Russelia – Measures Affecting the Importation of Sheep and Sheep Products from Aldousia

by

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1. Aldousia is a developed country and a Member of the WTO. Aldousia's economy specializes in sheep farming, and an important part of its export income derives from ovine products, including live animals, meat, dairy products and wool.

2. In the past two decades, Aldousia has also become a world leader in bio and agrotechnological research. In 1996, Aldousian researchers successfully cloned a female sheep through the process of Somatic Cell Nuclear Transfer (SCNT). SCNT allows the creation of genetic replicas of selected animals that exhibit specific (and desirable) traits. This in turn permits the production of elite animals for further breeding that may, for example, provide higher quality meat (e.g., modest level of marbling, proper tenderness, firmness) and other derivative products (such as dairy goods). Cloning may also decrease the costs of production associated with the traditional breeding process through higher productivity of meat and/or milk or by increasing resistance of cloned animals and their offspring to certain diseases that normally affect animals.

3. Since 1996, researchers in many other jurisdictions around the world have conducted successful cloning of various species of mammals. However, before the launch of the Aldousian commercial project there were only several thousand cloned animals in existence worldwide. To date, cloning is not conducted on a commercial scale or basis
in other jurisdictions. In fact, in several key markets, regulators and industry have maintained moratoria, implicit or explicit, de facto or de jure, on the sale of products derived from cloned animals or from their offspring.

4. No such moratorium has been put in place in Aldousia. Indeed, in January, 2010, a five-member committee established by the Expert League of Scientists in Aldousia (ELSA), an Aldousian statutory body that advises the Government on all scientific issues, issued a position paper according to which "existing research has yielded no results indicating that there are differences between the safety of food originating from cloned animals or their progeny and the safety of food originating from traditionally bred animals" (the "2010 ELSA Report"). The Report also concluded that no specific issues for animal health were indentified.

5. **Podsnap Inc.** ("Podsnap") is a company incorporated in Aldousia, jointly owned by the Government of Aldousia and the Aldousian Sheepbreeders Association (ASA) that specializes in farming industry and food processing.

6. Two out of five of the members of the ELSA committee mentioned in paragraph 4 supra are directors on the board of Podsnap.

7. On 15 April, 2010, the Chief Executive Officer of Podsnap announced that the Company's scientists had perfected techniques for large-scale cloning of sheep, and had reproduced, through cloning methods, a large stock of stud rams, representing the best qualities of a number of important Aldousian breeds of sheep. Podsnap intended to make these cloned stud rams available to sheep breeders on both domestic and international markets.

8. In August, 2010, in close collaboration with the ASA and with the positive opinion of the ELSA that was based on the 2010 ELSA Report, Podsnap began introducing cloned stud rams into conventionally bred flocks of sheep in Aldousia. The aim was to accelerate the process of gaining genetically desirable traits in sheep, in comparison to conventional breeding methods. Given the relatively rapid ovine cycle of reproduction, and the continued introduction of cloned stud rams, it was expected that within 10 years, the majority of sheep raised in Aldousia could be of cloned ancestry.

9. **Russelia** is a developing country and a Member of the WTO. Most of its Gross Domestic Product is based on agricultural crops. It is a significant consumer of sheep and sheep products but it maintains only a small domestic production. Most of its sheep imports are from Aldousia; and from Zamyatin, another developing country and WTO Member.

10. Russelian research institutions do not have the capacity to perform cloning or to conduct first-hand research on cloned animals.
11. In 2000, the Government of Russelia issued an advisory statement, according to which "until sufficient scientific evidence is collected, and a full risk assessment is conducted, the importation and marketing of any animal suspected of being a cloned creature, or any offspring thereof, shall be suspended".

The statement added that "this precaution is not merely necessary to protect human, animal and plant life and health, but is a basic requirement of public morals in our society".

12. In September 2005, a report commissioned by the Russelian Ministry of Health, bearing the title "Cloned Animals and Derivative Products: A Scientific Risk Assessment" (the "2005 Russelian Report") determined that "cloned animals and products derived from cloned animals may pose certain risks to human health and to the health of other animals. On the basis of existing evidence, these risks should be considered to be of low probability, but at a level that is higher than merely hypothetical. Russelia has adopted a high level of human and animal health protection, and therefore the importation of cloned animals and their derivative products, should not be permitted under Russelian Law". However, the "2005 Russelian Report" did not identify any specific risks associated with cloned animals.

13. The "2005 Russelian Report" was authored by a special research group, employing primarily qualitative methods and heavily based on opinions expressed by Russelian and Zamyatinian scientists with respect to research conducted in research centres around the world.

14. Following the "2005 Russelian Report"., the Russelian Parliament adopted the Cloning Precaution Statute (CPS), that introduced a general ban on the importation and marketing of any cloned animals and their progeny for the purpose of their subsequent breeding and/or slaughter and of any food products derived from such cloned animals or progeny. "Progeny" of cloned animals was defined in the CPS as “... any animal with at least one cloned parent animal or any precedent cloned ancestor.” The CPS was notified as required by the relevant provisions of WTO Law.

15. On 1 September 2010, the Russelian Customs and Border Control (RCBCA) Administration began enforcing the CPS by barring the entry of sheep and sheep products from Aldousia, unless the importer could prove that the goods were not cloned animals or their progeny, or derivatives thereof, by producing evidence of the ancestry of the animal or animal product in question.

16. Zamyatin followed suit on 15 September, 2010, imposing a similar ban on importation and marketing of cloned animals and derivative products. However, industry reports indicated that during the second half of August 2010 and first half of September 2010, about 100 Aldousian cloned stud rams had been imported to Zamyatin and introduced into flocks with the intention of using them in reproduction
The importation of Zamyatinian sheep and sheep products to Russelia remains unaffected by the CPS and RCBCA enforcement activities.


18. On 01 October, 2010, Russelia responded to Aldousia's request for consultations. In its response it included a document entitled "Survey and Assessment of Risks Associated with Cloned Sheep and Derivative Products", dated 15 September, 2010 (the "2010 Russelian Report"). This report was prepared by the same research group that drafted the "2005 Russelian Report". The "2010 Russelian Report" noted that it "seriously considers views adopted by researchers that are divergent from mainstream research" but also acknowledged that "the majority of such evidence is inconclusive or speculative with respect to the existence of risks to human and animal health". Russelia admits that the "2010 Russelian Report", which it refers to as a risk assessment, was performed only after the adoption of the CPS, and in parallel with the commencement of its enforcement by the RCBCA, predominantly in response to critical remarks that had been received from Aldousia concerning the lack of sufficient scientific basis of the CPS. Nevertheless, Russelia emphasizes that the risk assessment confirmed the existence of relevant risk and identified those areas, where due to uncertainty it was not possible to perform an adequate risk assessment.

19. The "2010 Russelian Report" was based on experiments and analysis conducted in research centres around the world, as published in scientific journals. The 2010 Report identified the following risks:

(a) One specific risk for animal health (specifically for the health of progeny of cloned animals) is connected to epigenetic effects that sometimes appear in cloned animals, including sheep, and may in some instances be heritable. Although the DNA sequence of a cloned organism remains the same as the DNA sequence of the original, an organism’s genes may, due to epigenetic effects (factors such as the cloning process itself or environmental conditions), behave differently despite the lack of changes in the DNA. The “2010 Russelian Report” noted that due to epigenetic effects, the birth mortality rate of cloned sheep was higher than the comparable rate among non-cloned counterparts. Young cloned sheep also tended to suffer from illnesses more frequently or develop some abnormalities that did not appear in their ancestors. The "2010 Russelian Report" did not provide a probabilistic estimation of the relevant risk. However, it included a qualitative assessment, which described the existing risk as very small, albeit, in the opinion of Russelian scientists, not negligible.

(b) With regard to other potential risks, the “2010 Russelian Report” noted that due to the novelty of the cloning technique, there is great uncertainty as to the potential consequences for human health and health of other animals (mainly offspring); the Report specifically highlighted the limited quantity of available
scientific data with regard to sheep (the majority of scientific studies concentrated on other animals such as cows and pigs) and very small sample sizes that have been used in different scientific investigations around the globe. In this context, the Report concluded, again on the basis of minority scientific opinions, that physiological differences between cows, pigs and sheep combined with the novelty of the cloning technique make any meaningful extrapolation between those species impossible. With regard to the general lack of data, Russelia is particularly concerned with the following issues:

(1) potential long-term health effects that may result from cloning; in particular Russelia believes that it may be necessary to examine a number of generations of cloned animals and their progeny to fully assess potential risks. Such examinations would have to be conducted with respect to every species, including sheep, and every particular breed, and in a variety of different circumstances, such as changed environments;

(2) potential risks resulting from cloned animals that are kept in normal farming conditions; all available data concern laboratory observations (in the majority of the cases only with respect to cows and pigs);

(3) impact of cloning on the immune functions of cloned sheep and the susceptibility of these animals to infections, as well as whether any such impact may in turn increase the exposure of humans to transmissible disease agents constituting a human health risk;

(4) possibility of inducing genetic mutations in sheep in the SCNT process (including silent mutations that may express themselves only in the distant future) and transmissibility of such mutations; if such effects occur this may have effects on the health of offspring as well as human health (e.g. allergenic reactions);

(5) finally, since the cloning technology is so new it is possible that there are risks, which are even not considered now ("we don’t know what we don’t know").

(c) The “2010 Russelian Report” therefore concluded, with regard to those potential risks, that given the uncertainty that exists regarding future risks, and taking into account the high level of human and animal health protection sought by Russelia, a temporary, precautionary import ban on commercial imports and marketing of cloned animals, particularly sheep, their progeny and derivative products, is justified. At the same time, the Report suggested undertaking further research to address outstanding issues.

20. In its response to the Aldousian request for consultations, Russelia announced that it had decided to launch two comprehensive, 10-year research programs that would fully
investigate: (1) the risks to health and life of sheep related to cloning; and (2) the potential human health risks that may result from consumption of products from cloned sheep and/or from animal health issues, particularly with regard to matters indicated in the “2010 Russelian Report”. However, since Russelia is a developing country, the research budget that may be dedicated to the research programs is only limited. Russelia also indicated that it welcomes Aldousian assistance in conducting these projects, and would be willing to permit the importation of cloned stud rams and sperm from Aldousia for the purpose of scientific research only.

21. On 20 November, 2010, following continued consultations between Aldousia and Russelia that failed to resolve the dispute, Aldousia requested the establishment of a panel at a meeting of the WTO Dispute Settlement Body (DSB). Russelia did not object to the establishment of a panel at that meeting, and the DSB therefore established the panel. Zamyatin reserved its rights as a third party in the panel proceedings.

22. In its request for a panel, Aldousia asserts that the CPS import ban on cloned animals (and their progeny) as well as products derived from such animals; and the enforcement of the CPS by the RCBCA with respect to all sheep from Aldousia as well as products derived from them, are not compatible with the requirements of the SPS Agreement. Aldousia does not make any claim under any other of the Covered Agreements.

23. Aldousia argues that there is no difference in terms of safety between cloned sheep (and their progeny) and traditionally bred counterparts. This also means that any meat and milk derived from them does not pose any higher risks as compared to meat and milk from conventional bred sheep. In particular, it argues that the measures introduced by Russelia:

(a) constitute SPS Measures within the meaning of the SPS Agreement;

(b) are neither necessary nor based on scientific principles and maintained without sufficient scientific evidence in contradiction to Article 2.2 of the SPS Agreement;

(c) are not based on a proper risk assessment as required by Article 5.1 and Annex A(4) of the SPS Agreement;

(d) are more trade-restrictive than necessary in violation of Article 5.6 of the SPS Agreement;

(e) cannot be considered as falling with the scope of Article 5.7 of the SPS Agreement;
(f) arbitrarily and unjustifiably discriminate between sheep and sheep products from Aldousia and sheep and sheep products from Zamyatin, and constitute a disguised restriction of trade, that is inconsistent with Article 2.3 of the SPS Agreement.

24. In addition to rejecting all Aldousia's claims under the SPS Agreement, Russelia makes an alternative claim, whereby its measures are justified either under Article XX(a) or (b) of the GATT 1994.
Indicative References:

- General Agreement on Tariffs and Trade (GATT) 1994
- Agreement on the Application of Sanitary and Phytosanitary Measures (1994)
- Understanding on Rules and Procedures Governing the Settlement of Disputes (1994)

World Trade Organization Cases:

- Panel Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, WT/DS26/R/USA

Selected Literature:


Guzman, Andrew., *Dispute Resolution in SPS Cases*, in Dan Horovitz, Daniel Moulis & Debora Steger (eds.), *Ten Years of WTO Dispute Settlement*, International Bar Association: 2007


**Other Documents:**

Please note that the reference to the EFSA and FDA risk assessments is provided only in order to assist teams in understanding the scientific complexities related to cloning. Scientific data that are included in both assessments are not to be used in the parties’ argumentation.
