

STATEMENT OF EFSA

Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive¹

European Food Safety Authority^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the European Food Safety Authority (EFSA) carried out a revised exposure assessment for children of Sunset Yellow FCF (E 110) from its use as a food additive, based on the revised proposed use levels as provided by the European Commission. Four scenarios have been considered, differing only by the maximum permitted levels for use in flavoured drinks: 10, 15, 18 and 20 mg/l respectively. Revised exposure estimates have been calculated for Tier 2 applying the same methodology used by the Panel on Food Additives and Nutrient Sources added to Food (ANS) for the re-evaluation of food colours, based on the revised use levels combined with food consumption data for children. These exposure estimates could be considered as conservative as it is assumed that the food additive is used at the maximum permitted levels for all authorised uses. The mean anticipated dietary exposure to Sunset Yellow FCF in European children (aged 1-14 years) range from 0.02 to 0.4 mg/kg bw/day, and the high level estimates range from 0.08 to 1.2 mg/kg bw/day. The main contributors to the total anticipated exposure to Sunset Yellow FCF are non-alcoholic flavoured drinks and desserts including flavoured milk products. For all scenarios the high level exposure estimates for children calculated with the proposed revised Maximum Permitted Levels are below the temporary ADI of 1 mg/kg bw/day for all European countries considered (maximum of 0.8 mg/kg bw/day) except for UK pre-school children who might slightly exceed the ADI in scenarios 3 and 4 (1.1 and 1.2 mg/kg bw/day respectively).

© European Food Safety Authority, 2011

KEY WORDS

Sunset yellow, E 110, revised MPLs, dietary exposure

¹ On request from the European Commission, Question No EFSA-Q-2011-00934, issued on 26 August 2011.

² Correspondence: ans@efsa.europa.eu

Suggested citation: European Food Safety Authority; Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive. EFSA Journal 2011;9(9):2349. [10 pp.] doi:10.2903/j.efsa.2011.2349. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following a request from the European Commission, a revised exposure assessment for children of Sunset Yellow FCF (E 110) from its use as a food additive was carried out for children, based on the revised proposed use levels presented in the Terms of Reference. Four scenarios have been considered, differing only by the maximum permitted levels for use in flavoured drinks: 10, 15, 18 and 20 mg/l respectively.

Several food consumption databases were used to conduct the revised exposure assessment: data from the EXPOCHI project and UK NDNS survey.

Revised exposure estimates have been calculated for Tier 2 applying the same methodology used by the Panel on Food Additives and Nutrient Sources added to Food (ANS) for the re-evaluation of food colours, based on the revised proposed use levels as provided by the European Commission combined with food consumption data for children. These exposure estimates could be considered as conservative as it is assumed that the food additive is used at the maximum permitted levels for all authorised uses.

The mean anticipated dietary exposure to Sunset Yellow FCF in European children (aged 1-14 years) ranged from 0.02 to 0.4 mg/kg bw/day. The main contributors to the total anticipated exposure to Sunset Yellow FCF are non-alcoholic flavoured drinks and desserts including flavoured milk products.

At the high level, exposure estimates range from 0.08 to 1.2 mg/kg bw/day from scenario 1 to scenario 4. For all scenarios the high level exposure estimates for children calculated with the proposed revised Maximum Permitted Levels are below the temporary ADI of 1 mg/kg bw/day for all European countries considered (maximum of 0.8 mg/kg bw/day) except for UK pre-school children who might slightly exceed the ADI in scenarios 3 and 4 (1.1 and 1.2 mg/kg bw/day respectively).

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background as provided by the European Commission.....	4
Terms of reference as provided by the European Commission.....	4
Assessment	6
1. Introduction	6
2. Dietary exposure.....	6
2.1. Revised Maximum Permitted Levels (MPLs).....	6
2.2. Method	6
2.3. Dietary exposure	7
References	9
Glossary and abbreviations	10

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The European Commission is currently finalising a proposal to revise the maximum permitted levels for Sunset Yellow (E 110). The revision takes into account the conclusion of the Scientific Opinion of the ANS Panel related to the re-evaluation on the safety of that colour. The Panel reduced the ADI to 1 mg/kg (temporary ADI) and concluded that exposure is generally well over the revised ADI.

It is therefore appropriate to reduce the current conditions of use and use levels for Sunset Yellow, in order to ensure that the new ADI is not exceeded any more. The levels proposed should be safe for the consumers.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 31 of Regulation (EC) No 178/2002⁴, on 29 July 2011 the European Commission requested the European Food Safety Authority to provide technical assistance in the form of new exposure assessment for children to Sunset Yellow FCF (E 110), based on currently available consumption data and revised uses of Sunset Yellow FCF proposed by the Commission, considering four different levels (10, 15, 18 and 20 mg/l) for the flavoured drinks and the proposed levels for all other food categories, as listed in Table 1.

Table 1: Revised food uses and Maximum Permitted Levels

Food category	Revised MPL (mg/l or mg/kg)	Restrictions/exceptions
Flavoured fermented milk products including heat treated products	5	
Other creams	5	Only flavoured creams
Unripened cheese excluding products falling in category 16	0	Only flavoured unripened cheese
Edible cheese rind	0	
Processed cheese	0	Only flavoured processed cheese
Cheese products (excluding products falling in category 16)	0	Only flavoured unripened cheese
Edible ices	0	
Fruit and vegetable preparations excluding compote	35	Only mostarda di frutta
Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	0	except chestnut puree
Other similar fruit or vegetable spreads	0	except <i>crème de pruneaux</i>
Other confectionary including breath refreshing microsweets	35	only candied fruits and vegetables
Other confectionary including breath refreshing microsweets	10	except candied fruits and vegetables
Chewing gum	10	
Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	35	
Batters	35	Only batters for coating
fine bakery wares	0	Only batters for coating
Non heat treated processed meat	15	Only <i>sobrasada</i>
Casings and coatings and decorations for meat	35	Only decorations and coatings except edible external coating of <i>pasturmas</i>

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

Casings and coatings and decorations for meat	0	Only edible casings
Processed fish and fishery products including mollusks and crustaceans	0	Only surimi and similar products and salmon substitutes
Processed fish and fishery products including mollusks and crustaceans	0	Only fish paste and crustacean paste
Processed fish and fishery products including mollusks and crustaceans	0	Only precooked crustacean
Processed fish and fishery products including mollusks and crustaceans	0	Only smoked fish
Fish roe	100	Except sturgeons' eggs (caviar)
Seasonings and condiments	0	only seasonings, for example curry powder, tandoori
Mustard	50	
Soups and broths	0	
Sauces	0	including pickles, relishes, chutney and picalilli; excluding tomato-based sauces
Protein products, excluding products covered in category 1.8	20	only meat and fish analogues based on vegetable proteins
Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5),	10	
Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet),	10	
flavoured drinks	10/15/18/20	
Cidre and perry	1	Excluding <i>cidre bouché</i>
Fruit wine and made wine	1	
aromatized wines	50	Only <i>bitter vino</i>
aromatized wine-based drinks	50	Only <i>bitter soda</i>
Aromatized wine-product cocktails	50	
Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	100	only alcoholic drinks with less than 15 % of alcohol
potato-, cereal-, flour- or starch-based snacks	0	Excluding extruded or expanded savoury snack products
Processed nuts	0	Only savoury coated nuts
Desserts excluding products covered in category 1, 3 and 4	5	
Food supplements supplied in a solid form including capsules and tablets and similar forms	10	
Food supplements supplied in a liquid form	10	
Food supplements supplied in a syrup-type or chewable form	10	Only solid food supplements

ASSESSMENT

1. Introduction

Following a request from the European Commission, the European Food Safety Authority (EFSA) carried out a revised exposure assessment of Sunset Yellow FCF (E110) from its use as a food additive for children, based on the revised proposed use levels presented in the Terms of Reference (Table 1).

In its opinion of 24 September 2009, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) has established a temporary ADI of 1 mg/kg body weight (bw)/day for Sunset Yellow FCF. In the same opinion, the ANS Panel evaluated the safety in use of Sunset Yellow FCF. The mean dietary exposure estimates for children calculated on the basis of the Maximum Permitted Levels defined in the Council Directive 94/36/EC⁵ (Tier 2) ranged from 0.3 to 2.5 mg/kg bw/day, and from 0.7 to 6.7 mg/kg bw/day at the 95th percentile, thus exceeding the temporary ADI. For Tier 3 (refined exposure estimates calculated on the basis of reported use levels) the Panel concluded that the mean and high percentile of exposure estimates for children can be higher than the temporary ADI at the upper end of the range.

2. Dietary exposure

2.1. Revised Maximum Permitted Levels (MPLs)

The calculations of revised dietary exposure estimates to Sunset Yellow FCF have been performed using the revised use levels as defined in the Terms of Reference (Table 1).

The revised use levels proposed for Sunset Yellow FCF are lower for all food categories compared to those considered in the former EFSA evaluation (EFSA, 2009), and for 18 of the food uses currently permitted, the levels are set to zero.

For the food category “Flavoured drinks”, four different levels are considered in this revised exposure assessment: 10, 15, 18, 20 mg/l. Thus, the results of four different scenarios are presented in this statement.

2.2. Method

The dietary exposure to Sunset Yellow FCF was assessed using the tiered approach used by the ANS Panel for the re-evaluation of food colours.

For the purpose of obtaining exposure estimates based on the revised MPLs, only Tier 2 calculations, combining national data on food consumption with the revised proposed MPLs, have been performed. As previously stated by the ANS Panel, such exposure estimates could be considered as conservative as it is assumed that the food additive is used at the maximum permitted levels for all authorised uses.

Exposure estimates for children (aged 1-14 years old, overall range of body weight: 16-54 kg) have been performed by the Panel, based on summary statistics (average all population and P95 consumers only) from detailed individual food consumption data from 11 European countries (Belgium, France, the Netherlands, Spain, Czech Republic, Italy, Finland, Germany, Greece, Cyprus and Sweden) provided by the EXPOCHI (“Individual food consumption data and exposure assessment studies for children”) consortium (Huybrechts et al., 2010) and for UK pre-school children (aged 1.5-4.5 years

⁵ European Parliament and Council Directive 94/36/EC · el of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.09.1994, p.13.

old, weighing 15 kg on average) from UK NDNS, 1992-1993 data available from the UNESDA report (Tennant, 2006) which provides the average and the 97.5th percentile intake.

2.3. Dietary exposure

Revised exposure estimates have been calculated using the revised MPLs with national food consumption data for children.

Table 2 summarises the anticipated exposure of children to Sunset Yellow FCF for the revised proposed uses and use levels (Table 1), taking into account each of the four scenarios for non-alcoholic flavoured drinks, which correspond to different levels of use (10, 15, 18, 20 mg/l). For the 11 countries covered by the EXPOCHI population, the overall range of the exposure estimates (minimum and maximum) is given.

Table 2: Summary of revised exposure to Sunset Yellow FCF in children for the four scenarios

	Children (UK & EXPOCHI population)			
	Mean exposure		Exposure for high level consumers	
	EXPOCHI (Min – Max)	UK	EXPOCHI (Min – Max)	UK
	mg/kg bw/day			
Scenario 1: flavoured drinks=10 mg/l + all other food categories with revised MPLs	0.02 – 0.15	0.20	0.08 – 0.39	0.61
Scenario 2: flavoured drinks=15 mg/l + all other food categories with revised MPLs	0.02 – 0.19	0.28	0.11 – 0.53	0.90
Scenario 3: flavoured drinks=18 mg/l + all other food categories with revised MPLs	0.02 – 0.22	0.33	0.14 – 0.69	1.07
Scenario 4: flavoured drinks=20 mg/l + all other food categories with revised MPLs	0.03 – 0.24	0.37	0.15 – 0.76	1.19

The mean dietary exposure to Sunset Yellow FCF in European children (aged 1-14 years) ranges between 0.02 and 0.20. for scenario 1, between 0.02 and 0.28 for scenario 2, between 0.02 and 0.33 for scenario 3 and between 0.03 and 0.37 for scenario 4.

The exposure for high level consumers range between 0.08 and 0.61 for scenario 1, between 0.11 and 0.90 for scenario 2, between 0.14 and 1.07 for scenario 3 and between 0.15 and 1.19 for scenario 4.

The main contributors (>10% in all countries) to the total revised exposure to Sunset Yellow FCF are non-alcoholic flavoured drinks: from 51 to 88 % for exposure scenario 1, to 67 to 94 % for exposure scenario 4. Desserts, including flavoured milk products account for 19 to 41% for exposure scenario 1 to 11 to 27 % for exposure scenario 4 in 10 countries (all countries, except Czech Republic and UK). Confectionery is the third contributor but only in 2 countries and accounting for less than 10%.

The highest exposure estimates refer to UK pre-school children (for mean and high consumers) for the four scenarios. UK is the only country where the exposure estimates are above the temporary ADI of 1 mg/kg bw/day for high level consumers for scenarios 3 and 4. This might be linked to the low body weight (15 kg on average) of these young children (1.5 to 4.5 years old).

CONCLUSIONS

Following a request from the European Commission, a revised exposure assessment of Sunset Yellow FCF (E 110) for children was calculated based on the revised proposed use levels as provided by the European Commission, and with reference to the exposure assessment methodology used by the Panel on Food Additives and Nutrient Sources added to Food (ANS) for the re-evaluation of food colours. Four scenarios have been considered, differing only by the maximum permitted levels for use in flavoured drinks: 10, 15, 18 and 20 mg/l respectively.

The mean anticipated dietary exposure to Sunset Yellow FCF in European children (aged 1-14 years) ranged from 0.02 to 0.4 mg/kg bw/day. The main contributors to the total anticipated exposure to Sunset Yellow FCF are non-alcoholic flavoured drinks and desserts including flavoured milk products.

For high level consumers, exposure estimates range from 0.08 to 1.2 mg/kg bw/day from scenario 1 to scenario 4. For all scenarios the high level exposure estimates for children calculated with the proposed revised Maximum Permitted Levels are below the temporary ADI of 1 mg/kg bw/day for all European countries considered (maximum of 0.8 mg/kg bw/day) except for UK pre-school children who might slightly exceed the ADI in scenarios 3 and 4 (1.1 and 1.2 mg/kg bw/day respectively).

REFERENCES

- EFSA, 2009. Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive. The EFSA Journal 1330, 1-44.
- Gregory JR, Collins DL, Davies PSW, Hughes JM and Clarke PC, 1995. National Diet and Nutrition Survey; Children aged 1½ to 4½ years. HMSO, London.
- Henderson L, Gregory J, Swan G, 2002. National Diet and Nutrition Survey: adults aged 19 to 64 years. Volume 1: Types and quantities of foods consumed. TSO, London: 2002. Available from: www.food.gov.uk/science/dietarysurveys/ndnsdocuments/ndnspreviousurveyreports
- Huybrechts I et al., 2010. Long-term dietary exposure to different food colours in young children living in different European countries. Scientific report submitted to EFSA. EFSA-Q-2010-00787. Available from: <http://www.efsa.europa.eu/en/scdocs/doc/53e.pdf>
- Tennant D, 2006. Screening of Colour Intakes from Non-Alcoholic Beverages. Report prepared for the Union of European Beverages Associations (UNESDA), December 2006.

GLOSSARY AND ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS	Panel on Food Additives and Nutrient Sources added to Foods
bw	body weight
EC	European Commission
EFSA	European Food Safety Authority
EXPOCHI	Individual food consumption data and exposure assessment studies for children