Evaluation of artificial and natural food colours – recent developments in Europe

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Outline of talk

- Background to concerns about synthetic food colours
- Trend towards use of natural colours
- EFSA re-evaluation of colours
- Difficulties in assessing natural colours
- Examples of analytical challenges
- Future prospects
Consumer concern about artificial colours

- Southampton study - widespread publicity
- Exposure to mixtures of synthetic colours + benzoic acid preservative
- Hyperactivity

Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial

Donna McCann, Angelina Barrett, Alison Cooper, Debbie Crumpler, Lindy Dale, Kate Grimshaw, Elizabeth Kitchin, Kris Lok, Lucy Porteous, Emily Prince, Edmund Sonuga-Barke, John O’Warner, Jim Stevenson

Summary

Background We undertook a randomised, double-blinded, placebo-controlled, crossover trial to test whether intake of artificial food colour and additives (AFCA) affected childhood behaviour.

Methods 153 3-year-old and 144 8/9-year-old children were included in the study. The challenge drink contained sodium benzoate and one of two AFCA mixes (A or B) or a placebo mix. The main outcome measure was a global hyperactivity aggregate (GHA), based on aggregated 2-z scores of observed behaviours and ratings by teachers and parents, plus, for 8/9-year-old children, a computerised test of attention. This clinical trial is registered with Current Controlled Trials (registration number ISRCTN74481308). Analysis was per protocol.

Findings 16 3-year-old children and 14 8/9-year-old children did not complete the study, for reasons unrelated to childhood behaviour. Mix A had a significantly adverse effect compared with placebo in GHA for all 3-year-old children (effect size 0.20 [95% CI 0.01–0.39], p=0.044) but not mix B versus placebo. This result persisted when analysis was restricted to 3-year-old children who consumed more than 85% of juice and had no missing data (0.32 [0.05–0.60], p=0.02). 8/9-year-old children showed a significantly adverse effect when given mix A (0.12 [0.02–0.23], p=0.023) or mix B (0.17 [0.07–0.28], p=0.001) when analysis was restricted to those children consuming at least 85% of drinks with no missing data.

Interpretation Artificial colours or a sodium benzoate preservative (or both) in the diet result in increased hyperactivity in 3-year-old and 8/9-year-old children in the general population.

Ref: The Lancet, Vol. 370, Issue 9598, 1560-1567
Illegal use of Sudan dyes in spices

- Significant media coverage
- Large-scale withdrawal of retail products containing chilli powder adulterated with illegal dyes including Sudan I.
Consumer mistrust of artificial colours– move towards natural colours

Why you should NEVER trust labels on food: 'Fresh' food that isn't fresh. 'Natural' colours that are chemicals and 'real' fruit juice that only 5 per cent fruit
EU Directives on Food Colours (94/36/EC)

- Annex I - List of permitted food colours
- Annex II - List of foodstuffs which may NOT contain added colours
- Annex III - List of foodstuffs for which only certain permitted colours can be added

Currently 42 EU approved food colours, including derivatives (E100-E180)

- Including 14 are artificial colours,
- Including 10 are natural colours
- Remainder are substances with colouring properties such as calcium carbonate, titanium dioxide, iron oxides & hydroxides, aluminium, silver and gold
Risk assessment in the EU undertaken by EFSA

The 4 Step Risk Assessment Process

- **Hazard Identification**: What health problems are caused by the pollutant?
- **Dose-Response Assessment**: What are the health problems at different exposures?
- **Exposure Assessment**: How much of the pollutant are people exposed to during a specific time period? How many people are exposed?
- **Risk Characterization**: What is the extra risk of health problems in the exposed population?
EFSA Scientific Panels

- Animal health and welfare (AHAW)
- Biological hazards (BIOHAZ)
- Contaminants (CONTAM)
- Plant health (PLH)
- Feed (FEEDAP)
- Nutrition (NDA)
- Additives & Nutrient Supplements (ANS)
- Contact materials, Enzymes, Flavourings (CEF)
- GMO (GMO)
- Pesticides (PPR)
EU requirements for risk assessment of food additives


- Food additives must be kept under continuous observation
- Food additives must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.
- All food additives which were permitted before 20 Jan 2009 shall be subject to a new risk assessment carried out by EFSA.
Many of the evaluations of food colours are very old.

For some colours many new studies have become available and should be included in the evaluation.

Food colours were deemed as a priority for EFSA.

The order of priorities for the re-evaluation of the remaining permitted food additives will be set in a re-evaluation programme.
Information required for risk assessment of food colours

- Chemical identity of colour
- Specification including impurities
- Stability and fate in foods
- Use levels in foods
- Consumption data for individual foods
- A specified range of toxicological studies
Uncertainty in risk assessment

- Some colours can be complex mixtures
- Colours contain impurities - specifications
- Some colours are partially unstable during processing/storage – is the substance consumed the same as the one added
- Levels of use – maximum permitted use levels cf. actual use levels
- Food consumption patterns – differences across Europe
- Toxicological studies – is the substance tested the same as that occurring in feed
Risk assessment of Brilliant Blue FCF (E133)

- Trarylmethane synthetic food colouring substance
- EU maximal allowed use level of 20 to 500 mg/kg in various foodstuffs
- EU maximal allowed use levels up to 200 mg/L in beverages.
Specifications of Brilliant Blue FCF

- Purity of not <85% total colouring matter including <6% subsidiary colouring matters.
- Twenty four commercial samples of Brilliant Blue FCF were found to contain magenta subsidiary colour at levels ranging from 0.1% to 0.8%.
- Five subsidiary colours - derivatives of benzenesulphonic acid present in commercial Brilliant Blue FCF.
- The Panel further noted that the specifications for Brilliant Blue FCF need to be updated.
## Exposure estimates UK adult population

<table>
<thead>
<tr>
<th>Approach</th>
<th>Intake (mg/kg bw/day)</th>
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</thead>
<tbody>
<tr>
<td>Tier 1- Budget method</td>
<td>8.1</td>
</tr>
<tr>
<td>Tier 2 Maximum Permitted Level</td>
<td></td>
</tr>
<tr>
<td>• Mean exposure</td>
<td>0.9</td>
</tr>
<tr>
<td>• Exposure 95&lt;sup&gt;th&lt;/sup&gt; percentile</td>
<td>3.3</td>
</tr>
<tr>
<td>Tier 3. Maximum reported use levels</td>
<td></td>
</tr>
<tr>
<td>• Mean exposure</td>
<td>0.6</td>
</tr>
<tr>
<td>• Exposure 95&lt;sup&gt;th&lt;/sup&gt; percentile</td>
<td>3.0</td>
</tr>
</tbody>
</table>
Main contributors to exposure – Tier 3

- Non-alcoholic beverages contribute 13 to 53% intake
- Fine bakery wares (e.g. Viennoiserie, biscuits, cakes, wafer) - 12 to 64%
- Sauces, seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney and piccalilli - 14 to 60%
- Confectionery - 19 to 24% of exposure in 2 countries
- Extruded or expanded savoury snack products -17% of exposure in 1 country.
EFSA conclusions concerning Brilliant Blue FCF

New chronic toxicity study in rats with NOAEL of 631 mg/kg bw/day used to allocate a new ADI = 6 mg/kg bw/day (uncertainty factor 100)

- JECFA assigned an ADI of 12.5 mg/kg bw/day in 1970.
- SCF revised the ADI to 10 mg/kg bw/day in 1984

Exposure well below ADI – no changes needed.
Complex synthetic colours

Some colours such as the caramels are produced by chemical reactions, resulting in complex mixtures of ill defined composition

<table>
<thead>
<tr>
<th>Mass range (g/mol)</th>
<th>Composition</th>
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<tbody>
<tr>
<td>0-1000*</td>
<td>56-60%</td>
</tr>
<tr>
<td>1000-10,000</td>
<td>ca. 20%</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>20-30%</td>
</tr>
</tbody>
</table>

*Disaccharides, glucose, 1,6-anhydroglucose, laevulinic acid, 5-HMF
Specifications for Class III Ammonia Caramel


<table>
<thead>
<tr>
<th>Substance</th>
<th>Maximum permitted level</th>
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<tr>
<td>4-Methylimidazole (4-MEI)</td>
<td>&lt;250 mg/kg</td>
</tr>
<tr>
<td>2-Acetyl-4-tetrahydroxy-butylimidazole(THI)</td>
<td>&lt;300 mg/kg</td>
</tr>
</tbody>
</table>

- Minor constituents, should be reduced as much as technologically feasible.
- Specifications for the caramel colours should include maximum levels for constituents of possible concern not yet included in the specifications, such as for example 5-HMF.
Source material for natural colours

Natural colours can have considerable complexity

- Various source materials
- Complexity in composition of extracted colouring principle
- Co-extractives from plant or animal source materials

Need to compare exposure from natural sources with exposure from added colour
Example – mixed carotenes & β-carotene (E160a)

**Sources :-**
- Palm fruit oil – acetone, methanol and/or hexane solvent extraction
- Carrots - acetone, methanol and/or hexane solvent extraction
- Algae – edible oil extraction

Typically contain α- and β-carotene + minor amounts of γ-carotene + lycopene
Example – Beetroot Red E-162

Source:- Red beets – pressing or aqueous extraction

Content of red betanin not less than 0.4%, but contains betacyanins, betaxanthins etc. + sugars, salts, proteins and nitrate.
EFSA guidance on submission of food additive evaluations

Scientific Opinion, published August 2012 (EFSA Journal 2012, 10:2760)

Identity of the substance

- Single substances
- Simple mixtures
- Complex mixtures not derived from botanical sources
- Polymers
- Additives derived from botanical sources
- Nanomaterials
- Substances containing microorganisms or derived from microorganisms
Future prospects

- More detailed requirements for submissions for approval of additives
- More focus on specifications
- More questions about fate and stability
- Tiered approach to toxicological testing

- Tier 1 – minimal data
- Tier 2 more extensive data for compounds which are absorbed and/or demonstrate (geno)toxicity
- Tier 3 should be performed on a case-by-case basis taking into consideration all the available data, to elucidate specific endpoints
Thank you very much for your attention

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