

Submission to The Food Standards Agency on the “Proposed regulations of the European Parliament and of the Council on novel foods intended to replace and repeal the current Novel Food regulation (EC) No. 258/97”

RSPCA, June 17th 2008

The RSPCA has three concerns with regard to the proposed Novel Food Regulation. These relate to:

- (i) the scope of the legislation and the definition of a novel food within this, and whether the definition includes cloned animals and their offspring;
- (ii) the labelling of novel foods; and
- (iii) methods of safety assessment for novel foods and the need to limit any use of living animals in scientific procedures as part of such assessments.

The RSPCA’s particular concerns relate to the creation and subsequent breeding of cloned animals and how the legislation applies to this. There are serious ethical and animal welfare issues associated with these processes and the RSPCA believes they should not be applied to agricultural (livestock/food) animals (see attached submission to EFSA).

Should such concerns be ignored, and cloned animals or their offspring enter the food chain, then the Society believes food products derived from such animals should be subject to a strictly applied authorisation process. This should consider the ethical and animal welfare issues, and impose an obligation for appropriate labelling.

(i-a) Definition of a novel food and scope of the legislation – Cloning:

It is not clear what sort of ‘non-traditional breeding technologies’ would be covered by this legislation (see text below).

Recital 6 of the ‘*Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No. XXX/XXXX*’, states that:

*“It should also be clarified that a food should be considered as novel **when to it is applied a production technology which was not previously used**. In particular, **emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation**. Novel food should therefore include foods derived from plants and animals, **produced by non-traditional breeding techniques**, and foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.”*

Article 3.2.a-ii states that:

*“Novel Food’ means ... food of plant or animal origin when to the plant and animal is **applied a non-traditional breeding technique not used before 15 May 1997**”.*

Non-traditional breeding techniques need to be defined. To avoid confusion the regulations should include definitions of non-traditional breeding techniques, those techniques not considered to be non-traditional, and non-traditional techniques which are excluded from the regulation.

The Food standards Agency (FSA) and UK Government state that cloned animals fall under the current EC Novel Foods regulation. However their inclusion within the proposed regulations needs legal clarification. If cloning technologies are to be allowed then this should be explicitly stated as a non-traditional breeding technique within Article 3.2 (above).

(i-b) Definition of a novel food and scope of the legislation – Offspring of clones:

It is unclear as to whether the proposed regulation would cover food products from the offspring of cloned animals. Under the current proposals (Article 3.2.a-ii), it appears that a non-traditional breeding technique, i.e. cloning, has to be 'applied' to the animal from which the food product originates for the food product to be deemed novel and thus covered by the proposed regulation. Offspring of cloned animals are likely to be produced through traditional breeding techniques and therefore fall outside the scope of the proposed regulation. The RSPCA feels it is necessary that products from the offspring of cloned animals be included within this regulation. This is paramount given the concerns that have been raised regarding the health and welfare of the offspring of clones (see attached submission to EFSA), and the substantial public concern surrounding the issue of cloning and its implications for the food chain^{1,2}. The definition of a novel food should therefore be expanded to include those animals that are 'derived' from an animal to which a non-traditional breeding technique has been applied.

As stated in the European Commission's Evaluation Report³ the stage at which there would be a generation deemed not 'novel' and thus not covered by this regulation, would also need to be determined. This would have to be agreed upon through informed scientific opinion.

(ii) Labelling:

Labelling requirements should enable full tracability of products from clones and their offspring throughout the food chain and enable 'final users' to make an informed choice through providing accurate information on the source, composition and properties of the novel food. The provision in the draft regulation for the labelling of novel foods is not adequately covered, highlighting only that labelling should not 'mislead' the consumer and failing to impose that labelling should enable the consumer to make an informed choice (see text below).

Recital 21 of the 'Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No. XXX/XXXX', states that:

"Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC ... (see below) ... of the European Parliament and of the council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of food stuffs. In certain cases it might be necessary to

¹ FSA (2008). Cloned animals research report published. <http://www.food.gov.uk/news/newsarchive/2008/jun/clone>

² FSA (2008). Animal Cloning and Implications for the Food Chain: Findings of research Among the General Public. 14th May 2008 Job No.558/ Version 3.

³ http://ec.europa.eu/food/food/biotechnology/novelfood/evaluation_report_en.pdf (p5)

provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations”.

Article 7.2. states that:

*“The entry of a novel food in the Community list shall include a specification of the food, and, **where appropriate**, specifically the conditions of use, additional specific labelling requirements to inform the final consumer and/or a post-market monitoring requirement”.*

Article 7.2.a-i of the ‘*Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of food stuffs*’, states that:

*“The labelling and methods used must not ... be such as could **mislead** the purchaser to a material degree, particularly as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production”.*

Labelling requirements are covered effectively in Recitals 20, 21, and 22; and Articles 12, 13 and 14 of the *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed*. Labelling of ‘novel foods’ could be covered by inserting a specific labelling section into the draft regulation, with statements to the effect of:

“Novel foods are subjected to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of food stuffs. Thus labelling must not mislead the purchaser as to the nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production, of novel foods.”⁴

“Harmonised labelling requirements should be laid down for all novel foods to provide final users with accurate information on the source, composition and properties of the novel food, thereby enabling the user to make an informed choice.”⁵

“In addition, the labelling should give information about any characteristic or property which renders a novel food different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the novel food and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.”⁶

Food products derived from animals which have been produced using non-traditional breeding technologies, as well as the offspring of such animals, should be clearly labelled with the origin so that consumers can identify the product. In particular, the Commission should impose specific labelling requirements for products from cloned animals and their offspring. Given the animal welfare

⁴ Adapted from Recital 21 of the *Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No. XXX/XXXX*.

⁵ Adapted from Recital 20 of the *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed*.

⁶ Adapted from Recital 22 of the *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed*.

issues and the concern the general public has with regards to both food safety and animal health and welfare, the omission of such information would inhibit the 'final user' from making an 'informed choice'. Thus a further statement to this effect should be added to the draft regulation:

"Labelling of food products derived from cloned animals, or their offspring, and food containing such products should include objective information so as to identify such products. Clear labelling, irrespective of the detectability of any difference between such a product and one from a non-cloned individual facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production."⁷

(iii) Safety assessment:

The use of animals in scientific procedures designed to assess food safety is not explicitly required by the legislation. However, it is possible that animal studies (e.g. 90 day feeding studies in rats⁸) will be part of some safety assessment requirements. Given the commitment of the UK Government and EU Commission to replacing animal studies with humane alternatives, it is important to cross-reference this novel food legislation with Directive 86/609, which, in Article 7.2, requires alternatives to living animals to be used if these are available.

This submission was prepared by Kerry Westwood BSc PhD, Nikki Osborne BSc PhD, and Amanda Gibbs LLB MBA (Legal Practice), on behalf of the Royal Society for the Prevention of Cruelty to Animals.

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⁷ Adapted from Recital 21 of the *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed*.

⁸ Food Standards Agency, 23 April 2008, Consultation: Impact Assessment of EU Proposal for a regulation on novel foods. Pp5.