

13 January 2011

To: Interested Parties

FOOD FROM DESCENDANTS OF CLONED ANIMALS

I am writing to seek your views on a potential change to the Agency's advice on the interpretation of the novel foods regulation (Regulation (EC) 258/97) in respect of food from the descendants of cloned cattle and pigs.

The novel foods regulation applies to any food or food ingredient that was not consumed to a significant degree within the European Union before May 1997, but the scope of the regulation excludes "foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use".

The Food Standards Agency is the competent authority for novel foods in the UK. The Agency's advice until now has been that food from descendants of cloned animals, as well as from clones themselves, falls within the scope of the regulation and is not covered by the exception mentioned above. This is based on the reasoning that any descendant of a cloned animal would not exist without the original non-traditional breeding practice (cloning) and descendants should therefore not be regarded as "obtained by traditional breeding practices".

However, the legislation can also be interpreted to apply only to food from cloned animals themselves. This position is based on the reasoning that "obtained by traditional breeding" should logically apply only to the animal that is the source of the food. One argument in favour of this interpretation is that it is impossible to determine, by examination or testing, which breeding practices were used to obtain an animal's ancestors, and there are no systems for the identification and traceability of farm animals that are produced by different breeding practices. This makes it very difficult to enforce the regulation in relation to descendants of non-traditionally bred animals, and this was presumably not the intention of the legislation.

Ultimately it is a matter for the Courts to decide on the interpretation of legislation and regulatory bodies such as the FSA can only offer advice. In the case of the novel foods regulation, an EU regulatory committee – the Standing Committee on the Food Chain and Animal Health – is able to decide whether a particular type of food falls within the definition of "novel food". This Committee is chaired by the European

Commission who have not placed this issue on the agenda, despite our requests for them to do so.

The issue of animal cloning (for food production) was discussed by the Agency's Board at its open meeting on 7 December 2010. The Board agreed that the marketing of products obtained from cloned animals should be subject to authorisation as novel foods but, based on the current evidence, there are no food safety grounds for regulating foods from the descendants of cloned cattle and pigs. This conclusion was reached after reviewing the latest advice from the European Food Safety Authority and from the Advisory Committee on Novel Foods and Processes.

In view of the Board's discussion, the Agency is minded to adopt the position that foods obtained from the descendants of clones of cattle and pigs do not require authorisation under the novel foods regulation. This would be in line with the current view of the European Commission and others. However, before making such a change we are seeking views of interested parties, by means of this letter.

The Agency would expect that, if this revised interpretation of the novel foods regulation is adopted, there will be a positive economic impact on any business looking to place on the market food such as meat and milk from the conventionally-bred immediate offspring of cloned animals or from subsequent generations of such offspring. Whilst such foods would of course have to comply with all other aspects of food law, there would not, according to this revised interpretation, be a requirement for such foods to be authorised as novel foods before they could legally be placed on the market.

However, the Agency is not currently in a position to assess the scale of this potential impact, or any other aspect of the impact of the position the Agency is minded to adopt. Therefore, as well as views on the wider aspects of the Agency's proposed change in its advice, we will welcome comments specifically on the potential economic impact of that change.

If you have any comments that you would like us to consider before making this proposed change in our advice, please provide them in writing no later than **10 February 2011**, to:

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We intend to collate and publish the responses that we receive. Please make clear in your response if any or all of your comments should not be made public.

Please feel free to pass on this letter to any others with an interest who do not appear on the attached copy list.

Yours sincerely

Dr Sandy Lawrie
Head of Novel Foods Unit

Agricultural Industries Confederation
Agriculture and Horticulture Development Board
Association of Independent Meat Suppliers
Assured Food Standards
BPEX
British Hospitality Association
British Meat Processors Association
British Pig Association
British Retail Consortium
Compassion in World Farming
Consumer Focus
Country Land and Business Association
Dairy Council
Dairy UK Ltd
Dairy UK Northern Ireland
DairyCo
EBLEX
Food and Drink Federation
Food Ethics Council
Friends of the Earth
GM Freeze Campaign
Greater London Forum for Older People
International Meat Traders Association
Local Government Regulation
Local Government Regulation
National Beef Association
National Consumer Federation
National Council of Women of Great Britain
National Farmers' Retail and Markets Association
National Farmers' Union
National Federation of Meat and Food Traders
National Federation of Women's Institutes
National Office of Animal Health Ltd
National Pig Association
National Sheep Association
Netmums
Northern Ireland Meat Exporters' Association
Provision Trade Federation
Royal Agricultural Society of England
Royal Association of British Dairy Farmers
Royal Society for the Prevention of Cruelty to Animals
Soil Association
Sustain: the alliance for better food and farming
Ulster Farmers' Union
Which?
WWF UK