Introduction to the AFC Panel

Stakeholder Consultative Platform
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Panel on food Additives Flavourings, processing aids and materials in Contact with food (AFC)

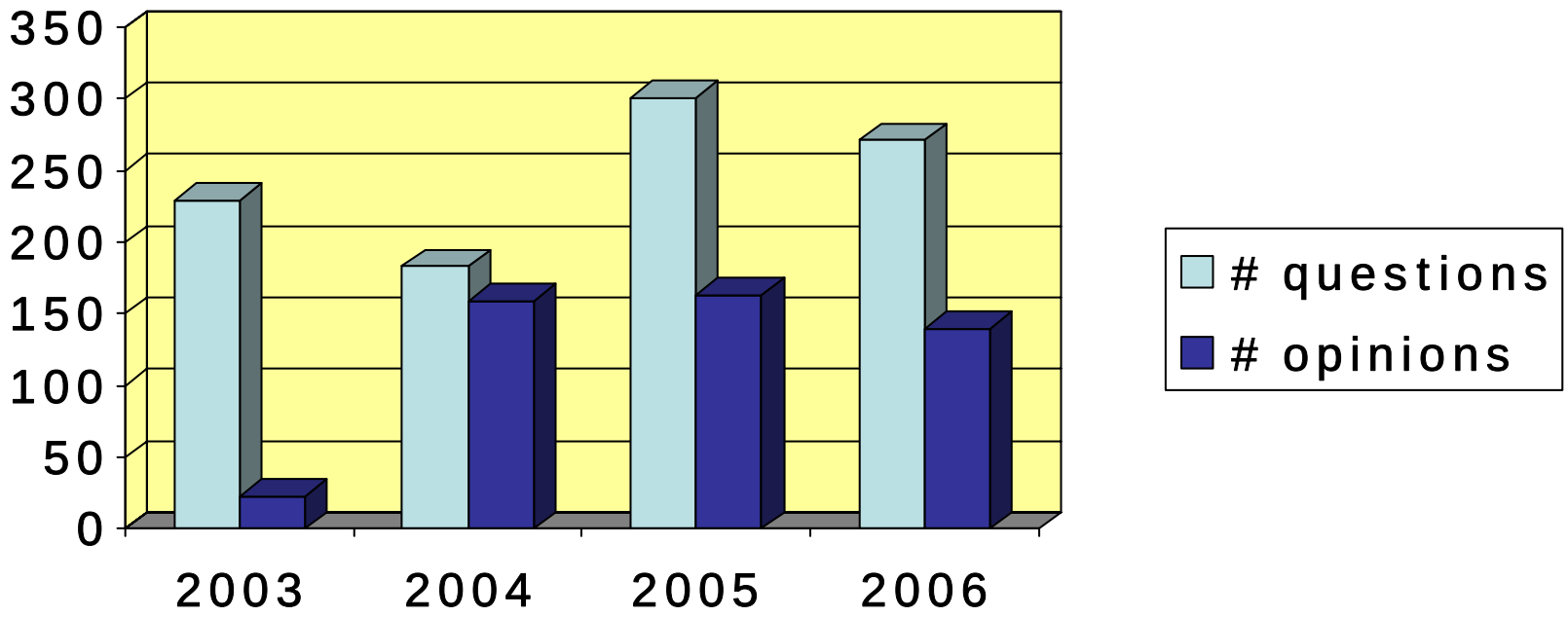
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AFC Panel tasks

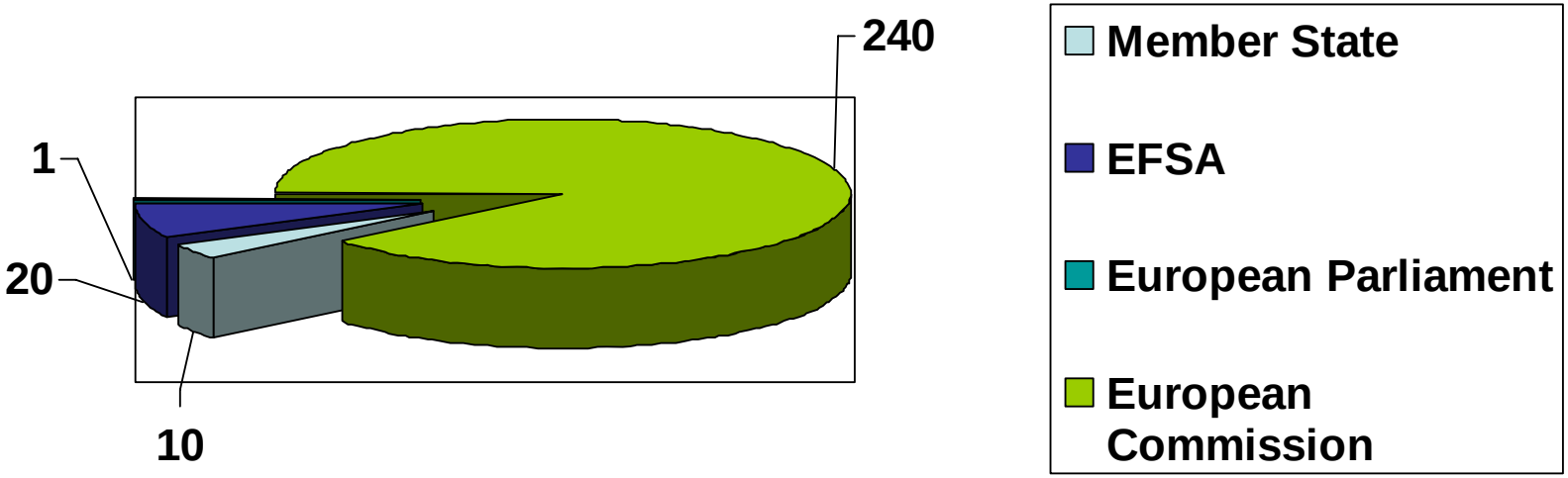
- **food Additives (e.g. colours, sweeteners, antioxidants, etc)**
- **Flavourings (Chemical substances (FGE), “active principles”, smoke flavourings)**
- **processing aids (e.g. solvents, filtering agents,…)**
- **Contact materials (monomers and additives, recycling, active and intelligent packaging)**
- **nutrient sources (e.g. food supplements) (only safety of source, but not nutritional efficacy)**
- **enzymes**
- **processes (e.g. irradiation, but not heating)**
- **any other substance** deliberately added to food **(but not ”novel food”)**

European Food Safety Authority

Number of questions and opinions



Origin of requests for 2006



Types of questions 1

Regulated substances (dossiers)

- Through MS according to legislation (COM informed, but **not** issuing **Terms of Reference**), deadline 6 months (smoke flavourings and FCM)
- ToR through COM. Negotiated deadline (6-12 months). (additives, (new) flavouring substances, nutrient sources, extraction solvents, decontamination of carcasses

NB: EFSA is NOT authorising substances

Types of questions 2

Authorised substances (emerging issues)

- ToR from COM (or MS or self tasking) (e.g. aspartame, Southampton study,…)

Authorised substances (“routine” re-evaluation)

- ToR from COM. (e.g. nisin, natamycin, “all food colours”)

Unregulated substances (emerging issues)

- ToR from COM (or MS or self tasking) (e.g. ITX from printing ink, semicarbazide as reaction product,

efsa
European Food Safety Authority

Scientific Activity 2006

Panel	Number of questions received	Number of opinions adopted	Number of scientific reports and pesticides conclusions
AFC	166	39	
AHAW	19	10	
BIOHAZ	14	17	
CONTAM	5	6	
FEEDAP	33	32	
GMO	11	7	
NDA	24	4	
PPR	10	17	
PLH	36	0	
SC	1	3	
Zoonoses	8	1	3
PRAPeR	-	-	31
Methodology	-	-	4
TOTAL	**327**	**136**	**38**

Total number of scientific outputs: 174

AFC working groups

Three standing WGs (+ ad hoc WGs)

("permanent" members + ad hoc experts)

Standing WGs meet 4-6 times a year, ad hoc WGs according to need

- **Additives (including nutrient sources)**
  - Ad hoc: Aspartame (ended), aluminium (active), irradiation (coming)
- **Flavourings**
  - Flavis, Smoke flavouring
- **Food Contact Materials**

Process of evaluating regulated substances (dossiers)

- Receive request with dossier (Commission or through MS)
- Check validity and inform WG
- Appoint rapporteur (when relevant: contractor)
- Discussion of draft opinion in WG. If adopted to plenary. Else back to rapporteur or applicant.
- Discussion of draft in Plenary. If adopted published on the web when latest changes have been introduced. Otherwise it can be deferred to a coming plenary, referred back to WG or to applicant.

Process of evaluating substances

- Most questions on regulated substances are based on a dossier submitted by the applicant according to agreed and detailed guidelines on how to submit a dossier
- Often the Panel (through the secretariat) will request further documentation from petitioner, in which case the ”clock will stop”. Can happen several times if needed.

- Emerging issues (unregulated substances or “old” regulated substances) because of high profile and new studies being published (e.g. UK study on colours and aspartame) not based on dossiers (even if regulated) and need special literature search by Panel/secretariat.

AFC additives

Colours, sweeteners and additives other than colours and sweeteners

- Presently 15 dossiers on agenda. Some new while others are new requests for ”old” additives (e.g. new specification or new applications). Some under evaluation while others wait for submission of requested data.
- Re-evaluation: Presently looking at colours (45). Next groups to be initiated through 2008 (could be antioxidants, preservatives, stabilisers (gums), sweeteners?,) (in all around 300 E numbers)
- New Regulation: A ”peak” of submissions may be expected when new procedures come into force.

Food colours

- Illegal colours (Sudan red I, II, III, IV, Para red,..)
- Re-evaluation of food colours

  45 colours (natural, synthetic, inorganic)

  Open call for data

  Red 2G first colour evaluated, negative opinion

  Several opinions close to adoption by WG and Panel, but put on hold while waiting for the outcome of Southampton study

Food colours 2

Southampton study (FSA UK)

- Largest study ever, randomly selected
- 6 colours and Na benzoate in two mixes
- Mix A effect on 3 yrs but not 8/9 yrs
- Mix B effect on 8/9 yrs, but not 3 yrs
- Effect only in ”responders” (linked to allergy?)
- Difficult to interpret

Sweeteners and other additives

Sweeteners

- Aspartame
- Neotame
- Steviol glycosides (stevioside, stevia)
- All the ”old ones” (saccharin, cyclamate, acesulfame K,..)

Others

- Preservatives
  - Benzoic acid and benzoates (Southampton study), Nisin, natamycin, Parabens
- Antioxidants (BHA and BHT need a brush up)
- Aluminium compounds (new JECFA PTWI)

AFC nutrient sources 1

NOT nutritional value, but safety and bioavailability of source

- **F**oods for **S**pecial **M**edical **P**urposes (**FSMPs**)
  - N-Acetyl-L-methionine, tocopherylPEGsuccinate (vit E)
- Foods for **PAR**ticular **NUT**ritional Purposes (**PARNUT**s)
  - L-Carnitine-L-tartrate, tocopheryl succinate (vit E)

nutrient sources 2

- Food supplements
  - 500 substances (~300 ”one page dossiers” ~85 withdrawn)
  - Vitamins in various forms
  - Minerals in new compounds (orotates, pidulates, …
  - Others (”vitamin” U, boron, vadium, silicium, tin, nickel, + lithium and strontium compounds)
- Food in general (fortification)
- Some issues complicated because of unclarity between Novel Food Regulation and legislation on nutritional substances (e.g. lutein, lycopene, vitamin K2

AFC food contact materials (FCM)

- Monomers and additives in plastics
  - **Catch up from closing of positive list (~75 substances**
  - **New submissions**
- Recycling
- Active and intelligent packaging
- ? Coatings, printing inks, paper and board, ….

FCM special issues

- Semicarbazide
- Phthalates
- BADGE and NOGE
- ESBO in baby food
- ITX isopropylthioxanthone
- Bisphenol A

AFC flavourings

Flavouring substances

- Not yet regulated but intention is to create a positive list by end 2008
- Based on the Register of flavouring substances (~2800 substances)
- Some evaluated by Council of Europe, JECFA (before 2000) and SCF.
- Rest (to be) evaluated by EFSA (AFC) including JECFA evaluations from 2000 to 2006
- Substances not in the Register considered as ”newly notified substances”

Flavouring substances 2

- Evaluation differs from other regulated substances and considered in groups (FGE)
- Several already evaluated and some withdrawn from Register others need further scrutiny
- Process delayed because of deviations from procedure applied by SCF and JECFA (e.g. in exposure estimates (MSDI and m-TAMDI))
- Basic evaluation expected by spring 2008 allowing to initiate the positive list.
- Rest will follow during 2008 to allow for all presently considered substances to be included when positive list comes into force.

Flavouring substances

- New regulation will necessitate new guidelines for submission of data.
- It is foreseen that around 25 new substances will be notified per year (9 months deadline)
- Likely that tendency will go more towards individual evaluation rather than group evaluation.

Flavourings ”active principles”

- Undesirable substances occurring naturally in spices and other foods. Not allowed to use as such, but accepted up to certain levels when coming from food ingredients.
- Examples are coumarin, pulegone, thujone, estragole, hydrocyanic acid. Listed in annex II
- Discussion in Council whether limits needed for coumarin or whether there is at all a need for a such annex.
- AFC clearly stated that (un-reviewed) results from one substance (estragole) cannot automatically be extrapolated to cover other substances (as e.g. coumarin, hydrocyanic acid) with totally different toxicological profile and in different matrices.

AFC smoke flavourings

- Not regulated before
- Complex mixtures not fully defined.
- 16 dossiers received initially
- 3 rejected because of invalid dossiers
- 1 negative review, product withdrawn
- 12 remaining waiting for reception and evaluation of requested further data

AFC Enzymes

- Until now only those enzymes considered food additives have been regulated. All considered processing aids not regulated except for France, Denmark and partly UK (voluntary system)
- So far only one enzyme evaluated by AFC (as food additive) (Thrombin/fibrinogen complex (”glue” meat pieces together) (not yet authorised).
- Working on guidelines. Draft expected to be sent to public consultation end this year.
- When new Regulation adopted ~200 initial applications expected. Consider ”fast track” for enzymes already approved according to procedures similar to SCF guidelines (DK,F, UK)

AFC Processing aids

Definition controversial and currently again being discussed in connection with new Regulation

- Extraction solvents (regulated) (dimethyl ether)
- Filtering aids (PVPP)
- Most food enzymes (to change)
- Disinfection of food (additive?) and food ingredients (semicarbazide after hypochlorite treatment of carrageenan and egg powder)
  - **Decontamination of carcasses**

AFC processes

- Irradiation (one request received from COM)
- New processes
  - **Treatment with ”cold” and ”cleaned” smoke**
- NOT cooking (acrylamide, furan, IQ, ..= CONTAM Panel)
- Smoking? (PAH in food = CONTAM Panel)

AFC: any other added substanses

- **Functional substances** (not regulated p.t.)
- Taurine, glucurono-gamma-lactone, caffeine, in ”energy drinks”
- Resveratrol (”French paradox”) substance
- Glucosamine
- Many others used in some Member States

New challenges

Nanoparticles

- Advanced in nutrient sources
- First dossier received for FCM
- Could also be relevant for food additives, flavourings, processes (?), …
- Novel food?

Creation of 2 new Panels

- Management board decided on 11 September 2007 to create two new Panels to replace AFC

- Panel 1: Food additives and nutrient sources added to food and food supplements (as well as all other substances added deliberately to food (except those covered by Panel 2))
- Panel 2: Food contact materials, flavourings and enzymes (as well as processing aids and processes)

Timetable for split of AFC Panel

- Commission to propose change of founding Regulation
- Standing Committee for the food chain and animal health to adopt change
- Launch call for expression of interest of membership of the new Panels
- Selection of suitable candidates in shortlist
- Nomination of members by Management Board


Thank you for your attention