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Natural Food Colours Association

Effects of Europe's Regulatory Changes

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Agenda

- EFSA Food Additive Re-evaluation
- Summary of conclusions (food colours)
- Next steps, risk management process

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EFSA Food Additive Re-evaluation

- EFSA was tasked by the European Commission to re-evaluate ALL food additives, authorised before December 2009
- To be completed by 2020
- Based on EFSA's advice, Commission and member states could decide whether to change the conditions of use for an additive or, if needed, remove it from the EU list of authorised food additives to protect consumers

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EFSA Food Additive Re-evaluation

- Food colours were the first group of food additives subject to re-evaluation
- In December 2006, the AFC Panel made its first public call for data for food colours

"The process of re-evaluation of all the food colours currently authorised (both of natural origin and synthetic) has started in 2006 and should end in 2008"

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EFSA Food Additive Re-evaluation

- Calls for data requested:
  - •Information on data on the safety of the colours not previously reviewed in the current scientific opinions by SCF and JECFA,
  - •availability of original study reports as evaluated by the SCF and JECFA,
  - •Information on the purity of colours presently in use, including particle size when relevant,
  - •Information on production methods,
  - •Information on the analytical methods available for determination in food,
  - •Information on present use patterns (intake, actual use levels and exceptions to these levels).

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EFSA Food Additive Re-evaluation

- The first outcome of the re-evaluation was in 2007 on E 128 Red 2G, authorised (at that time) to colour burger meat and breakfast sausages
- EFSA concluded that this colour is converted to aniline (carcinogen) by the body and is unsafe to use as a food colour in humans
- Commission took emergency measures suspending the use of this colour in July 2007

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EFSA Food Additive Re-evaluation

- In 2008 the re-evaluation process was diverted to cover the so called ‘Southampton Six’ colours:

- Tartrazine (E102), Quinoline Yellow (E104), Sunset Yellow FCF (E110), Ponceau 4R (E124), Allura Red AC (E129), Carmoisine (E122)

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EFSA Food Additive Re-evaluation

- Finally in EFSA published its final two Opinions for Annatto Extracts (E 160b) in August 2016 and titanium dioxide (E 171) in September 2016
- Overall 41 food colours were assessed (in 10 years)
- Programme continues with non colour additives
  - Over 200 to be completed by 2020

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Summary of Conclusions

Natural colours only

E Number	Common Name	Date Opinion Adopted	Date Opinion Published	ADI decision (as mg/kg bw/day)
E 160d	Lycopene	30 January 2008	14 April 2008	set at 0.5
E 161b	Lutein	07 July 2010	28 July 2010	set at 1
E 100	Curcumin	07 July 2010	06 September 2010	set at 3
E 161g	Canthaxanthin	10 September 2010	06 October 2010	remains at 0.03
E 150 a,b,c,d	Caramels	03 February 2011	08 March 2011	Group ADI of 300, but 100 for E 150c
E 170	Calcium Carbonate	05 July 2011	26 July 2011	ADI 'Not specified'
E 160 a (i) & (ii)	Mixed carotenes/betacarotene	15 February 2012	14 March 2012	No ADI established
E 160 e	β-apo-8'-carotenal	07 December 2011	14 March 2012	set at 0.05
E 153	Vegetable Carbon	16 February 2012	27 April 2012	No ADI established
E 163	Anthocyanins	13 March 2013	23 April 2013	No ADI established
E 101 (i) and (ii)	Riboflavin (& phosphate)	12 September 2013	22 October 2013	No ADI established
E 140(i)	Chlorophylls	15 April 2015	07 May 2015	No ADI established
E 140(ii)	Chlorophyllins	15 April 2015	07 May 2015	No assessment completed
E 141(i) and (ii)	Copper chlorophylls and chlorophyllins	09 June 2015	30 June 2015	No assessment completed
E 120	Cochineal, Carmines and carminic Acid	27 October 2015	18 November 2015	ADI remains at 5 (2.5 as carminic acid)
E 172	Iron oxides and hydroxides	17 November 2015	08 December 2015	No assesment completed
E 162	Beetroot Red	17 November 2015	09 December 2015	No ADI established
E 160 c	Paprika Extract	19 November 2015	10 December 2015	set at 24 as extract , 1.7 as carotenoids
E 160(b)	Annatto Extracts	29 June 2016	24 August 2016	6 for bixin, 0.3 for norbixin
E 171	Titanium Dioxide	28 June 2016	14 September 2016	Not established

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Summary of Conclusions

Example –Lutein

- The ANS Panel established an ADI of 1 mg/kg bw/day and noted that this ADI refers to lutein derived from Tagetes erecta containing at least 80% carotenoids

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Summary of Conclusions

Example –Riboflavin and phosphate

- Due to the absence of carcinogenicity/chronic toxicity studies and lack of relevant reproductive and developmental toxicity studies, the Panel considered that it is not appropriate to allocate an ADI. The Panel concluded, despite the uncertainties in the database, that riboflavin (E 101(i)) and riboflavin-5′-phosphate sodium (E 101(ii)) are unlikely to be of safety concern at the currently authorised uses and use levels as food additives.

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Summary of Conclusions

Example –Anthocyanins

- The Panel concluded that the currently available toxicological database was inadequate to establish a numerical ADI for anthocyanins
- Therefore the Panel would recommend that appropriate characterisation and toxicological data should be required to permit a further re-evaluation of anthocyanins including comparative data on anthocyanins (E 163) produced by aqueous extraction

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Summary of Conclusions

Example –Chlorophyllins

- Considering the absence of relevant ADME and toxicity data, and because chlorophyllins (E 140(ii)) are neither natural constituents of the regular diet nor metabolites of chlorophylls in humans, the Panel concluded that it was not possible to assess the safety of chlorophyllins (E 140(ii)) as food additives

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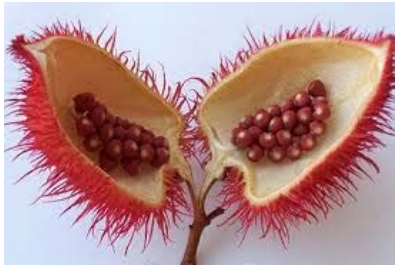
Summary of Conclusions

Example –Annatto



- However, the maximum limits for the impurities of toxic elements (arsenic, lead, mercury) should be revised in order to ascertain that the annatto extracts as food additives will not be a significant source of exposure to these toxic elements in foods. Moreover, the Panel recommended that a maximum limit for cadmium should also be included in the specifications

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Next Steps – Risk Management

- Commission now has to act on the findings where:
  - EFSA was not able to re-evaluate, and therefore to reconfirm, the safety of an additive and/or derive an Acceptable Daily Intake (ADI) due to the lack of relevant scientific data.
  - EFSA lowered the ADI of an additive due to the limited availability of toxicological data.
  - The exposure assessment carried out by EFSA suggests a potential exceedance of the ADI for one or more population groups.
  - EFSA raised issues concerning the specifications of some additives as laid down in Commission Regulation (EU) No 231/2012

Next Steps – Risk Management

- Commission has published its approach to the Opinions which need a follow up
- IMPORTANT: The colours in question can stay on the market as currently approved until the follow up is complete

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Next Steps – Risk Management

- For those Opinions which need a follow up Commission will publish a call for data (new tox studies) on the DG Sante website:
- http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

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Next Steps – Risk Management

- STEP ONE
  - Parties have six weeks to register their interest in the additive and to provide data
  - Commission publishes the list interested parties on the website
- STEP TWO
  - Within 12 or 24 weeks the interested parties need to confirm the deadline and milestones to submit the requested data
  - Commission publishes the data to be submitted plus the milestones and deadline on the website

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Next Steps – Risk Management

- Commission will send the data to EFSA for evaluation. Based on EFSA final scientific opinion, Commission will make a risk management decision on the fate of a specific additive

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Next Steps – Risk Management

- Commission have stressed that there will be no further calls for data
- Should the requested new data not be provided (by the deadline) or be insufficient then Commission will make a decision based on the current opinion, which includes delisting the additive

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Next Steps – Risk Management

- The same process will be followed for those additives where the exposure or specification is under review, but EFSA may not necessarily be involved

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Next Steps – Risk Management Experiences to date

- At the time of writing there are no calls for data for food colours
- Calls for data exist for sorbates (at Step 2) and sulphites (at Step 1)
- For sorbates 21 interested parties have expressed interest in retaining sorbates as food additives and 15 parties have declared they will submit data
- Interested parties are global manufacturers and trade associations

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Next Steps – Risk Management Experiences to date

- Call for data on sorbates includes
  - Data on the genotoxicity of calcium sorbate;
  - Data on the reproductive toxicity of sorbic acid/potassium sorbate;
  - Data on the lowest achievable limits for the impurities of toxic elements;
  - Data on the use of divalent transition metals as catalysts in the manufacturing process of sorbic acid.

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Summary

- Be prepared!!!

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