



What Is an Acceptable Daily Intake (ADI)?

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1. What is an ADI?

The Acceptable Daily Intake (ADI) is defined as an estimate of the amount of a food additive, expressed on a bodyweight basis that can be ingested on a daily basis over a lifetime without appreciable risk to health. "Without appreciable risk" means based on the current knowledge, there is confidence that no harm will result, even after a lifetime of exposure to the additive concerned. The ADI is usually given as a range of milligrams per kilogram of bodyweight per day.

2. What is the purpose of an ADI?

ADIs serve to protect the health of consumers and to make international trade in food easier. The ADI is a practical approach to determining the safety of food additives and is a means of achieving some harmonisation of regulatory control. The advantage of regulatory and advisory bodies setting ADIs for food additives is that they are universally applicable in different countries and to all sectors of the population.

3. Who determines the ADI?

Basically, expert scientific committees advise national and international regulatory authorities. The safety assessments of food additives have developed along similar lines in individual Member States in the European Union and in the wider international community. The main international body that addresses the safety of food additives is the Joint Expert Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The setting of international standards has become increasingly important in recent years as the World Trade Organisation arrangements specify that Joint FAO/WHO and Codex Alimentarius Commission (Codex) standards apply to the safety and composition of foods worldwide. The "Codex General

Standard for Food Additives" (GSFA, Codex STAN 192-1995) which was originally adopted in 1995 is currently under development and is regularly updated to include additional food additive provisions adopted by the Codex Alimentarius Commission. It outlines the conditions under which permitted food additives may be used in all foods. At EU level, additives approved for use are specified in European legislation and are given an E-number. These additives are evaluated by the European Food Safety Authority's (EFSA) Scientific Panel on Food Additives and Flavourings (FAF). As part of its safety evaluations EFSA establishes, when possible (i.e. when sufficient information is available), an ADI for each additive.

4. How is the ADI determined?

The general criteria for the use of food additives set out in the EU regulations stipulate that additives can be approved only if they present no hazard to human health at the level of use proposed, based on the scientific evidence available. The safety evaluation is based on a scientific review of all pertinent toxicological data on the specific additive, including both observations in humans and mandatory tests in animals. In the EU, all the evidence is reviewed by EFSA. The toxicological tests required by the regulatory authorities include lifetime feeding studies and multigenerational studies that determine how the additive is handled by the body in order to assess any possible harmful effects of the additive or its derivatives. The starting point for establishing the ADI is the determination of the "No Observed Adverse Effect Level" (NOAEL) for the most sensitive adverse effect relevant to human health in the most sensitive species of experimental animal. The NOAEL is, therefore, the highest dietary intake level of an additive at which no adverse effects were observed in the studies and it is expressed in milligrams of the additive per kilogram of bodyweight per day (mg/kg bodyweight/day). To derive the ADI, the NOAEL is divided by a safety factor, usually 100, in order to ensure a large margin of safety.

5. Why is a safety margin necessary?

Firstly, the NOAEL is determined in animals, not humans. It is therefore prudent to adjust for possible differences by assuming that man could be more sensitive than the most sensitive test animal. Secondly, the reliability of toxicity tests is limited by the number of animals tested. Such tests cannot represent the diversity of the human population, subgroups of which may show different sensitivities (e.g. children, the old and the infirm). Again, it is prudent to adjust for these differences.

6. What safety margin is normally used when determining levels of food additives?

Traditionally, the World Health Organisation has used a safety or uncertainty factor of 100, based on a 10-fold factor to allow for differences between animals and an average human, and a 10-fold factor to allow for differences between average humans and sensitive subgroups (pregnant women, the elderly). However, this may be varied according to the characteristics of the additive, the extent of the toxicology data and the conditions of use.

7. Is it acceptable for an individual to exceed the ADI on any

given day?

The consumption of an additive above its ADI on a given day is not a cause for concern because the ADI has a large built-in safety factor and in practice, consumption above the ADI on one day is more than accounted for by consumption below the ADI on most other days. As mentioned, an ADI references a life-time long exposure situation, and is not a reference value for a single occasion. However, if an intake figure indicates that the ADI may be regularly exceeded by certain sectors of the population, it may be necessary for the European Food Safety Authority to advise a reduction of levels in foods consistent with the amount needed to achieve its function, or to reduce the range of foods in which the additive is permitted for use. Because of the large safety margin used in setting the ADI, it is likely that an ADI for a given additive would have to be exceeded by some considerable amount for there to be any risk of harm to human health.

8. How are dietary intakes of food additives monitored?

The monitoring of food additive intake is carried out by individual Member States on advice from the European Food Safety Authority. The ADI is compared with "average" and "extreme" consumption estimates in the population as a whole or in particular subgroups of the population. Provided that intakes for average and extreme consumers are within the ADI, it is unlikely that any harm will result. To ensure that consumers are not exceeding the ADI by consuming too much or too many products containing a particular additive, EU legislation requires that intake studies be carried out regularly to assess any changes in intake patterns.