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INDUSTRY PERSPECTIVES:

Proposal for a Regulation of the European Parliament and of the Council on Novel Foods and Amending Regulation (EC) 1331/2008 [common procedure]

EFSA's 13th Scientific Colloquium:
'What's new on Novel Foods'
19-20 November 2009

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Discussion Points

- **Scope of the Regulation**
- **Definitions**
- **Procedure for Determination of Novel Food Status**
- **Application Procedures and Technical Guidance**
  - Novel foods
  - Traditional foods from a third country
  - Special obligations on the food business operator
  - Data protection
- **Transition Measures**
- **Conclusions**
- **Specific Comments for Discussion Groups**

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Scope of the Regulation

- **Now clearer**
- **Supplements *vs.* food**
- **GMOs out of scope**
- **New forms vitamins and minerals out of scope**
- **But existing forms from new sources and new process techniques in scope**
  - Difficult to define and enforce in many cases

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Definitions

- **“Novel food" means food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, including:**
  - Novel food groups completely replaced (*i.e.* not exhaustive?)
    - Animal – non traditional breeding technique before 15 May 1997 (was Dolly the Sheep before this date?)
    - Plant origin- non-traditional breeding technique before May 1997 (not GMO)
    - Engineered nanomaterials
  - Traditional food from a third country
    - “primary production” – not extracts?
    - “customary diet” (difficult to define?, who says?)
    - “large part of population” (what does “large” mean?)
    - “25 years” – different to Traditional Herbal Medicines
- **What about microorganisms and fermentation products? (assume they are in scope)**
- **What about plant extracts? (assume they are in scope)**

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Definitions

- **Classification of SCF – Problems arise…adapt GM categories?, what about fermentation products?**

SCF Classification		Animal Non-traditional	Plant Non-traditional	Nanomaterial
Class 1	Pure chemicals or simple mixtures from non-GM sources			X
Class 2	Complex NF from non-GM sources (extracts)	X	X	
Class 3	Non- traditional breeding techniques plants and their products		X	
Class 4	Non-traditional breeding techniques animals and their products	X		
Class 5	Microorganisms and their products			
Class 6	Foods produced using a novel process	?	?	X

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Procedure for Determination of Novel Food Status

- **Check with Competent Authority**
  - No real change, so still scope for confusion
  - It can take a very long time
  - Many applications are because no one can confirm either way
  - Consultation procedure between Member States to be formalised to avoid current catalogue issues - the sooner the better
- **Standing Committee still an option**
- **Commission still gets out of day to day decisions on whether something is novel so does not solve one of the main problems of the existing procedure (*i.e.* a simple central decision on whether something is "novel")**

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Application Procedures and Technical Guidance

- **Follows Common Authorisation Procedure (1331/2008)**
- **Centralised so up to 100 less scientists review the dossier**
- **Stop clocks allowed so time to approval can still take as long as it does now**
- **The actual dossier requirements compared to additives, enzymes and flavourings are very similar so could we have a "Common Scientific Guidance Document" to cover all?**
- **Why not also include vitamins and minerals, since some are in scope and some out of scope**
- **The approach could be modular to allow EFSA to be more efficient such as having:**
  - Working Group on Technical aspects of dossiers (specification, processing etc)
  - Working Group on Exposure/intakes
  - Working Group on Nutrition
  - Working Group on Toxicology

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Application Procedures and Technical Guidance

- **Traditional foods from third countries**
  - Theoretically quicker procedures
  - Practically the documented data demonstrating the safe history of use will be hard to nail down scientifically
    - Expert opinion (like Traditional Herbal Medicines)
    - Testimony from Third country Competent Authorities?
  - More of a risk management procedure asking EFSA to largely conduct?
  - Expectations are high but it remains to be seen if such a procedure will be quicker
  - For whole foods it should be more straight-forward
  - Anything else will have problems

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Application Procedures and Technical Guidance

- **Special obligations on the food business operator**
  - Post-market surveillance still a possibility
  - Obligation to inform of any new scientific or technical data becomes available that might affect the safety – difficult to define and enforce

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Application Procedures and Technical Guidance

- **Data Protection**
  - Worded the same as for Health Claims (1924/2006)
  - Will have the same problems of interpretation
  - When will the decision be taken if it applies?
    - Before EFSA would be best to check for whether cited data meets legal definition laid down in Article 12 (whether or not it is later decided by EFSA to be pivotal)
  - If and when it is working it will be welcomed by industry

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Transition measures

- 24 month implementation period
- Still in 90 day period at this time then transferred to new procedure
- What if you have proprietary data now and are stuck beyond the 90 day stage?
- Do you re-submit under new procedure?
- At any time the application can be withdrawn for Traditional Foods [Art 8 (6)]
- Is this possible for novel foods???

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Overall Conclusions

- Anything must be better than the old regulation
- Centralisation of risk assessment makes common sense
- But the most important step as to whether something is “novel” is not centralised
- Traditional Foods assessment is largely risk management (taking things on trust) and so EFSA will have difficulties
- Process will be simpler but not necessarily take less time
- Overall should be more science based and less biased towards particular Member States which tend to handle most dossiers

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Specific Comments for Discussion Group 1 – History of Safe Use

- Big question is who verifies “safe”
- There are a lot of “experts” about but some are more expert than others
- Registration/certification requirements?
- Should third country competent authorities confirm?

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Specific Comments for Discussion Group 2 - Intakes

- **Same food surveys as for food additives**
- **There is a need for an up to date and representative food consumption database or some simply models to validate e.g. the UK NDNS**
- **Intakes estimations are not the same as for additives**
- **Novel Food ingredients have targeted foods in many cases for specific nutritional purposes**
  - E.g. adding DHA to a yoghurt “shot” means you assess the intake of yoghurts directly consumed not all foods that may contain yoghurt such as a curry sauce etc.
  - Additives intakes would model for every direct and indirect use

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Specific Comments for Discussion Group 3 - Toxicology

- Current toxicological requirements seem fair
- Traditional use is difficult to define scientifically especially for extracts, but can model in the EFSA botanicals guidance into revised dossier requirements
- Allergenicity requirements (proving a negative) need more clear guidance from EFSA because they have killed a number of applications in the past
- Central guidance document for all new food ingredients, additives, vitamins and minerals, enzymes etc., would be a good idea to sit with the Common Authorisation Procedure

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Specific Comments for Discussion Group 4 - Nanotechnology

- Definition is key
- And when nano-particles were orginally present. If always then no issue
- Thereafter initial focus should be on pharmacokinetics (i.e. first basic consideration for all new materials)
- Then normal toxicology guidance/decision trees should apply – we do not need to reinvent the wheel
- Operator and environmental toxicity (inhalation) may be much more important