Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC)

Presentation to EFSA
Management Board

27 March 2007

NATURE OF AFC WORK

- Focus is on chemical safety evaluation and risk assessment
- Most questions originate from the need to have a safety evaluation prior to legislative approval of a chemical for use in the EU
- Most questions address the generic safety of a chemical or a group of related chemicals in food
- Majority of questions relate to substances not previously evaluated at the EU level
- Panel works mainly from data submitted by industry

USE OF DATA SUBMITTED BY INDUSTRY

- It is industry's responsibility to assemble a comprehensive dossier on the substance for which they are seeking approval
- A good dossier should contain all the relevant unpublished data that the industry has generated and refer to all the known published data
- It is the responsibility of the Panel and its WGs to critically evaluate all the submitted data, including in depth assessment of individual study reports, exposure estimates & publications
- The Panel may gather extra information
  e.g. when there are other relevant data in the public domain
- The Panel often performs its own exposure assessments

HOW RELIABLE ARE DATA SUBMITTED BY INDUSTRY?

Toxicity studies conducted for regulatory submission usually:

- Follow internationally agreed protocols
- Are conducted to GLP standards in laboratories that are regularly inspected by national authorities
- Are submitted as full study reports in which the validity of the overall results and conclusions can be checked against, for example, individual animal data, other statistical tests, etc

WHY ARE MOST PUBLISHED AFC OPINIONS POSITIVE?

- With a new substance, industry is unlikely to request approval if the data clearly show a safety issue at anticipated intakes
- The inherent toxicity of substances used or proposed as food additives or flavourings is generally low
- The intakes of substances used as flavourings or in food contact materials are often low
- When the Panel considers there are safety concerns about a substance not yet on the market, an opinion is not usually published
  - ❖ The petitioner is informed and asked to submit further data, conduct further research, or the petition may be withdrawn

MEETINGS HELD
May 2003 – Feb 2007

AFC Plenary	Flavourings WG	FCM WG	Additives WG
21	17	17	21

Does not include meetings of ad hoc WGs on:
Aspartame 6, Smoke flavourings 9, Aluminium 1 (just started)
FLAVIS 15

Number of questions to AFC 2003-2007

Food additives	45
Flavourings	41 (comprising 2800 substances on EC Register plus 911 from JECFA)
Smoke flavourings	17
Processing aids	4
Food contact materials	182
Food supplements/PARNUTS	248
TOTAL Excludes re-evaluation of all Additives	**537** 350 (as c.175 opinions)

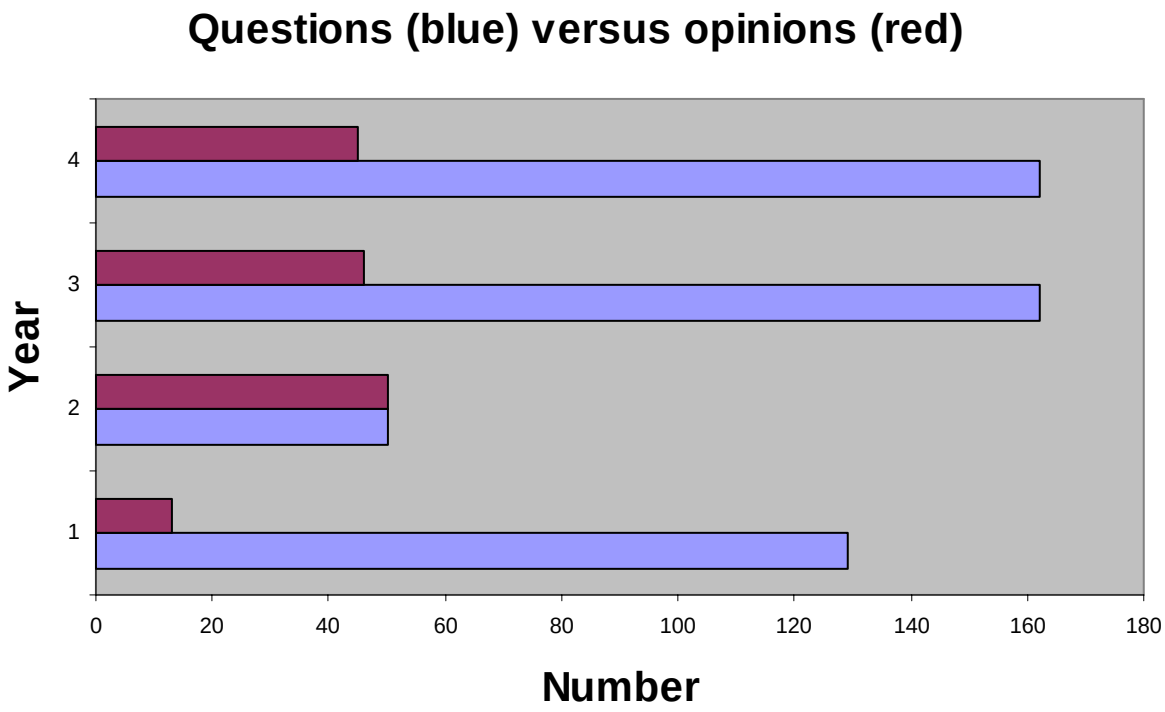
Number of opinions adopted by AFC 2003 - 2007

	Total 166	Flavs	FCMs	Adds/ Suppts	Other
2003	13	0	9	4	0
2004	50	5	27	9	9
2005	46	8	23	4	11
2006	45	6	20	15	4
2007	12	4	3	5	0

ADDITIONAL WORK ANTICIPATED 2007-2009

TOPIC	Number of dossiers	Deadlines/Start
Additives: re-evaluation of all permitted E nos.	350	10 years in total Started 2006
Food irradiation	None provided – update of all SCF opinions	9 months Start 2007
New flavourings	130 known + 10 new per year	July 2007 or later Start 2007
Enzymes	200 known + 10 new per year	6 months Start 2008/9
Active and intelligent packaging	Not known	6 months Start 2008
Recyled packaging	Not known	6 months Start 2009

Comparison of Questions put versus Opinions issued 2003-2006



RESOLVING THE WORKLOAD ISSUES

- Contracting out preparatory work
  - The Panel already contracts out preparatory work on flavourings, FCMs, re-evaluation of additives
- Article 36 co-operation
  - Likely to focus on broad issues that underpin opinions
- Increasing the Panel's scientific secretariat
  - This would help with preparation work and reduce the rapporteuring load for Panel members

But these options do not address the fundamental issue:

The Panel could not deal with any increased output from the WGs without adding extra meetings to an already demanding schedule

RESOLVING THE WORKLOAD ISSUES

- Could some questions be answered by the secretariat?
  - Yes, but majority of questions to AFC derive from EU legislation requiring an opinion from the Panel
- Could more questions be answered by WGs?
  - Yes (e.g. evaluations of non-complex substances) but, as above, legislation does not allow for this
- Could substances evaluated by EU national authorities or JECFA be fast-tracked through EFSA?
  - Yes, this is a possibility, if it is recognised in the framing of future legislation

RESOLVING THE WORKLOAD ISSUES

- Better prioritisation of questions by the Commission and by EFSA
- Better refinement of broad questions
- Avoiding the adoption of product by product authorisation in future legislation
  - All legislation to which AFC evaluations currently relate takes a generic approach (authorisations of chemicals not formulated products)

RESOLVING THE WORKLOAD ISSUES

- Creating a new Panel
  - There is enough work among the overloaded Panels to justify creation of a new Panel
- Redistributing the workload of Panels
  - The remits of Panels with overlapping areas of topics and/or required expertise could be redistributed

SUMMARY

- The AFC Panel has a high output from its “army of volunteers” and its secretariat
- The workload of the Panel will further increase in the foreseeable future
- Advice on urgent public health issues is and will continue to be prioritised
- Deadlines on non-urgent issues will, increasingly, not be met
- Changes to Panel remits and ways of working are needed if EFSA is to meet the needs of its customers and maintain the good will of its experts