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Jiri Sochor
European Commission
Directorate-General for Health and Consumer Protection
Unit E3 - Chemicals, contaminants and pesticides
232 rue Belliard
1049 Brussels
Via E-mail: jiri.sochor@ec.europa.eu

Dear Dr. Sochor:

The International Association of Color Manufacturers (IACM) is the trade association that represents the global color industry, comprised of manufacturers and end-users of coloring substances that are used in foods, including natural and synthetic colors. IACM appreciates the opportunity to provide the following comments and recommendations in response to DG Sanco's request for comments in the changes in specifications as a follow-up to the re-evaluation program.

<u>E 110 Sunset Yellow FCF</u>

Comments requested on:

A. The possible inclusion of more detailed information as regards the levels of identified sulphonated subsidiary dyes in the specifications, i.e.:

Sodium salt of 4-[(2-hydroxy-1 naphthalenyl)azo]benzenesulphonic acid (Orange II). Not more than 1%
Sodium salt of 6-hydroxy-5-(phenylazo)-2-napthalenesulfonic acid – level to be discussed
Trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulphonic acid – level to be discussed (around 4 %)
Trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-5,7-napthalenedisulfonic acid - Not more than <0.05%

IACM members wish to state that Sunset Yellow manufactured for use in the USA and in Europe complies to the US FDA and JECFA specifications and with current EU specifications. With regards to the higher sulphonated subsidiary colors, trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulphonic acid (CAS Reg. No. 50880-65-4) is synthesized and added intentionally to Sunset Yellow to improve solubility of the final color. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-5,7-napthalenedisulfonic acid is an isomer of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulphonic acid and both are

summed together in the US FDA (21CFR 74.706) to be "Not more than 5%".[1] No other information on trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-5,7-napthalenedisulfonic acid was found. One of our members is working on impurity profiling for the constituent trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-5,7-napthalenedisulfonic acid. The work will be completed in 10 weeks.

B. The possible update of the specifications as regards the percentage of material not accounted for that may represent sodium chloride and/or sodium sulphate (this issue is relevant for other synthetic colors as well)

Principal uncolored components
Sodium chloride Not more than 15 %
Sodium sulphate

As stated above, Sunset Yellow is manufactured to comply with US Food and Drug Administration (FDA) and Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications. These include a maximum limit of moisture and salts of 13.0% and 15.0%, respectively. Sunset Yellow is subject to the process of batch certification at the USA FDA. As part of this process, the US FDA returns the results of chemical analysis back to the manufacturer and examples of these records can be submitted to the EC for inclusion in the updated specifications for this color. Without conducting detailed chemical analysis of the material marketed in Europe, we cannot comment on the nature and quantity of constituents that compose the remaining 15% of the material that may not be accounted for in the current specifications.

<u>E 132 Indigo Carmine</u>

Comments requested on:

A. Possible update of the manufacturing process reflecting the manufacturing processes of the material used in in the Borzelleca et al. studies (1985, 1986) and Borzelleca and Hogan (1985).

The manufacturing process for commercial scale production has not changed since the time that these studies were conducted. The manufacturing process for the material used in toxicity testing studies was specifically adapted to produce material of as high purity as possible for the purpose of the studies (personal communication). The intention of the study directors was to obtain results that would be directly attributed to the coloring agent.

B. Update of the assay – increase to 93 % pure coloring

Currently, the color is manufactured with purity levels that vary between 85-92% that meet the current purity standards in the US, as well as European and JECFA specifications. Only a few batches of material achieve purity higher than 90%. While the additional purification is possible to be achieved on the scale of material needed for testing, as was done for the studies referenced above, it is not practically or economically feasible to adopt for commercial scale

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=74.706

production on a routine basis. Based on feedback from color manufacturers, the increase of purity to 93% would present a significant burden on the industry without adequate justification and evidence of a commensurate benefit. The material of lower purity that was used in the Dixit and Goyal (2013) study was of uncertain source. IACM has tried unsuccessfully to obtain documentation on the material sold by the company (ASES Chemical Works[2]) listed in the study. Documentation is not available readily on the company's website (links are not functional[2]). IACM has contacted the company directly and has not received response to our request for certificate of analysis for the material sold by the company. Therefore, the material used in the Dixit and Goyal (2013) study cannot be assumed to be available readily or comparable in quality to material manufactured for use in the European market. In addition, the Dixit and Goyal (2013) study had several other limitations and it is unfortunate that it was given so much weight it in EFSA's safety evaluation of indigo carmine and used to set a safety standard.

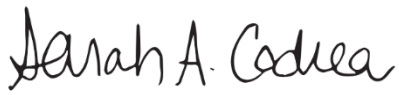
C. Update as regards the percentage of the material not accounted for (sodium chloride and sodium sulphate – the same issue as for E 110)

Without conducting detailed chemical analysis of the material marketed in Europe, we cannot comment on the nature and quantity of constituents that compose the remaining 15% of the material that may not be accounted for in the current specifications. The data can include analytical data of representative batches in the EU market, including spectra that demonstrate presence or absence of additional peaks and/or identification and characterization of other constituents.

The attached spreadsheets provide a comparative summary of existing specifications for Sunset Yellow and Indigo Carmine in different regions.

IACM appreciates the opportunity to provide feedback to DG Sanco on its initiative to update the specification requirements for certain permitted food colors. Please do not hesitate to contact me directly with any further questions.

Sincerely,



Sarah Codrea
Executive Director

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2 http://ases.co.in/prodetail.aspx?id=634&pname=INDIGO%20CARMINE&sid=0&ftype=&flag=I%25&product_code=

Global Sunset Yellow Specifications

Country		U.S.	E.C.	F.A.O./W.H.O. JECFA	Japan	Korea	China
	Alternate name/ Registration number	FD&C Yellow No. 6	E 110 Sunset Yellow FCF	INS 110 Sunset Yellow FCF	Food Yellow No. 5	Food Yellow No. 5	Sunset Yellow FCF GB6227.1-2010
Item (FDA COA nomenclature)	**Chemical tested**						
Pure Dye		87.0% min.	85.0% min.	85.0% min.	85% min.	85% min.	87.0% min.
Chlorides & Sulfates (As sodium salts)		--	--	--	5.0% max.	5.0% max.	--
Moisture & Salts		13.0% max.	--	15.0% max.	--	--	13.0% max.
Loss on drying		--	--	--	10.0% max.	--	
Water Insoluble Matter		0.2% max.	0.2% max.	0.2% max.	0.2% max.	0.2% max.	0.20% max.
Intermediates		--	0.5% max.	0.5% max.	0.5% max.	--	--
Sulfanilic Acid	Sodium salt of 4-aminobenzenesulfonic acid	0.2% max.	--	--	--	--	0.20% max.
Schaeffer Salt	Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid	0.3% max.	--	--	--	--	0.30% max.
Triazene (DAADBSA on US FDA)	Disodium salt of 4,4'-(1-triazene-1,3-diyl)bis[benzenesulfonic acid]	0.1% max.	--	--	--	--	0.1% max.

Disodium Salt of 6,6'-oxybis (2- naphthalene-sulfonic acid) (DONS on US FDA)	Disodium salt of 6,6'-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.	1.0% max.	--	--	--	--	1.0% max.
Subsidiary Dye		--	5.0% max.	5.0% max.	nd	--	4.0% max.
Higher Sulfonated	Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries	5.0% max.	--	--	nd	--	--
Lower Sulfonated	Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid	1.0% max.	--	2.0% max.	nd	--	--
Total Primary Amines (as Aniline) (a.k.a. Unsulfonated primary aromatic amines (as analind))		--	0.01% max.	0.01% max.	0.01% max.	--	0.01% max.
Aniline		250 ppb max.	--	--	--	--	--
Benzidine		1 ppb max.	--	--	--	--	--
4- Aminobiphenyl		15 ppb max.	--	--	--	--	--
4- Aminoazobenzene		50 ppb max.	--	--	--	--	--

1-(Phenylazo)-2-naphthalenol (Sudan 1)		10 ppm max.	0.5 ppm max	1 ppm max.	--	--	10 ppm max
Azobenzene		200ppb max.	--	--	--	--	--
1,3-Diphenyltriazene		40 ppb max.	--		--	--	--
Ether Extracts		--	0.2% max.	0.2% max.	--	--	--
Mercury		1 ppm max.	1 ppm max.	--	--	--	1 ppm max.
Arsenic(as As)		3 ppm max.	3 ppm max.	--	4 ppm max.	4 ppm max.	1 ppm max.
Heavy Metal (as Pb)		--	--	--	20 ppm max.	20 ppm max.	--
Lead (Pb)		10 ppm max.	2 ppm max.	2 ppm max.	--	--	10 ppm max
Cadmium		--	1 ppm max.	--	--	--	--

Global Indigo Carmine Specifications

Country		**U.S.**	**E.C.**	**F.A.O./W.H.O. JECFA**	**Japan**	**China**
	Alternate name/ Registration number	FD&C Blue No. 2	E 132 Indigotine, Indigo Carmine	INS 132 Ingidotine (Indigo Carmine)	Food Blue No. 2	GB 28317-2012
FDA COA nomenclature	Chemical tested					
Pure Dye		≥85.0%	≥85.0%	≥85%	≥85.0%	≥85.0%
Chloride & Sulfate (As sodium salts)		--	--	--	≤7.0%	
Moisture and Salts		≤15%	--	≤15%	--	≤15%
Loss on drying		--	--		≤10.0%	
Water Insoluble Matter		≤0.4%	≤0.2%	≤0.2%	≤0.20%	≤0.20%
Isatin-5-sulfonic acid	Isatin-5-sulfonic acid	≤0.4%	--	--	--	--
5-sulfoanthranilic acid	5-sulfoanthranilic acid	≤0.2%	--	--	--	--
Isomeric Dye	Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H -indol-2-ylidene)-2,3-dihydro-3-oxo-1H -indole-5-sulfonic acid	≤18%	--	--	--	--
Lower Sulfonated Dye	Sodium salt of 2-(1,3-dihydro-3-oxo-2H -indol-2-ylidene)-2,3-dihydro-3-oxo-1H -indole-5-sulfonic acid	≤2%	--	--	--	--
Subsidiary Dye		≤1.0%	--	≤1.0%	--	--
Sum of Isatin-5-sulfonic Acid, 5-sulfoanthranilic acid and Anthranilic acid		--	≤0.5%	--	--	--
Unsulfonated primary aromatic amines（as aniline)		--	≤0.01%	≤0.01%	--	
Ether Extractable matter		--	≤0.2%	≤0.2%	--	

Lead（as Pb)		≤10ppm	≤2ppm	≤2ppm	--	≤10ppm
Arsenic(as As)		≤3ppm	≤3ppm	--	≤4ppm(as As2O3)	≤1ppm
Mercury (as Hg)		≤1ppm	≤1ppm	--	--	--
Cadmium		--	≤1ppm	--	--	--
Heavy Metal (as Pb)		--	--	--	≤20ppm	--
Heavy Metal (as Fe)		--	--	--	≤500ppm	--