

**FOOD FROM DESCENDANTS OF CLONED ANIMALS
CONSULTATION RESPONSES (Jan-Feb 2011)**

| No | Respondent | Comments |
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| 1 | Derrick Hargreaves | <p>whilst I do not have sufficient knowledge of the issues to make a valuable comment regarding the safety of food or of products from cloned animals, I do have a concern that when a particularly profitable animal is raised and then cloned it will lead to a form of "in-breeding".</p> <p>I believe that this would, in time, cause a weakening of the national herds' health.</p> <p>I also have concerns, which are probably regarded as paranoid, re issues being found in the long term future causing a situation similar to the BSE crisis and the resultant deaths from NvCJD.</p> |
| 2 | Judy Steele | <p>I do not think that it is wise to include meat and milk from the offspring of cloned animals in the food chain without first conducting extensive work based on the precautionary principal before marketing it.</p> <p>I believe that the public has the right to know if the food they are eating is produced by cloned animals or their offspring.</p> |
| 3 | Stuart Brough | <p>I inspect food businesses, factories, farms and consumer groups and there is a great deal of concern over the recent stories of cloned milk etc potentially entering the food chain. Many people view cloning on a par with GM crops, however there are additional concerns over animal health and welfare.</p> <p>Personally I do not know if there has been enough research and enough generations of cloned animals and their offspring to correctly address issues such as welfare, increased susceptibility to disease or similar issues. I would hope that as part of their considerations both you and the EFSA and EC would examine and comment on these issues to address public concern.</p> <p>The related issue I would hope you consider is that of labelling and how consumers, and enforcement bodies, will be able to identify products from cloned animals or their offspring. Again the GM example would be one I would refer to where mandatory labelling of contains or may contain is required. Without this I feel many consumers would lose already shaken confidence in the food chain and may even feel pressured or bullied by big industry and what many believe is a faceless EU or similar imposing rules on them with which they do not agree. I feel the UK has a reputation for requiring clear labelling and whilst some regulations and Court rulings have eroded this new regulations and products should always aim for clear, honest and informative labelling.</p> |
| 4 | John Barker | <p>I would like to compare this subject to a GM tree. If a pest resistant apple tree was developed, and the reason it was resistant was that it produced large amounts of cyanide in apples thereby making them inedible to, in this example, the pest of humans, any tree grown from a seed from one of the apples, producing apples with the same properties (i.e. containing cyanide) would not provide an acceptable product for consumers.</p> <p>In terms of an opinion regarding whether or not food from descendants of cloned animals should be considered as acceptable, I would propose that the question should be is food from cloned animals acceptable or not. If not, food from their descendants is not acceptable. If yes, then, irrespective of whether or not the animal is a clone or the offspring of a clone, food from the animal is acceptable.</p> <p>Most likely there would be no issue regarding human health, however consumer perception is not likely to accept this, and any product sold as "from descendants of cloned animals" would undoubtedly demonstrate this.</p> <p>Given the choice, I would not purchase food from descendants of cloned animals unless it</p> |

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| | | <p>was considerably cheaper than the competition. Consumers have the right to decide.</p> <p>Difficulties in differentiating products from descendants of cloned animals, from non-descendants of cloned animals, should warrant severe penalties to any company found selling the foods fraudulently.</p> <p>(P.S. if you choose to publish my comments, I would appreciate it if you could let me know where)</p> |
| 5 | Food Solutions Ltd | <p>We notice that EFSA has indicated that there are no food hazards encountered by the consumption of meat from either cloned animals or their offspring.</p> <p>However we are advised that cloned animals themselves may not be suitable for human consumption due to their premature aging.</p> <p>We would therefore submit that we see no reason that the offspring of cloned animals should be subject to the novel foods regulations.</p> <p>Those regulations were introduced to prevent novel ingredients coming on to the market before they had been properly assessed for safety. We strongly support this concept. It is logical and wise. Clone offspring have been bred normally and could not be said to be significantly different from the progeny of cross-breeds.</p> |
| 6 | Ann Upton | <p>I understand from the Farmer's Guardian, you are seeking views on above. I would then like to put forward my very strong views about this matter. It is a subject that has been highlighted in a magazine which I have read recently and I have done some research on this.</p> <p>Cloning is widely recognised as causing appalling suffering to farm animals. The majority of cloned embryos die during pregnancy. Of those that survive, a significant proportion die shortly after birth or during the following weeks from cardiovascular failure, respiratory problems, liver or kidney failure, immuno-deficiencies or musculoskeletal abnormalities. In a 2008 report, the European Group on Ethics concluded that "considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified." It added it "does not see convincing arguments to justify the production of food from clones and their offspring"</p> <p>Please could you pass on my disappointment to Rt Hon Caroline Spelman, Secretary of State, DEFRA, that the Coalition Government is not opposing the sale of meat and milk from cloned animals and their offspring.</p> <p>I urge you all to rethink this position and take the lead in pressing the EU partners to ban all aspects of cloning animals for food.</p> |
| 7 | Carol Oliver | <p>I am writing to express my horror that cloned farm animals may soon be permitted to enter the human food chain in the UK.</p> <p>Whether there are any safety issues or not, only time can tell - it's far too soon to say! But apart from potential safety issues, animal cloning is immoral. If it wasn't an immoral practice, it would have been extended to humans.</p> <p>In any case, cloned animals are known to suffer far higher incidences of organ failure and other problems such as compromised immune systems. Cloning is a very unethical practice which should end.</p> <p>I certainly won't ever knowingly buy food products related to cloning.</p> |
| 8 | WWF-UK | WWF-UK will not be responding as this is not a key area of expertise or work focus for us. |
| 9 | Ian Crute, Agriculture and | See Annex 1 |

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| | Horticulture Development Board | |
| 10 | Greater London Forum for Older People | <p>following discussion with our groups I would like to make the following comments</p> <ul style="list-style-type: none"> • People are not happy with the decision • There should be some form of labeling on products so that people have a choice in the food they eat • Some side effects take many years to incubate therefore there must be some form of monitoring for any unexpected side effects in the future. |
| 11 | NFU | See annex 2 |
| 12 | Zoe Cawston (Milk and beef producer) | <p>I would liked to register my complete disapproval of meat and milk from the descendants of cloned cattle and pigs entering the food chain.</p> <p>I understand that this proposed relaxation of the rules to allow the sale of such products into the food chain would be in line with the rest of Europe. We in Great Britain have some of the most rigorous standards of food production in the whole of Europe, if not the world, and I feel that this step would be lowering our standards to that of the rest of Europe.</p> <p>The cloning of animals is a relatively new phenomenon and it will take many years before any risks to humans will become known.</p> <p>I do hope that this decision will not be passed through without taking into consideration the views of the general public and producers.</p> |
| 13 | Sue Batchelor | See Annex 3 |
| 14 | Robert Boyd | please ensure that an evaluation of the exploitation of meat from cloned animals in food retail and manufacturing is carried out without delay and before any further instance of cloned meat in the food supply occurs. |
| 15 | Sue Paskins | <p>I find the use of cloned animals, and the health etc problems they suffer more than I want, or need, to be associated with.</p> <p>I believe very strongly that any cloned meat or diary produce should be clearly marked as such, that gives me choice. If the producers are so sure that this is not a problem then they would not objet to marking their produce as "from cloned animals"</p> |
| 16 | Muriel Alleaume | <p>I am appalled by the European countries' weakness to resist this horror from the state when we know that this practice is harmful and at the very best, has not been subject to any long term effect on our health and our environment.</p> <p>There is NO place for cloning in the UK or EU, and there are very good reasons to ban the practice of cloning, as well as imports of clones, cloned embryos and semen and their food products across the whole of the EU.</p> <p>I hope that moral and values will supersede this insanity that is currently taking place</p> |
| 17 | Joyce Szameitat (Germany) | <p>I have been informed that the FSA is conducting a consultation on food from clones and their offspring.</p> <p>I want a ban, but if this fails I would like to point out that I want all products from clones and their offspring to go through a full food safety assessment under the Novel Food Regulations.</p> |
| 18 | Brian and Janet Edwards | <p>We are writing to express our total opposition to the proposal to allow the meat and milk from the offspring of clones to enter the food chain.</p> <p>This proposal should be shelved until there is absolute proof of no long term detriment to human health and that the issue of animal suffering is resolved.</p> |

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| | | If these issues are finally resolved, consumer choice must be upheld by clear labelling. |
| 19 | Provision Trade Federation | <p>PTF's members are companies of all sizes involved in supplying bacon and ham; dairy products of all kinds, including milk powders, cheese, butter, yogurt and other dairy desserts; and canned foods. Our members include importers and exporters of these products, as well as UK processors.</p> <p>We support the FSA's planned revised interpretation of the Novel Foods Regulation with respect to food from the descendants of cloned cattle and pigs, that these foods are not novel foods and do not require novel foods authorisation.</p> |
| 20 | Soil Association | See Annex 4 |
| 21 | Cherry Lavell | <p>I am very concerned that food from the offspring of cloned animals is already entering the food chain, when there has been only very limited safety testing of such products.</p> <p>EU regulations do not allow regulation of these products, so there is no check on the safety of the food, no check on animal welfare (about which there are justifiable concerns anyway), and no environmental checks.</p> <p>FSA recently changed its position on the clones question after advice from ACNFP said they believed there were no grounds to regulate on the basis of food safety. But there has been so little testing done and so few data are available that it is hard to see how ACNFP could come to such a conclusion, still less that FSA needs to accept it. Cloning does cause genetic disruption and this could result in un-looked for changes in milk or meat -- and it cannot be categorically stated that no danger would result, even in subsequent generations of the cloned animals.</p> <p>The history of the last couple of centuries is littered with appalling mistakes -- when an exciting new development was allowed to forge ahead without proper evaluation of the risks. I'll just mention asbestos, radium, thalidomide, DDT to refresh memories. Don't let's have another one now ranging free!!</p> <p>The European Parliament voted seven or eight months ago for a moratorium on cloning and imports until a legislative framework could be agreed. That is a sensible adoption of the precautionary principle.</p> <p>I find it very worrying that FSA is now abandoning the precautionary principle and letting the products of cloned animals out into the market place. We simply do not know enough and I think this is a highly irresponsible act.</p> <p>What I wish to see is a total ban on food from clones and their offspring. If this is not done, then I would want a <i>full food safety assessment</i> to be made under the Novel Food Regulations.</p> |
| 22 | Bronwen Roberts | As someone who is very concerned about the whole issue of cloning of animals both from the invasive and cruel techniques used on the surrogate mothers used to produce clones and the fact that there have been no sufficient long term studies into the impact of cloned foodstuffs on human health I would like to endorse the letter written to the Food Standards Agency addressed to yourself by the Soil Association in response to the request for views on the potential change in the FSA's interpretation of the Novel Foods Regulation. |
| 23 | Dr Anne Taylor, North Tillydaff Farm | See Annex 5 |
| 24 | Xuela Edwards | <p>Setting aside my views on the ethics of using cloning, I would like to call for a precautionary approach.</p> <p>As a consumer, I would prefer that products derived from cloned animals, and their offspring, are labelled as such. I appreciate that this requires separate monitoring in the food</p> |

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| | | <p>chain and therefore places a burden on the industry but food is already, quite rightly, a heavily regulated business.</p> <p>I don't know what the standard period of time is for monitoring health and diet issues but I would suggest that products need to be monitored for at least two decades. At this stage, those in favour of using products from the offspring of cloned animals will be able to draw on sound, long-term evidence to support claims of food safety.</p> <p>During this test period, people who choose not to support the practice of cloning for commercial gain, have the opportunity to exercise their consumer rights by not purchasing these products. I think this is fair.</p> |
| 25 | Mr Carter | <p>If a Cloned creature isn't a 'novel food' I really wonder about your definition of 'novel'.</p> <p>We don't want this in the food chain, and we DEMAND that it be labelled as being of cloned descent if you are going to ignore the public concerns.</p> <p>Who is benefitting from this unnecessary abomination?</p> |
| 26 | Pete Riley, GM Freeze | See Annex 6 |
| 27 | Compassion in World Farming | See Annex 7 |
| 28 | Animal Concern Advice Line | <p>I would like to make a belated and brief comment on proposals to treat food products obtained from the descendants of cloned animals as non-novel foods and allow them to enter the human food chain with no special labelling or identification.</p> <p>I have been involved in the issue of animal cloning since the early 1980's and have debated with several researchers who pioneered cloning, including members of the Edinburgh team who produced Dolly the sheep. I must stress that I have been more involved in areas concerning cloning of genetically modified animals for use in production of medications and organs for xenotransplantation than in cloning of animals in the food industry. However the actual cloning procedures and side-effects caused are the same no matter the purpose for which an animal is cloned.</p> <p>I am of the opinion that it is unlikely that products obtained from cloned animals will differ (apart from a more uniform quality) from those obtained from animals bred by less intrusive scientific means. However there have been major animal welfare problems caused by cloning. A high percentage of cloned animals die at birth or are born malformed and die or have to be destroyed soon after. It has also been shown that those animals which appear to be normal at birth can become ill later in life and can suffer prematurely from debilitating conditions such as arthritis. I believe Dolly the sheep was euthanized due to such complications and I understand some of the team who worked on that project have spoken out about the welfare drawbacks of cloning animals.</p> <p>If products from cloned animals and their descendants are to be sold in the UK I would request that they are clearly labelled as such. This would mean incorporating a phrase such as; "Part or all of this product came from a cloned animal or its descendants" in product labelling. With the traceability requirements of farmed animals it should not be difficult to identify such products. This labelling would allow consumers who wish to avoid purchasing such products on animal welfare grounds to make an informed decision just as they can when purchasing eggs.</p> |
| 29 | Annika Findlay | <p>I am deeply surprised to know that you are contemplating introducing food from cloned animals and their descendants into our food chain. Not only that, but I am horrified that you would recommend not labelling it as such, although I suspect that comes from the knowledge that no-one would buy it if they knew it was from cloned animals.</p> <p>I don't understand why it would even be contemplated. Why introduce animals that are known to have more health problems and abnormalities, and require more veterinary</p> |

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| | | <p>input? The consequences of eating products that are prone to abnormalities (not to mention the extra drugs that will have been injected into them) will only show themselves in the longer term.</p> <p>It is your responsibility to ensure the health of this country is not adversely affected.</p> <p>It is your responsibility not to sway to pressure from corporate interests trying to make alot of money on the backs of our health.</p> <p>It is your responsibilitiy to make sure that all food is correctly labeled - it is your responsibility to make sure we are not misled.</p> |
| 30 | BMPA | <p>The BMPA believes that decisions made on food safety should be based on the latest scientific evidence. While there was logic in the FSA's original interpretation that all foods produced from pigs and cattle descended from a clone were covered by the requirements of the novel foods regulation, scientific evidence indicates that there is no difference in food safety concerns between these foods and foods derived from conventionally bred cattle and pigs.</p> <p>We, therefore, support the FSA's proposal that foods obtained from the descendants of clones of pigs or cattle do not require authorisation under the novel foods regulation.</p> <p>The economic impact of this change of policy is hard to assess due to the current reluctance of retailers to sell these foods.</p> |
| 31 | Which? | See Annex 8 |
| 32 | RSPCA | See Annex 9 |
| 33 | National Standing Committee on Farm Animal Genetic Resources | <p>The Committee would like to respond to your consultation launched on 14 January 2011.</p> <p>The Committee's views on cloning are set out in its statement of 13 September 2010 (copy attached).</p> <p>The Committee believes that UK and EU policy should be based on evidence, should take account of benefits as well as risks, and should be proportionate to the risks. It should also be enforceable. In these respects, the Committee considers that cloning can offer benefits and that from a scientific viewpoint, restrictions on the immediate offspring or further descendants of clones, and products from these animals, would be disproportionate and currently unenforceable especially in relation to imported products.</p> <p>The Committee therefore strongly supports the proposed change to the Agency's advice on its interpretation of the novel foods regulation.</p> |
| 34 | Nutrition Society | <p>The Nutrition Society welcomes the opportunity to comment on the proposed change to the Agency's position with regard to food products from descendants of cloned animals. The Society supports the proposal, but wishes to include the following comments.</p> <p>The Society concurs that there are no known safety issues relating to removing the novel food status of food products from descendants of cloned animals, as discussed by the Advisory Committee on Novel Foods and Processes (see discussion document ACNFP100/7, November 2010) and FSA board, on 7 December 2010. However, any emerging evidence should be monitored.</p> <p>With regard to any impact the proposal may have on the population's nutritional status, the limited data presented in the ACNFP document suggests there is no significant variation between the nutritional composition of meat and milk from cloned animals and that from conventional animals. Indeed, the biological nature of a clone means that this is to be expected. Data relating to the composition of food from the descendants of cloned animals are even more limited. The Society does not expect that there should be significant variation, however the data suggesting a change in fatty acid profile are noted, and therefore the Society advises that there should be some investment in monitoring</p> |

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| | | products for any potential health issues for consumers. |
| 35 | RSPCA | (duplicate of #32) |
| 36 | Dairy UK | <p>Dairy UK supports the proposal by the FSA 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.</p> <p>This is the logical position to take given that there are no food safety grounds for regulating foods from the descendants of cloned cattle and pigs and that no traceability system exists, or can be put in place, to monitor the descendants of clones. The change in policy will also bring the UK into line with the interpretation given to the regulation by the European Commission and other European nations.</p> <p>If, as a result of this consultation, the FSA does change its policy, then it is important that it robustly defends its position in public, and reassures consumers that there are no food safety implications involved and that separate labelling is not warranted.</p> |
| 37 | John Wilson | <p>I am writing in response to your request for comments from interested parties regarding the proposed changes 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.</p> <p>I disagree with the revised interpretation of the novel food regulation.</p> <p>I base my view, on the key elements of the right to health, freedom of choice, and genetic diversity.</p> <p>Here are a few points I would like to make.</p> <p>Regarding the above wording, I am extremely concerned that there seems to be a bias and limit in its concern towards economic considerations, instead of a comprehensive view of the wording to consider the fuller picture of the goal of human health in relation to agricultural products. From a human health point of view must heed what the scientists say. The EFSA Scientific community in its scientific opinion on cloning acknowledges that "Uncertainties in the risk assessment arise due to the limited number of studies available, the small sample sizes investigated and, in general, the absence of a uniform approach that would allow all the issues relevant to this opinion to be more satisfactorily addressed."</p> <p>The science is just not there, and it is reckless to proceed along this path, without further investigations.</p> <p>From a freedom of choice viewpoint I am concerned that this dilution in the definition of novel foods may mean that there will be some kind of mis-representation on the labels that consumers scan prior to a food purchase. What exactly is the case here? Would food labels contain a note to indicate that we are purchasing cloned food? From a scientific point of view, it is just not clear as to the safety of this cloning process on human health, and for many people they would take a great deal more convincing. Many would opt not to consume cloned food, and need clarity at the purchase stage.</p> <p>Finally, one of the principles built in to the fabric of nature, is genetic diversity. This cloning process goes against that principle. Life survives by generating many different forms to ensure the continuation of life. To attempt to reverse the principle, seems like trying to swim upstream. Why do it? Just because we can.</p> <p>Cloning has to be kept under very tight control, in every sector of concern, including definitions of novel etc. until this process and its risk are better understood.</p> |
| 38 | FDF | As you know, we have been following debates on the issue of cloning in the context of the ongoing review of the novel foods legislation, and indeed as a result of the incident in August 2010 when it appeared that products of cattle descended from clones had been placed on the market in the UK and elsewhere in Europe. We commented at that time that, |

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| | | <p>whilst the UK food and drink manufacturing industry has no current interest in marketing products from cloned animals or their offspring, there were no apparent food safety issues relating to such products and we had reservations about the ability to trace products beyond the clone itself. Consequently we support the position outlined in paragraph 4 of your letter and the FSA Board's recommendations made at the 7 December 2010 meeting, thus the proposal 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.</p> <p>We regret that we have no specific information to help inform FSA's economic impact assessment, but it is reasonable to assume that, if the decision were to be taken to include offspring and descendants of clones within the scope of the novel foods Regulation, a significant economic burden could be placed on food and drink manufacturers to ensure that their animal-derived products <i>did not</i> come from the offspring or descendants of clones.</p> |
| 39 | World Society for the Protection of Animals (UK) | See Annex 10 |
| 40 | Alan Yates | As an enforcement officer who has had experience in considering the application of the novel food regulations to the issue of cloned animals I would agree with the FSA Board's proposals to move to a position of not applying the Novel Foods requirements to foods from the descendants of cloned cattle and pigs. This would bring the FSA into line with the views of the European Commission and the European Food Safety Agency. |
| 41 | Consumer Focus Scotland | <p>Consumer Focus Scotland would like to thank you for sending us the above consultation document and for giving us the opportunity to comment. I am writing to advise you that on this occasion, we will not be submitting a response. This is not because we do not think this is an important issue; rather we must make decisions as to which consultation papers we respond to on the basis of our available resources, and our current work programme which does not include the issues contained in your consultation document.</p> <p>Consumer Focus Scotland is the independent consumer champion for Scotland. We aim to influence change and shape policy to reflect the needs of consumers. We do this in an informed way, based on the evidence we gather through research and our unique knowledge of consumer issues. As a result, is frequently requested to put forward comments on consultation papers on a wide variety of issues by many different agencies. Unfortunately, we are unable to respond to all of these, for the reasons outlined above.</p> <p>For the avoidance of doubt, please do not treat this letter as a substantive response to the consultation document.</p> |
| 42 | John Sleith | <p>It is my view that Food from the Descendants of Cloned animals should be treated as novel foods and subject to authorisation in terms of the regulations. While such foods may represent no health risk to the consumer, this authorisation process would necessitate a rigorous examination of the issues concerned and ultimately be of reassurance to the public that the food they are consuming is safe.</p> <p>At the very least, there should be a requirement that such foods are clearly labelled in order that purchasers can make an informed choice when buying food.</p> |
| 43 | NFU Scotland | See Annex 11 |
| 44 | | (Confidential) |
| 45 | Scottish Government (Health Protection Team) | From a health perspective we are content with what is being proposed. There should be no issue about the meat from cloned animals in terms of human consumption. The products are broken down and digested as protein in the gut and as such the genetic structure is irrelevant to the health of human consumers. |

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| | | There will be a broader issue about the ecological impact of cloning of animals which goes well beyond this from a policy perspective, but I would imagine that that is something for Ministers to consider in light of advice from advisory committees/expert groups. |
| 46 | Mr B Baker | As a farmer it looks like a common sense interpretation of the facts and we fully support its adoption. |
| 47 | Mrs M Mreuger | I am not in agreement with sales of milk and meat from descendants of cloned animals. our farmers need to be encouraged in producing meat and milk without resorting to this repulsive method. |

Ian Crute (Agriculture and Horticulture Development Board)

The Agriculture and Horticulture Development Board (AHDB) is an independent levy board whose role is to improve industry efficiency and competitiveness. Within AHDB there are three Sectors with responsibility to the livestock industries in Great Britain: DairyCo (GB Dairy), EBLEX (Beef and Sheep in England) and BPEX (Pigs in England). The AHDB strategy for improving efficiency is to increase production with reduced use of resources; referred to as “sustainable intensification”. AHDB considers worthy of consideration any progressive scientific techniques which contribute to sustainable intensification provided they are safe for consumers and do not compromise the welfare or health of production animals. On this basis, we consider the use of cloned animals in genetic improvement of livestock to be potentially advantageous.

The research evidence available to date indicates that the food products from the descendants of cloned animals (meat and milk) shows no substantial difference to conventionally produced meat and milk, and therefore is unlikely to present a food safety risk. The US Food and Drug Administration (FDA), interpret the data to mean that there is no risk to public health from the dairy foods made with the milk of cloned animals and their progeny.

There is evidence that cloning techniques can lead to a higher frequency of offspring mortality during pregnancy and birth compared with normal pregnancy, and can result in a larger than average progeny at birth (Large Offspring Syndrome). This has also been noted following embryo production with *in vitro* fertilisation and hence may be a factor associated with embryo culture rather than cloning *per se*. There is no evidence to indicate the Large Offspring Syndrome carries through to the progeny of clones.

Cloning techniques are useful for accelerating the benefits that can be derived from genetically superior animals carrying combinations of important traits such as disease resistance or feed conversion efficiency. Increasing access to such elite animals for breeding has the potential to contribute significantly to production efficiency and sustainability. At present, cloned animals are still largely being used in an experimental context but they could in future become used routinely in mainstream animal breeding. The predictions about the desired attributes of progeny derived by conventional breeding techniques inevitably carry a high level of uncertainty because of the genetic recombination which occurs during the formation of sperm and eggs. The higher level of probability of producing genetically superior progeny from elite parental animals whose worth has been clearly demonstrated represents a potentially important innovation. Cloning extends the availability and access to the very best breeding animals once they have been identified.

The relative number of cloned animals compared to those produced by conventional reproduction is always likely to be small and the value of such animals means that they are highly unlikely to be slaughtered from meat. Consequently, the concern of the consumer relates exclusively to progeny derived from elite cloned breeding females and/or semen from elite cloned males. Such progeny are essentially produced by conventional breeding methods.

For the reasons outlined above, and on the basis of current evidence, AHDB would support the FSA position of clarifying the interpretation of the novel food regulations along the lines indicated in your letter of 13 January. We are firmly of the view that food products (meat or milk) derived from the progeny of cloned animals (and any subsequent progeny) should not be considered to be novel foods.

NFU (Helen Ferrier)

The NFU represents more than 55,000 commercial farmer and grower members in England and Wales. In addition we have 41,000 countryside members with an interest in farming and the countryside.

The NFU was encouraged by the FSA Board conclusions at its meeting on 7 December 2010 that it would not be appropriate to require authorisation of food products from the descendants of cloned livestock under the EU Novel Foods Regulation. The UK government should certainly base its policy on the evidence in relation to the difference between animals with and without clones in their heritage. The offspring are indeed “obtained by traditional breeding”.

As stated by the ACNFP, the resulting meat and milk are substantially equivalent to any other products, and any compositional differences are within the normal range. Given this, and the trade in semen and the bulking that happens in the food supply chain, it would be neither appropriate nor practical nor possible to identify every animal with cloned ancestors, or their products, separately from animal identification and food traceability systems. The food and farming businesses involved could not be expected to give guarantees to regulators or their customers that no progenitors were clones.

We described our views on this issue in letters from our President Peter Kendall to Tim Smith and Lord Rooker ahead of the two recent Board meetings at which cloning was discussed (dated 26 Nov and 13 Sept).

It is very difficult for us to estimate how many cattle in the UK may have clone progenitors or how much meat and milk this would translate to at retail level. There is certainly trade in livestock genetic material between the UK and countries where cloning is used commercially, most notably the US. While the technology is still new, very expensive and not yet widespread commercially, there is potential for one cloned elite bull to produce many 10s of 1000s of daughters who will themselves produce offspring and very many litres of milk, and sons that will in turn produce 10s of 1000s of calves etc., in many countries. The economic impact of each producer having to apply for novel foods authorisation is incalculable so attempting to assess the positive economic impact on farmers of the Agency’s proposed interpretation is problematic. Similarly, trade disputes and disruption that could arise from the UK taking a different position to the rest of Europe, or Europe differing from third countries, would have an economic impact but it would be very difficult to estimate. The burden on dairy farmers of having to give assurances to processors that there are no clones in the heritage of their animals may simply be signing a form. However, the liability they could be exposed to if this was somehow found not to be the case, despite having acted in good faith, would be damaging. For processors, manufacturers or retailers to give such assurances to customers would in turn be very misleading and impossible to verify, despite not being intended to deceive.

If you would like to discuss anything in our response, please contact Dr Helen Ferrier, Chief Science and Regulatory Affairs Adviser.

Sue Batchelor

Commercial cloning is growing in the US, mostly in high-performance dairy cattle and pigs. Already embryos produced from cloned dairy cattle have been imported in the UK and calves born as a result. Meat from at least one of these clone offspring was sold as food, and more could follow unless tighter controls are introduced to ban cloning and the import of cloned animals, embryos and semen and their products. A number of dairy calves were born from the same cloned breeding stock that could produce milk for the food chain in the immediate future.

I gather that in recent months the Food Standards Agency (FSA) has changed its position on whether food from clone offspring requires approval under the Novel Foods Regulations and that they now consider that no such approval is required on food safety grounds, despite **considerable scientific uncertainty and lack of data**. They accept that products from the cloned animals themselves would require approval because they are not the product of “traditional breeding” (although this is unlikely to happen because of their high value).

The change is that they feel the offspring of clones are produced by the normal method of reproduction – fertilising an egg with sperm – although mainly using artificial insemination. They are wrong. Cloned offspring are **not** the production of “traditional breeding” as the FSA claims: at least one of their parents was **not** bred by natural fertilisation. The FSA feels that **such foodstuffs resulting from this second generation won't be required to obtain novel food approval before they can be sold**. This is very worrying. **We need labelling so we can make the choice**.

Cloning has a very poor success rate, many embryos and young animals die as a result of genetic changes occurring during the procedure, and this causes **severe suffering and health problems for surrogate mothers** (eg, large calves mean Caesarian sections are common) **and the cloned calves**. I gather both the FSA and European Food Safety Agency (EFSA) argue that the genetic changes are corrected in the next generation and there is no evidence that there would be a risk to health to people consuming products from these animals. **This is too early to say**. How long-term are the checks they have made?

However the EFSA has admitted that the food safety assessment of cloned offspring is based on **a small set of data**, and there is **limited evidence** to show if the genetic disruption caused by cloning cannot result in unexpected change in milk or meat which could be harmful. **Adverse effects on human health arising from cloning cannot yet be ruled out because data on products from clones and their offspring is too limited**.

Furthermore, cloning is a continuation of selective breeding programmes that themselves have resulted in serious health and welfare problems in livestock and poultry breeds used in intensive systems.

I feel strongly that the UK Government is wrong in being supportive of cloning to the point at they do not even want the food products from the offspring of cloned animals to be labelled. The public which is largely ignorant of this cannot **make an informed choice**. We are usually so ready to follow the dictats of the EU, yet in this case we ignore the fact that politicians in the EU are more sceptical, and the European Parliament voted in July 2010 for a moratorium on cloning and imports while the legislative framework for a ban is agreed. How come we can go against the EU in this case?

I suspect that the genie is already out of the bottle and food producers (I can't call them farmers) no longer know themselves which animals are which, so it is a case of closing the stable door after the horse has bolted. However, I still think that if a ban is now impossible, an attempt should be made to label foodstuffs in case new evidence comes to light in the future to connect problems with the eating of cloned food. (CJD comes to mind)

Soil Association

We write in response to your letter (13th January 2011) regarding the potential change of the FSA'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 Soil Association is extremely concerned that the FSA is considering changing its advice to the position that "there are no food safety grounds for regulating foods from the descendants of cloned cattle and pigs." The Soil Association believes that the impact of foodstuffs from cloned animals on human health can not at this point be adequately assessed on the basis of existing scientific data. In particular there have been no long-term studies into possible impacts. Indeed, the EFSA Scientific Committee in its scientific opinion on cloning¹ acknowledges that:

"Uncertainties in the risk assessment arise due to the limited number of studies available, the small sample sizes investigated and, in general, the absence of a uniform approach that would allow all the issues relevant to this opinion to be more satisfactorily addressed."

A detailed reading of their advice shows that it is littered with issues where the scientific research on human health impacts is considered inadequate or limited: With regard to the compositional comparison of meat and milk derived from clones and progeny of clones, the EFSA clearly states that *"it should be acknowledged that the data base is limited."* The inadequacy of the research in relation to the toxicity and allergenicity testing of meat and milk products from cloned animals is particularly worrying. The Scientific Committee warns that

"Conventional toxicity tests are designed for individual chemicals and have major limitations for the testing of whole food. Foodstuffs are bulky, lead to satiation and can only be included in laboratory animal diets at lower multiples of expected human intakes. In addition, a key factor to consider in conducting animal studies on whole foods is the nutritional value and balance of the diets used, to avoid the induction of adverse effects, that are not related directly to the material itself (ACNFP, 1998). The testing of large amounts of milk and meat may be a particular problem in laboratory rodents with respect to departure from their normal diet, which is primarily plant-based."

Thus, it concludes that in relation to toxicity and allergenic testing *"These results are only indicative as the rat and mouse models are not specific for human allergenicity predictive testing."*

The Committee warns of other potential problems with clones With regard to veterinary drug residue levels it states: *"As animal clones generally need more intensive care... the use of veterinary medicinal products for treatment may be greater than that in their natural comparators."*

¹ European Food Safety Authority (2008) *Scientific Opinion of the Scientific Committee Food Safety, Animal Health and Welfare and Environmental Impact of Animals¹ derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals.* (<http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf>).

With regard to public health risks it concludes “...as information is limited on the immunological competence of clones, it is unclear, in cases where the pathogen is zoonotic in nature, whether or not the prevalence of such infection or infestation (and related public health risk) is the same as that of the conventionally produced animal.”

In its letter the FSA requests views on the wider impacts of the Agency’s change in its advice. A very significant impact concerns animal welfare. The Soil Association is opposed to the cloning process because it is damaging to animal welfare at all stages of the cloning process. Cloned animals and their surrogate mothers suffer a variety of health problems and abnormalities. These are noted by the EFSA Scientific Committee in addition to their clear acknowledgement of the inadequate state of the scientific research in this area:

“A significant proportion of clones, mainly within the juvenile period for bovines and perinatal period for pigs, has been found to be adversely affected, often severely and with fatal outcome.”

“... clones and their progeny have not yet been studied throughout the whole of their natural life span.”

“The current welfare assessment is extrapolated from mainly animal health data. The welfare of both the surrogate dam and a significant proportion of clones has been found to be affected by the adverse health outcomes observed.”

The FSA also invites comments on the potential economic impact of the change. The uncertainties surrounding many of the impacts of cloning are potential economic risks to the agricultural sector. As previously mentioned there are risks over animal disease. The reduction of genetic diversity could also have an impact in this regard; as the EFSA states “An increased homogeneity of a genotype within a population may increase the susceptibility of an animal population to infection and other risk factors.”

The presence of unlabelled cloned meat and milk in the food chain could have a negative impact on consumer trust in the food chain. The unlabelled use of cloned farm animals fundamentally undermines the freedom of choice of farmers and consumers to avoid these animals and products, because of a lack of transparency in their regulation and traceability.

The FSA state that this ruling “...would be in line with the current view of the European Commission and others.” However, the FSA fails to acknowledge that in July 2010 the European Parliament voted for a moratorium on cloning and imports while the legislative framework for a ban is agreed.

At a time when Government is expressing a desire to move towards ‘honest labeling’ of food, so consumers understand what they are purchasing and know its provenance, cloned animals should not be allowed to enter the food chain. Consumers have the right to know what they are buying and the production processes and values behind their food and drink. The FSA used to say it would defend this consumers right to know. This proposal suggests your priorities have changed.

Dr Anne Taylor, North Tillydaff Farm

I am writing in response to your request for comments from interested parties regarding the proposed changes 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.

I am against any relaxation in the standards. If these standards are reduced, it makes a mockery of the system, and a mockery of the level of bureaucracy that is now imposed on anyone involved in animal husbandry in this country. If the double tagging system does not allow the tracking of individual animals and their ancestry so that food quality can be maintained and controlled, then what on earth is the point of it?

The Food Standards Agency should have more input than concern over 'just' food safety. There are also ethics to consider. If the FSA does not consider ethics as part of their remit, then who is left to control ethics in our food supply? We know that the production of cloned animals involves much suffering, so allowing offspring of the animals to then enter the food chain without labelling or further tracking implies a lack of concern over the ethical misjudgements and suffering which was involved in the production of the 'parents' of those offspring.

Back to the issue of food safety, where are the long term safety tests to understand what happens to the physiology and biochemistry of the cloned animals and their progeny? What are the cloned traits which were deemed desirable in the progeny of those cloned animals? Cloning is obviously not a natural breeding method, and your consultation document seems to demonstrate that already the FSA has lost control over what is being done. That, surely, is no reason to just 'give up' and allow the products of cloned animals and their progeny to flood the market. Surely a better route would be to put a moratorium on the cloning of animals, and the importing of cloned animals into the UK food chain, and if there is no documentation to prove that the animal or produce is not from a cloned animal, then it isn't allowed into the country or into the food supply. Otherwise, the FSA may as well give up and disband, and leave the 'free market' to do whatever it wants.

As a consumer and a producer, I want to be able to choose food which I know has been ethically produced, know the source, and feel confident that only natural methods of breeding have been involved. There is already too much uncertainty and confusion in the way that food is labelled, or not labelled (eg the lack of labelling of products of animals which have been fed on GM foods is a travesty!). Consumers need confidence in the market. Without that confidence, the market will shrink, and people will shy away from anything they're unsure of, and rightly so. Please ensure that the FSA exists to support the consumer and the ethical producer, to support ethics as well as safety, and does not kow tow to those who seek to dilute the quality and traceability of the food we eat.

Pete Riley, GM Freeze

GM freeze is opposed to cloning because it is a new and unproven technology with a number of serious problems associated with it including:

- High failure rates of cloning procedures.
- High death rates in cloned embryos and young animals.
- High rates of caesarean sections for surrogate dames.
- Poor life expectancy for clones.

In addition, the possibility of health impacts from consuming products from clones and their descendents have not been ruled out because there are too few data and there is an acknowledged need to investigate the epigenetic impacts in more detail.

EFSA's latest opinion (i) acknowledged the uncertainties arising from limited data:

“Uncertainties in the risk assessment arise from the limited number of studies available, the small sample sizes investigated and the absence of a uniform approach to allow all the issues relevant to this opinion to be addressed.”

The ACNFP acknowledged the need to study possible epigenetic effects on meat and milk, saying, *“Further evidence is required on how the rearing of animals in different environments may affect the meat and milk.”* (ii)

GM Freeze therefore believes that the suggested change in policy on the application of the Novel Food Regulations only to clones themselves, and not their descendents, is premature and unjustified. Products from clones themselves are unlikely to enter the food chain (at least in the short term). Given that cloned offspring are already present in the UK, and their products could enter the market in the near future, the decision not to regulate the products of descendents under the Novel Foods Regulations would effectively give cloning the go ahead in the UK without a means to regulate it or label products (as consumers overwhelmingly demand).

GM Freeze does not accept the FSA's argument in support of their revised position that:

“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.”

There are already several quality assurance schemes operating in the UK that rely on audited paper trails to ensure traceability and quality for customers rather than verification by direct testing. For instance, The Red Tractor Scheme, Fairtrade and Organic labels all deal with broadly-based methods of production for which no analytical test procedures exist. They all work, so it is hard to understand why the FSA is so fixated upon being able to test for clones and their offspring.

A test is not, in any case required, to operate a labelling system for clones and their offspring. In our view, all records relating to the cattle breeding and imports should be legally required to have a section dealing with any cloned ancestors in the breeding line. In livestock, such as pigs, where there is currently a lack of transparency about breeding lines, there is nothing to prevent the government introducing similar paperwork and passports as are used for cattle and tagging of animals. An additional benefit of this would be from a biosecurity point of view, (given the role pigs and sheep had

in spreading the foot and mouth virus in the 2001 epidemic) because it would enable animals to be traced between farms and markets.

The FSA's proposals also ignore the fact that there is a very strong argument for banning cloning completely on animal welfare grounds (which we set out above). However, Novel Food Regulations do not cover animal welfare matters. The European Union is currently looking at the regulation of cloning, and we will be pressing to ensure that this covers all aspects including health, welfare and possible environmental impacts of cloning in addition to ethics. It is therefore premature even to debate labelling until an overall decision on whether to allow cloning and the sale of products from clones and descendents is finally decided at EU level.

We share the view of the European Group on Ethics (EGE) in Science and New Technologies to the European Commission (iii) that:

“Considering the current level of suffering and health problems of surrogate dams and animal clones, the Group has doubts as to whether cloning for food is justified...At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring.”

GM Freeze believes that the FSA's current recommendation that the products of descendents of clones should not be assessed under the Novel Food Regulations evades the issue of how cloning should be regulated. We have no doubt that it should be until the EU decides whether or not there should be permanent ban.

The introduction of interim legislation to control the prevailing situation across the UK and ban products from clones and their offspring entering the market would make sound sense given that there:

- Are at least 96 offspring of clones already existing in the UK.
- Is deep public concerns about the practice of cloning.
- Is clear recognition in the FSA's consultation letter that the products of cloned offspring cannot exist without cloning taking place.

This would bring the situation under control and allow a reasoned debate to take place about the future of cloning, free from the distraction of cloned products entering the market.

Notes

(i) European Food Safety Agency, 2008. Scientific Opinion of the Scientific Committee Food Safety, Animal Health and Welfare and Environmental Impact of Animals¹ derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals. (Question No EFSA-Q-2007-092) EFSA Journal 767 ;1-49.

(ii) Food Standards Agency 2010, Animal cloning for food production. Paper to Board 7 December 2010.

(iii) The European Group on Ethics in Science and New Technologies to the European Commission, 2008. Ethical aspects of animal cloning for food supply - Opinion No 23
http://ec.europa.eu/european_group_ethics/publications/docs/opinion23_en.pdf

Compassion in World Farming

Compassion in World Farming is very concerned that the FSA is minded to recommend that the Novel Foods Regulation excludes products obtained from the descendants of cloned cattle and pigs.

The FSA says: "This would be in line with the current view of the European Commission and others." However, the European Parliament is opposed to the sale of products from clones or their descendants, a position which Compassion supports.

The animal welfare impacts of the Agency's proposed change in its advice are outlined below. We also look briefly at consumer opinion, possible economic impacts and legal obligations.

The animal welfare impacts of cloning and the associated drive to produce the most high yielding animals

Cloning presents severe animal welfare challenges arising directly from its use and also through exacerbation of the problems caused by selective breeding.

The objective of commercial farm animal cloning is to maximize apparent profit by reproduction of the most high-yielding animals. Yet fast-growing and high-yielding animals already suffer health and welfare problems, such as painful lameness in cows and pigs, and mastitis in dairy cows. The natural lifespan of a cow can be 20 years, but high-yielding dairy cows are now routinely culled at around three lactations, often because of health problems such as lameness and infertility which are exacerbated by high productivity.

Scientific Opinions by the European Food Safety Authority (EFSA) show that cloning entails serious health and welfare problems for both cloned animals and their surrogate dams.

EFSA has concluded that "the health and welfare of a significant proportion of clones ... have been found to be adversely affected, often severely and with a fatal outcome". A significant proportion of clones die in the early stages of life from health problems such as cardiovascular failure, respiratory difficulties and immune system deficiencies (EFSA 2008).

EFSA also states that there is an increase in pregnancy failure in cattle and pigs that are carrying a clone and increased frequencies of abnormal or difficult births especially in cattle. This, together with the increased size of cloned offspring, makes Caesarean sections more frequent in cattle carrying a clone than with conventional pregnancies (EFSA 2008).

Clearly one cannot have descendants of clones without first producing clones and yet, equally clearly, the production of clones entails substantial suffering.

The cloning of the most fast growing and high yielding animals will lead to an even higher proportion of animals suffering from serious health and welfare problems.

EFSA has concluded that "genetic selection for high milk yield is the major factor causing poor welfare, in particular health problems, in dairy cows" (EFSA 2009) and that genetic selection of pigs for rapid growth has led to leg disorders and cardiovascular malfunction (EFSA 2007).

Therefore, to be meaningful the Novel Foods Regulation must extend to the descendants of clones. This has been recognised by the European Group on Ethics (EGE) which concluded that "considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified". The EGE added that it "does not see convincing arguments to justify the production of food from clones and their offspring" (EGE 2008).

Consumer interests

The FSA says its priority is protecting consumer interests in relation to food. The signs are that consumers do not want animal cloning. The FSA 2009 'Evidence Review of Public Attitudes to

Emerging Food Technologies' found that "the technologies which give rise to the most concerns are GM and animal cloning" (FSA 2009).

69% of respondents in the European Commission's 2008 Eurobarometer agreed that "using cloning for food production purposes would be unacceptable because it would mean that animals were treated as commodities rather than creatures with feelings" (European Commission 2008).

Potential economic impact

There is a growing global recognition that some of the ways in which we manipulate and rear farm animals for our food are unacceptable. For example, in many EU countries, including the UK, Germany and the Netherlands, consumers are increasingly showing their preference for eggs from free-range hens.

According to the 2008 Eurobarometer, 80% of Europeans responded that animal cloning is not needed to maintain competitiveness in the food industry (European Commission 2008).

Given the suffering of the animals used in cloning process, we believe consumers would not wish to support such an industry. By extension, consumers are unlikely to want products from descendants of cloned animals. A modern farming industry should reject any involvement in farm animal cloning and in breeding from cloned animals and a forward-looking government would ban cloning outright.

Legal obligations

The conciliation procedure between the Council and the European Parliament on the proposed Novel Foods Regulation is underway. It is the welfare implications of cloning that are the principal subject of this conciliation procedure.

According to EU Directive 98/58/EC: "Natural or artificial breeding or breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned must not be practised" and: "No animal shall be kept for farming purposes unless it can reasonably be expected, on the basis of its genotype or phenotype, that it can be kept without detrimental effect on its health or welfare."

Paragraph 28 of Schedule I to the Welfare of Farmed Animals (England) Regulations 2007 provides that: "Natural or artificial breeding or breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned, must not be practised."

Under the Treaty on the Functioning of the European Union Member States are obliged to "pay **full** regard to the welfare requirements of animals" when formulating and implementing the Union's policies on agriculture (emphasis added).

Conclusion

Cloning presents severe animal welfare impacts, and is commercially driven to reproduce the highest yielding animals, who are already prone to health and welfare problems due to breeding for high yield.

We urge the Food Standards Agency to strongly recommend to the UK government that the Novel Food Regulation must include products from the descendants of cloned animals.

Compassion believes that in any case there should be a ban on the sale of meat and dairy products from both clones and their offspring.

Which?

INTRODUCTION

Which? welcomes this opportunity to submit comments in response to the Food Standards Agency's (FSA's) request for views on a potential change to its advice on how to interpret the novel foods regulation (Regulation (EC) 258/97) in respect of food from the descendants of cloned cattle and pigs.

The Agency's proposal would change its advice that food from the descendants of cloned animals, as well as from clones themselves, fall within the scope of the Regulation.

We do not agree with this proposed change in interpretation for the reasons set out below and hope that the Agency can reconsider its position and also continue to support a requirement that the food from the descendants of cloned animals, including cloned cattle and pigs, as well as clones themselves, should be subject to approval under the revised novel foods regulation currently at the conciliation stage between the European Council and Parliament.

CONSUMER ISSUES

Consumer research conducted by Which? has shown that the issue of animal cloning for food production causes concern for many consumers. A Which? survey in February 2008 (1) found a high level of concern over the use of cloning. Just 13 per cent agreed that cloning should be used to produce animals for food production and 80 per cent said that they would prefer to buy foods that were not produced using cloned animals. Little distinction was made between the products of clones and their offspring with the same number (81 per cent) concerned about eating meat from clones and about eating meat from the offspring of clones. Eighty per cent were concerned about eating dairy or other products from these animals and 91 per cent thought that foods produced using cloned animals should be clearly labelled.

These views were reinforced by EU Eurobarometer surveys and research conducted by the FSA (2). The FSA deliberative workshops, for example, found that people saw few benefits and were worried about the animal welfare implications. They were also concerned that once cloning was used for food production, it could be used for humans. They therefore wanted regulation to address the entire process from animal breeding and welfare to food production and human health and stressed the importance of effective traceability and clear labelling of food derived from clones and their offspring.

FOOD SAFETY AND OTHER ISSUES

The justification given for the FSA's proposed change of advice is that the FSA Board agreed that *"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"*.

We are concerned about this view because it assumes that the only issue to be taken into account when looking at product authorisation is food safety when, although food safety is obviously crucial, the novel foods regulation is broader than this.

The proposed change to advice also fails to recognise the limitations of the European Food Safety Authority (EFSA) advice, which although suggesting that there is no indication of any new safety issues for products of the descendants of clones from the available evidence, explicitly states that information on clone offspring is limited (3). The EFSA Opinion highlights that: *“While cloning has been applied to several animal species, only in the case of cattle and pigs has there been sufficient data available to perform a risk assessment. Uncertainties in the risk assessment arise due to the limited number of studies available, the small sample sizes investigated and, in general, the absence of a uniform approach that would allow all the issues relevant to this opinion to be more satisfactorily addressed”* (4).

RISK ASSESSMENT AND RISK MANAGEMENT

We consider that in finalising its advice, the FSA should ensure that it takes into account the purpose of the risk assessment and the broader risk management decision about authorisation of a product. It should also take into account the need to apply the precautionary principle where there is scientific uncertainty.

The current novel foods regulation requires a risk assessment to be carried out by the relevant body within the Member State where the product is to be marketed, along with the following requirement in Article 6 which makes it clear that other considerations, in addition to food safety concerns, can be taken into account when deciding whether or not a product should be authorised, which are consistent with consumers' desire for informed choice, highlighted in the consumer research:

6(4): *“The Member State concerned shall without delay forward the report of the competent food assessment body to the Commission, which shall forward it to the other Member States. Within a period of 60 days from the date of circulation of the report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing of the food or food ingredient concerned. The comments or objections may also concern the presentation or labelling of the food or food ingredient”*.

The General Food Law Regulation (Regulation (EC) 178/2002 (5)) also makes it clear that *“It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.”* (Recital 19).

Article 6 of the Regulation expands on this, setting out how EU risk analysis should be conducted: *“risk management shall take into account the results of the risk assessment, and in particular, the opinions of the [European Food Safety] Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5”*.

This is consistent with Codex Alimentarius Commission guidance on risk analysis for member governments (6).

Article 7 sets out that “In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.”

CONCLUSION

In view of the limitations of EFSA's risk assessment and scientific uncertainties associated with the use of cloning in animal production for food as well as the broader issues that need to be addressed as part of novel food authorisation, we hope that the FSA can reconsider its approach and continue to support the need for approval of food from the descendants of cloned animals, as well as from clones themselves. This interpretation should be applied in the context of the current Regulation and possible revised Regulation.

Notes:

¹ 1968 members of the public representative of the general population of the UK were interviewed face to face in February 2008.

² Animal cloning and implications for the food chain, Findings of research among the general republic, Creative Research for the Food Standards Agency, 14th May 2008.

³ Update on the State of Play of Animal Cloning, European Food Safety Authority, EFSA Journal 2010:8(9):1784.

⁴ Food safety, animal health and welfare and environmental impact of animals derived from cloning by Somatic Cell Nucleus Transfer (SCNT) and their offspring and products obtained from those animals, Scientific Opinion of the Scientific Committee, The EFSA Journal, 15 July 2008

⁵ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

RSPCA

I am writing to inform you that the RSPCA remains opposed to the cloning of animals for food production purposes because of the animal welfare and ethical concerns inherent in the process. The health and welfare status of any animal used in food production is very relevant to the issue of food safety and so we support the Agency's original position that "*food from descendants of cloned animals, as well as from clones themselves, falls within the scope of the regulation (EC 258/97)*". We are therefore of the opinion that this advice should remain unchanged.

Our concerns regarding the cloning of animals are that the process: involves procedures that have great potential to cause animals pain, suffering or distress; is inefficient and requires a very large number of animals to produce a single clone; and could greatly reduce genetic diversity within livestock populations, increasing the chances of whole herds being negatively affected, or wiped out by disease(s) or other risk factors, to which they are equally susceptible. It also increases the perception of animals as commodities, or units of production, for human use or gain, rather than as sentient beings and, in our view, is being pursued without any documented need for this application of the technology, and in spite of public concerns relating to the use of biotechnology in food production.

We believe all these concerns remain highly pertinent since a descendant of a cloned animal would not exist without the original cloned animal having been created. To ignore the animal welfare and ethical concerns associated with the act of cloning would in itself be unethical, and no studies on the welfare of the descendants of cloned animals have been reported in livestock species (EFSA, 2008). All the literature on animal cloning is based upon work carried out in highly monitored populations and environments, and so it is not yet known whether cloned animals or their offspring will experience any adverse health, or welfare issues when introduced to 'everyday'/ commercial livestock production systems (EFSA, 2008). This is a very real concern given the problems that occurred when BST use in cattle moved from the laboratory to the farm.

The EFSA scientific committee opinion related to the early identification of emerging risks (2006) states that "*the Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission*", where an emerging risk is "*an issue that in the future may pose a risk to the health of the consumer, animals, or the environment*". We would therefore question whether the FSA is in a position to change its current advice on food products from the descendants of cloned animals given the information gaps we have highlighted above and that in your letter you state 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 from different breeding practices*".

Should the FSA change its opinion as is currently proposed, then the descendants of animals carrying a genetic modification, for example to confer disease resistance, would also be excluded from the scope of the Novel foods legislation on the grounds that they are 'traditionally bred', despite the fact that food products would contain 'foreign DNA' whose impact on food safety has not been assessed.

World Society for the Protection of Animals (UK)

Thank you for the opportunity to comment on the possibility that foods obtained from descendants of clones of cattle and pigs might no longer require authorisation under the novel foods regulation.

The World Society for the Protection of Animals (UK) urges rejection of that change. It would be severely damaging to animal welfare and objectionable to public opinion, with little benefit to society in terms of food availability or quality.

We note from the FSA letter of 13 January 2011 that the novel foods regulation excludes foods and food ingredients obtained by traditional propagating or breeding practices and that to date the FSA has reasoned that descendants of clones would not exist without the original cloning and should therefore continue to be covered.

Further, the letter points out that if food from descendants of clones is excluded from the regulation, “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.” So such a change would effectively give approval for continued and probably increased production of clones, by removing restrictions on sale of their offspring for food, despite the fact that production of those offspring would necessarily involve the routine, non-traditional practice of cloning.

The Farm Animal Welfare Council, in its submission to a consultation by the European Group on Ethics in Science and New Technologies in 2007, said the following:

Cloning has a low success rate, with most embryos dying at an early stage. Of those that survive throughout pregnancy, as many as one third die before birth or in the first few months of life, and many of those that live to maturity have abnormalities. In addition, the techniques needed to obtain eggs are invasive. Progeny of clones have fewer apparent welfare problems, but this does not make cloning for subsequent production of progeny acceptable ... Animal cloning for food is opposed by a large majority of the public in Europe ... It seems that most people regard the technique as unnecessary, and as an inappropriate treatment of the animals that are kept for our food. Were cloning for food to be permitted, the message would be given that what the public thinks is being ignored by EU law makers.

The World Society for the Protection of Animals (UK) strongly believes that foods obtained from descendants of clones of cattle and pigs should continue to require authorisation under the novel foods regulation, and indeed should be denied such authorisation.

NFU Scotland

Interpretation of the Novel Foods Regulation

1. NFUS believes it is essential to differentiate between clones and their progeny in any regulation that is applied to cloning. For food production, it could be considered reasonable for clones themselves to come under novel foods regulations as they are produced using novel techniques, despite the fact that food products from them do not differ from non-clones. However, the progeny of clones are produced through sexual reproduction and should not therefore be treated any differently in terms of food product legislation.
2. We believe that the Agency's current advice on the interpretation of the novel foods regulation is unworkable and unenforceable. We welcome the fact that the Agency is proposing to change its advice on the interpretation of the novel foods regulation after reviewing the latest advice from the European Food Safety Authority and from the Advisory Committee on Novel Foods and Processes. The proposed change will bring the UK in line with the advice given by the European Commission and others.
3. Current Agency advice requires producers to declare if cattle or pigs for sale have a clone anywhere in the animal's ancestry. The current requirements in the EU for tracing clones and their progeny means that there is no mechanism by which a producer can give such an assurance. Consequently the law as defined presently by the FSA cannot be policed.
4. The current UK FSA interpretation of the EU law makes it entirely impossible for not just any farmer but also any UK retailer to guarantee that products being sold have no clones in their ancestry. Imported meat or dairy products from anywhere in Europe, North America or South America may contain products produced from the direct or distant progeny of clones and there is no prospect now, or at any time in the future, of guaranteeing that this is not the case.
5. In view of the above NFUS is pleased to support the Agency's proposed position that foods obtained from the descendants of clones of cattle and pigs do not require authorisation under the novel foods regulation. We note that this would bring the UK in line with the view of the European Commission and others.