

# Prevention vs. Precaution

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# “Generally Accepted Scientific Evidence”

- **Is the “bedrock” of scientific assessment**
- **Applies equally to the evaluation of potential benefit as it does to potential risk**
- **It is the interpretation of the outcomes of scientific assessment that varies**
- **The recommendations for many key nutrient intakes in the EU are largely based on biochemical, observational and epidemiology data, often based deficiency.**
  - E.g. vitamin c and scurvy
- **Disease risk reduction claims have also often based on the same types of studies.**
  - E.g. fish consumption and heart disease

# Cause-Effect Relationship

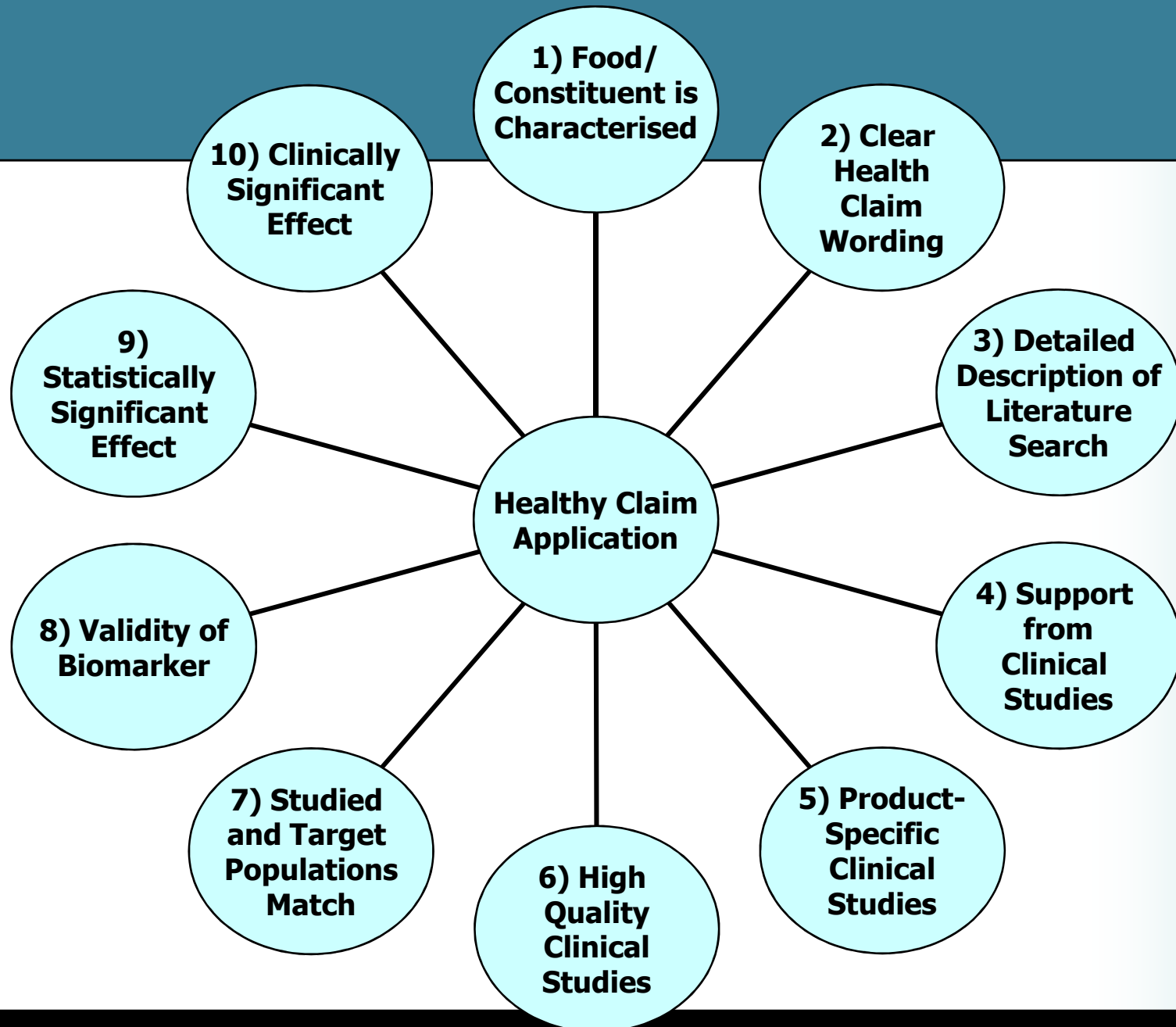
- **EFSA's mandate from the Commission requires them to establish whether a "cause-effect relationship" between intake of the proposed food/ingredient and the claimed effect**
- **It does not directly permit EFSA to report on the levels of evidence**
- **Is such a black and white principle strictly applicable to scientific assessment?**
- **Does it support innovation?**
- **Especially at the early stages of knowledge**

# EFSA Guidance

- **Is based on absolutely sound scientific principles**
- **Nobody can have complaints about the dossier format**
- **Nobody has reason to question EFSA's integrity**
- **They should be allowed to get on with their job**
- **They should be consulted when new legislation is being prepared that involves them**

# EFSA Guidance

- **EFSA are clearly struggling with the regulatory compromise that was made between all parties to allow the “2-speed” assessment of claims (i.e. the Article 13 list vs full applications)**
- **They deal with all submissions by applying the “golden standard” based on an evaluation of the “totality of the data”**
- **In the case of the “Article 13 List”, it is arguable whether they have been provided with the information required to fully assess claims**
- **The Article 13 list has wasted a great deal of everyone’s time!**



# Example of Safety

## Food Additives and Children's Behaviour

- **In March 2008 EFSA evaluated “The Southampton Study” (McCann et al., 2007)**
  - **Tartrazine (E102), Quinoline Yellow, (E104), Sunset Yellow FCF (E110), Ponceau 4R (E124), Allura Red AC (E129), Carmoisine, (E122) and sodium benzoate (E211)**
  - **As part of the evaluation the statistical analysis “...was repeated using a more justifiable and conventional statistical model, and this was supplemented by a set of additional analyses with the aim of aiding the interpretation of the results.”**

*The EFSA Journal (2008) 660, 1-5*

# The “Southampton Study”

- **“There are thus a number of uncertainties that are apparent from this new research, some of which are echoed in earlier research. These include:**
  - **the limited consistency of the results with respect to age and gender of the children, the effects of the two mixtures of additives tested and the type of observer (parent, teacher or independent observer);**
  - **the unknown clinical relevance of the novel metric, i.e. the GHA score;**
  - **the unknown relevance of the small effect size (as was also seen in the meta analysis of earlier studies by Schab and Trinh, (2004));**
  - **the fact that the study has not been designed to identify the effects of individual additives;**
  - **a lack of information on dose-response;**
  - **the lack of a biologically plausible mechanism for induction of behavioural effects from consumption of food additives.”**

# The “Southampton Study”

- “The Panel concludes that the McCann *et al.* study provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in children selected from the general population excluding children medicated for ADHD, although the effects were not statistically significant for the two mixtures in both age groups.
- Since mixtures and not individual additives were tested in the study by McCann *et al.*, it is not possible to ascribe the observed effects to any of the individual compounds.
- The clinical significance of the observed effects also remains unclear”

# The Result of EFSA's Assessment

- **REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives**

## ANNEX V

List of the food colours referred to in Article 24 for which the labelling of foods shall include additional information

Foods containing one or more of the following food colours	Information
Sunset yellow (E 110) (*)	'name or E number of the colour(s)': may have an adverse effect on activity and attention in children.
Quinoline yellow (E 104) (*)	
Carmoisine (E 122) (*)	
Allura red (E 129) (*)	
Tartrazine (E 102) (*)	
Ponceau 4R (E 124) (*)	

(\*) With the exception of foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells.

# Example of Efficacy

## DHA and ARA and development of brain and eyes

- **EFSA delivered Opinion on 8 September, 2008 and concluded:**
  - **“The consumption of baby foods/formula supplemented with DHA and ARA from six months to one year of age might have a beneficial effect on visual acuity maturation in infants breast-fed during the first 4-6 months of age.**
  - **On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA and ARA starting at six months of age and the neural development of the brain and eyes in infants and young children up to the age of three years.**

*The EFSA Journal (2008) 794, 1-2*

# The Result of EFSA's Assessment

- **Draft COMMISSION REGULATION of on the authorisation of health claims made on food and referring to the reduction of disease risk and to children's development and health**
- **Voted on with qualified majority at Standing Committee on Food Chain and Animal Health 20<sup>th</sup> February 2009**
- **Claim was rejected**

# Comments in Preamble to Regulation

- **“In addition, the Authority concluded that the consumption of baby foods/formula supplemented with DHA and ARA from six months to one year of age might have a beneficial effect on visual acuity maturation in infants breast-fed until the age of 4-6 months.**
- **The Authority concluded also that no evidence has been presented on the effects of DHA and ARA supplementation starting at six months of age on visual maturation in healthy infants that had not been breastfed but fed unenriched formula during the first months of life. A health claim reflecting this conclusion could not comply with the general principles and conditions set out in Regulation (EC) No 1924/2006, and especially in Article 3, 5 and 6, and should not be authorised. “**

# Outcomes of Risk Management

- Southampton Study – Precautionary Principle Applied and labelling mandated in legislation
  - ‘name or E number of the colour(s)’: may have an adverse effect on activity and attention in children.
- DHA/ARA – addition to the Annex of Rejected Claims..
  - “The consumption of baby foods/formula supplemented with DHA and ARA from six months to one year of age might have a beneficial effect on visual acuity maturation in infants breast-fed during the first 4-6 months of age”
  - What if subsequent science/epidemiology shows it is very important, for the maintenance long term neuronal/cognitive development of children?
  - It certainly will not do them any harm
  - Should we encourage more science with a qualified claim or simply reject?

# Prevention vs. Precaution Summary

- **We start with good scientific assessment**
- **Many health benefits can only reach a degree of scientific certainty after long term study**
  - Double Blind Placebo Controlled Clinical Studies are usually short to medium term studies
  - Epidemiology/observational/biochemical studies provide much of the basis for population dietary guidelines for disease risk reduction/maintenance of health
    - For example we know fish consumption reduces the risk of death from heart disease, but not exactly why
- **Can we afford to ignore emerging science?**

# Scientific Assessment Issues Facing EFSA

- **Too many claims with too little data – a fault of the regulation**
- **A shortage of experts – resource issue**
- **Very short timelines mandated for assessments and next to no time for “stop-clocks” – a fault of the regulation**
- **Insufficient flexibility to issue opinions that reflect the strength of the evidence and the use of terms “may” and “might” (perhaps even as temporary claims would be a potential solution) – a fault of the mandate to EFSA**
- **BUT dialogue with stakeholders and small changes can amend these issues**

# Adoption of Claims into Regulation

- **Many stakeholders**
- **27 Member States**
- **Under-resourced Commission?**
- **Regulation is too complex and rigid**
- **At the end the issue has always been enforcement and the removal of the cowboys**
- **The Article 13 list has given them some breathing space and treated them the same as those who are trying to do things properly**
- **3 month scrutiny period means that claims voted on in Feb 09 will not be adopted until October!**

# Industry Obligations

- **Much of the industry realises it needs to conduct more and higher quality studies to prove efficacy**
- **They are supportive of this approach so long as there is reward for doing it properly**
- **Many of the studies that EFSA has criticised for poor design, statistical validity etc., have been conducted in Universities with for the purpose of publication, not dossier submission**
  - Academia needs to “up it’s game” in many cases if they are to continue to get funding from the food industry
  - CROs already function to good laboratory practice
- **Support proprietary data claims strongly for those with emerging and proprietary data**

# And what about consumer understanding?

- **Can we allow consumers to make their own judgements so long as they are given proportional and clear information?**
- **A lot of consumers work in the food industry!**

# Overall Conclusion

- **We need to simplify things!**
- **Minimise the legislation**
- **Maximise the guidance to allow flexibility**
- **Recognise that innovation needs reward and that the food industry employs many people**
- **Allow the consumer to make an informed choice**

# Thank you!

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