CRISPR cattle given regulatory clearance in the US

EU could be affected by imports

21 March 2022 / The US FDA (Food and Drug Administration) has decided in favour of allowing CRIPSR/Cas cattle with short, slick coats for agricultural purposes. The shorter hair is said to let the cattle more easily withstand hot weather, and thus gain weight faster. However, the supposed advantages of the gene scissors application are questionable – and the desired characteristics can also be achieved using conventional breeding.

The animals will be marketed by Recombinetics and its affiliated company Acceligen, which have also filed for patents on the cattle. The companies developed the cattle by using CRISPR/Cas to alter the genes of a receptor for the hormone prolactin. The aim was to generate cattle with shorter hair, a trait called SLICK which is already known from traditional breeding. Animals with this breeding trait are, according to various studies, better able to cope with higher ambient temperatures.

This is the second time that the US has attempted to market cattle genetically engineered with CRISPR/Cas. In 2019, the FDA rejected the approval of hornless cattle engineered with New GE (New Genetic Engineering). At that time, it was shown that the processes of genetic engineering had caused genes from bacteria to be unintentionally integrated into the genome of the cattle. It was subsequently found that these genetic irregularities had already been passed on to the next generation. All the genetically engineered cattle had to be slaughtered. Nevertheless, experts who are now calling the SLICK GE cattle a success were also involved in these previous experiments.

Other unintended genetic changes were found in the approved the Recombinetics cattle, these were, however, considered to be less severe. At the same time, the data provided by the FDA includes no indication of whether the animals will stay healthy over their lifetime. The reason: only four calves were examined, one of which was not genetically engineered, probably because the gene scissors had failed to work as expected. Another calf died unexpectedly, but the FDA assumes that this incident was not related to the genetic intervention.

To produce the cattle, the gene scissors were injected into embryos, which were then transferred to surrogate mother cows. This process is known to be associated with failures and also diseased animals. It is remarkable that neither of the 'successfully' genetically engineered animals show the intended changes consistently in all the cells of their body. This phenomenon is known as genetic mosaicism or chimeric formation.

Experts are warning that breeding material, such as sperm, could be imported into the EU. Such imports would be subject to EU GMO regulation. Currently, the company would have to file an application for approval and develop suitable methods for the identification of the animals. However, according to some projected EU Commission plans, regulations could be changed in the near future enabling possible imports without any effective controls being in place. Testbiotech is warning that the genetically engineered animals could rapidly spread throughout cattle populations, and thus spread genetic irregularities and disorders.

There is real doubt as to whether there is a need at all for such cattle: from the perspective of technology assessment, they do not appear to have any real benefits compared to cattle bred using conventional methods. On the other hand, many farmers and breeders will be put off by the uncertainties associated with unintended genetic changes, the additional need for animal experiments and the effects of patenting.

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Further information: The FDA report [2]







<u>News agency reporting the approval</u> [3] <u>International patent application (WO2017053315)</u> [4] <u>US patent application (US20200296941)</u> [5]

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