



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 26 October 2010**

**7512/10  
ADD 1**

**PV/CONS    15  
ENV 169**

**ADDENDUM to DRAFT MINUTES**

---

Subject:            **3002nd** meeting of the Council of the European Union (**ENVIRONMENT**), held  
in Brussels on 15 March 2010

---

**ITEMS OF THE AGENDA CONCERNING**  
**PUBLIC DELIBERATIONS**<sup>1</sup>

**Page**

**"A" ITEMS (doc. 7265/10 PTS A 24)**

Item 1.	Proposal for a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 .....	3
---------	---	---

◦

◦      ◦

---

<sup>1</sup> Deliberations on Union legislative acts (Article 16(8) of the Treaty on European Union), and other deliberations open to the public and public debates (Article 8 of the Council's Rules of Procedure).

**1. Proposal for a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001**

- Adoption of
    - (a) the Council's position  
11261/2/09 DENLEG 51 CODEC 893 REV 2
      - + REV 2 COR 1 (fi)
      - + REV 2 COR 2 (de)
      - + REV 2 COR 3
    - (b) the statement of the Council reasons  
11261/09 DENLEG 51 CODEC 893 ADD 1
      - + ADD 1 REV 1
      - + ADD 1 REV 1 COR 1
      - + ADD 1 REV 1 COR 2 (de)
- 6163/10 CODEC 90 DENLEG 18
  - + ADD 1
  - + ADD 2

The Council approved its position at first reading, in accordance with Article 294(5) of the Treaty on the Functioning of the European Union, with the Greek and the United Kingdom delegations abstaining (Legal basis: Article 114 of the TFEU).

**Statements by the 24 Member States\***

**Concerning all aspects of cloning techniques of animals**

"We note the Council agreement on the fact that cloning techniques of animals, such as the somatic nuclear cell transfer technique, have specific characteristics that imply that the Novel Food Regulation cannot manage all the issues of cloning.

We also note that the majority of Member States are of the view that food produced from animals obtained by using a cloning technique and from their offspring should be regulated by specific legislation. Consequently, such foods should be excluded from the scope of the Novel Food Regulation as soon as specific legislation has become applicable. In the meantime, and in order to avoid any legislative gaps, those foods should be covered by the scope of the Novel Food Regulation.

---

\* Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

In this context all relevant aspects of the cloning technique, in particular animal health, animal welfare, ethical questions, food safety and trade related aspects should be carefully assessed.

In view of the result of this assessment, we note the agreement of the majority of the Member States to request the Commission to submit to the Council and to the European Parliament a proposal for specific legislation concerning all aspects of cloning techniques."

#### **Statement by the United Kingdom and the Netherlands**

"The Netherlands and the United Kingdom wish to put on record why we could not add our support to the statement tabled by the 24 Member States and in particular wish to emphasise the importance of adhering to the principle that legislation should be evidence-based and that legislative solutions should not be decided before completing detailed assessments.

In their statement, the Member States request the Commission to submit to the Council and to the European Parliament a proposal for specific legislation concerning all aspects of cloning techniques. The Netherlands and the UK recognise that specific legislation might be needed governing food produced from animals using a cloning technique and from their offspring. However, until such time as the Commission has undertaken an assessment of the need for such legislation and submitted a report to the Council and EP as foreseen in Article 24(2) of the text at first reading, we believe it is premature to call for wide ranging legislation until the outcome of the Commission report is known and, if necessary, a detailed impact assessment has been produced."

#### **Statement by Greece**

"Greece abstains from the vote on the Council position at first reading on a proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

Greece considers that food produced from animals bred using cloning techniques and from their offspring should not be included in the scope of the above proposal. We believe that in order to protect human health, the health and well-being of animals and the sustainability of the environment, the placing of such foods on the internal market should be prohibited.

This position is dictated by, among others, the need to apply the precautionary principle since, based on scientific evidence to date, potential future dangers arising from the application of animal cloning techniques to food production cannot be ruled out. We would further emphasise that our position reflects the great sensitivity and negative attitude of Greek public opinion as a whole with regard to the issue of food from cloned animals."

### **Statement by Germany**

"During the discussions on adapting the proposal for a Regulation of the European Parliament and of the Council on novel foods to the Treaty on the Functioning of the European Union (TFEU), Germany expressed major reservations on the envisaged approach i.e. inclusion, on the one hand, of novel foods within the scope of Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings but provision, on the other, of another authorisation procedure for the substances already falling under the Regulation. Germany still has those reservations.

Nevertheless, in order not to stand in the way of a compromise solution or the adoption of a common position, withdrawing its reservations, Germany supports the approach proposed for adapting the Regulation to the TFEU.

However, Germany continues to take the view that there is no justification for adapting specific points of Regulation (EC) No 1331/2008 by means of a special regulation on novel foods. A key aim of the review of Regulation (EC) No 258/97 is to extend the scope of Regulation (EC) No 1331/2008 on novel foods, thus applying the authorisation procedure under Regulation (EC) No 1331/2008 to novel foods. The approach currently proposed will not achieve the intended aim of harmonising the authorisation procedure in the food sector.

Moreover, clarification is still required on a number of horizontal questions which could also be of vital importance to the current legislative proposals."

### **Statement by the Commission**

"The Council's political agreement of June 2009 considered that the adaptation of the definition of engineered nanomaterials to the scientific and technical progress and to the definitions subsequently agreed at international level should be made in accordance to the regulatory procedure with scrutiny. In the current Council's position at first reading the adaptation of this definition is limited to the adoption of further criteria to clarify it.

First, this modification implies that any adaptation of the definition itself would only be possible through the ordinary legislative procedure. The Commission opposes to this limitation as it would prevent this definition to reflect the best state of science and would have negative consequences for the innovation in the food industry.

In addition, the Commission opposes the adoption of further criteria to clarify definitions through implementing acts pursuant to Article 291 TFEU. The Commission considers that the adoption of these criteria implies supplementing non essential elements of the Regulation and thus they should be adopted through delegated acts pursuant to Article 290 TFEU. This applies to definitions laid down in Article 3(2)(a)(i) to (iv) on sub-categories of novel foods, to Article 3(2)(c) on engineered nanomaterials, and to Article 3(2)(d) and (e) related to traditional foods from third countries."

---