FOOD REGULATORY SCIENCE UPDATE

The United States Food and Drug Administration (US FDA) announces that it is "revoking the authorization for the use of FD&C Red No. 3" also known as Erythrosine, to be used as a food additive – What does this decision mean for other regulators around the world?

The FDA announced its decision to revoke the approval of Erythrosine as a food additive through a communication released on 15 January 2025.

What is important to note is that the US FDA's announcement was **not** the result of an updated risk assessment or a change in the risk profile of this coloring agent. It is rather the application of a consideration that is specific to the US Food and Drug Legal System called the "Delaney Clause". In simple terms, the **Delaney Clause** is a provision in U.S. food law that prohibits the approval of any food additive found to cause cancer in **humans or animals**, regardless of the level of risk or exposure. It was added in 1958 to the Federal Food, Drug, and Cosmetic Act (FDCA) and named after Congressman James Delaney.

In this case, the US FDA characterizes this decision in its communication as a "**matter of law, based on the Delaney Clause**". The decision to revoke the approval of this food additive was prompted by a response to a petition received by the US FDA and was supported "among other data and information" with "two studies that showed cancer in **laboratory male rats** exposed to high levels" of Erythrosin, "**due to a rat specific hormonal mechanism**".

The US FDA also noted in the information released to the public that the way Erythrosine "causes cancer in male rats **does not occur** in humans". The US FDA communication went on to add that the levels of Erythrosine to which humans are typically exposed are "**much lower than those that cause the effects shown in male rats**". Also, "studies in **other animals and in humans did not show these effects**".

This is a further reiteration that the risk profile for this food additive has not changed and that previous assessments, including those published by the Joint Expert Committee on Food Additives (JECFA), which conducted its reassessment of this substance in 2018, remain valid. During its 86th meeting, JECFA reviewed new data on Erythrosine and concluded that there was no reason to revise the existing Acceptable Daily Intake (ADI). The Committee reaffirmed the ADI of 0–0.1 mg/kg body weight, maintaining that the current levels of exposure, including other sources, do not pose a safety concern.

In Conclusion, the US FDA decision is the result of a US-based legal environment and should not have impacts on other food regulators' decision.

The use of food additives should continue to be governed by the two key principles:

A. The technical justification of use: chemicals should not be added to food, unless there is a need or a justification to do so.

B. The safety rationale: the use as a food additive is assessed and is not posing a health concern, under the approved conditions of use.

As a reference Erythrosine is also known as: **FD&C Red No. 3** (used in the U.S. for food, drug, and cosmetic applications); **Erythrosin** (alternate spelling); **Red Dye No. 3** and **E127** (European food additive code).

Depending on its authorization, Erythrosine is used as a **color additive** in foods and beverages to give foods and drinks a bright, cherry-red color. This additive was reported of low use and when used it could be found in candies, cake decorations, cherry-flavored products (like maraschino cherries), ice creams, bakery products, snack foods.

Key Messages

- There is no new Health Risk Assessment or new Scientific Information related to Erythrosine as a food additive, that changes its risk profile.
- The US FDA decision is the result of a US-based legal environment and should not have impacts on other food regulators' decision.
- Based on the available evidence, the current levels of exposure to Erythrosine when used as a food additive, are not a cause for concern.