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Evaluation of certain food additives and contaminants

Thirty-fifth Report of the
Joint FAO/WHO Expert Committee on
Food Additives



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3.1.2 Enzyme preparations

Enzyme preparations derived from Aspergillus niger

As a consequence of its review of general specifications for enzyme preparations, the Committee reconsidered the evaluation of enzymes derived from *Aspergillus niger* made at the thirty-first meeting (Annex 1, reference 77). At that meeting, the Committee established a single ADI for several separate enzyme preparations derived from *Aspergillus niger* of 0–1 mg of total organic solids per kg of body weight. The enzyme preparations for which this ADI was established were carbohydrases, amyloglucosidases (EC 3.2.1.3), endo-1,3(4)- β -glucanase (EC 3.2.1.6), hemi-cellulase, pectinases (EC 3.1.1.11; 4.2.2.10; 3.2.1.15), and protease.

In view of the fact that *Aspergillus niger* is a common organism in food, that many strains have had a long history of use as an enzyme source, and that the numerous studies of various preparations from various strains have demonstrated no hazard to human health, the numerical ADI that was earlier established for each of the above-listed enzyme preparations from *Aspergillus niger* was changed to an ADI “not specified”.

A toxicological monograph was not prepared.

None of the existing specifications for enzyme preparations derived from *Aspergillus niger* were reviewed.

Annex 2

ACCEPTABLE DAILY INTAKES, OTHER TOXICOLOGICAL INFORMATION, AND INFORMATION ON SPECIFICATIONS

Substance	Specifications ¹	Acceptable daily intake (ADI) for humans and other toxicological recommendations
A. Food additives		
<i>Emulsifiers</i>		
Polyglycerol esters of fatty acids	S	0–25 mg/kg of body weight ²
Sucrose esters of fatty acids	R	0–10 mg/kg of body weight ³
Sucroglycerides	S	0–10 mg/kg of body weight ³
<i>Enzyme preparations</i>		
Enzymes derived from <i>Aspergillus niger</i>	S	ADI "not specified" ⁴
<i>Flavouring agents</i>		
Benzyl acetate	S	0–5 mg/kg of body weight ⁵
Cinnamaldehyde	S	No ADI allocated ⁶
Dihydrocoumarin	N, T	No ADI allocated ⁷
Ethyl vanillin	R	0–5 mg/kg of body weight ⁵
Fumaric acid	R	ADI "not specified" ^{4, 8}
Quinine	R	0–0.9 mg/kg of body weight ⁵
<i>Food colours</i>		
Canthaxanthin	S	No ADI allocated ⁹
Carotene preparations from natural sources	R, T ¹⁰	No ADI allocated ¹¹
Curcumin	S	0–0.1 mg/kg of body weight ⁵
Paprika oleoresin	R	No ADI allocated ¹²
Turmeric oleoresin	R	No ADI allocated ⁹
<i>Thickening agents</i>		
Gum arabic	R	ADI "not specified" ⁴
Modified celluloses	S	ADI "not specified" ^{4, 13}
<i>Miscellaneous food additives</i>		
Ferrous lactate	N	[0.8 mg/kg of body weight ¹⁴]
2-Nitropropane	R, T	No ADI allocated ¹⁵
Tannic acid	R, T	ADI "not specified" ^{4, 16}
Lactoperoxidase/thio-cyanate/hydrogen peroxide system for milk preservation	¹⁷	Acceptable ¹⁸

Substance	Provisional tolerable weekly intake (PTWI) for humans
B. Contaminants	
Patulin	7 µg/kg of body weight
Polychlorinated biphenyls (PCBs)	PTWI not established ¹⁹

Substance	Specifications ¹
C. Food additives (specifications only)	
Carob bean gum	R
Citric and fatty acid esters of glycerol	R
Iron oxides used as food colours	R
Modified starches	R

Notes to Annex 2

1. N, new specifications prepared; R, existing specifications revised; S, specifications exist, revision not considered or not required; and T, the existing, new, or revised specifications are tentative and comments are invited (see Annex 3).
2. Applies to polyglycerol esters of fatty acids having an average chain length of up to three glycerol units.
3. Group ADI for sucrose esters of fatty acids and sucroglycerides.
4. ADI "not specified" means that, on the basis of the available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary.
5. Temporary acceptance (see Annex 3).
6. The previous temporary ADI was not extended (see Annex 3).
7. See Annex 3.
8. Group ADI for fumaric acid and its salts.
9. The previous temporary ADI was not extended.
10. Specifications apply to carotenes from algal and vegetable sources (see Annex 3).
11. Insufficient information was available on toxicity and/or chemical composition to permit establishment of an ADI.
12. Self-limiting as a spice extract.
13. Group ADI for ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose. The ability of modified celluloses to produce laxative effects should be taken into account when they are used as food additives.
14. Provisional maximum tolerable daily intake for iron from all sources.