European Legislation on Novel Foods
Current State of Play

EFSA Conference on Novel Foods

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The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission.

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Revision of Novel Food Legislation

- Commission proposal January 2008
- Adoption according to co-decision procedure
- Parliament first reading vote March 2009
- Council political agreement June 2009

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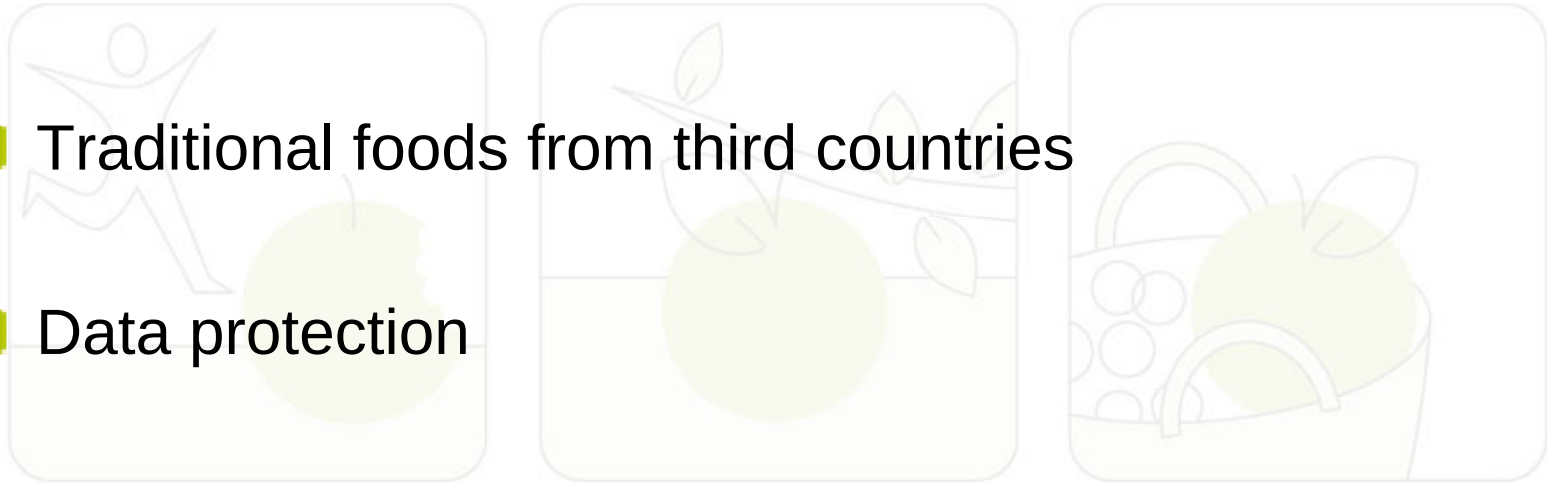
Main issues of Novel Foods Revision

- Centralization of the authorisation procedure
- Traditional foods from third countries
- Data protection
- Cloning and nanotechnologies



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Update of Novel Food Definition

- Keeps the reference date of May 97
- Repeals the N.F. categories
- Definition based on food definition of General Food Law and specific cases (cloning, new production processes, nanomaterials, traditional foods from third countries)

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Common Authorisation Procedure

- COM to make prior administrative check of validity of applications
- EFSA opinion within 9 months
- COM authorisation decision within 9 months based on comitology with scrutiny
- Adoption of E.C. implementing rules before date of entry into application

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Traditional Foods from Third Countries

- To find a shorter and more proportionate procedure to avoid unnecessary trade barriers
- Notification procedure to the Commission and possible objections from M.S. and EFSA
- Not agreed by M.S. and replaced by procedure similar to C.A.P. with shorter deadlines (9 months in total)
- EC list of traditional foods from third countries
- Adoption of E.C. implementation rules

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EFSA Risk Assessment

- EFSA opinion within 9 months
- Food safety assessment and where applicable animal health and welfare aspects
- Adapted risk assessment for traditional foods from third countries based on history of safe food use

Transitional measures

- Any application submitted to a M.S. before date of entry into application to be examined under new regime
- Except if national assessment report forwarded to Commission

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COM Risk Management

- If EFSA issues a favourable opinion, COM drafts a regulation updating the E.C. list within max 9 months
- Adoption of COM regulation according to comitology procedure with scrutiny except when data protection
- COM regulation taking into account EFSA opinion, EECG, M.S. views, EC law and where applicable other legitimate factors

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E.C. List

- Community list of authorised N.F.
- Generic authorisations except where data protection
- Updates made by COM and published in OJEU
- Inclusion of current authorisations into EC list
- EC authorisations may include specifications, conditions of use and labelling requirements

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Data Protection

- To stimulate innovation from food industry
- On request by applicants
- Granted for a 5 year period followed by a generic authorisation decision
- Individual decision concerning a single applicant
- Other applicants need their own scientific data or an agreement with first applicant for their use
- Commission decision based on EFSA specific assessment

Criteria for granting data protection

- 3 criteria for granting data protection
  - New scientific evidence and /or proprietary data
  - Exclusive right of reference to proprietary data
  - Could not have been authorised without submission of these data

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Nanotechnologies

- Category (f) **(Regulation EC 258/97)**

« foods and food ingredients to which has been applied a production process not currently (May 1997) used, where that production process gives rise to **significant changes in the composition or structure of the foods of food ingredients** which affect their nutritional value, metabolism or level of undesirable substances ».

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Nanotechnologies

- Draft definition of « engineered nanomaterials »
- Explicit reference to nanomaterials in the definition of novel foods
- Labelling of nanomaterials on a case by case basis

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Draft Definition of Engineered Nanomaterials

- Any intentionally produced material
- One or more dimensions of the order of 100 nm or less that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less
- Including structures, agglomerates or aggregates which may have a size above the order of 100 nm but retains properties that are characteristic of the nanoscale

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Conclusions

- Major changes compared to current system
- Remaining issues on cloning and nanotechnologies
- Implementing rules and guidelines