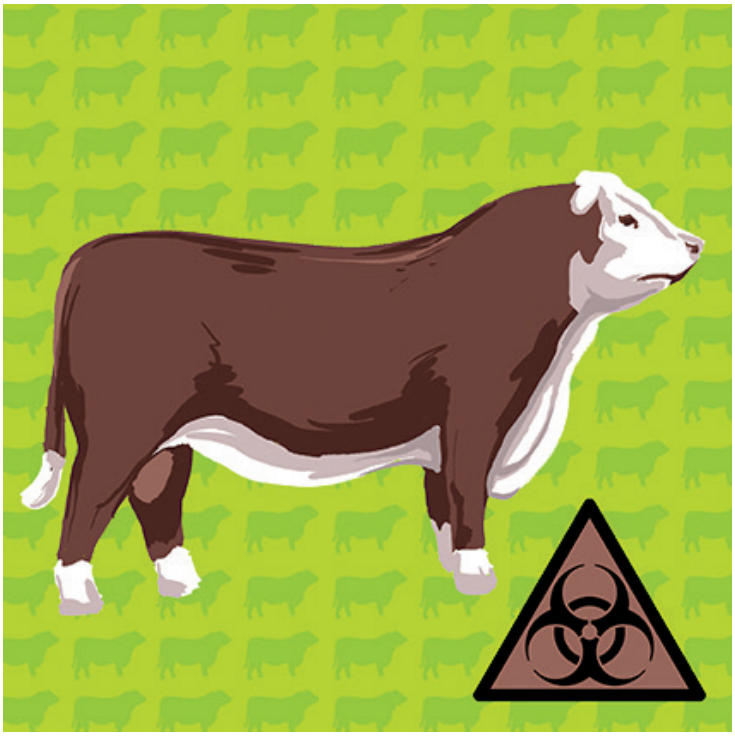

TEST BIOTECH

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Institute for Independent
Impact Assessment in
Biotechnology

Breeding material from cloned bulls in the US imported into the EU - and related current gaps in regulation

Transparency and freedom of choice put at risk by the CETA free trade agreement

Frank Brendel & Christoph Then, February 2017
www.testbiotech.org

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Research commissioned by the Greens/EFA Group in the EU Parliament

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Inhaltsverzeichnis

Overall Summary

The aim of the project was to investigate the possible points of entry into the EU of breeding material, more specifically sperm cells from cloned bulls. On the basis of the information available, we have further included in this paper a section containing a discussion relating to the potential need for future regulation.

In order to collect the information available, we examined relevant data bases and registers, and also identified companies supplying this kind of material. In addition, we gathered feedback from professional breeder organisations in Germany and the Netherlands.

Over the course of our research, we identified the planned free trade agreement CETA as a major obstacle in regard to possible future regulatory initiatives aiming to improve transparency and traceability.

In more detail, our findings were as follows:

1. Available information on the import of bull sperm from the US into the EU

- In terms of overall quantity, in 2015, around 40 tons of bull sperm were supposedly imported into the EU from the US, with a commercial value of more than 38 million US$. Canada also exports bull sperm but, currently, in smaller quantities.
- The official figures on overall imports of bull sperm do not appear to be fully consistent and in some respects contradict information received from importers.
- The import statistics available do not provide any information regarding imports of breeding material stemming from cloned bulls.

2. Usage of sperm from cloned bulls for cattle breeding in the EU

- Professional breeder associations in Germany and the Netherlands state that no offspring from cloned bulls are used by their breeders; however, no access was provided to the breeding registers.
- Research in a UK breeding register allowed the identification of some animals as the offspring of cloned bulls.

3. Regulatory gaps and challenges

- Currently, only a limited amount of data is available, from which it is impossible to draw sufficiently reliable and comprehensive data on the imports of sperm from cloned bulls and their usage in European cattle breeding programs.
- As long as this information is not made available, all further steps in breeding and food production will lack transparency.
- Consequently, products from the offspring of cloned bulls can be placed unnoticed on the EU market and seriously limit or remove choices for farmers, food producers and consumers.
- A system of mandatory registration and labelling of relevant imports and downstream products is needed to improve transparency and traceability; this has been requested by the European Parliament.
- The framework of the planned free trade agreement CETA does not foresee the introduction of new mandatory labelling regimes in order to provide transparency and consumer choice; on the contrary, such labelling regimes might be considered to be unjustified barriers to trade.

- Before CETA comes into effect, the EU and Canada should agree on mandatory labelling of products that, even though they might be indistinguishable in their final composition, stem from processes that, for example, raise ethical, social or environmental concerns; this cannot be regarded as a violation of the treaty.
- The EU Ptarliament should not adopt CETA without an additional clarification to enhance transparency and consumer choice. If CETA does go ahead without additional clarification, the EU Parliament might find itself in serious conflict with its own demands, goals and achievements.

1. Background

Artificial insemination is a well-established and widely used practice in cattle breeding. Professional breeders produce, pack and sell sperm from bulls that are judged to have the capacity to pass on characteristics of commercial value (such as a high amount of milk or good quality meat) to their offspring.

Genetic characteristics introduced in bulls via artificial insemination can spread widely throughout cattle populations and their offspring. Just one single bull can have more than 100 000 offspring. This means that if any undesirable genetic material is introduced into cattle populations without this being know, the following generations and products derived thereof can be impacted on an enormous scale.

In the US specific companies are known to clone bulls for usage in cattle breeding and also to sell sperm from these cloned bulls. Other countries cloning animals for food production are, according to the EU Commission, Argentina, Australia, Brazil and Canada[1]. Cloned bulls with the desired breeding characteristics can still be used for breeding even if, for example, the original bulls are too old to perform or are already deceased. US companies offering this kind of product include, for example, Bull Barn Genetics[2], Matt Lautner Cattle[3], SEK Genetics[4], Top Sires Semen Distribution[5], TransOva (Intrexon)[6], Universal Semen Sales[7] and ViaGen (Intrexon)[8]

Cloning animals for food production has drawn various criticisms, not least due to animal welfare problems: To successfully clone a bull, several hundred embryos have to be transferred to surrogate cows. Many of the cloned animals and their surrogate mothers suffer from serious illnesses, or are born only to die very soon afterwards.[9]

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1 Proposal for a COUNCIL DIRECTIVE on the placing on the market of food from animal clones /* COM/2013/0893 final - 2013/0434 (APP) */

2 http://www.bullbarn.com

3 http://www.mattlautnercattle.com/

4 https://sekgenetics.com/

5 http://www.topsires.com

6 http://transova.com/

7 http://universalsemensales.com

8 https://www.viagen.com/

9 EFSA (2008): Scientific Opinion of the Scientific Committee on a request from the European Commission on 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. The EFSA Journal (2008) 767, 1-49, https://www.efsa.europa.eu/en/efsajournal/pub/767

There are, for example, many technical problems related to current technologies used in animal cloning that have been reported in EFSA (2008)[10] opinions.

Observed adverse effects are related to systemic disturbances in the regulation of the genome, many of which, such as enlarged organs and overly heavy stillborn calves, are categorised under the heading 'Large Offspring Syndrome' (LOS). These effects are known to have many different causes and display a broad range of symptoms.

In addition, there are some remaining uncertainties in regard to risks for consumers, since it is difficult to assess all the relevant components in products, such as milk and meat. It has to be taken into account that major changes in the composition of such products will occur in response to the age, the diet and health of all animals: while differences between the cloned and conventionally bred animals might be subtle and difficult to identify.[11] Consequently, most experts would not consider, for example, that meat and milk derived from cloned cattle would be different in composition to milk and meat, compared to those products derived from conventional breeding[12]. This also has consequences in regard to the traceability of the relevant products since they can only be identified through documentation and registration. Without this information, neither the breeding material, nor the offspring, could be traced efficiently.

For many experts, the concerns about animal welfare problems are the most relevant. For example, in its 2008 report[13], the European Group on Ethics of Science and New Technologies (EGE) looked at the level of suffering and health problems of surrogate animals and animal clones, and concluded that there is no justification for allowing the cloning of animals for food production. Consequently, the main differences between products derived from cloned cattle in comparison to those derived from conventionally bred cattle are not related to the final product, but to the process of cloning the animals.

Contrary to the US position, the cloning of animals for food production is not something that is acceptable in the EU. This is clearly evident in polls conducted by Eurobarometer.[14]

There are also no commercial entities known in the EU that offer cloning services for food production.

The cloning of animals for food production is a highly sensitive issue in the EU, and this is reflected in initiatives started at the EU Parliament[15], the German Bundestag[16] and the German government[17] for an outright ban, or registering and labelling of relevant animals and products derived thereof.

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10 See above, EFSA (2008)

11 For overview see: Cloning farm animals - a ´killing application´?, Testbiotech, 2010, www.testbiotech.org/en/node/380

12 See above EFSA (2008) and FDA, Food and Drug Administration (2008): Animal Cloning: A Risk Assessment. Center for Veterinary Medicine, U.S. Food and Drug Administration, Department of Health and Human Services, Pages 1-968, www.fda.gov/cvm/CloneRiskAssessment_Final.htm

13 EGE, The European Group on Ethics in Science and New Technologies to the European Commission (2008): Ethical aspects of animal cloning for food supply, opinion number 23, stopogm.net/sites/stopogm.net/files/ethicalcloning.pdf

14 ec.europa.eu/public_opinion/flash/fl_238_en.pdf

15 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0285+0+DOC+XML+V0//EN

16 https://www.bundestag.de/dokumente/textarchiv/2015/kw19_de_klonen_von_tieren/372158

17 www.cdu.de/sites/default/files/media/dokumente/koalitionsvertrag.pdf

In the "European Parliament legislative resolution of 8 September 2015 on the proposal for a directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (COM(2013)0892 – C7-0002/2014 – 2013/0433(COD))[18]", the EU Parliament adopted the position that the EU should prohibit

"the cloning of animals"

as well as

"the placing on the market of animal clones and embryo clones and import of animal clones, embryo clones, descendants of animal clones, germinal products of animal clones and of their descendants, and food and feed from animal clones and their descendants".

Furthermore

"Animals shall not be imported from third countries unless the accompanying import certificates show that they are not animal clones or descendants of animal clones."
"Germinal products and food and feed of animal origin shall not be imported from third countries unless the accompanying import certificates show that they are not derived from animal clones or descendants of animal clones."

Currently, these initiatives are still pending at the EU Council. No final decision has been taken as yet.

18 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0285+0+DOC+XML+V0//EN

2. The results in detail

Against this background, our research aimed to identify relevant imports into the EU of sperm from cloned bulls, which is categorised as "germinal products" as mentioned in the resolution of the EU Parliament.

This approach was chosen due to the fact that artificial insemination is widely used in cattle breeding, and the results of breeding can impact all further downstream products and markets in cattle production and food production.

Other "germinal products" used in cattle production are, for example, embryos produced by in vitro fertilisation (IVF) in the laboratory[19]. However, these techniques are – compared to the artificial insemination of cows - rarely used.

The import of bull sperm is regulated by EU Directive 88/407/EEC.[20] This directive also provides a list of sampling stations that are entitled to import bull sperm into the EU. Currently, such institutions exist in the US[21], Canada[22] and Australia[23].

Our research focussed primarily on imports from the US, because US companies are considered to have a leading position in cloning bulls for food production.

We found that databases, such as Eurostat, contain specific figures on the import of bull sperm, and, therefore, we expected to find some detailed information about the origin and volume of these imports.

2.1 Import of bull sperm into the EU

Research was conducted in two public databases: The statistics of the German Federal Office in Wiesbaden (Destatis)[24] and Eurostat[25]. The search was targeted to product specification number 05111000 (sperm from bulls).

19 Similar to the process known of in vitro fertilisation, IVF, in humans.
20 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01988L0407-20111101
21 http://ec.europa.eu/food/sites/food/files/animals/docs/semen-ova_us_bov_scc.pdf
22 http://ec.europa.eu/food/sites/food/files/animals/docs/semen-ova_ca_bov_scc.pdf
23 http://ec.europa.eu/food/sites/food/files/animals/docs/semen-ova_au_bov_scc.pdf
24 http://www-genesis.destatis.de/genesis/online/data
25 http://ec.europa.eu/eurostat/data/database

Bereinigte EXTRA-EU Importe nach Zollregime, nach HS6 [DS-041718]			
Exportierte Daten	17.11.16		
Quelle der Daten	Eurostat		
PARTNER	USA		
PRODUCT	051110		
STAT_REGIME	NORMAL		
INDICATORS	QUANTITY_100KG		
DECLARANT/PERIOD	Jan.-Dez. 2013	Jan.-Dez. 2014	Jan.-Dez. 2015
OESTERREICH	1	1	0
BELGIEN (und LUXBG -> 1998)	0	0	0
BULGARIEN	0	0	0
ZYPERN	2	5	5
TSCHECHISCHE REPUBLIK (CS->1992)	1	0	0
DEUTSCHLAND (und DD vom 1991)	6	7	10
DAENEMARK	4	1	2
ESTLAND	:	0	:
SPANIEN	7	7	7
FINNLAND	1	0	0
FRANKREICH	6	5	4
VEREINGTES KOENIGREICH	67	28	22
GRIECHENLAND	2	6	3
KROATIEN	:	1	0
UNGARN	1	1	0
IRLAND	1	2	1
ITALIEN	4	4	4
LITAUEN	0	0	0
LUXEMBURG	:	:	:
LETTLAND	1	1	1
MALTA	1	1	1
NIEDERLANDE	127	154	347
POLEN	1	1	1
PORTUGAL	3	4	3
RUMAENIEN	0	0	1
SCHWEDEN	4	3	1
SLOWENIEN	0	0	0
SLOWAKEI	0	0	0
Sonderzeichen:			
:	nicht verfügbar		

Figure 1: Research conducted in the Eurostat database for product specification number 05111000, results in 100 kg (Date 17.11. 2016) http://ec.europa.eu/eurostat/data/database

2. The results in detail

Bereinigte EXTRA-EU Importe nach Zollregime, nach HS6 [DS-041718]			
Exportierte Daten	17.11.16		
Quelle der Daten	Eurostat		
PARTNER	USA		
PRODUCT	051110		
STAT_REGIME	NORMAL		
INDICATORS	VALUE_IN_EUROS		
DECLARANT/PERIOD	Jan.-Dez. 2013	Jan.-Dez. 2014	Jan.-Dez. 2015
OESTERREICH	100.014	99.543	25.278
BELGIEN (und LUXBG -> 1998)	126.250	240.239	234.171
BULGARIEN	89.045	91.900	77.049
ZYPERN	135.122	201.829	250.991
TSCHECHISCHE REPUBLIK (CS->1992)	688.119	760.599	829.162
DEUTSCHLAND (und DD vom 1991)	1.199.437	2.093.197	2.222.998
DAENEMARK	294.447	326.374	516.106
ESTLAND	:	34.397	:
SPANIEN	2.073.843	2.691.543	3.563.022
FINNLAND	42.979	30.390	6.870
FRANKREICH	471.016	474.114	335.755
VEREINGTES KOENIGREICH	9.961.461	13.842.459	16.739.697
GRIECHENLAND	84.606	164.631	141.369
KROATIEN	:	104.411	117.946
UNGARN	1.174.708	1.409.353	1.534.951
IRLAND	130.573	284.323	514.927
ITALIEN	3.302.947	3.986.397	4.304.926
LITAUEN	120.654	161.898	122.284
LUXEMBURG	:	:	:
LETTLAND	230.023	230.985	235.520
MALTA	49.306	23.414	55.542
NIEDERLANDE	2.158.303	3.595.263	4.542.326
POLEN	1.035.763	1.035.424	1.019.679
PORTUGAL	535.913	637.729	650.101
RUMAENIEN	109.390	88.543	190.445
SCHWEDEN	317.571	207.471	211.903
SLOWENIEN	71.622	4.051	100.746
SLOWAKEI	100.845	166.862	72.190
Sonderzeichen:			
:	nicht verfügbar		

Figure 2: Research conducted in database Eurostat, product specification number 05111000, results value in Euro (Date 17.11. 2016) http://ec.europa.eu/eurostat/data/database

These databases only provide information on the overall import of bull sperm into the EU; there is no specific registration of sperm from cloned bulls. The companies and breeders that export or import the bull sperm are informed if the bull is cloned. However, this information is only made available from trader to trade, and no such information is made available in the official import registers, or to the competent authorities.

The fact that the material from cloned bulls is not registered in any official database, or by any competent authority, was confirmed in direct communication with the relevant customs department at Frankfurt Airport in Germany (PCF Perishable Center Fraport).

Nevertheless, the information from these databases was helpful in assessing the current situation more generally. In accessing the databases, we are aware that different approaches were used to prepare the figures:

- Destatis shows the country of origin for all imports (in this case the US), regardless of whether the products were imported directly, or via transit countries.
- Eurostat contains figures in regard to the first country where the imports enter the EU. For example, if products are first imported into Netherlands and are then taken to Germany, Eurostat will not list the transfer to Germany.

Consequently, results from these databases can be expected to differ. For example, Destatis will generally show higher amounts of imports into Germany compared to the ones from Eurostat (see Table 1). The reason is probably that many imports might first enter the EU, for example, via Rotterdam and from there be transported to a final destination in Germany.

Table 1: Import of bull sperm from the US into Germany 2013-2015, source: Destatis and Eurostat

Year	Database	2013	2014	2015
Tons	Destatis	1,3	1,2	1,5
	Eurostat	0,6	0,7	1,0
Value in €	Destatis	2.272.000	3.017 000	3.405 000
	Eurostat	1.199 437	2.093 197	2.222 998

There are further discrepancies within the figures in Eurostat that cannot be explained easily: While the Netherlands is by far the country with highest number of tons / per year, the value of bull sperm imported to the UK is much higher (see Table 2). Therefore, serious doubts remain about whether the criteria used for determining the weight and/ or the value of the imports are clearly defined and comparable.

2. The results in detail

Table 2: Overall import of bull sperm T from the US into the EU and into some selected countries (top six) 2013-2015, source: Eurostat

Year	Categories	2013	2014	2015
All	Tons	23,6	21,1	41,3
	Value in €	24.603.957	32.987.339	38.615.954
Netherlands	Tons	12,7	15,4	34,7
	Value in €	2.158 303	3.595 263	4.542 326
UK	Tons	6,7	2,8	2,2
	Value in €	9.961 461	13.842 459	16.739 697
Germany	Tons	0,6	0,7	1,0
	Value in €	1.199 437	2.093 197	2.222 998
Spain	Tons	0,7	0,7	0,7
	Value in €	2.073 843	2.691 543	3.563 022
France	Tons	0,6	0,5	0,4
	Value in €	471 016	474 114	336.766
Italy	Tons	0,4	0,4	0,4
	Value in €	3.302 947	3.986 397	4.304 926

Import data from Canada in Eurostat reveals further inconsistencies. Remarkably, according to Eurostat, the most relevant country for the import of bull sperm from Canada is the Netherlands.

Table 3: Overall import of bull sperm from Canada into the EU and some selected countries (top six) 2013-2015, source: Eurostat

Year	Categories	2013	2014	2015
All	Tons	28,4	27,8	24,0
	Value in €	20.903.958	20.885.370	20.455.669
Netherlands	Tons	24,8	24,8	21,4
	Value in €	6.976.509	7.483.241	6.621.653
UK	Tons	1,7	1,4	0,8
	Value in €	3.584.566	3.427.309	3.605.936
Spain	Tons	0,5	0,4	0,2
	Value in €	2.616.660	2.475.210	2.105.267
Italy	Tons	0,2	0,2	0,2
	Value in €	1.831.588	1.717.104	1.866.188
France	Tons	n.a.	0,1	0,1
	Value in €	1.602.835	1.431.554	1.188.471
Germany	Tons	0,1	0,1	0,2
	Value in €	317.536	313.949	860.454

The figures given in tons and for value in Euros are inexplicable. Whereas, in 2015, the Netherlands imported 89, 2 % in tons of all imports into the EU, the value of these imports is only 32,4 % of all imports. The UK, on the other hand, imports 3,7 % in tons of all imports into the EU, and the value of these imports is given as 17,6 % of all imports.

In regard to the imports from Canada, further inconsistencies were observed in our research: According to information from Semex (Germany), which is one of the largest sperm importers, this company imported around 270.000 portions of bull sperm portions from Canada into Germany via Frankfurt Airport in 2015. However, according to Destatis, the overall number of imported sperm portions from Canada in 2015 was just 142.901.

Table 4: Import of cattle sperm from Canada into Germany 2013-2015, source: Destatis

Year	2013	2014	2015
Portions	82.201	145.469	142.901
Tons	0,1	0,1	0,2
Value in €	318.000	314.000	860.000

On request, Destatis replied that they had double-checked their figures and there was no mistake in the figures they gave us.

As a result, the import figures for bull sperm in general already suffer from several uncertainties and inconsistencies. Beyond that, transparency regarding imports of sperm from cloned bulls is completely lacking.

2.2 Usage of sperm from cloned bulls in EU breeding programs

We conducted interviews with relevant breeder organisations in Germany (German Cattle Breeders´ Federation), the Netherlands (CRV Holding BV) and the UK (Holstein and British Friesian Society). We asked for information on registered cattle with parents or grandparents registered as cloned cattle, and about the handling of semen from cloned bulls in the home countries of the breeder organisations mentioned.

On its website, the German Cattle Breeders´ Federation (Arbeitsgemeinschaft Deutscher Rinderzüchter, ADR)[26] portrays itself as the umbrella organisation of organised cattle breeding in Germany, and comprises all breeding organisations, organisations for artificial insemination and represents the entire organised cattle breeding sector in Germany.

According to the German Cattle Breeders´ Federation, the official breeding register of cattle breeding in Germany does not show any entries of animals stemming from cloned ancestors.

In cattle breeding, cloned animals are marked by the suffix "ETN". This suffix means Embryos derived from Nuclear Transfer. In comparison, the suffix ET is used for animals derived from Embryo Transfer (without cloning).

The German Cattle Breeders´ Federation statement was made in regard to dairy as well as meat production, and covers information for two generations (parents and grandparents). The ADR cannot exclude with absolute certainty that no import of sperm from cloned bulls took place in the past, however, it considers this to be unlikely.

This information could not be double-checked by accessing the German breeding registers kept by German cattle breeding organisations. These registers are classified as private property, to which the public and competent authorities have only limited access. Naturally, some uncertainties remain about the factual situation in Germany.

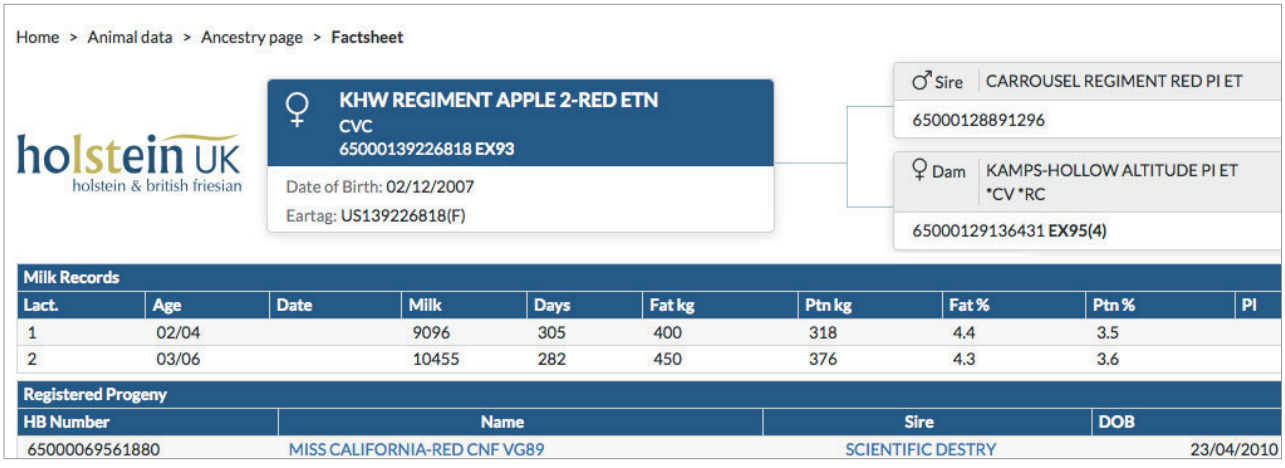
26 http://www.adr-web.de/home_gb.html

The CRV Holding BV[27] membership base is comparable to the German Cattle Breeders´ Federation. According the spokesperson of the German Cattle Breeders´ Federation, the CRV covers around 90 percent of organised cattle breeding activity in the Netherlands. In addition, the CRV is a globally important player in the commercial import and export of breeding material.

According to the CRV, the situation in the Netherlands is similar to that in Germany. The official stance of the CRV is currently that "no semen has been imported from cloned bulls into the Netherlands".

These statements are backed up by interviews conducted with Semex (Germany), a company which imports large quantities of semen from North America into the EU. According to this company, no sperm from cloned bulls was imported into Germany or the EU. The reason given by Semex is that such imports would be contrary to the interests of the EU breeder associations. Interestingly, Semex (Canada) did have material from cloned bulls some years ago.[28] But, currently, commercial activity in bull cloning appears to have no relevance for Semex.

According to the online data base of the Holstein and British Friesian Society in the UK, two dairy cows were marked with "ETN" and registered as being of US origin. This information means these cows stem from cloned animals in the US. The cows are registered as "KHW Regiment Apple 2-Red ETN"[29], born 2007, and "MS Chassity Snow Caitlyn ETN"[30], born in 2011. One the cows gave birth to a female calf in 2010 (female "Miss California Red"). The other gave birth to a male calf through embryo transfer.


Home > Animal data > Ancestry page > Factsheet

holstein UK
holstein & british friesian

♀ KHW REGIMENT APPLE 2-RED ETN
CVC
65000139226818 EX93
Date of Birth: 02/12/2007
Eartag: US139226818(F)

♂ Sire CARROUSEL REGIMENT RED PI ET
65000128891296

♀ Dam KAMPS-HOLLOW ALTITUDE PI ET *CV *RC
65000129136431 EX95(4)

Milk Records

Lact.	Age	Date	Milk	Days	Fat kg	Ptn kg	Fat %	Ptn %	PI
1	02/04		9096	305	400	318	4.4	3.5	
2	03/06		10455	282	450	376	4.3	3.6	

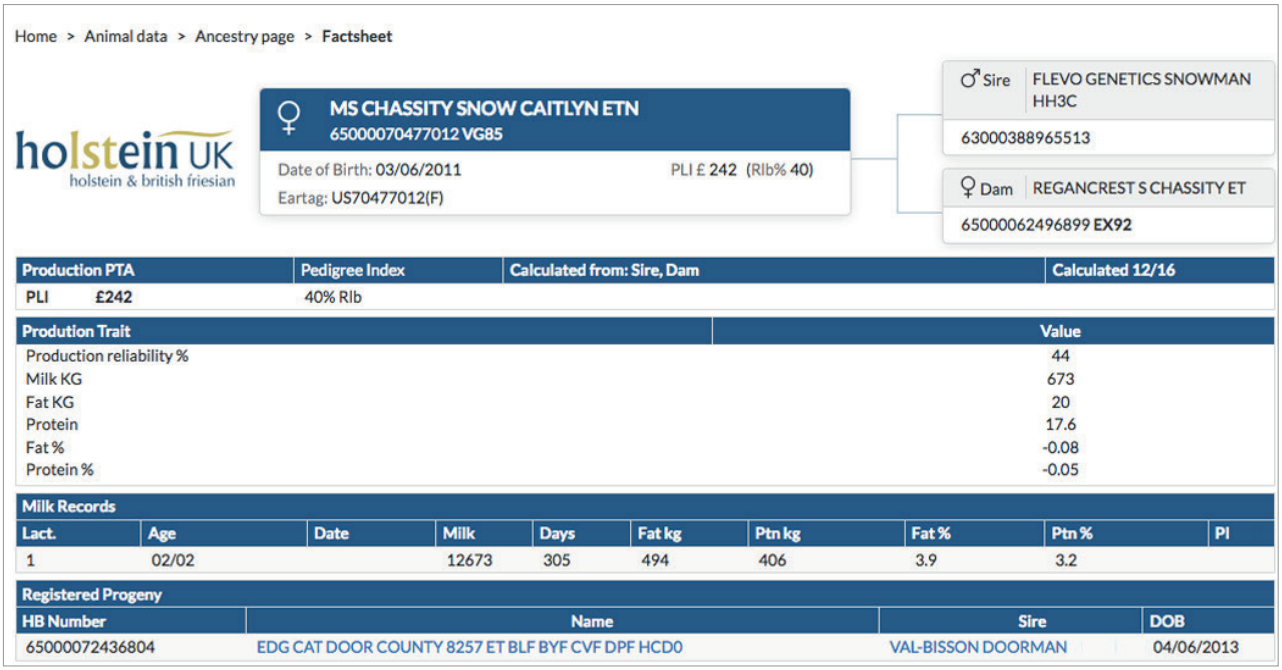
Registered Progeny

HB Number	Name	Sire	DOB
65000069561880	MISS CALIFORNIA-RED CNF VG89	SCIENTIFIC DESTRY	23/04/2010

Figure 3: "KHW Regiment Apple 2-Red ETN" and offspring as registered in the database Holstein, UK
http://www.holstein-uk.org/animaldata/animal/factsheet/39767109

27 https://www.crv4all.de/uber-crv/crv-weltweit/
28 http://www.semex.com/downloads/BalanceFall2007.pdf
29 http://www.holstein-uk.org/animaldata/animal/ancestry/39767109
30 shttp://www.holstein-uk.org/animaldata/animal/ancestry/39933761

2. The results in detail



Home > Animal data > Ancestry page > Factsheet

holstein UK
holstein & british friesian

♀ **MS CHASSITY SNOW CAITLYN ETN**
650000704770 12 VG85
Date of Birth: 03/06/2011 PLI £ 242 (RIb% 40)
Eartag: US70477012(F)

♂ Sire FLEVO GENETICS SNOWMAN HH3C
63000388965513

♀ Dam REGANCREST S CHASSITY ET
650000624968 99 EX92

Production PTA		Pedigree Index	Calculated from: Sire, Dam	Calculated 12/16
PLI	£242	40% RIb		

Prodution Trait	Value
Production reliability %	44
Milk KG	673
Fat KG	20
Protein	17.6
Fat %	-0.08
Protein %	-0.05

Milk Records

Lact.	Age	Date	Milk	Days	Fat kg	Ptn kg	Fat %	Ptn %	PI
1	02/02		12673	305	494	406	3.9	3.2	

Registered Progeny

HB Number	Name	Sire	DOB
650000724368 04	EDG CAT DOOR COUNTY 8257 ET BLF BYF CVF DPF HCD0	VAL-BISSON DOORMAN	04/06/2013

Figure 4: "MS Chassity Snow Caitlyn ETN" and offspring as registered in the database Holstein, UK http://www.holstein-uk.org/animaldata/animal/factsheet/39933761

The Holstein and British Friesian Society did not respond to, or answer any questions regarding the origin and destination of these animals.

3. Regulatory needs and obstacles

The European Parliament, in its legislative resolution of 8 September 2015[31], made some specific proposals regarding which measures should be taken to avoid breeding material from cloned animals being used in food production and entering the EU market:

> *"In order to ensure that import certificates accompanying animals and germinal products and food and feed of animal origin indicate whether they are, or are derived from, animal clones or descendants of animal clones, the Commission shall adopt specific import conditions under Article 48 or Article 49 of Regulation (EC) No 882/2004 of the European Parliament and of the Council (…) and shall, if necessary, present a proposal to amend other legislation in the field of animal health or zootechnical and genealogical conditions for imports."*

> *"To provide competent authorities and economic operators with the information they need (…), traceability systems shall be established for:*
> *(a) animal clones;*
> *(b) descendants of animal clones;*
> *(c) germinal products of animal clones and of their descendants."*

Indeed, such measures, if applied, would serve to close relevant regulatory gaps and provide the information necessary to improve transparency and traceability, and also enable farmers and consumers to avoid products derived from cloned animals.

However, since the EU is on the brink of implementing the new Comprehensive Economic and Trade Agreement (CETA) with Canada, the question arises as to whether CETA would still allow such traceability systems to be established once the agreement is adopted.

In 2014, the German Bundestag Research Services[32] conducted some interesting research and analysis, which is very relevant in this context. This confidential, but leaked document, is related to specific goals of the German government. According to the coalition treaty[33], the German government is committed to advocating a ban in the EU on cloned animals; it is also committed to advocating mandatory labelling for food products derived from the offspring cloned animals. As the coalition treaty[34] reads:

> *"At European level, we advocate a ban on animal cloning and on the import of cloned animals and their meat. We strive for mandatory labelling for the offspring of cloned animals and their meat."*

According to the coalition treaty of the German government, mandatory labelling is also foreseen for food products derived from animals fed with genetically engineered plants.

The dossier of the German Bundestag Research Services aimed to investigate the question of whether the realisation of the above goals could be hampered or impeded by either the process of negotiations on CETA, or the adoption of the free trade agreements CETA and TTIP[35]. The dossier does, indeed,

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31 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0285+0+DOC+XML+V0//EN

32 Unpublished report by the German Bundestag's Research Services, 'EU-Kennzeichnungspflicht für Lebensmittel aus mit GVO gefütterten Tieren', PE 6 – 3000 – 141/14, 15. August 2014, leaked by PowerShift – Verein für eine ökologisch-solidarische Energie- & Weltwirtschaft e.V., 19.11.2014. www.testbiotech.org/node/1838

33 www.cdu.de/sites/default/files/media/dokumente/koalitionsvertrag.pdf

34 www.cdu.de/sites/default/files/media/dokumente/koalitionsvertrag.pdf

35 Transatlantic Trade and Investment Partnership, free trade agreement planned with the US

identify major obstacles. These obstacles concern the mandatory labelling of products derived from cloned animals and food products derived from animals fed with genetically engineered plants. In legal terms, no difference is made between these two objectives . In fact, it asserts that the introduction of new mandatory labelling might be considered to be in conflict with the overall goal of the FTA to reduce unjustified barriers to trade:

> *"Against the background of the WTO legal provisions and the objectives set out in the TTIP agreement and CETA, secondary legislation on mandatory labelling could be described as an obstacle to trade that is incompatible with the objectives of the CETA and TTIP negotiations at issue."*

In consequence, after the adoption of CETA, the introduction of mandatory labelling might face legal challenges. From a legal perspective, these problems would also concern products derived from cloned animals:

> *The objective of the TTIP and CETA free trade agreements is a major reduction or removal of non-tariff trade barriers. This carries an inherent and significant risk that any extension to mandatory labelling as set out in the TBT and SPS agreements for products derived from animals fed with GE products will be left wide open to legal challenges, both from the USA and Canada, after the agreements come into effect.*

The question of whether or not mandatory labelling can be established under CETA, is mostly dependent on the criteria defined in the Agreement on Technical Barriers to Trade (TBT Agreement), which has already been adopted under the umbrella of the World Trade Organisation (WTO). In essence, this agreement allows mandatory labelling only as long as the import of products of similar or equal characteristics ("like products") are regulated in the same way. In general, technical regulations must not create "unnecessary obstacles to international trade".

However, as the WTO dispute settlement procedure on genetically engineered plants shows[36], there is no common understanding between Canada and the EU on which criteria are allowable under the TBT agreement. In short, on the EU side, specific processes for production can trigger mandatory labelling, while for Canada, only the characteristics of the final product are relevant in deciding whether something should be considered to be a "like product".

These contradictions were not resolved in the text of CETA. Nowhere in treaty does it state that mandatory labelling can be established, even if products seem equal in composition, but stem from processes that differ in regard to ethical, social or environmental criteria. In awareness of current EU regulations (such as Directive 2001/18 or 1829/2003 on GMOs), this gap or grey area in the text of CETA is relevant for others areas beyond the issue of products derived from cloned animals.

Consequently, the transparency essential to enable informed choice in regard to products derived from cloned animals remains a matter of uncertainty, and – according to the dossier of the German Bundestag Research Services – there is a high risk that new mandatory labelling as demanded by the EU Parliament will not be allowed.

It has to be taken into account that the TBT agreement has been in effect since 1995, and will not be changed by CETA. However, in assessing the future situation, CETA would substantially change the legal framework in which the TBT Agreement will be applied. Under WTO rules, dispute settlement

36 DISPUTE DS291, DS 292, DS 293, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm

cases could only be filed by another WTO member. Now, CETA would establish new governance rules that would increase the pressures on legal standards that could be seen as a violation of the TBT agreement. This scenario will facilitate legal challenges brought by newly established regulatory committees and companies. In such circumstances, it might become much more complicated to develop and extend the established system of transparency as demanded by the EU Parliament than under the WTO.

In regard to the cloning of animals for food production, Canada cannot be considered to be the most relevant player. However, the legal framework that would be established by CETA is likely to reshape markets and the role of specific stakeholders. For example, the US cloning companies might expand economic activity to Canada and thereby acquire a legal position to challenge the EU regulation. As a result, it is very likely that future mandatory labelling of products derived from the cloning of animals for food production would be amongst those issues substantially impacted by CETA.

Consequently, there are justified concerns that CETA would be in conflict with the EU Parliament's intention to establish "traceability systems" for "animal clones" "descendants of animal clones" and "germinal products of animal clones and of their descendants", and its ambition to ban specific imports from entering the market,

The EU Parliament, therefore, should seek clarification on the criteria that can be applied to justify such traceability systems in order to prevent any challenge as "unnecessary obstacles to international trade", if the EU eventually does decide to make traceability labelling mandatory for products from cloned animals.

Furthermore, the European Parliament in its resolution of 8 July 2015 regarding the negotiations for the Transatlantic Trade and Investment Partnership (TTIP)[37] made clear statements that a free trade agreement should not undermine the EU's future regulations on cloning:

> *"(c) regarding regulatory cooperation and coherence pillar and NTBs:*
> *(i) …to ensure similarly that it will not affect standards that have yet to be set in areas where the legislation or the standards are very different in the US as compared with the EU, such as, for example, the implementation of existing (framework) legislation (e.g. REACH), or the adoption of new laws (e.g. cloning),…*
> *(iii) to recognise that, where the EU and the US have very different rules, there will be no agreement, such as on public healthcare services, GMOs, the use of hormones in the bovine sector, REACH and its implementation, and the cloning of animals for farming purposes, and therefore not to negotiate on these issues…".*

In conclusion, before CETA can be adopted, further legal guarantees are needed in order to safeguard that in the future, competent authorities, farmers, food producers and consumers will not be deprived of access to the relevant information. Otherwise, both the power of the EU legislators and consumer rights will be substantially undermined.

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37 European Parliament resolution of 8 July 2015 containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP) (2014/2228(INI)), see www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015 0252+0+DOC+XML+V0//EN

4. Conclusions

The most relevant results from this research are:

- There is no official registration of imports into the EU of bull sperm from cloned animals. The only data available are those on the overall imports of bull sperm into the EU, without any mention of whether, or not, they come from cloned bulls.
- The publically available information on data regarding the import of semen from the US / Canada are not fully consistent. As a result, there are some uncertainties in regard to the actual amounts of bull sperm being imported into the EU.
- Direct communication with professional breeder associations in the Netherlands and Germany showed that the associations are aware of the problem. They try to avoid having any offspring from cloned bulls in their breeding programs, and state that, so far, no imports have been registered.
- Compared to Germany and the Netherlands, the situation in UK is different: There are several animals on the register of the „Holstein and British Friesian Society“, which most likely stem from US cloned bulls.
- Under the planned free trade agreement CETA, it might become impossible to restrict the import of breeding materials from cloned animals, or to introduce mandatory labelling as demanded by the EU Parliament.
- In the light of these findings, before agreeing to the free trade agreement, the EU Parliament should seek legal certainty on the extent to which mandatory labelling, or the restriction of imports of reproductive material of clones, would still be possible under CETA. Otherwise, the EU Parliament´s intention to safeguard the interests of breeders, farmers and consumers is likely to be seriously undermined and impeded.