfold interindividual differences may occur in this sensitivity [2].

The established ADI values are verified and changed, according to the newest experimental results. ADI values are not established for substances with cancerogenic properties. All additives permitted to food have to be toxicologicaly evaluated, have established values of ADI or in case ADI not specified can be used in accordance with good manufacturing practice.

Only for few contaminants PMTDI or PTWI have been established – table I. Besides metals, the PTWI have been established for patulin – 7 μg/kg b.w. and ochratoxin – 112 ng/kg b.w. [6, 7].

The PTWI was discussed also for benzo/a/pyrene and polychlorinated biphenyls. However, the presently available data are not sufficient for establishing quantitative levels. PTWI values serve for establishing of maximal levels of contaminants in food.

The Commission of Alimentary Codex presented in 1993 for the first time a project of a general standard for food contamination. According to this document, for the assessment of contamination are required: toxicological information, analytic data and data on the magnitude of intake. A continuation of these works is the proposal of the classification of food contaminanats – FAO/WHO 1994.

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OCENA BEZPIECZEŃSTWA ŻYWNOŚCI

Streszczenie

W ocenie bezpieczeństwa żywności uwzględniane są wymagania mikrobiologiczne i fizyko-chemiczne. Nieodpowiednia jakość żywności może powodować zaburzenia organizmu prowadzące niejednokrotnie do pojawienia się ostrych objawów chorobowych. Zachorowania i zatrucia pokarmowe powodowane są głównie obecnością drobnoustrojów chorobotwórczych i ich toksyn, rzadziej zanieczyszczeń chemicznych.

Substancje chemiczne obecne w żywności mogą być różnorodnego pochodzenia. Stanowią jej zanieczyszczenia lub są dodawane celowo ze względów technologicznych.

Zanieczyszczenia chemiczne z uwagi na ich toksyczność powinny być eliminowane lub ograniczane. Ich obecność w żywności może wynikać z zanieczyszczenia środowiska, zastosowanego procesu technologicznego obejmującego poszczególne etapy uprawy roślin, hodowli zwierząt lub przechodzenia z aparatury i opakowań. W żywności mogą występować także naturalne substancje toksyczne.

Zanieczyszczenia chemiczne wywołują na ogół odległe skutki, gdyż występują w żywności zazwyczaj w ilościach niewielkich a nawet śladowych.

Zapewnienie bezpieczeństwa żywności dokonuje się poprzez ocenę toksykologiczną substancji występujących w żywności, określenie poziomów uznanych za bezpieczne lub tolerowane dla człowieka oraz regulacje prawne.

REFERENCES

1. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Experts Consultation, Geneva, 13 – 17 March, 1955. – 2. Environmental Health Criteria 70. Principles for the safety assessment of food additives and contaminants in food. WHO. Geneva 1987. – 3. Evaluation of certain food additives and contaminants. WHO Technical Report Series 776, 1989. 4. Evaluation of certain food additives and contaminants. WHO Technical Report Series 837, 1993. – 5. *Motarjemi Y., Käfersteub., Moy G., Quevedo F.*: Contaminated weaning food: a major risk factor for diarrhoea and associated malnutrition. Bulletin WHO, 1993, 71, 79. – 6. Toxicological evaluation of certain food additives and contaminants. WHO Food Additives 1990, 26, 143. – 7. Toxicological evaluation of certain food additives and contaminants. WHO Food Additives 1991, 28, 365. – 8. *Walker R.*: Principles of safety assessment; toxicology. ILSI Europe. Second Workshop on the Scientific Basis for Food Safety and Nutrition Policy, Warsaw, 1993.

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