Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to

2-Isopropyl thioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) in food contact materials

Question numbers EFSA-Q-2005-240 & EFSA-Q-2005-241

Adopted on 7 December 2005

SUMMARY

The European Food Safety Authority is asked to carry out risk assessment for substances intended for use in materials in contact with food, according to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food. In particular, on the basis of Art.29 of Regulation (EC) No 178/2002, EFSA is asked to advise the Commission on the risk for human health of the use of the substances 2-isopropyl thioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) as photoinitiators in inks applied to food packaging materials.

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food noted that inks applied to food packaging materials are not covered by specific European legislation. However, materials and articles intended to come in contact with foods should comply with the general criteria laid down in Art.3 of Regulation (EC) No 1935/2004, i.e. should not transfer their constituents in food in quantities which could endanger human health or bring about unacceptable changes in composition or characteristics of foodstuffs. These criteria are also reiterated in the Council of Europe Resolution AP (2005)2 adopted on 14 September 2005 on printed materials and articles intended to come in contact with food.

Industry reported the results of analytical tests on the occurring levels of ITX and EHDAB in a number of food products packaged in cartons printed with UV-cured inks containing ITX and EHDAB as photoinitiators.
In the milk products intended to be consumed in the first year of life, the level of ITX ranged from 120 to 305 µg/l. The available data (two samples only) on ITX in growing up milk (for aged 12 months on) were 74 and 445 µg/l. ITX was found at 600 µg/l in a single sample of flavoured milk tested. No data on EHDAB levels were reported for these products.
In the milk and soy based products tested, not specifically intended for babies, the level of ITX ranged from 54 to 219 µg/l and the level of EHDAB ranged from 27 to 134 µg/l,

for pack sizes of 1000 ml. In a chocolate milk sample (200 ml pack size) ITX was 295 µg/l and EHDAB was 148 µg/l.
In fruit juices, fruit nectars and drinks indicated as "cloudy" due to the presence of fruit pulp and fibres, the levels of ITX ranged from <5 µg/l to 249 µg/l and the levels of EHDAB ranged from <5 µg/l to 125 µg/l. The highest values were reported for smaller pack sizes.
In the fruit juices, fruit nectars, water, and the drinks indicated as "clear", neither ITX nor EHDAB were detected (detection limit: 5 µg/l).

Exposure assessment was performed by the Panel based on different concentration values. In all exposure scenarios, potential exposure to EHDAB was calculated based on concentration values set at half of the concentration of ITX.
Based on a potential concentration of 250 µg/l of ITX and 125 µg/l of EHDAB in affected milk, potential dietary exposure in infants at the 95th percentile of consumption is respectively 43 µg/kg bw/day and 22 µg/kg bw/day. This level of exposure refers only to infants fed exclusively with liquid infant formulae packaged in cartons printed with UV-cured inks.
For young children, the exposure scenario was based on the hypothesis that half of their food and beverages consumed would be packaged in cartons printed with UV-cured inks. Considering a mixed diet with both milk and fruit juices contributing to packaged foods and beverages, an exposure scenario based on a potential concentration of 125 µg/l of ITX and 63 µg/l of EHDAB would lead to a potential dietary exposure of respectively 12 µg/kg bw/day and 6 µg/kg bw/day in young children at the 95th percentile of consumption. Based on a potential concentration of 250 µg/l of ITX and 125 µg/l of EHDAB assuming that all affected food is milk products only, potential dietary exposure in young children at the 95th percentile of consumption is respectively 23 µg/kg bw/day and 11 µg/kg bw/day.
In the adult, a conservative assumption could be that of the consumption of 3 kg packaged food and beverages each day, half of which being packaged in UV-printed cartons. It leads to an overall potential consumption of 1.5 kg/day of affected products Based on a potential concentration of 250 µg/l of ITX and 125 µg/l of EHDAB in affected products, potential dietary exposure in adults is respectively 6 µg/kg bw/day and 3 µg /kg bw/day. Based on a potential concentration of 125 µg/l of ITX and 62 µg/l of EHDAB in affected products, potential dietary exposure in adults is respectively 3 µg/kg bw/day and 1.5 µg/kg bw/day.
The Panel noted that due to their high consumption of food per kg body weight, infants exclusively fed with infant formulae packed in cartons printed with UV cured inks are potentially more exposed to ITX and EHDAB than other population groups.

ITX was tested with contradictory results in limited genotoxicity studies *in vitro*; however clearly negative results were obtained in two adequate *in vivo* studies. In conclusion, the existing *in vivo* genotoxicity studies do not indicate a genotoxic potential for ITX. No other toxicity data on ITX are available.

In view of the lack of other toxicity data no further comment on the safety of ITX can be made.

EHDAB is not genotoxic and not teratogenic. The NOAEL for general toxicity in 4-week oral studies was 100 mg/kg bw. A large (2500 or greater) margin of safety can be calculated for all exposure scenarios. It is concluded that the occurrence of EHDAB in food from its use in inks applied to food packaging materials is of no safety concern.