

CLONED ANIMALS

1. The Board will recall that there have been a number of articles in the press in the course of this week regarding cloned animals, and specifically reporting that embryos derived from cloned cattle have been imported into the EU leading to the birth of at least one calf on a farm in the UK. This note provides an update to the Board following its discussions at the Board meeting on 11 January.
2. The media articles follow the publication by the US Food and Drug Administration of its risk assessment of cloned animals on 28 December. The FDA has a voluntary agreement with the US industry that cloned animals should not be used for food production, and FDA's press release indicates that this arrangement should remain in place.
3. In the EU, food from cloned animals falls under the EC Novel Foods Regulation and would require a pre-market safety assessment, including an evaluation of the need for such foods to be specially labelled. To date no such application has been received or carried out in the EU. When the FSA became aware of the story regarding the birth of the calf, the position regarding the offspring of cloned animals was not clear and the FSA asked for this to be clarified by the Commission at an EC Novel Foods Working Group which was due to take place on 12 January.
4. In advance of the meeting the Commission informed the FSA that its position was that cloning animals for their meat or milk constitutes a new production method which needs to be assessed for its food safety implications under the EC Novel Food Regulation. In the absence of an EU assessment under the Novel Food Regulation, the Commission recognised that it was not yet possible to evaluate the possible food safety implications of meat and milk from the offspring of cloned animals. It considered that before products from cloned animals or their offspring can be allowed to enter the food chain in the EU, their safety should be assessed under the Novel Food Regulation. The Commission explained that it would discuss the matter shortly with Member State experts (at the 12 January working group) with a view to formally requesting a scientific opinion from the European Food Safety Authority. This scientific opinion should be delivered on the basis of a set of data to be compiled according to EFSA requirements.
5. At the meeting on 12 January, Member States agreed that products from cloned animals and their offspring fall under the scope of the EC Novel Foods Regulation, and that there should be a discussion at an EC Standing Committee on which sections of the Novel Foods Regulation apply to products from cloned animals and their offspring. A number of Member States also agreed that the European Food

Safety Authority should be consulted on the safety of products from cloned animals and their offspring.

6. The next stage is that the Commission will produce a paper on the above points for discussion at a future Standing Committee meeting. We do not have a date for this yet.

Contact

Novel Foods, Additives and Supplements Division

Clair Baynton (Tel 020 7276 8566)

Sandy Lawrie (Tel 020 7276 8565)