Re-evaluation of azo dyes as food additives: Problems encountered

Aryl azo compounds are widely used as colorants (azo dyes) in a wide range of products including textiles, leather, paper, cosmetics, pharmaceuticals and food. As part of its systematic re-evaluation of food additives, the European Food Safety Authority (EFSA) has carried out new risk assessments of all azo dyes permitted in food. EFSA has also evaluated a number of azo dyes found illegally in food in recent years, including Sudan dyes, Para Red and Orange II. The re-evaluation of all food colours, including the azo dyes, was considered high priority (i) because colorants were among the first additives to be assessed by the Scientific Committee on Food, many years ago, (ii) because of concern regarding possible health effects of artificial colours arising since the original evaluations. Concerns included behavioural effects in children, allergic reactions, genotoxicity and possible carcinogenicity. Of the 11 previously authorised azo dyes (Red 2 G, Tartrazine, Sunset Yellow FCF, Azorubine, Ponceau 4R, Allura Red AC, Amaranth, Brilliant Black BN, Brown FK, Brown HT and Litholrubine BK), the Acceptable Daily Intake (ADI) for Red 2 G was withdrawn because of concerns regarding genotoxicity and carcinogenicity of its metabolite aniline. EFSA re-established ADIs for the other 10 azo dyes although those for Sunset Yellow FCF and Ponceau 4R were reduced, based on new toxicological data or re-interpretation of existing data. The regulatory consequences of EFSA's re-assessments include removal of the authorisation for Red 2 G, new labelling provisions and reductions in the Maximum Permitted Levels for some azo dyes in food.

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