



Study on the labelling of products from cloned animals and their offspring

Final report

Main text

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Glossary of terms

Term	Definition
Artificial insemination (AI)	Process of depositing sperm cells collected from a male animal into the reproductive tract of a female with the intend to fertilise it
Breeding	Controlled reproduction of domestic animals to improve desirable qualities.
Clone	Organism that is genetically identical to the organism from which it is derived
Production herd	Collection of animals of the same species kept wholly or mainly for the products which they produce (e.g. milk, meat)
Cross breeding	Mating of animals from two breeds
Dam	The female parent of an animal
DNA profiling	Technique used to identify individuals by characteristics of their DNA (deoxyribonucleic acid - the molecule carrying most of the genetic instructions organisms).
Embryo transfer	Technique used in breeding in which an embryo from a donor female animal is transferred to the uterus of a recipient female animal.
Generation interval	The average time interval between the birth of parents and the birth of their offspring.
Heifer	A young cow which has not given birth to a calf
Hybrid	Cross between two different breeds through sexual reproduction
Multiplier herds	Herd which, as part of a breeding system, produces hybrids
Nucleus herds	Animal herd, that as part of a breeding system produces purebred breeding stock
Offspring (progeny, descendants)	Organism or organisms resulting from sexual or asexual reproduction
Pedigree	Record of ancestry of an animal
Purebred breeding animals	Animal, the parents and grandparents of which are entered or registered in a herd-book of the same breed, and which is itself either entered or registered and eligible for entry in such a herd-book.
Reproductive materials/germinal products	Semen, oocytes and embryos collected or produced from breeding animals for the purpose of assisted reproduction.
Zootechnics	Science concerned with the domestication and breeding of animals

Abstract

An obligation to label food based on whether it is derived from clone offspring would require all livestock animals to be assigned an individual identity and have their parentage and clone status recorded. Significant investment in data systems would be required to record and transfer the information. Additional costs that could reach beyond €800 million a year would be incurred. Almost 80% of these costs would fall on the pig sector. The costs would arise even if there were no clones used in the European Union's livestock production sector or that of its trading partners. Costs are also insensitive to the definition of clone offspring and the number of animals that fall within it. Claims for clone ancestry based on a documented system alone would not be verifiable. A universal system of DNA profiling could potentially provide verification but at a cost that could reach over €9 billion a year on the basis of the assumptions used here. Such a DNA sampling and storage or profiling system would be without precedent in scale and complexity. There is no known use of the cloning technique in the EU for farming purposes and no expectation of increased uptake of the technique in the immediate future.

Résumé

Une obligation d'étiqueter les denrées alimentaires obtenues à partir d'animaux clonés impliquerait d'attribuer une identité à chacun des animaux d'élevage, et de consigner leur filiation et leur statut de clone. L'enregistrement et le transfert de ces informations supposeraient un investissement conséquent en systèmes de données. Les coûts supplémentaires occasionnés pourraient dépasser 800 millions d'euros par an. Près de 80 % de ces dépenses concerneraient le secteur porcin. Les coûts augmenteraient même en l'absence d'utilisation de clones par le secteur de la production animale de l'Union Européenne ou par ses partenaires commerciaux. Ils sont en outre indépendants de la définition de progéniture de clone retenue, et du nombre d'animaux qui répondraient à cette définition. L'éventualité d'une ascendance clonée fondée uniquement sur un système documenté ne serait pas vérifiable. Un système généralisé de caractérisation par l'ADN permettrait vraisemblablement une telle vérification, mais à un coût pouvant dépasser 9 milliards d'euros par an, selon les hypothèses utilisées ici. Un tel prélèvement et stockage d'ADN — ou autre système de caractérisation génétique — serait sans précédent par son échelle et sa complexité. Il n'existe pas d'utilisation connue de la technique du clonage dans l'UE à des fins agricoles, et l'on ne s'attend pas à un recours accru à cette technique dans un avenir proche.

Executive Summary

Introduction

This study was ordered by the European Commission to examine the implications of labelling products derived from the offspring of clones and, where possible, quantify the associated costs. The study examines the implications of labelling products derived from the offspring of clones.

The report describes the current situation in the European Union (EU) and third countries with respect to the use of livestock cloning, the recording of livestock ancestry, the tracing of livestock and the tracing and labelling of animal products. The investments and other costs associated with implementing a labelling system for products derived from clone offspring are identified where possible. It covers the beef, dairy, pig, sheep and goat and horse sectors and is concerned with both meat and dairy products. The main focus is on the beef, (bovine) dairy and pig sectors because of their importance to the EU livestock sector.

Information was gathered through a comprehensive literature review, review of sectoral productivity and economic data sets, expert information and interviews with expert stakeholders across the EU including representatives of individual companies and business associations in the following areas: animal genetics, animal breeding, trade in live animals and food products, animal slaughtering and meat cutting, meat and dairy processing and retailing. Academic experts and Member State officials were also consulted. A cost analysis was carried out using the standard cost model approach which has been used in a number of similar exercises for the Commission.

Context

Evidence suggests that cloning of animals for food production is not practised in the EU at this time. The only known use of cloning techniques in livestock production in the EU is for high value sports horses. Cloning cannot generate 'better' genetics, it can only reproduce existing genetics. This limits its perceived utility to an EU breeding sector that seeks continued improvement in livestock performance. Also, there is a widespread belief that consumers would be unwilling to purchase products labelled as being derived from clones. No application for the marketing of food from clones has been submitted in the EU. This perceived consumer resistance and industry indifference means that significant growth in the use of the technique in the EU is not anticipated in the next five to ten years. There is, however, the possibility that food derived from clone offspring might be offered to consumers as a result of imports from third countries of meat and dairy products, imports of live animals and imports of genetic materials used to breed animals in the EU.

Animal welfare considerations and general ethical concerns have given rise to calls for Union rules restricting the use of cloning for farming purposes and to ban the marketing of food from clones and in response the European Commission has presented two proposals for directives¹.

The core components of a system capable of supporting the labelling of food products derived from clone offspring are:

- **Ancestry recording in livestock breeding:** the recording and verification of the ancestry of animals in a database where clone animals are identified;
- **Individual animal identification:** assigning an identity to each individual animal.

¹ http://ec.europa.eu/food/animals/welfare/other_aspects/cloning/index_en.htm

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- **Information on cloning status passed forward through the supply chain** so that information on the clone offspring status of animals can be carried through the food chain and ultimately be presented on labels.
 - A **verification mechanism** to allow verification of the clone status of each animal, such as a register holding a DNA sample or DNA profile test result.

European Parliament proposals² for mandatory labelling for food derived from the offspring of cloned animals did not provide a working definition of 'clone offspring', i.e. how many generations would be covered. The clone offspring definition adopted would, however, influence the number of animals that are classified as clone offspring, and so affect the cost of an obligation to trace and label those animals.

The current situation

The impacts and costs of a clone offspring labelling obligation stem from the difference between what would be required to support such an obligation and current practice. The current practice is explained in the following.

The commercial breeding sector

There are substantial differences in the structure of the commercial breeding sector by species in terms of the distance between elite breeding animals and production animals (meat or milk) and the use of breeding technologies such as artificial insemination (AI).

There are also differences in the number of animals that can be produced each year by females. Where AI is used (such as in the bovine dairy and pig sectors), the potential for a small number of clones to result in a large number of clone offspring is large. The implication of this is that, for any definition of clone offspring, the number of animals that would be classified as clone offspring (and the amount of derived product in the food chain) would vary significantly by species.

Extent of animal ancestry recording

There is no compulsory system for ancestry recording in the EU. Pedigree recording systems are used by breeding organisations to record parentage information, for breeding animals that are entered in herdbooks on a voluntary basis. There is considerable variation across the EU and across species in terms of the proportion of animals for which ancestry information is recorded. It is estimated that for the EU as a whole ancestry recording takes place, at least for the sire and dam, for approximately 47% of total cattle, about 10% of pigs; 5-10% of sheep and goats; and around 75% of horses.

EU law requires that information on the dam and sire be recorded for individual registered horses (about 75% of the total horse population) and that the dam be recorded for individual bovine animals. To allow the labelling of products derived from clone offspring it would be necessary to extend the recording of ancestry information to all animals. The number of generations the records would have to cover would be determined by the clone offspring definition that is used.

Individual animal identification

Each individual animal would need to be linked to its ancestry information and this information would need to be passed through the food supply chain.

All bovine animals in the EU are currently individually identified throughout their whole life and imported cattle are individually identified from the point of entry into the EU. However, in the pig sector identification is done on a batch basis and only breeding

² e.g. Motion for a Resolution pursuant to Rule 120 of the Rules of Procedure on cloning of animals for food supply. European Parliament. B7-0000/2013. 11/12/2013.

pigs (15-20% of the total) are individually identified. Approximately two-thirds of sheep are individually identified, as are up to 80% of goats and up to 75% of horses.

There are no requirements to record any information for individual pigs, sheep or goats. The ancestry recording and individual animal identification necessary to support a labelling system is therefore only available for 75% of the EU horse population and not for any other species.

Traceability of animal food products to the individual animal

The General Food Law³ requires food businesses to provide information that identifies the batch or consignment. Information must be available one step forward at each point in the supply chain and one step back.

This does not allow food to be traced to individual animals. The link is broken well before the product reaches the consumer. In the dairy sector the link to individual animals is broken immediately after milking as milk from different animals is mixed on farm. In the meat sector the link can be broken before slaughter where animals are not individually identified (pigs and most sheep and goats) or at and immediately after slaughter when carcasses are cut into primal cuts and combined into batches of product (all species). If the individual identity were retained initially, this would be lost under further processing, e.g. into minced meat and meat preparations/products.

Linking animal products to the individual animals from which they originate would therefore require further development of the systems. The alternative, in the context of a labelling obligation for products derived from clone offspring, is segregation of clone offspring and derived products from the rest of the supply chain.

Current requirements for labelling

As a general principle of EU food law, information provided to consumers should enable them to make informed choices and should not be misleading. The EU has detailed requirements for food labelling but there is no requirement for any linkage between meat and livestock products and ancestry information of individual animals. This means that the current rules on labelling do not put a framework in place that could be used to facilitate the labelling of meat from the offspring of clones.

The implications for livestock breeding and production

The introduction of labelling to identify products from clone offspring would require universal ancestry recording, cumulative through the generations and consistent with the operating definition of 'clone offspring', and the identification of all animals. The same information would need to be known for genetic breeding material, animals and livestock products imported from third countries. Current systems do not provide for this and so this capability would need to be developed.

The implications vary by species and Member State. For example, in the bovine dairy sector animals are already individually identified and the recording of the dam is required; more extensive ancestry recording is relatively common. However, in the pig sector, most animals are not currently individually identified and ancestry recording for production animals is uncommon.

Animal ancestry recording and identity recording systems

Investments would be needed in databases and supporting communications infrastructure and related services for recording identity and ancestry. Systems for pigs, sheep and goats would require significant further development to support individual identity recording and the extension of ancestry recording beyond existing use of herdbooks to the full population. Systems for tracking animal movements

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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.

through the supply chain would require development and investment. A single register, integrated with the identity register, would need to be constructed for each species in each Member State and those registers be linked together at EU level.

The available evidence suggests that extension of ancestry and identity systems to meet the requirements of clone offspring labelling would trigger extension and upgrade costs measured in the tens of millions of euro for the EU-28 as a whole, and possibly in the hundreds of millions of euros. These systems would require maintenance and administration.

Additional obligations and costs imposed on livestock producers and traders

Familiarisation with the obligations. Livestock producers, markets and assembly centres, and slaughterhouses would incur costs in understanding and preparing for compliance with legislation relating to labelling of products derived from the offspring of clones. Businesses in sectors where there is already individual identification of animals and ancestry recording is common (e.g. breeding of pedigree herds of dairy cattle) would see little impact. By contrast, large scale pig producers would face significant changes. The total cost to the EU livestock industry would be in excess of €363 million as a one-off cost. Exporters to the EU and EU importers of genetic material would also face familiarisation costs.

Tagging. Animals would need to be tagged with an EID ear tag to support more rapid processing and reduce the error rate in data capture, such as at slaughter. This would cost around €504 million per year for the EU livestock industry, including the cost of replacement tags assuming a 3% loss rate. Some 92.5% of this cost would be incurred in the pig sector, 6.5% in the sheep sector and the remainder in the caprine sector.

Identity and ancestry registration costs. Only where animals do not currently have their identity or ancestry recorded would the obligation require additional measures. It is assumed that these two activities could take place simultaneously. The combined cost for the EU livestock industry would amount to around €317.4 million per year, 84% of which would be incurred in the pig sector, 11% in the sheep sector, and 5% in the other livestock sectors.

Movement records. Animal movements would need to be recorded on an individual basis. For most pigs and sheep batch rather than individual recording is currently used. The net impact on costs is not easily determined. Using electronic identification for all animals will be more expensive but it will facilitate cost savings (as compared to manual reading of tags), especially at markets and slaughterhouses.

Modification of existing breeding and production practices and supporting systems

Implementing individual identification and ancestry recording would force more fundamental changes in practice for some parts of the livestock sector. In intensive pig production it is common for semen from three to ten boars to be mixed for use in AI to improve the farrowing rate, making the identification of the sire impossible. In extensive livestock systems it is not possible to assign paternity where there is more than one male animal; it can also be difficult to assign a given young animal to a specific dam with full confidence.

The potential role of DNA sampling, testing and profile recording

A labelling system could be constructed using documented systems only, but with no means to verify claims the system would be vulnerable to fraud. By itself a DNA test could not distinguish a clone offspring from a natural offspring of the same parent. The combination of DNA records and documented records could provide a much more robust control regime, though the practical challenges in constructing such a system are significant.

Taking and storing a DNA sample for each animal would be a new activity. The testing of the samples and test record management and storage would also be an additional activity and both would imply further costs. For the EU livestock sector as a whole these costs could amount to more than €9 billion a year, of which 77% would be incurred by the pig sector, 13% by the sheep sector, 8% in the beef and dairy sectors, and 2% in the other livestock sectors. Significant investment in infrastructure and capability would be required to deliver and support the services required.

Impacts on third countries supplying animals and genetic materials

The introduction of a labelling scheme would result in direct and indirect costs on third country livestock sectors importing genetic material and live animals to the EU. The definition of 'cloned offspring' used is important here.

Direct impacts. If 'clone offspring' is defined to include only the first generation offspring of a clone, then breeders in third countries would only need to identify whether the genetic materials exported to the EU were from a clone or not. Live animals exported to the EU could be designated as clone offspring. If the definition of clone offspring was extended to include second generation offspring (or beyond), it would become more difficult for a breeder in a third country to be certain of the clone status of the donor animal (for genetic materials) or the live animal. Breeders would need to put in place additional systems to check and verify the status of the genetic materials they use in their breeding programmes. The additional costs would be most significant in Canada and the US, with New Zealand and Australia also affected. If DNA-based verification mechanisms were required then the impacts would be significant.

Indirect impacts. If exporters were unwilling or unable to meet EU requirements then the EU could lose access to the high quality genetics that are currently imported. If a multi-generational definition of 'cloned offspring' were used such that a significant share of the genetic materials in third countries was classified as clone offspring, then EU importers may stop using imported genetic material.

Conclusions on the impact on the EU livestock and breeding sector

Based on the analysis undertaken, a clone offspring labelling obligation would trigger additional operating costs in the order of €10 billion per year if a DNA verification system were required, and around €800 million per year in the absence of such a system. The scale of costs is sufficient to suggest that income and output levels in EU livestock production would be affected. These costs would be incurred even if there were no clone offspring in the livestock sector, and irrespective of the definition of clone offspring adopted. The majority of the €10 billion annual cost (78%) would be incurred in the pig sector, 13% in the sheep sector, 6% in the bovine sector and the remainder in goat and horse production.

Labelling would also require enabling investment in information infrastructure to support the transmission of clone offspring information through the supply chain and across Europe, linking identity to ancestry, and accommodating trade within the EU and with third countries. DNA-based verification would require substantial additional investments.

The implications for food supply chains

Changes to animal product traceability systems and supply chains

For information on the clone heritage status of individual animals to be carried through to the labels of the food products derived from those animals there needs to be the appropriate internal traceability and documentation systems in place at intermediate meat handling operations, such as slaughterhouses, cutting and processing plants. Existing traceability requirements in the EU do not, in general, extend to linking individual animals with their food products beyond the carcass level. There is no forward transmission of information on individual animals with their products. The link

to the individual animal is broken at slaughter; for milk products the link is broken on farm.

Meat production. Information on identity and clone offspring status would need to be carried over from the slaughtered animal to the food products derived from that animal. The information would then need to be passed *forward* through the supply chain to facilitate the appropriate labelling of the product for the final consumer. If the slaughterhouse was able to carry the animal identity through the slaughter process to the whole cuts of meat then it would be possible for the slaughterhouse to notify the next stage in the supply chain of the clone status of those cuts. This retention of identity on whole cuts would not be feasible for minced meat and other products that require the mixing of raw materials from more than one animal. For such products, batch traceability would be required to separate the two categories of meat in the supply chain if products were to carry labels that reliably distinguished between items derived from clone offspring and those that were not.

Dairy production. The mixing of milk on farm precludes the link to individual animals. Further mixing then takes place in tankers and again at the dairy preventing even the identification of a single farm of origin. This mixing also precludes the use of DNA testing to determine the individual animals that produced milk and its derivatives. The only way to link milk to the individual animal would be to stop mixing milk from different animals. However, this would not be commercially viable and the modern milk supply chain would no longer be possible. The only possible way to identify the clone status of milk would be to use a batch identification system within segregated supply chains. This would add complexity and significant cost to the management of the dairy supply chain.

Labelling changes

Under a negative labelling policy, all animal products would need to indicate the clone status of the animal from which they are derived. Costs associated with label redesign would therefore be incurred under any definition of clone offspring and with any level of presence of clone offspring in the food chain. The literature suggests that design and printing costs for a new label formulation would be small compared to the other costs triggered by the obligation. However, labelling products as not being derived from clone offspring could be seen to be misleading consumers if there was no known use of cloning in the food chain for that particular species.

Supply chain responses to clone offspring labelling obligation

A labelling obligation is likely to lead to the exclusion of clones (and clone offspring) from the EU food chain because consumers are perceived to be unwilling to buy products derived from clone offspring and the food supply chain is unwilling to offer such products. If there is no added value to the consumer it is unlikely that products derived from clones could attract the price premium that would be required to compensate for the additional costs of segregation, and so they would be unlikely to attract investment. However, even in the absence of product from cloned offspring, the EU livestock sector, the EU food processing and manufacturing sector, the EU's trading partners and the food retail and food service sectors would still incur the costs of providing ancestry information, linking this to individual animals, transmitting it through the supply chain and meeting labelling requirements. A share of these costs would be passed on to consumers.

Implications for the trade in food products

Imports. Operators in countries exporting to the EU will be obliged to comply with labelling requirements and this will result in additional costs. The magnitude of impact would depend on the definition of clone offspring used. A second (and subsequent) generation definition will result in larger costs being incurred than a first generation definition.

Third countries would need to adapt their food production systems in all of the ways outlined in this study. There are too many unknown factors and too much variation among trading partners, and by species, for it to be feasible to estimate the additional costs that would be incurred in doing this. The cost would, however, be substantial. All imports of meat and dairy products would need to be accompanied by information on their clone offspring status. Effects on imports are most likely to occur for beef (Brazil, Argentina and Uruguay, Australia and the US, all countries where there are records of the cloning technique being used in livestock production); the sheep meat trade would also be affected (New Zealand and Australia).

Exports. A labelling requirement would increase EU production costs and this would decrease EU competitiveness on international meat and dairy markets. The impacts here would be mainly in the bovine dairy and pig sectors.

In conclusion

The analysis suggests that a clone offspring labelling obligation could have a measurable impact on important parts of the EU agri-food sector, and on related food prices faced by consumers. It would require introducing individual identification and ancestry recording for all food producing animals. The pig sector and, to a lesser extent, sheep production, would be most affected. With the approach specified the majority of costs do not vary with definition of clone offspring used or with the prevalence of clone genetics. It is instead the capability to track clone offspring that determines the cost burden. Safeguarding the claims made through system via a DNA-based verification results in substantially higher expense. The fact that many food products are made using raw material from more than one animal means that clone offspring labelling would require establishing additional supply chains, and have significant implications for production costs. Consultations suggest products derived from clone offspring would be scarce if the labelling obligation was introduced.

Résumé analytique

Introduction

Cette étude a été commandée par la Commission européenne dans le but d'examiner les implications d'un étiquetage de produits issus d'animaux descendant de clones, et d'en quantifier les coûts associés, lorsque cela est possible. L'étude analyse les répercussions d'un étiquetage des produits issus de descendants de clones.

Le rapport expose la situation actuelle dans l'Union européenne et les pays tiers quant à l'utilisation du clonage du bétail, l'enregistrement de l'ascendance du bétail, la traçabilité du bétail ainsi que le suivi du cheminement, la traçabilité et l'étiquetage des produits animaux. Les investissements et autres dépenses liées à la mise en œuvre d'un système d'étiquetage des produits issus d'animaux descendant de clones ont été identifiés, chaque fois que possible. Le rapport couvre les secteurs bovin, laitier, porcin, caprin, ovin et équin et s'intéresse aussi bien à la viande qu'aux produits laitiers. Il se concentre sur les secteurs de la viande bovine, des produits laitiers (bovins) et sur le secteur porcin, en raison de leur importance au sein du secteur du bétail de l'UE.

Les informations ont été collectées à partir d'un examen approfondi de la documentation disponible, d'une analyse des ensembles de données sectorielles en matière de productivité et d'économie, d'informations émanant de spécialistes et d'entretiens avec des intervenants experts de l'ensemble de l'UE, notamment des représentants d'entreprises et d'associations professionnelles dans les domaines suivants : génétique animale, reproduction animale, commerce d'animaux vivants et de denrées alimentaires, abattage et découpe de viande, transformation et distribution de viande et de produits laitiers. Des spécialistes universitaires et des fonctionnaires des États membres ont également été consultés. Une analyse des coûts a été menée grâce à l'approche standard de modèle de coûts précédemment utilisée pour différents exercices semblables pour la Commission.

Contexte

D'après les données disponibles, le clonage d'animaux à des fins de production alimentaire n'est pas pratiqué à ce jour dans l'UE. La seule utilisation connue des techniques de clonage pour la production de bétail dans l'UE est celle des chevaux de courses de grande valeur. Le clonage ne peut « améliorer » les facteurs génétiques : il ne fait que reproduire la génétique existante. Cela réduit l'utilité qu'en perçoit un secteur de l'élevage de l'UE qui cherche à améliorer continuellement les performances du bétail. Il est en outre communément admis que les consommateurs refuseraient d'acheter des produits étiquetés comme étant issus de clones. Aucune demande de commercialisation de denrées alimentaires issues de clones n'a été soumise au sein de l'UE. En raison de cette perception d'un consommateur réticent et de l'indifférence du secteur, une croissance notable de l'utilisation de cette technique dans l'UE n'est pas attendue au cours des cinq ou dix années à venir. Il y a cependant une possibilité pour que les aliments issus d'une progéniture de clones soient offerts aux consommateurs en raison des importations de viande et de produits laitiers en provenance des pays tiers, des importations d'animaux vivants et des importations de matériels génétiques utilisés pour la reproduction des animaux dans l'UE.

Les considérations sur le bien-être des animaux et les préoccupations d'éthiques générales ont donné lieu à des appels pour que de l'Union instaure des règles pour restreindre l'utilisation du clonage à des fins agricoles et d'interdire la commercialisation de denrées alimentaires provenant de clones. La Commission européenne a ainsi présenté deux propositions de directives.⁴

⁴ http://ec.europa.eu/food/animals/welfare/other_aspects/cloning/index_en.htm

Les principaux éléments d'un système à même de permettre l'étiquetage des produits alimentaires issus d'animaux descendant de clones sont les suivants :

- **Enregistrement de l'ascendance au cours de l'élevage du bétail :** l'enregistrement et la vérification des ascendants des animaux dans une base de données où les animaux clonés sont identifiés ;
- **Identification individuelle des animaux :** assigner une identité à chaque animal pris séparément.
- **Transfert de l'information du statut de clone à travers la chaîne d'approvisionnement :** d'une telle façon que l'information sur le statut de descendant de clone des animaux peut circuler dans la chaîne de production et figurer en dernier lieu sur l'étiquette.
- Un **mécanisme de vérification** permettant de s'assurer du statut de clone de chaque animal, par exemple un registre contenant les échantillons d'ADN ou les résultats de test de caractérisation ADN.

Les propositions du Parlement européen⁵ pour un étiquetage obligatoire des aliments issus de la progéniture d'animaux clonés n'a pas fourni de définition opératoire de « progéniture de clone », à savoir combien de générations seront couvertes. La définition de progéniture de clone adoptée devrait cependant influencer le nombre d'animaux qui seront classifiés en tant que progéniture de clone, et influencer sur le coût d'une obligation de traçabilité et d'étiquetage de ces animaux.

Situation actuelle

Les conséquences et les coûts associés à une obligation d'étiquetage de la progéniture de clones découlent de l'écart entre ce qui serait nécessaire au respect d'une telle obligation d'une part, et les pratiques actuelles d'autre part. La situation actuelle est expliquée ci-dessous :

Le secteur de l'élevage commercial

Il existe d'importantes différences structurelles dans le secteur de l'élevage commercial selon les espèces, en termes d'écart entre les animaux de reproduction d'élite et la production animale (viande ou lait), et d'utilisation de technologies d'élevage telle que l'insémination artificielle (IA).

On observe aussi des différences dans le nombre d'animaux pouvant être produits chaque année par les femelles. Lorsque l'IA est utilisée (notamment dans les secteurs porcins et des vaches laitières), il existe un fort potentiel pour qu'un nombre réduit de clones engendre un grand nombre de descendants. Il en résulte qu'indépendamment de la définition de progéniture de clone, le nombre d'animaux qui seraient classés comme tels (et la quantité de produits dérivés dans la chaîne alimentaire) serait hautement variable d'une espèce à l'autre.

Étendue de l'enregistrement d'ascendance des animaux

Il n'existe pas de système obligatoire pour l'enregistrement de l'ascendance dans l'UE. Des systèmes d'enregistrement des pedigrees sont utilisés par les organisations d'élevage afin d'obtenir des informations de filiation — inscrites dans des livres généalogiques sur base du volontariat — pour les animaux de reproduction. Il existe de nettes différences à travers l'UE et entre les espèces, en ce qui concerne la proportion d'animaux pour lesquels l'information relative à l'ascendance est sauvegardée.

Il est estimé que dans l'ensemble de l'UE, l'enregistrement de l'ascendance a lieu, au

⁵ Par exemple : la proposition de résolution déposée conformément à l'article 120 du règlement sur le clonage d'animaux à des fins de production alimentaire. B7-0000/2013. 11/12/2013.

moins pour le père et la mère, à hauteur de : 47 % pour l'ensemble du bétail ; 10 % des porcs ; 5-10 % des chèvres et moutons ; et autour de 75 % des chevaux.

La législation de l'UE exige que les informations sur le père et la mère soient enregistrées pour les chevaux identifiés individuellement (environ 75 % de l'ensemble de la population équine), et que la mère soit enregistrée pour tous les bovins. Il faudrait, afin d'autoriser l'étiquetage des produits alimentaires issus d'animaux descendant de clones, étendre l'enregistrement des informations sur l'ascendance à tous les animaux. Le nombre de générations que le système d'enregistrement devrait contenir serait déterminé par la définition de progéniture de clone retenue.

Identification individuelle des animaux

Chaque animal devra être relié aux informations sur son ascendance, et cette information devra circuler le long de la chaîne d'approvisionnement alimentaire.

Tous les bovins sont actuellement identifiés séparément dans l'UE, tout au long de leur vie, et le bétail importé est également identifié individuellement à partir du moment de son entrée dans l'UE. Cependant, dans le secteur porcin, l'identification est effectuée par lots, et seuls les porcs reproducteurs (15-20 % du total) sont identifiés individuellement. Environ deux tiers des moutons, jusqu'à 80 % des chèvres et jusqu'à 75 % des chevaux sont identifiés individuellement.

Il n'existe aucune obligation d'enregistrement d'informations individuelles pour les porcs, les moutons et les chèvres. L'enregistrement de l'ascendance et l'identification individuelle des animaux, nécessaires à l'avènement d'un système d'étiquetage, ne sont ainsi disponibles que pour 75 % de la population équine de l'UE, et n'existent pour aucune autre espèce.

Traçabilité des produits animaux de chaque animal

La législation alimentaire générale⁶ impose aux entreprises du secteur alimentaire de fournir les informations identifiant le lot ou l'expédition. Ces informations doivent figurer en amont et en aval de chaque étape de la chaîne d'approvisionnement.

Cela ne permet pas la traçabilité d'un animal pris isolément. Ce lien est rompu bien avant que le produit atteigne le consommateur. Dans le secteur laitier, le lien avec l'animal est rompu immédiatement après la traite de lait, puisque le lait provenant de plusieurs animaux et mélangé dans l'exploitation. Dans la filière de la viande, ce lien peut être rompu avant l'abattage lorsque les animaux ne sont pas identifiés individuellement (les porcs, et la plupart des moutons et des chèvres) ou au moment et immédiatement après l'abattage lorsque les carcasses sont découpées en morceaux et mélangés dans des lots de produits (toutes espèces). Si l'identité est dans un premier temps sauvegardée, elle sera ensuite perdue par exemple lors de la transformation en viande hachée et en préparations/produits à base de viande.

Relier les produits animaux aux individus dont ils sont issus demanderait par conséquent un renforcement des systèmes. L'alternative, dans le cas d'une obligation d'étiquetage des produits issus de descendants de clone, consiste à séparer la progéniture des clones et ses produits dérivés du reste de la chaîne d'approvisionnement.

Prescriptions actuelles en matière d'étiquetage

L'un des principes généraux de la législation alimentaire de l'UE stipule que les informations fournies aux consommateurs doivent permettre à ceux-ci de choisir en connaissance de cause, sans prêter à confusion. L'UE a des exigences pour l'étiquetage détaillé des aliments mais aucune exigence concernant les liens entre la

⁶ Règlement (CE) n° 178/2002 du Parlement européen et du Conseil du 28 janvier 2002 établissant les principes généraux et les prescriptions générales de la législation alimentaire, instituant l'Autorité européenne de sécurité des aliments et fixant des procédures relatives à la sécurité des denrées alimentaires.

viande et les produits d'élevage et sur l'ascendance des animaux individuels. Cela signifie que les prescriptions actuelles en matière d'étiquetage ne mettent pas en place un cadre qui pourrait être utilisé pour faciliter l'étiquetage de la viande issue de la progéniture des clones.

Implications pour la production et l'élevage du bétail

L'introduction d'un étiquetage permettant d'identifier les produits provenant de descendants de clones demanderait un enregistrement généralisé de l'ascendance — sur plusieurs générations, et conforme à la définition opératoire de « progéniture de clone » — ainsi que l'identification de tous les animaux. Les mêmes informations devraient alors être connues pour le matériel d'élevage, les animaux et les produits issus du bétail qui sont importés depuis des pays tiers. Les systèmes actuels ne le permettent pas : une telle capacité serait par conséquent à développer.

Les implications varient d'une espèce à l'autre et selon les États membres. Ainsi, dans le secteur des vaches laitières, les animaux sont d'ores et déjà identifiés individuellement et l'enregistrement de la mère est requis ; un enregistrement de l'ascendance plus approfondi est assez fréquent. Cependant, dans le secteur porcin, la plupart des animaux ne sont à ce jour pas identifiés individuellement, et l'enregistrement de l'ascendance pour les animaux de rente est peu fréquent.

Enregistrement de l'ascendance des animaux et systèmes d'enregistrement de l'identité

Des investissements seraient nécessaires en bases de données ainsi qu'en infrastructures de communications et services liés pour l'enregistrement de l'identité et de l'ascendance. Des systèmes pour les porcs, les moutons et les chèvres nécessiteraient un important développement supplémentaire afin de permettre l'enregistrement de l'identité et l'extension de l'enregistrement de l'ascendance à l'ensemble des animaux, au-delà de l'utilisation existante de livres généalogiques. Les systèmes de suivi des mouvements d'animaux au fil de la chaîne d'approvisionnement demanderaient à être renforcés, et imposeraient des investissements. Un registre unique, intégré au registre d'identité, devrait être mis en place pour chaque espèce et pour chaque État membre ; ces registres seraient alors regroupés à l'échelle de l'UE.

Les données disponibles portent à croire qu'une telle croissance des systèmes d'ascendance et d'identité, à même de répondre aux besoins d'un étiquetage des animaux descendant de clones, déclencherait une hausse des dépenses se chiffrant en dizaines de millions d'euros pour l'ensemble de l'UE-28, voire en centaines de millions d'euros. Ces systèmes supposeraient de la maintenance et de l'administration.

Obligations et coûts supplémentaires imposés aux producteurs et vendeurs de bétail

Familiarisation avec les obligations. Les producteurs, marchés et centres de rassemblement du bétail, ainsi que les abattoirs, auraient à engager des frais pour comprendre puis se préparer à agir en conformité avec la législation relative à l'étiquetage des produits issus d'animaux descendant de clones. Les entreprises des secteurs pour lesquels une identification individuelle des animaux et un enregistrement de l'ascendance sont fréquents (par ex. élevages de troupeaux de vaches laitières de race) ne seraient que faiblement touchées. À l'inverse, les grandes exploitations de producteurs porcins feraient face à des changements drastiques. Le coût global pour le secteur du bétail de l'UE dépasserait 363 millions d'euros de coût ponctuel. Les exportateurs vers l'UE et les importateurs de l'UE de matériel génétique dépenseraient également pour se familiariser.

Marquage. Il conviendrait de marquer les animaux au moyen d'une étiquette électronique d'oreille, pour permettre un traitement plus rapide et une réduction du taux d'erreurs au cours de la collecte de données, notamment lors de l'abattage. Cela coûterait autour de 504 millions d'euros par an pour l'ensemble du secteur du bétail de l'UE, ce qui comprend les dépenses liées au remplacement des étiquettes, en

supposant un taux de perte de 3 %. Non loin de 92,5 % de ce montant échoirait au secteur porcin, 6,5 % au secteur ovin et le reste dans le secteur caprin.

Coût de l'enregistrement de l'identité et de l'ascendance. L'obligation n'imposerait des mesures supplémentaires que là où les animaux n'ont à ce jour pas d'identité ou d'ascendance enregistrée. Nous supposons que ces deux activités pourraient avoir lieu simultanément. Le coût total pour le secteur du bétail de l'UE s'élèverait à près de 317 millions d'euros par an, dont 84 % reviendraient au secteur porcin, 11 % au secteur ovin et 5 % aux autres secteurs de l'élevage.

Enregistrement des mouvements. Les mouvements d'animaux devront être consignés pour chaque animal. Pour la plupart des porcs et des moutons, l'enregistrement se fait actuellement par lot plutôt que par individu. L'impact net sur les coûts n'est pas facile à déterminer. Utilisation de l'identification électronique pour tous les animaux sera plus chère mais facilitera les économies (par rapport à une lecture manuelle des marquages), en particulier sur les marchés et les abattoirs.

Modification des pratiques de production et d'élevage existantes, et des systèmes qui les soutiennent

La mise en œuvre d'une identification individuelle et d'un enregistrement de l'ascendance entraînerait de plus profondes modifications des pratiques dans certains domaines du secteur du bétail. Dans la production intensive de porcs, il est fréquent que le sperme de trois à dix verrats soit mélangé pour servir à une IA afin d'améliorer le taux de mise bas, ce qui empêche toute identification du père. Dans les systèmes d'élevage extensifs, il est impossible de déterminer une paternité en présence de plus d'un mâle, et il peut aussi être difficile d'attribuer un petit à une mère sans risque d'erreur.

Rôle potentiel des prélèvements d'ADN, des tests et de l'enregistrement des profils génétiques

Un système d'étiquetage pourrait être mis en place par le seul usage de systèmes documentés, mais il serait plus vulnérable aux fraudes en raison de l'absence de moyens de vérification des déclarations. Un test ADN ne permettrait pas à lui seul de distinguer un descendant cloné d'un descendant naturel du même parent. L'association d'enregistrements ADN et d'enregistrements documentés autoriserait un régime de contrôle autrement plus performant, même si les défis pratiques à relever pour la construction d'un tel système sont de taille.

Prélever et stocker un échantillon d'ADN pour chaque animal constituerait une nouvelle activité. Les épreuves sur les échantillons, la gestion de l'archivage des tests et leur stockage signifieraient également une activité et des dépenses supplémentaires. Pour l'ensemble du secteur du bétail de l'UE, ces coûts s'élèveraient à plus de 9 milliards d'euros par an, dont 77 % reviendraient au secteur porcin, 13 % au secteur ovin, 8 % aux secteurs de la viande bovine et des produits laitiers, et 2 % aux autres secteurs d'élevage. D'importants investissements en infrastructures et en capacités seraient nécessaires pour fournir et soutenir les services requis.

Impacts sur les pays tiers fournissant des animaux et du matériel génétique

L'introduction d'un système d'étiquetage entraînerait des coûts directs et indirects pour les secteurs du bétail de pays tiers exportant du matériel génétique et des animaux vivants vers l'UE. La définition de « progéniture de clone » retenue est ici particulièrement importante.

Impacts directs. Si la « progéniture de clone » est définie de façon à n'inclure que la première génération de descendants d'un clone, les éleveurs de pays tiers auront seulement besoin de déterminer si le matériel génétique exporté vers l'UE provenait d'un clone ou non. Les animaux vivants exportés vers l'UE pourraient être signalés en tant que descendants de clone. Si la définition de la progéniture de clone était étendue à une deuxième génération de descendants (ou plus), il deviendrait beaucoup plus

difficile pour un éleveur d'un pays tiers d'être certain du statut de clone de l'animal donneur (pour du matériel génétique) ou de l'animal vivant. Les éleveurs devraient alors mettre en place des systèmes supplémentaires pour vérifier et garantir le statut du matériel génétique qu'ils utilisent dans leurs programmes de reproduction. Les dépenses supplémentaires seraient particulièrement importantes au Canada et aux États-Unis ; la Nouvelle-Zélande et l'Australie seraient également touchées. En cas d'obligation de mécanismes de vérification utilisant l'ADN, les impacts seraient considérables.

Impacts indirects. Si les exportateurs se montraient réticents ou incapables de respecter les exigences de l'UE, alors celle-ci pourrait perdre l'accès au matériel génétique de haute qualité qu'elle importe actuellement. Dans le cas où une définition multi-générationnelle de la « progéniture de clone » était retenue, et qu'une part importante du matériel génétique des pays tiers se voyait par conséquent classée comme telle, les importateurs de l'UE pourraient cesser d'utiliser du matériel génétique importé.

Conclusions sur l'incidence sur le secteur de l'élevage et du bétail de l'UE

D'après l'analyse effectuée, une obligation d'étiquetage des descendants de clones entraînerait des coûts de fonctionnement supplémentaires de l'ordre de 800 millions d'euros par an si cela s'accompagnait d'un système de vérification de l'ADN, et de près d'un milliard d'euros par an en l'absence d'un tel système. De tels montants suffisent pour suggérer que cela aurait une incidence sur les revenus et les niveaux de rendement des producteurs de bétail dans l'UE. Ces coûts seraient engagés même en l'absence de descendants de clones dans le secteur du bétail, et quelle que soit la définition de progéniture de clone adoptée. La plus grande partie des 10 milliards d'euros de dépenses annuelles reviendrait au secteur porcin (78 %), 13 % au secteur ovin et 6 % au secteur bovin et le reste aux secteurs caprin et équin.

L'étiquetage imposerait par ailleurs de favoriser les investissements en infrastructures d'informations à même de transmettre des informations relatives à la progéniture de clones tout au long de la chaîne d'approvisionnement, et à travers l'Europe, mais aussi de relier l'identité à l'ascendance, et d'adapter le commerce au sein de l'UE et avec les pays tiers. Une vérification à partir d'ADN impliquerait de substantiels investissements supplémentaires.

Implications pour les chaînes d'approvisionnement alimentaires

Modifications des systèmes de traçabilité et des chaînes d'approvisionnement des produits animaux

Il faut, si l'on veut que l'information liée au statut d'une ascendance clone pour des animaux (pris de façon individuelle) circule jusqu'à figurer sur l'étiquette des denrées alimentaires issues de ces animaux, que soient mis en place des systèmes internes adéquats de traçabilité et de documentation au niveau des opérations intermédiaires de manipulation de la viande, par exemple dans les abattoirs et les usines de découpe et de transformation. Dans l'UE, les exigences en matière de traçabilité ne vont généralement pas jusqu'à relier un animal donné aux produits alimentaires qui en sont issus au-delà du niveau de la carcasse. Il n'existe pas par la suite de transmission des informations couplant un animal et ses produits. Le lien avec l'animal est rompu lors de l'abattage, et même dès le niveau de la ferme pour le lait.

Production de viande. Les informations relatives à l'identité et au statut de progéniture de clone devraient circuler depuis l'animal abattu jusqu'aux denrées alimentaires issues de cet animal. Il faudrait dès lors que ces informations soient *relayées* à travers la chaîne d'approvisionnement afin de faciliter le bon étiquetage du produit pour le consommateur final. Si l'abattoir était en mesure de conserver l'identité de l'animal au cours du processus d'abattage et jusqu'aux pièces entières de viande, il serait alors possible que l'abattoir notifie à l'étape suivante de la chaîne d'approvisionnement le statut de clone ou non de ces pièces. Un tel maintien de l'identité jusqu'à la découpe

s'avèrerait impossible pour la viande hachée ou d'autres produits impliquant le mélange de matières premières provenant de plus d'un animal. Pour de tels produits, une traçabilité par lot s'imposerait afin de séparer les deux catégories de viande dans la chaîne d'approvisionnement, si ces produits devaient être amenés à porter des étiquettes établissant une distinction fiable entre ceux issus d'une progéniture de clone, et ceux ne l'étant pas.

Production laitière. Le mélange de lait à la ferme exclut tout liens avec les animaux pris individuellement. D'autres mélanges ont lieu dans les citernes, puis à nouveau à l'usine laitière, ce qui empêche jusqu'à l'identification des exploitations d'origine. Le fait de mélanger écarte de même l'éventuelle utilisation de test ADN pour déterminer quel animal a produit un lait particulier et ses dérivés. La seule manière de relier le lait à un animal donné serait de cesser de mélanger le lait provenant de différents animaux. Cela ne serait néanmoins pas viable d'un point de vue commercial, et la chaîne moderne d'approvisionnement en lait ne serait plus possible. Le seul moyen d'identifier du lait issu de progénitures de clone consisterait à utiliser un système d'identification par lot au sein de chaînes d'approvisionnement séparées. Cela ajouterait en complexité et entraînerait des coûts considérables pour la gestion de la chaîne d'approvisionnement en produits laitiers.

Modifications de l'étiquetage

Dans le cas d'une politique d'étiquetage négatif, tous les produits animaux devraient comporter l'indication du statut de clone de l'animal dont ils sont issus. Cela entraînerait des coûts liés à l'adaptation de l'étiquette, indépendamment de la définition de progéniture de clone retenue, et quel que soit le degré de présence de descendants de clones dans la chaîne alimentaire. La documentation indique que les coûts de la conception et de l'impression d'un nouveau type d'étiquette seraient mineurs, en comparaison des autres dépenses induites par l'obligation. Cependant, on peut estimer qu'étiqueter des produits d'une espèce animale donnée comme n'étant pas issus de la progéniture de clone pourrait induire les consommateurs en erreur, dans le cas où il n'existait pas d'utilisation connue du clonage dans la chaîne d'approvisionnement alimentaire de cette espèce.

Incidence de l'obligation d'étiquetage de la progéniture de clones sur la chaîne d'approvisionnement

Une obligation d'étiquetage conduirait certainement à l'exclusion des clones (et de leur progéniture) de la chaîne alimentaire de l'UE, puisque l'on considère que les consommateurs sont réticents à l'idée d'acheter des produits issus de descendants de clones, et que la chaîne d'approvisionnement alimentaire ne souhaite pas offrir de tels produits. S'il n'existe aucune valeur ajoutée pour le consommateur, il est peu probable que les produits issus de clones affichent des prix plus élevés, ce qui serait nécessaire pour compenser les coûts supplémentaires associés à la séparation de cette filière. Il est tout aussi peu probable que ces produits attirent les investissements. Néanmoins, même en l'absence de produits issus de descendants de clones, le secteur du bétail de l'UE, le secteur de transformation et de fabrication des produits alimentaires de l'UE, les partenaires commerciaux ainsi que les secteurs des services alimentaires et de la distribution alimentaire dans l'UE devraient tout de même assumer les dépenses associées au fait de fournir des informations sur l'ascendance, de les transmettre le long de la chaîne d'approvisionnement, et de respecter les exigences en matière d'étiquetage. Une partie de ces dépenses retomberait sur le consommateur.

Implications pour le commerce des denrées alimentaires

Importations. Les exploitants des pays qui exportent vers l'UE seront contraints à agir conformément aux dispositions d'étiquetage, ce qui entraînera des coûts supplémentaires. L'importance de cet impact dépendra de la définition de progéniture de clone retenue. Une définition incluant une seconde génération (et les suivantes) entraînera des coûts supérieurs à une définition se limitant à la première génération.

Les pays tiers devront adapter leurs systèmes de production alimentaire dans toutes les composantes présentées dans cette étude. Les facteurs inconnus sont trop nombreux, les partenaires commerciaux trop divers, et les espèces trop différentes pour qu'il soit envisageable d'estimer les dépenses supplémentaires associées à une telle adaptation. Ces coûts seraient de toute façon considérables. Toutes les importations de viande et de produits laitiers devraient comporter des informations relatives à leur statut de progéniture de clone. Les incidences sur les importations seraient probablement plus fortes pour la viande bovine (Brésil, Argentine et Uruguay, Australie et États-Unis, en somme tous les pays dans lesquels on sait que la technique de clonage est utilisée dans l'élevage). Le commerce de la viande ovine serait également touché (Nouvelle-Zélande et Australie).

Exportations. Une obligation d'étiquetage augmenterait les coûts de production de l'UE, ce qui affaiblirait sa compétitivité sur les marchés mondiaux de la viande et des produits laitiers. Les effets se ressentiraient ici principalement dans le secteur de la vache laitière et dans le secteur porcin.

En conclusion

L'analyse suggère que l'obligation d'étiquetage de la progéniture d'animaux clonée pourrait avoir un impact considérable sur des parties importantes du secteur agro-alimentaire de l'UE, et sur les prix alimentaires pour les consommateurs. Cela nécessiterait d'introduire un système d'enregistrement pour les identifications individuelles et les ascendances pour tous les animaux producteurs de denrées alimentaires. Le secteur porcin et, dans une moindre mesure, la production ovine, seraient les plus concernés par cette mesure. Selon cette approche, la majorité des coûts ne varient pas en fonction de la définition de la progéniture de clone utilisée ou en fonction la prévalence des clones génétiques mais varient en fonction des capacités à traquer la progéniture clonée. Préserver les allégations formulées par le système qui utilise une base de vérification des ADN est plus coûteux. Le fait que de nombreux produits alimentaires sont fabriqués à partir de matières premières de plusieurs animaux signifie que l'étiquetage de la progéniture de clone devrait établir des chaînes d'approvisionnement supplémentaires, et aurait des implications importantes pour les coûts de production. Les consultations suggèrent que les produits issus d'animaux descendant de clones seraient moindres si l'obligation d'étiquetage était introduite.

1 Introduction

Section summary:

The purpose of this study is to provide evidence to inform decisions on the regulation of animal cloning in the food chain in the European Union. Its specific objective is to research and document the implications of requiring the labelling of food derived from clone offspring within the European Union (EU), including the impacts on trade.

This study was commissioned to examine the implications of labelling products derived from clones and, where possible, quantify the associated costs. It considers the implications of a negative labelling system in which products carry a label indicating to the consumer whether or not they are 'clone-free'. It shows that such a label requires a pedigree recording, documentation and traceability system to be in place.

This report describes the current situation in the EU and third countries with respect to the use of livestock cloning, the recording of livestock ancestry, the tracing of livestock and the tracking tracing and labelling of animal products. The investments and other costs associated with implementing a labelling system for products derived from clone offspring are identified where possible.

In this study the implications of a labelling requirement have been explored by reference to bovine, porcine, ovine, caprine and equine animals and a number of specific food products. The main focus was on bovine and porcine animals because of their importance to the EU meat supply chain. Both meat and dairy production have been considered; particular attention was given to the dairy supply chain for bovine animals.

This is the final report. It has been prepared by a team led by ICF International. ICF was supported by Agra CEAS Consulting, Areté Consulting and experts from Wageningen University.

2 Method

Section summary:

The study results are based on desk research, a literature review, interviews, case studies and a cost analysis. The study is informed by targeted consultations with academic experts, animal breeders, Member State government officials, representatives of genetic improvement companies, commercial farmers, traders, representatives of slaughterhouses and cutting plants, processors, manufacturers and retailers.

2.1 Introduction

This section explains the study method adopted and how it was designed to respond to the particular challenges posed by the subject matter and context. Information was gathered from peer-reviewed literature, sectoral productivity and economic data sets, expert information, policy and sector-based documents, previous studies, grey literature, and interviews with expert stakeholders across the EU.

2.2 Literature review

Inclusion criteria that determined what publications were considered in the literature review were defined as follows:

- The source must have been published within the past 10 years (i.e. since 2004). The cut-off point was selected to take account of the introduction of 'one step forward, one step back' traceability in the food chain under Article 18 of Regulation (EC) No 178/2002 which was adopted in 2004 (and which came into force on 1st

January 2006). A small number of older studies were considered in special cases where more recent materials were not available. These were restricted to studies cited in recent publications and pertaining to issues for which information has not varied significantly over time.

- Eligible sources were peer reviewed journal articles, non-peer reviewed academic and government commissioned research, evaluations and grey literature.
- The review started with publications listed in the study terms of reference. Publications cited in these studies were also identified using a backward citation search. Additional literature was found using Google search, government and institutional websites and journal databases⁷. Documents were checked (where possible) against other sources to help assess the strength of the evidence, and ensure more robust sources were prioritised over weaker ones. Where materials related to the same issue, those with more recent information were prioritised. The literature review was updated throughout the study.

2.3 Interviews

The research team completed a large number of semi-structured interviews with stakeholders at EU and Member State level. Interviews were completed with representatives of individual companies and business associations in the following areas: animal genetics, animal breeding, trade in live animals and food products, animal slaughtering and meat cutting, meat and dairy processing and retailing. Academic experts and Member State officials were also consulted. A 'snowballing' technique was adopted to the interview programme to ensure that inputs were captured from the consultees with the most relevant knowledge for the study, rather than trying to anticipate in advance all possible consultees.

The subject matter created practical challenges for the research: stakeholders were often reluctant to provide information on the functioning of the supply chain because of the context in which the questions were being asked. The lack of animal cloning activity in the EU livestock sector, and lack of stakeholder enthusiasm for cloning, meant that it was necessary to construct scenarios and develop assumptions for a hypothetical market in which clone-derived products were marketed, and a labelling system was introduced to distinguish products derived from clone offspring. Consultees often struggled to see these scenarios as plausible.

The implications of the proposed traceability and labelling requirement have been explored by reference to the operation of specific supply chains. The case study research has been used to examine how those supply chains would need to be adapted to facilitate traceability of clone offspring and the communication of this information to consumers. The case studies were developed using the literature review and semi-structured interviews with companies and business associations active at different stages of the supply chain, Member State Competent Authorities and academic experts.

2.4 Cost analysis

The cost analysis has been carried out using the 'standard cost model' approach, i.e. cost elements have been identified and the unit cost multiplied by the number of times the cost will be incurred (number of animals, number of interventions required, etc.). This process involved the following steps:

- Elaboration of the stages in the supply chain from livestock breeding to final product;
- Identification of the points at which information is required and/or would need to be transmitted;

⁷ EBSCO, Science Direct and Sage Journals

-
- Assessment of current information availability and transmission;
 - Identification of gaps and points at which changes would be required;
 - Identification of the changes that would be required;
 - Estimation of the costs of enacting these changes.

The cost analysis made reference to data gathered during this study (e.g. on prices of electronic identifiers, on costs of database development), on official and third party data (e.g. Eurostat data on number of holdings, animal production; Member State data on number of animal movements; breeding association data on herdbook usage) and on other research (from academic journals, previous studies for the Commission and Member State governments, grey literature).

Prices for inputs (e.g. ear tags) vary within the EU market, by volume purchased, retailers, product specification etc. There is also significant variation in the estimates of time taken to perform particular tasks – by species and by scale of enterprise (e.g. very large slaughterhouse vs small slaughterhouse), and level of prior investment in technology. Economies of scale (e.g. in reading animal electronic identifiers) can be very significant. Input cost and time figures used here have been sense-checked against previous studies by JRC and other studies published by the European Commission, Member State governments and governments elsewhere (e.g. Australia).

There are well-known methodological challenges in determining the effective labour costs in agriculture relating to factors that include prevalence of self-employment and fragmentation of official data. Agriculture is not, as a consequence, included in the labour cost survey carried out by the European Commission every four years. Previous impact assessment studies have made reference to alternative (often rather old) data sets or made simplifying assumptions. This study made reference to recent research conducted for the European Parliament (European Parliament, 2015). General labour cost rates vary very significantly across the EU, creating additional issues when conducting EU-level analysis. A weighted average cost has been calculated for each livestock sector. No differentiation has been made between farm owner/manager inputs and agricultural labour inputs.

Given the above, the estimates provided here must be considered indicative of the order of costs rather than definitive. They provide information about the likely scale and distribution of cost impacts of a clone offspring labelling obligation but should not be taken as definitive or quoted without reference to the caveats provided.

3 Context

Section summary:

The core capabilities required of a clone offspring labelling system are: **ancestry recording** - the recording and verification of the ancestry of animals in a database where clone animals are identified; **individual identification** - assigning an identity to each individual animal; **information on clone status passed forward through the supply chain** such that it can ultimately be presented on labels to indicate to the consumer the presence of meat or dairy products derived from clone offspring; a **verification** mechanism to allow verification of the clone status of each animal. This could potentially be provided by a register holding a DNA sample or DNA profile for each animal.

The European Parliament proposals for mandatory labelling for food derived from the offspring of cloned animals did not define how many generations of descendants of a clone this requirement would apply to. The number of descendants of a given animal increases across the generations. If that animal is a clone then a wider definition results in more animals being categorised as clone offspring. Where cloning is used, this affects the share of production that would have to be labelled as derived from clone offspring, and what would need to be managed in segregated systems.

If food products not derived from clone offspring are to be labelled as such then every animal would need to have an individual identity assigned and its ancestry recorded so that its heritage could be established and derived products labelled accordingly. This applies under any definition of clone offspring. If there are clones in the system, the definition adopted does affect the number of animals defined as clone offspring. This requirement reaches out into any country that exports relevant products to the EU.

The breeding sector works to produce continual improvements but cloning can only ever reproduce existing animal genetics. The fact that the technique cannot move the performance frontier forward reduces its appeal to breeders. Cloning is not currently employed in the breeding sector for bovine, porcine, ovine or caprine animals in the EU. There are no known clones in the EU and very few offspring in the supply chain (possibly none for some livestock species). Use of the technique is not expected to increase in the near term, in part because there is a widespread belief in the EU food sector that consumers would be unwilling to purchase products labelled as having clone heritage. Firms have shown little interest in bringing such products to the market.

Cloning is used to a limited extent in some areas of livestock production in the USA and Canada. The EU imports reproductive materials from these countries; this trade could therefore result in clone offspring appearing in the EU food chain. Cloning in third countries, and trade in reproductive materials and live animals between them, could also result in meat and dairy products derived from clone offspring being imported into the EU. The more generations covered by the definition of clone offspring that is adopted, the more likely this becomes.

The production of meat and dairy products is an important part of the EU's agricultural economy. Bovine milk production was worth EUR 61 billion in 2014, pork EUR 34 billion, beef and veal EUR 41 billion, sheep and goat meat EUR 5.4 billion and horsemeat a little under EUR 1 billion. The EU is a net importer of beef and veal products, and of sheep and goat meat. It is a net exporter of pork and of dairy products. The main sources of imported beef and veal products are Brazil, Argentina and Uruguay. Ninety-five per cent of sheep and goat meat imports come from Australia and New Zealand.

3.1 Introduction

This section considers four issues that are important points of context to the analysis that follows later in the report. These are:

- The capabilities required of a system that can support the labelling of food products derived from the offspring clones and the labelling of other products as being not derived from clone offspring;
- The definition of 'clone offspring' and its implications for the labelling of food products derived from clone offspring;
- The current usage of cloning in animal breeding in the European Union and among relevant EU trading partners;
- The scale of EU production and trade in the livestock covered by this study and the food products derived from them.

3.2 The system capabilities required to support labelling

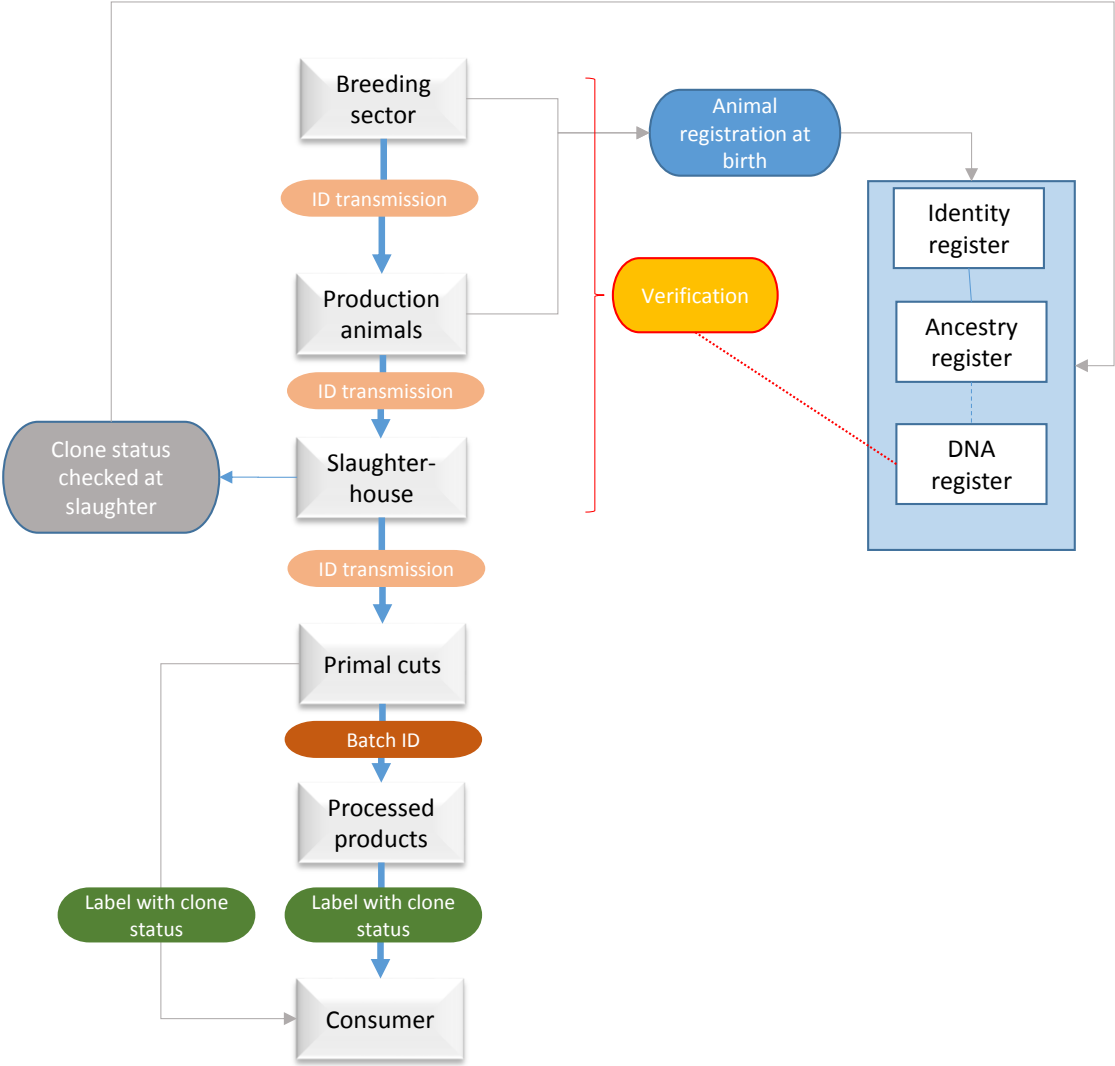
The core components of a system capable of supporting the labelling of food products derived from clone offspring are:

- **Ancestry recording in livestock breeding:** the recording and verification of the clone ancestry of animals, and clone animals being 'flagged' in a database;
- **Individual animal identification:** assigning an identity to each individual animal⁸.
- **Information on clone status passed forward through the supply chain:** so that information on the clone offspring status of animals, whether produced in the EU or in third countries, can be carried through to products and ultimately be presented on labels;
- A **verification mechanism** to allow verification of the clone status of each animal, such as a register holding a DNA sample or DNA profile test result.

Figure 1 shows a simplified schematic representation of a meat supply chain to illustrate the components and capabilities required – registration, transmission of identity information, labelling, and verification.

⁸ The study's baseline analysis assumes a mixed operating model in which offspring of clones coexist with other animals in breeding and production systems, rather than full segregation of clone offspring and 'conventional' supply chains. This drives the need for individual identification of animals.

Figure 1. Simplified representation of a meat supply chain and the components and capabilities required to supply clone offspring labelling for meat



Source: ICF International

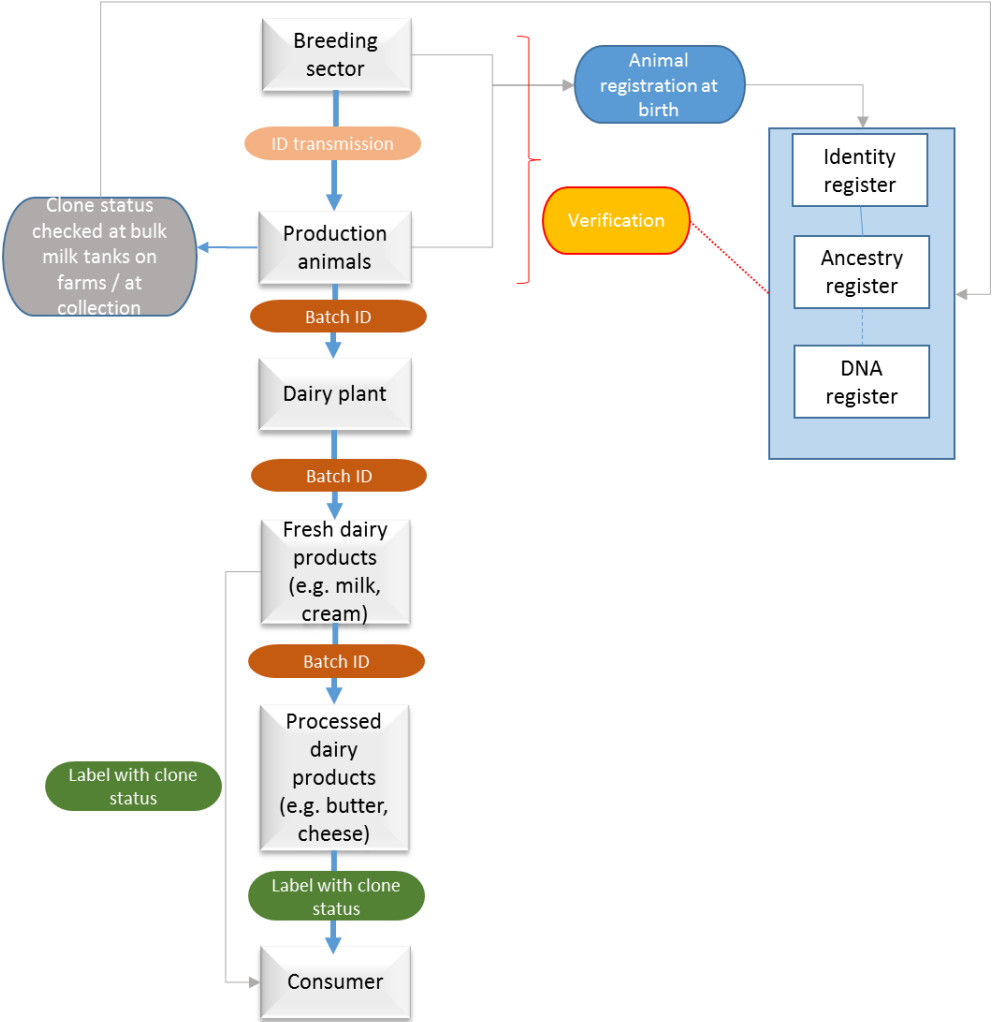
The process starts at the animal’s birth, when it would be given an identity and its ancestry recorded. The identity is passed through the supply chain. The animal’s clone status could be checked at any time, but would need to be ascertained when the animal produces food (milking or at slaughter). It may be possible to carry the identity through to primary processing. Where individual identity can no longer be retained (e.g. due to mixing of product from different animals) then segregation arrangements would be needed to keep products derived from clone offspring separate from other products.

In the case of dairy, the primary product is milk. In the milk supply chain, the milk of different animals is mixed at farm level. Milk from different farms is mixed during the process of it being collected from farms and further mixing takes place at the processing facility. Maintaining the link between individual animals and the food products they produce is technically infeasible in this sector using current dairy production methods. This segregation would therefore need to start further up the supply chain for dairy. Organic supply chains provide exemplars for this. This issue is covered in more depth later in the report. Figure 2 provides a representation of the milk supply chain.

The impacts of a clone offspring labelling obligation stem from the differences between what would be required to support such an obligation and current practice. The EU’s current systems have been assessed to determine whether they could be used as the

foundations of a system for tracking and labelling products derived from clone offspring. The chapters that follow focus on how the capabilities required could be constructed and maintained, and at what cost.

Figure 2. Simplified representation of a dairy supply chain and the components and capabilities required to supply clone offspring labelling for dairy products



Source⁹: ICF International

3.3 The impact of the definition of 'clone offspring'

The European Parliament proposals for mandatory labelling for food derived from the offspring of cloned animals¹⁰ did not provide a working definition of 'clone offspring', i.e. **how many generations of descendants of a clone fall within the scope of the**

⁹ Milk is collected together in bulk milk tanks at farm level where milk from different animals is mixed. Individual animal identity and ancestry information is lost. Milk from animals with clone ancestry can potentially be segregated into separate tanks on farm but this is unlikely to be practically feasible unless there are sufficient numbers of clone descendants. At collection, milk tankers which transport the milk to dairy processing plants, typically collect and mix milk from multiple farms. It is possible to collect clone milk separately provided there is segregation at farm level, or segregation of groups of farms with dairy animals of clone heritage (e.g. if tankers separate their collection rounds between farms with clone descendants, and those without). Clone status will therefore need to be verified earlier than in meat supply chains, at farm level, as milk from different animals would have been mixed by the time it reaches dairy processing plants.

¹⁰ e.g. Motion for a European Parliament Resolution on cloning of animals addresses labelling of food from the descendants of cloned animals. B7-0000/2013. 11/12/2013.

labelling requirement. The definition affects the complexity and cost of any system established to trace and label those animals.

Under a negative labelling regime universal registration and ancestry recording would be required under any definition of clone offspring. From a food producer's perspective any meat or dairy product might, in principle, be derived from an offspring of a clone. This means that an identification and ancestry recording infrastructure reaching all the way to animal breeders, whether in the EU or third countries, would be needed to determine the animal's status and ensure it was labelled appropriately. Information presented in section 4.2 shows how animals from the top of the 'breeding pyramid' pass into the food chain. Section 5.4 shows how registration and ancestry recording practice would need to change by comparison with current practice under a clone offspring labelling regime.

This analysis suggests that the registration and ancestry requirements of a labelling requirement are not affected by the number of generations covered by the clone offspring definition.

There is another category of impact that is affected by the scope of the definition. If there are clones in the system, the number of generations in the definition affects the number of animals defined as clone offspring. If a clone has, after three generations, thousands of offspring (e.g. because of the use of artificial insemination (AI)), then the product from these animals would all need to carry a positive label ('derived from clone offspring') and any processed products would need to be managed in a segregated environment. In a breeding pyramid where a clone has a few hundred offspring after three generations then the downstream impact is less.

Section 4.2 demonstrates the scale of this effect by illustrating the number of descendants that an animal can have under a typical breeding system for each of the species considered in this study.

3.4 The use of cloning and the market for food products derived from clone offspring

As yet, no application for the marketing of food from clones has been submitted. The research conducted for this study, and for a previous study by ICF International for the European Commission¹¹, suggests that the EU supply chain has little interest in bringing clone-derived products to the market¹². There is a widespread belief that consumers would be unwilling to purchase products labelled as being derived from clones.

Cloning techniques are not currently employed in the breeding sector for bovine, porcine, ovine or caprine animals in the EU. There are no known clones in the EU and very few offspring in the supply chain (possibly none at all for some of the species analysed).

If the Commission's proposal to ban animal cloning for food production is adopted then no animal clone should enter the food supply chain on EU territory. In these circumstances, the only way for offspring of clones to be produced is through the import from third countries of live animal clones or the import of reproductive materials from clones (or their offspring) for breeding purposes.

Cloning is used to a limited extent in some areas of livestock production in the USA and Canada. These countries are also important sources of reproductive materials used in the breeding sectors of some EU Member States/sectors. The scale of imports of reproductive materials and the ability to trace material from clones in third countries are therefore important considerations. Similarly, where animal products are imported from third countries (such as beef from Argentina or lamb from New Zealand), the frequency with which these are derived from the offspring of cloned animals and the extent to which it is

¹¹ ICF International, 2012.

¹² See also: Eurobarometer, 2008; Eurobarometer, 2010.

possible to trace these animals and their food products will have a major impact on trade if a labelling requirement is put in place.

Cloning can accelerate the transmission of genetic traits by enabling the production of a higher volume of reproductive materials of a given genotype over a given period of time. Simply stated, cloning allows for the rapid production of many animals that have the same genetic makeup. By using the technique to produce animals with high quality genetics, these qualities could be dispersed within the population of livestock animals more quickly than is possible with alternative breeding techniques.

The breeding sector is dynamic, working to produce continual improvements in performance. Cloning, however, can only ever reproduce existing animal genetics. Investment in 'copying' the animals of today is less attractive than developing the improved animals of tomorrow: by the time an animal has been cloned, genetic improvements in the sector will mean that other animals will outperform it. In countries with a good genetic base the benefit of cloning is therefore considerably less than in countries where there is scope to significantly improve the quality of the livestock genetics. These factors, together with the expense of the technique, help to explain why cloning techniques are developing comparatively slowly.

Livestock cloning technology is more advanced for the five livestock species analysed in this study than for other species. However, the current and anticipated use of the cloning technique for these five livestock species varies considerably. Table 1 summarises the current state of play of the use of the cloning technique in the EU and third countries, as well as anticipated future use.

The available evidence suggests that:

- In general, the cloning technique is used rarely across all species, both in the EU and third countries.
- Cloning requires the use of assisted reproductive techniques such as embryo transfer (ET) and AI, both in the initial cloning process and the propagation of the genetics of cloned animals.¹³
- Growth in the use of the technique in the EU is not anticipated to be significant in the next five to 10 years.
- In the EU, cloning is only undertaken for equine animals, but the focus is on obtaining high performance sport horses rather than on horsemeat production, although sport horses can enter the food chain at end of life.
- Outside the EU (e.g. in US) the technique is most commonly used in the bovine sector, but only for very high value breeding animals.
- Reproductive materials from clones have been used in the dairy breeding sector in the UK. This has resulted in a population of clone offspring estimated to be fewer than 100 bovine animals in this Member State. There are no other known populations of clone bovine offspring in the EU at present and no known clones.

¹³ The cloning process requires a genetic donor, egg donor and a surrogate mother. A nucleus from a somatic cell of the genetic donor is fused with an egg cell that has had its genetic content removed. The resulting embryo is transplanted into the surrogate mother. Cloning is typically used in livestock production to preserve and propagate the desired characteristics of elite breeding animals. Artificial insemination is important to this process as it enables the desired characteristics of elite cloned breeding animals to be transmitted faster and more widely (including between countries) to livestock populations intended for slaughter / food production than would be possible through natural service. The prevalence of AI is therefore an important consideration when assessing the prospects of clone descendants entering the production chain.

Table 1. Current and anticipated use of the cloning technique

	Current use		Anticipated use
	EU	Third countries	EU
Bovine (dairy)	Only offspring	Only breeding animals	Only offspring
Bovine (beef)	None	Uncommon	None
Porcine	None	Rare	None
Ovine	None	Very rare	None
Caprine	None	Very rare	None
Equine	Only breeding animals in the sport horse sector	Only breeding animals in the sport horse sector	Only breeding animals in the sport horse sector

Sources: European Commission (2013a); ICF (2012); expert consultation

Key: 'None' = no known use of the cloning technique for livestock production; 'Very limited' = use of the technique only in extremely rare cases; 'Only offspring' = use of the technique in the EU is currently or expected to be only for producing the offspring of clones, rather than clones themselves, and only in very rare cases.

In cases where the cloning technique is not currently used and unlikely to be used, a labelling requirement would impose additional requirements to regulate use of a technology that is not employed or likely to be so.

Bovine animals

The only known offspring of clones in the EU are a small number of dairy cows in the UK (about 100 animals out of a UK dairy cow population of almost two million animals and a total EU dairy cow population of almost 24 million animals). It may be that small numbers of clone offspring are present but undetected; there has been no requirement to identify them.

The economic incentives for use of cloning are greater for cattle than for the other species considered in this study because of the comparatively large number of offspring that can be produced from a single bull through use of AI. In the beef and dairy sectors, the elite genetics of top breeding animals can therefore be propagated more quickly into the herd than is the case for other species. It is also possible to freeze and use reproductive materials from clone bulls even when the original animals are deceased, as semen can be stored for up to 50 years (EFFAB, 2012, cited in European Commission, 2013a). This is not the case for some of the other species considered in the study, particularly pigs.

Despite these conditions, cloning is rarely used and its use is not anticipated to grow significantly in the future in the EU. The EU industry regards it as a useful technology for rapidly improving the genetic stock, but is less useful for breeding sectors at the technical frontier where improvements are sought.

There is some use of cloning to reproduce breeding animals in the bovine sector of a small number of third countries, the US, Canada, Argentina and Australia being

examples.¹⁴ Cloning for commercial livestock production¹⁵ may be taking place in other countries, such as Brazil, New Zealand, Chile, China and Uruguay, based on the presence of cattle cloning companies (ICF, 2012, cited in European Commission 2013a).

Porcine animals

There are no known populations of clone porcine offspring in the EU at present and no known clones (although there may be some unknown and unidentifiable offspring of clones).

Generation intervals¹⁶ are shorter in pig breeding than in cattle breeding so improvements can be observed more quickly (suggesting a reduction in the value of cloning). The value of a breeding pig is much lower than that of a bull and this renders cloning more expensive relative to the value of the animal. Pig semen does not freeze well and this further reduces the utility of technique since being able to freeze cloned semen improves the return on the investment. Freezing extends the time available to use the reproductive material and enables transport of the materials over longer distances and so to more markets.

The small amount of cloning of pigs that occurs outside the EU happens mostly in the US (European Commission, 2013a; ICF, 2012). It is possible that there is some cloning of pigs in China based on the presence of pig cloning companies in the country (ICF, 2012).

Ovine and caprine animals

There are no known instances of cloning technology being used for ovine or caprine livestock breeding purposes in the EU and no such use is anticipated. The demand for the use of cloning in the EU ovine and caprine sectors is minimal because of the limited use of AI in the breeding sector. The cost of the technique is high relative to the value of breeding animals and, since the AI process is more difficult for these animals, the genetics of cloned animals cannot be disseminated as easily. Cloning in the ovine and caprine breeding sectors is therefore less efficient and profitable.

A survey undertaken by the European Commission of third country Competent Authorities in 2012 and consultations with industry stakeholders carried out by the European Commission indicated that cloning of ovine animals outside the EU is very rare (reported in European Commission, 2013b). Some cloning of these animals is on-going in the US, but at very small scale (ICF, 2012).

Equine animals

Cloning is used to reproduce sport horses. Compared to other species, the value of an individual horse can be extremely high. Most male horses are castrated as foals, before they can show their performance as sport horses. This makes cloning attractive because it allows the creation of a fertile genetic copy of an infertile animal with a high breeding value. The same principle applies to high performing mares at the end of a sport career when it is too late for the animal to be used for breeding. There are no economic incentives for cloning horses used in food production, but offspring of clones and their descendants could enter the food supply chain from the sports horse market.

Cloning of horses is being undertaken in France and was practised in Italy but is not known to be undertaken in any other Member States (ICF, 2012). It happens in North

¹⁴ DG SANTE, European Commission, survey to Member States and third countries regarding cloning activity, 2012.

¹⁵ As distinct from cloning conducted for scientific research purposes. References to cloning activity in the remainder of this chapter refer to cloning in the commercial livestock production supply chain.

¹⁶ A generation interval is the average age of parents when their offspring are born. The generation interval 'regulates the speed with which selected animals contribute their better genes to the flock or herd, via their offspring' (Simm, 1998: 79).

and South America as well as South Korea. At least one company is importing cloned horses into the EU. These horses are born in the US and imported as foals.

In the future, cloned horses may also enter the EU from South America (ICF, 2012). Use of the cloning technique is likely to remain of interest to breeders of very high value animals.

3.5 The economic significance of the livestock sector

This study focuses on the supply chains for meat and meat products, and milk and dairy products from five animal species: bovine, porcine, ovine, caprine and equine animals, with particular emphasis on the bovine and porcine sectors. This sub-section explains the value and volume of domestic production of food products from these species, and the relative importance of their products for EU international trade.

3.5.1 EU domestic production

Bovine meat and dairy products and porcine meat products are significant contributors to agricultural output and incomes in the EU, both in quantity and value. The EU produced an estimated 7.7 million tonnes of beef and veal in 2014. This represented 17 per cent of total meat output (European Commission, 2015d). Between 2009 and 2014 beef and veal production averaged EU 31 billion per annum (Eurostat 2015).

EU production of milk was close to 148 million tonnes in 2014, a 4.5 per cent increase on 2103 (European Commission, 2015d). Milk production was worth around EUR 61 billion and accounted for 15 per cent of the value of total agricultural output in 2014 (*Ibid.*).

Pork production in the EU totalled 22.7 million tonnes in 2014 and represented over half of total meat output. Between 2009 and 2014, pork production represented 9-10 per cent of the value of the EU's total agricultural output, and was worth on average EUR 34 billion per annum during this period (*Ibid.*)

The EU produced 934,000 tonnes of sheep and goat meat in 2014, accounting for two per cent of total meat output. Domestic production was worth an estimated EUR 5.4 billion in 2014.

Around 63,000 tonnes of horsemeat was produced in the EU in 2013. Slaughter and processing is concentrated in Italy, Spain, Poland and France¹⁷ (Humane Society International, 2014). Domestic production of horsemeat generated around EUR 0.98 billion in 2014 (Eurostat, 2015).

3.5.2 Trade with third countries

There is significant trade in meat and animal products with third countries. The relative importance of imports varies across the five species.

The EU is a net importer of beef and veal products. Around 70 per cent of imports come from Brazil, Argentina and Uruguay in 2014 (countries where the cloning technique is known to be used). In 2014 beef and veal imports were worth over EUR 1.6 billion, equivalent to five per cent of gross domestic production.

The EU is self-sufficient in dairy production, and is a net exporter. In 2014, dairy exports were worth an estimated EUR 10.2 billion. The EU also imports smaller though notable quantities of dairy products, in particular cheese and to a less extent, butter. Imports of these dairy products were valued at EUR 705 million in 2014, which corresponded to about 1 per cent of domestic production (Eurostat, 2015).

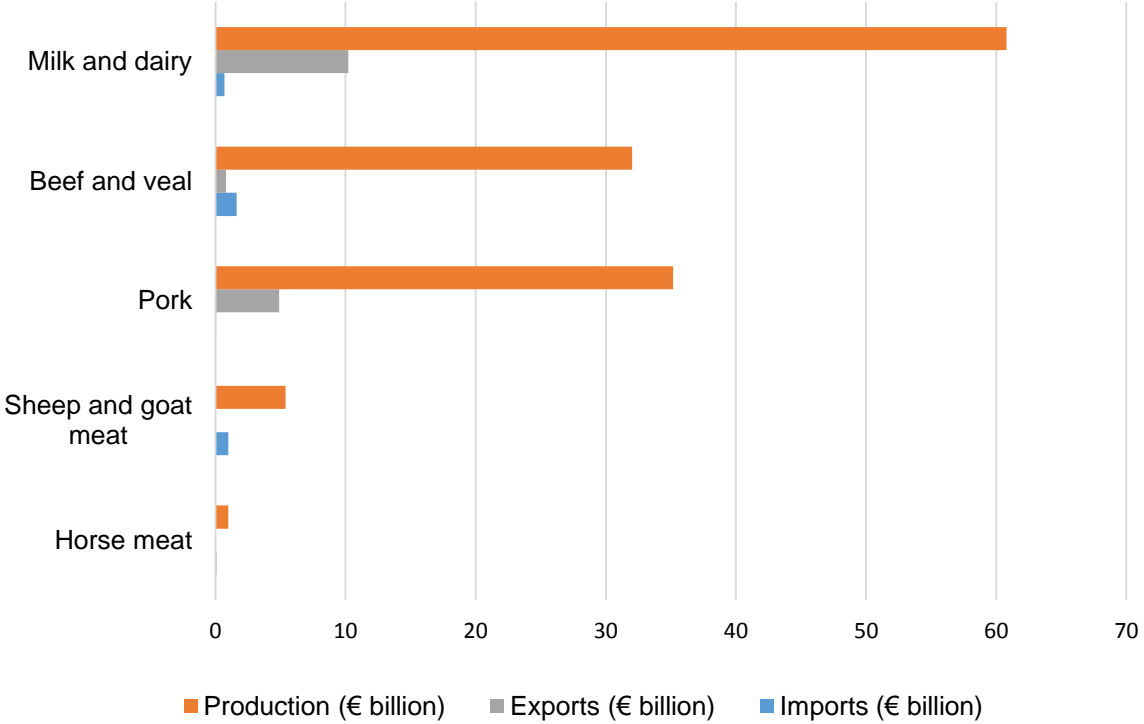
The EU is net exporter of pork. In 2014, domestic production of pork was valued EUR 35 billion; the value of imports corresponded to less than 1 per cent of EU production. Pork

¹⁷ Italy and Spain are the largest producers of horsemeat in the EU, slaughtering over 50,000 horses for meat production in 2013. These are followed by Poland (22,514 heads) and France (20,544 heads) (Humane Society International, 2014).

is the EU's most significant meat export. Pork exports accounted for eight per cent of domestic pork production in 2014 and were worth an estimated EUR 4.9 billion. Exports are forecast to increase by more than 20 per cent over the period up to 2024 (European Commission, 2014c).

The EU is a net importer of sheep and goat meat. Imports accounted for 18 per cent of total sheep and goat meat production in 2014 and were valued at close to EUR 981 million. New Zealand and Australia accounted for 95 per cent of the value of imports (Eurostat, 2015).

Figure 3. EU domestic production, imports and exports of meat and dairy products



Source: adapted from Eurostat, 2015

4 The current situation

Section summary:

There is a diversity of animal breeding arrangements in place in the EU across the five species of interest to this study. A key point of differentiation is the use of artificial insemination (AI), a technique that can accelerate the dissemination of high quality genetics through a population more quickly than natural breeding. AI is particularly common in the bovine dairy sector and in pig production.

To implement a labelling obligation it would be necessary to adapt the requirements to the structure of the production sector for each species. For example, while cloning technology is primarily used in the bovine dairy sector, there are connections between the beef and dairy cattle sectors which mean that a comprehensive system would need to be integrated across both sectors. The organisational structure of animal breeding varies across and within the individual species breeding sectors. In some areas there are large multinational companies and highly focused breeding objectives; in others breeding objectives are set by individual farmers.

The number of descendants that an individual animal might have varies significantly across the species. Over three generations, a boar in the pig sector might have more than 90,000 descendants, a breeding bull in the dairy sector 4,625 progeny, and a breeding buck in the goat sector just 760.

There is no compulsory system for ancestry recording in the EU. However, pedigree recording systems are used to record parentage information for some animals. Ancestry information is collected for most dairy cattle and horses whereas it is done for only around 10% of the pig herd.

All bovine animals in the EU are individually identifiable to the point of slaughter. Fewer than 20% of pigs are individually identified, nearly 70% of sheep, 80% of goats and 75% of horses. A key point in the current context is that for all species, animals from the nucleus breeding herd (where clones or first generation clone offspring are most likely to be found) pass into the food chain and thus could be used in food products.

Existing traceability systems do not, in general, allow products of animal origin (meat or milk) to be traced back to an individual animal. Products are identified almost entirely on a batch basis. The batch is traceable back to a group of animals. The batch may contain animals from different holdings. Traceability enables identification of the holdings from which a particular batch of food products was derived.

The EU has detailed requirements for food labelling but there is no requirement for any linkage between meat and livestock products and ancestry information of individual animals. This means that the current rules on labelling do not put a framework in place that could be used to facilitate the labelling of meat from the offspring of clones.

4.1 Introduction

This chapter provides a description of the main approaches to livestock breeding, the traceability systems in place for live animals and food products, and for food labelling. It covers all five species of interest, and focuses on the EU but considers third countries where appropriate. It describes those elements of the current system that could support the tracing of cloned offspring and their products through the supply chain, and those elements which preclude such tracing.

It provides information on:

- the breeding structures for each species, reflecting the current state of commercial livestock breeding (section 4.2);
- the number of descendants that a single animal could have in different breeding systems, and the links between the nucleus breeding herd and food production, to illustrate what would be required to ensure all clone offspring entering the food chain were properly identified and the consequences of using different definitions of 'clone offspring' (section 4.3);
- the current availability of ancestry information in slaughter/food production animals, outside the (pedigree) breeding sector (section 4.4);
- the current systems providing ancestry information for individual animals through several generations (section 4.5);
- the current system providing traceability of foodstuffs containing raw materials and the extent to which it could be used to trace food products derived from animals with clone ancestry (section 4.6); and
- current arrangements for labelling foodstuffs containing raw materials from animals with clone ancestry (section 4.7).

The feasibility and costs associated with a labelling requirement depend on the structure of the breeding sector for each species and the types of food products involved.

The research conducted for this chapter has identified the systems used today for the *majority* of food producing animals in the EU (focusing on the general case rather than exceptions). This includes systems that are in place for animal breeding and food production supply chains where cloning technology is most likely to be involved. Clone genetics could enter the EU breeding sector through the import of reproductive materials from third countries. Commercial breeding systems that rely on artificial insemination and embryo transfer (as opposed to natural mating) are therefore the most likely routes for first generation clone offspring to enter the food supply chain and the study focuses on these systems.

4.2 Commercial breeding structures

This section summarises the most common approaches to commercial breeding for each species in the EU and the scale of two practices that affect the feasibility and cost of a labelling requirement for products from clone offspring:

- the scale of imports of reproductive materials from third countries – the most likely way for clone genetics to enter the EU's livestock sector;
- the prevalence of artificial insemination and embryo transfer (technologies explained in Box 1), which influence the speed with which genetics are disseminated through a population.

Box 1: The role of assisted reproductive technologies in animal breeding

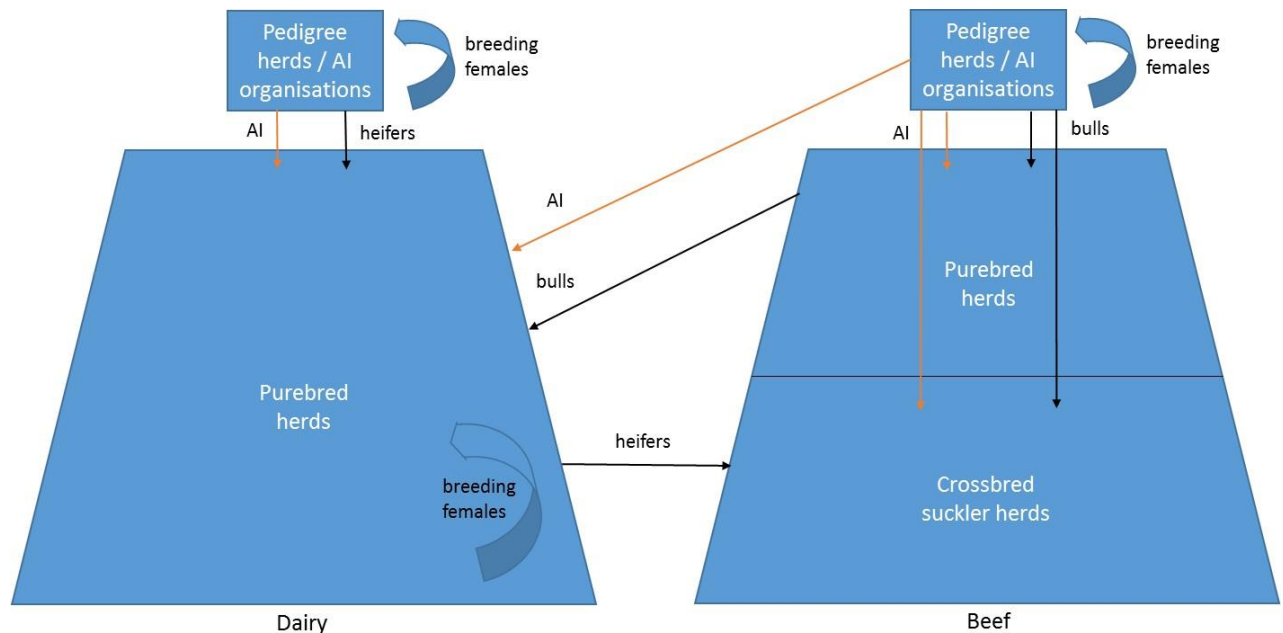
Assisted reproductive technologies can play an important role in genetic improvement. One of the most important and widely used of these technologies has been artificial insemination (AI). AI simplifies dissemination of superior genetics over a wider population base, from nucleus to slaughter/food production herds, with lower risk of disease transmission and a reduced genetic lag. AI is especially important for the transmission of genetics between countries because it avoids potential problems related to the transport of live animals. AI makes a significant contribution to across-herd genetic evaluation and selection in national and multinational breeding programmes for some species (particularly dairy cattle and pigs) (Knap et al., 2001 cited in Dekkers et al., 2011).

Embryo transfer is used to introduce genotypes to a population of animals quickly, inexpensively and without the risks of disease and other issues that can occur through the use of live animals. As with AI, the use of ET is limited to certain species.

4.2.1 Bovine animals – dairy and beef cattle breeding

There are two main commercial breeding structures for bovine animals in the EU: purebred dairy cattle breeding, with some crossbreeding of surplus dairy cows for veal production, and purebred or crossbred beef cattle breeding. The latter generally allows calves to suckle and is not connected with dairy production (Figure 4).

Figure 4. Cattle breeding pyramid – dairy and beef production



Source: ICF, based on expert consultation

In both cases, pedigree (nucleus) herds are maintained by multinational genetic improvement companies. Smaller companies operate primarily at national level, cooperatives, and many small companies operating in niche markets.

Commercial production is separated from the nucleus breeding populations. Nucleus herds produce elite sires. In commercial dairy production (i.e. purebred dairy herds), farmers rear their own female replacements for the herd, while using the genetics of the sire produced by breeding companies/cooperatives, mostly through AI. Purebred beef

cattle breeding has a similar structure to dairy cattle breeding, although the use of AI is less common. Commercial beef cattle are also produced through crossbreeding (e.g. in the UK and Ireland). A terminal bull¹⁸ is crossbred with the suckler females to produce slaughter animals.

The use of artificial insemination is standard practice in most of the dairy sector. In the Danish, Swedish and Finnish dairy sector AI is used in around 90 per cent of cases, while in the Netherlands and in some regions such as Bavaria and Brittany the proportion can reach close to 100 per cent.

Most bovine semen used for AI in the EU is produced in the EU, but semen doses are also imported from third countries. Eurostat data suggest around 10 million doses of bovine semen are imported each year¹⁹. Most are used in the dairy sector. Almost all originated in Canada and the United States. The rest were imported from New Zealand and Australia.

Artificial insemination is less common in the beef production sector: around 10 per cent of beef cattle produced in the EU are derived from a pregnancy where it has been used. There are exceptions: a larger proportion of the beef breeds, such as Belgian Blue, are artificially inseminated (EFFAB 2012, cited in European Commission, 2013a).

Embryo transfer is used more often for bovine animals than for the other species considered in this study. The procedure is expensive (on average, EUR 200-400 per procedure) and therefore only used when it is cost effective – usually on high-value animals to produce stock for nucleus breeding herds. An estimated 2-3 per cent of bovine dairy animals in the EU are bred using embryo transfer. EU aggregate statistics on imports of embryo from third countries are not available (IETS, 2014). Expert consultations undertaken for this study suggest that these figures are low. For example, in Italy it is estimated that just few hundreds of embryos per year are imported from the U.S. for the dairy sector, while imports of embryos of beef bovines are estimated to be close to zero.

Use of the embryo transfer procedure is rare for beef cattle. Much less than one per cent of beef animals are bred using embryo transfer.

4.2.2 Porcine animals

Pig breeding involves the dissemination of genetic changes from nucleus breeding farms down to a multiplier level and then from the multiplier level to farms producing slaughter animals. A typical pyramid for pig breeding is illustrated in Figure 5.

Nucleus herds are generally owned and managed by breeding companies or cooperatives. Multiplication is carried out by a different set of companies working under contract to the breeding companies. A third set of companies produce slaughter animals in commercial breeding operations.

The nucleus herds consist of purebred animals; these are crossed at multiplication level. One or two layers of crossbreeding may occur before the production level for slaughter animals is reached. At the final stage, the farmer uses a purebred terminal sire with a crossbred female; their offspring are slaughter animals. Animals from all stages, including the nucleus, go into the food chain. Dissemination of genetic traits typically takes three to five years from nucleus to slaughter herds (ICF, 2012).

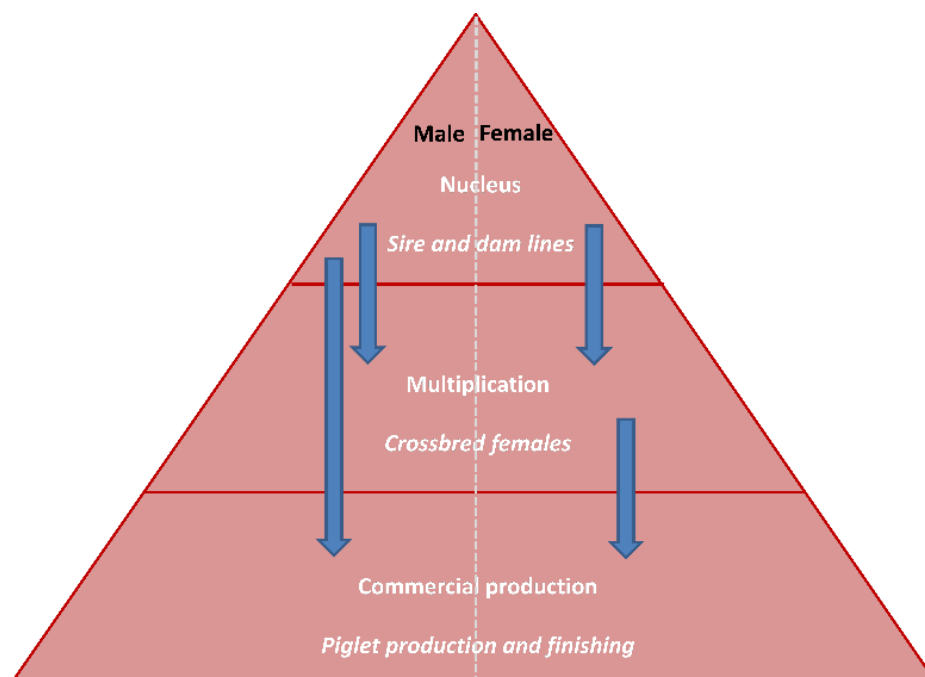
AI has replaced natural mating as the most widely used mode of pig breeding. Approximately 90 per cent of sows are impregnated through AI at the EU level. However, the proportion is higher in the main pig producing countries such as Denmark (where it is

¹⁸ A sire with genetics that are more suitable for breeding slaughter animals, rather than for further breeding improvement.

¹⁹ Eurostat and TRACES provide different estimates of the number of doses imported (as discussed in European Commission, 2013b).

approaching 100 per cent), France, Spain (UECBV, 2012, cited in European Commission, 2013a; expert consultation) and the Netherlands (where no natural mating is allowed).

Figure 5. Pig breeding pyramid



Source: Dekkers et al. 2011

The ratio of boars to sows in a national herd is an indicator of the prevalence of AI. There is on average one boar per 100 sows in Denmark, Ireland and the Netherlands. In many Member States, farms keep boars for natural mating in case a sow does not conceive through AI, but natural mating is rare.

Porcine semen is less traded between countries because freezing poses technical problems that are not encountered with bovine semen. Semen from porcine animals has been imported to the EU from Canada and the United States at a very small scale. Occasionally these materials have also been imported from Australia, although the volumes vary from year to year. The most recent available TRACES data (2007-2011) show that between 200 and 1,000 units of porcine semen were imported into the EU each year from these three countries combined (TRACES, 2012). By comparison, TRACES records between almost 400,000 and two million units of bovine semen being imported into the EU each year over that same period²⁰.

ET is very rarely used in pigs because the technique is difficult and complicated, requiring open surgery or expensive equipment. In practice, therefore, the technique is not used except in academic research. The proportion of production pigs produced through embryo transfer in the EU is close to zero; the same is likely to be true of third countries (expert consultation). Only Canada is known to export porcine embryos; 118 embryos were sent from Canada to France in 2014 (IETS, 2014); these are likely to have been used for research purposes.

4.2.3 Ovine animals

The ovine breeding sector is smaller and less structured than the equivalent bovine and porcine sectors. There are a few small companies operating in the EU in this sector plus pedigree breeders and farmers. Purebred breeding animals are kept by pedigree breeders. In the UK there are several multiplier levels in sheep breeding, starting with

²⁰ As noted above, there are differences between TRACES and Eurostat data on semen imports.

crosses of purebred hill sheep which produce females for midlands. These animals are crossed with another breed to produce a mule. The mule is crossed with a terminal sire to produce the slaughter animal. A small number of purebred breeding systems are also in operation, with the farm breeding its own replacements.

Natural mating is the primary method of breeding ovine animals. The use of AI is uncommon as it is not considered to be economically viable. A single AI procedure for one animal can cost EUR 200 and high value sheep are, on average, worth EUR 200. Only for very specific breeding purposes is the use of AI justified.

There are also technical constraints, as AI must be laparoscopically²¹ carried out by a vet. This is partly due to the anatomy of female sheep which make it comparatively difficult to administer artificial insemination techniques (Morrell, 2011). Fresh semen is typically used for AI since freezing ovine semen can lower the fertility rate.

In southwest France there are cooperatives using AI for approximately 300,000 sheep out of a sheep population in France of more than seven million animals (Eurostat, 2014). The technique is also used to a limited extent in Italy. On average, fewer than 1,700 units of ovine and caprine semen were imported into the EU per year in the period from 2007-2011 (TRACES, 2012). TRACES data do not provide separate figures for ovine and caprine animals.

Semen may be mixed to increase fertility. This complicates ancestry recording for animals produced in this way because the sire cannot be identified. Embryo transfer is rarely, if ever, used on ovine animals for the same reasons it is not used on pigs. No embryos were reported as imported into the EU in 2014 (IETS).

4.2.4 Caprine animals

Goat breeding is similar in structure to that of sheep. Few animals are pedigree recorded but there are approved breeding organisations that keep herdbooks. Dairy goat production follows a similar structure to that used for dairy cattle on food production farms with farmers using females from their own herd and buying in males for breeding. In the Netherlands all animals (including breeding animals) are owned by farmers, and the only Dutch AI centre for goats is a farmer-owned organisation (expert consultation). A structure in Spain is similar, animals are owned by farmers. Spanish farmer cooperatives, representing about 20 per cent of all goat farmers in Spain, are responsible for breeding and AI (expert consultation).²²

Buck kids are typically sold off for slaughter. In Spain, for example, most females are kept for breeding (each year, about 30 per cent of 'old' females are sent to the slaughterhouse), while only about two per cent of males are kept and the others are slaughtered. Goat breeding for meat production may involve some crossbreeding, but is relatively unstructured. In Spain, approximately 70 per cent of goats are considered to be 'purebred' (although only 10 per cent are estimated to be registered in herdbooks) and most animals belong to one goat breed for both dairy and meat production (expert consultation).

Artificial insemination is not considered an efficient goat breeding method as the average pregnancy rate from AI is 40 per cent (expert consultation). Its use tends to be restricted to specific breeds and for multiplying stock (EFFAB, 2012, cited in European Commission, 2013a). AI is applied to up to 15 per cent of the dairy goat herd in France and up to two per cent in the Netherlands (expert consultation). These two countries account for less than 15 per cent of the total EU goat population (Eurostat, 2014). Use of AI is less common elsewhere in the EU. Semen is mostly sourced nationally or bought from France.

²¹ Laparoscopy is a surgical technique and requires a veterinarian to carry out the procedure; its use in AI for sheep contrasts with AI performed on other species, which can be done vaginally and without the assistance of a veterinarian.

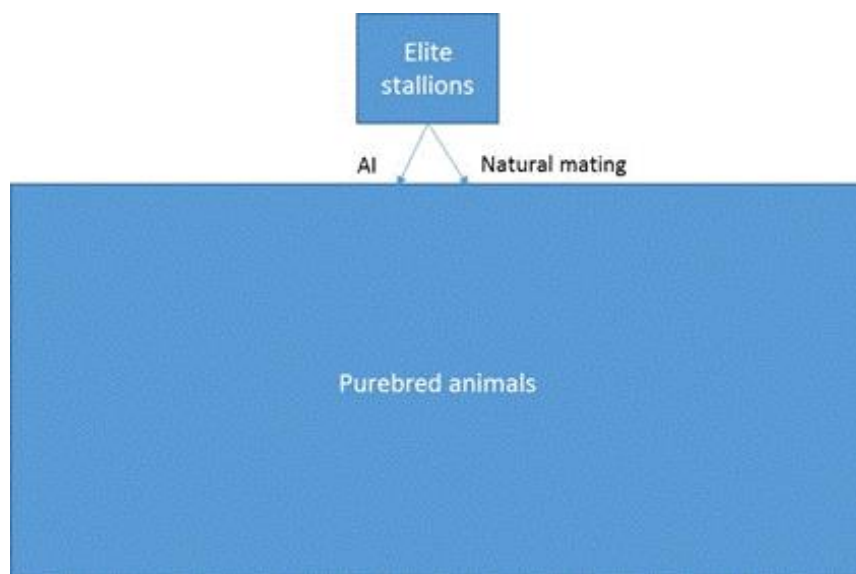
²² No details were provided regarding the breeding systems in farms not organised as cooperatives.

Embryo transfer is rarely if ever used on caprine animals for the same reasons it is not used on pigs. Only 13 embryos were reported to have entered the EU in 2014 and these were likely to be for research purposes.

4.2.5 Equine animals

The use of cloning is confined to sports horses and not horses used for food production, although sports horses may end up in the food chain at end of life. Horse breeding is primarily conducted by private individuals who own the breeding animals. Breeding associations or studbooks are responsible for the selection of the breeding stallions. A small population of elite male animals is involved in the propagation of a large population of sport and leisure horses (Figure 6).

Figure 6. Horse breeding structure



Source: ICF

Most horses in Europe are purebreds. At least one, and often several studbooks, for a breed can be found in most EU Member States. There is a large number of horse breeds across in the EU.

Approximately 40 per cent of all horses in the EU are warmbloods²³. Warmblood horse breeding involves AI, while AI is not allowed for thoroughbred breeding.²⁴ Sixty per cent of warmbloods are estimated to be bred through AI, though use of the technology varies around Europe.

Semen are imported from third countries; in 2011, approximately 260,000 units of semen were imported into the EU, more than 99 per cent of which originated from the U.S. Embryo transfer is not common in horse breeding. Fewer than a dozen embryos were reported as entering the EU from third countries in 2014 (IETS).

²³ Group of sport horse breeds, derived from crossing agricultural draft horses with thoroughbreds. The use of artificial insemination is increasingly used for warmbloods in order to select desired traits (Liljenstolpe, 2009).

²⁴ Thoroughbreds and warmbloods are both commonly used for horse racing. While AI is commonly practiced on warmbloods, this technique is not accepted for thoroughbreds, as established by the International Agreement on Breeding, Racing and Wagering (International Federation of Horseracing Authorities, 2015).

4.3 The number of progeny of a sire animal by species

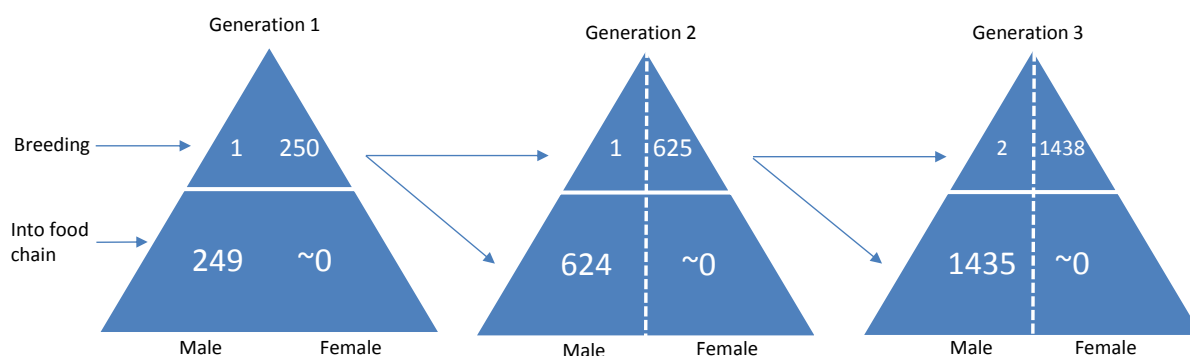
This section shows the number of progeny that a sire animal might have over three generations. If this animal was a clone then its offspring fall within the scope of the labelling obligation and the data show how the number of those offspring would vary by species and according to the definition adopted (i.e. the number of generations).

The figures are based on estimates provided by experts at Wageningen University. The numbers provided are calculated using 'plausible' averages, targets and assumptions derived from expert judgement. Averages do not exist for the scenarios set out in this section, and for some figures in each calculation no published references could be found. The actual number of descendants of a given animal will, in practice, vary very significantly across the various breeding systems used in the EU.

4.3.1 Bovine animals

On average a breeding bull produces 500 offspring where AI is used (as would be common in the dairy production sector); 250 daughters will be used in breeding and they will produce 1,250 second generation offspring. The third generation comprises 2,875 progeny (from 625 dams). Within three generations (i.e. 15-20 years) an average breeding bull produces 4,625 progeny (i.e. the total of all offspring in the first, second and third generations).

Figure 7. Illustrative example of bovine breeding system with use of IA (dairy cattle)



Source: Wageningen University

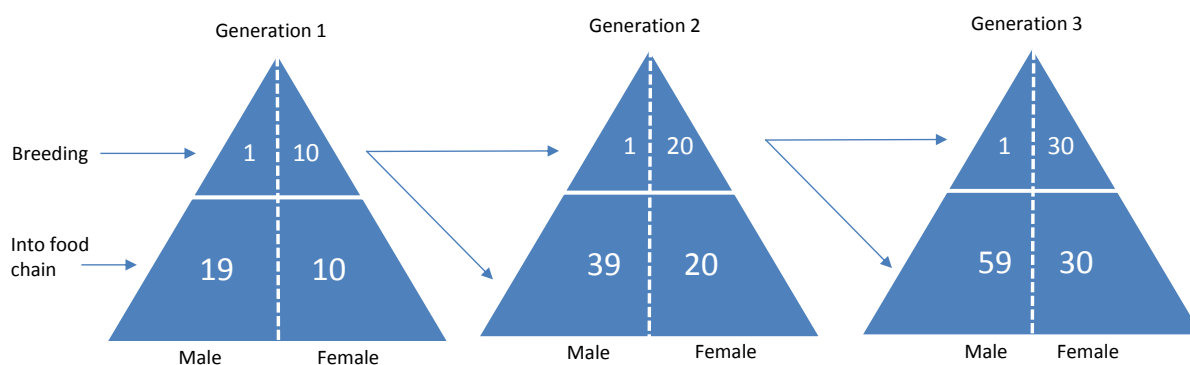
Table 2. Illustrative example of bovine breeding with the use of AI (dairy cattle)

	Number of breeding animals	Number of non-breeding animals	Total
1 st generation offspring	1 male and 250 females	~250	~500
2 nd generation offspring	1 male and 625 females	~625	~1,250
3 rd generation offspring	2 males and 1,438 females	~1,435	~2,875

Source: Wageningen University

By contrast, where natural mating is used (as would be common in the beef production sector), on average a breeding bull produces 40 offspring. Ten daughters will be used in breeding and they will produce 80 second generation offspring. The third generation comprises 120 progeny (from 20 dams). Within three generations (15-20 years) an average breeding bull has 240 progeny (i.e. the total of all offspring in the first, second and third generations).

Figure 8. Illustrative breeding system for beef cattle based on natural mating



Source: Wageningen University

4.3.2 Porcine animals

The number of offspring per boar strongly depends on the purpose of the line. Lines bred for producing dams of finisher pigs are referred to below as dam lines. Lines bred to produce the sires of a finisher pigs are called sire lines.

On average a nucleus boar produces 300 offspring where AI is allowed; two sons and 15 daughters will be used in nucleus breeding. This applies to both sire and dam lines. Dam line boars produce on average 3,401 progeny in the second generation and 22,000 progeny in the third generation. In contrast, sire line boars produce 30,645 second generation offspring. The third generation comprises 91,334 progeny (from 9 sires for breeding finisher pigs and 6 sires and 45 dams in the nucleus).

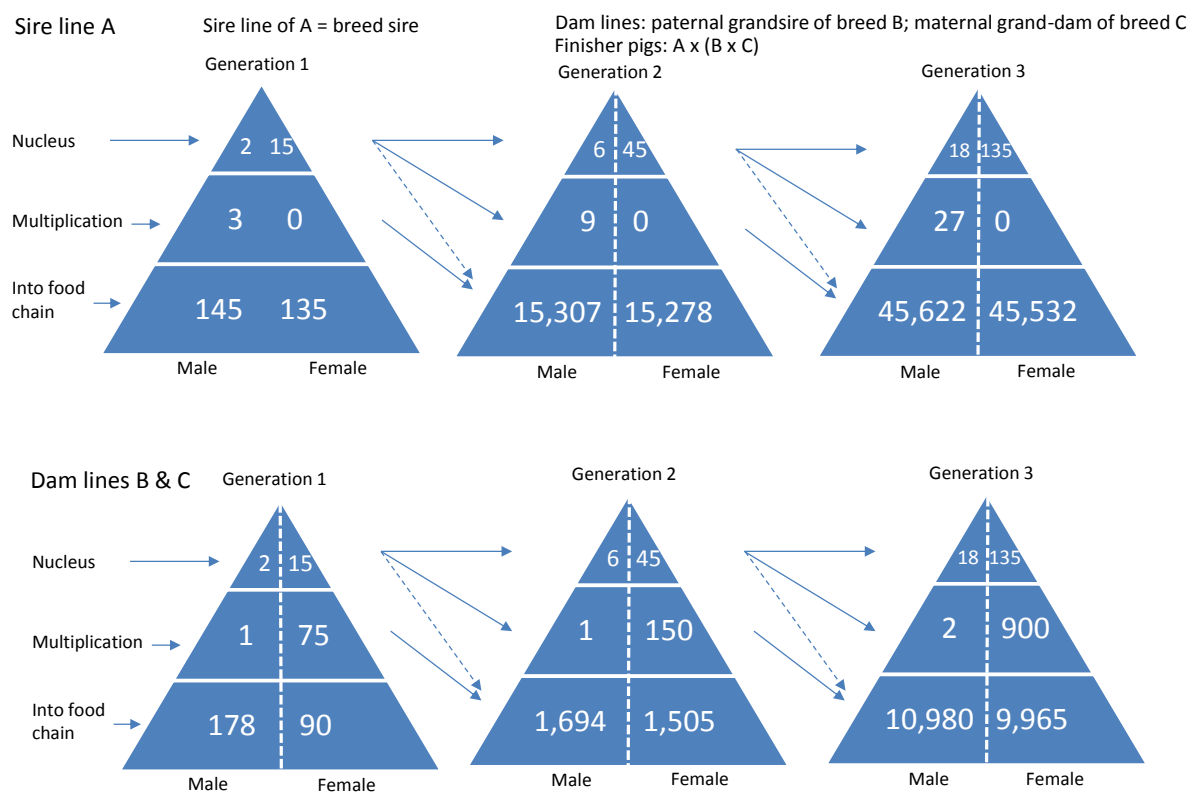
Within three generations (i.e. 5 years) an average sire line breeding boar potentially has 122,279 descendants (i.e. the total of all offspring in the first, second and third generations). The potential total of a dam line boar is 25,762 descendants. In practice, the number of descendants of a boar over three generations will vary enormously, due to inefficiencies and chance.

Table 3. Illustrative example of porcine breeding with the use of AI

	Number of breeding animals	Number of non-breeding animals	Total
1 st generation offspring	Two sons and 15 daughters (nucleus breeding); three more sons will be used for breeding finisher pigs	~280	~300
2 nd generation offspring	6 grandsons and 45 granddaughters in the nucleus and 9 grandsons for breeding finisher pigs	~30,585	~30,645
3 rd generation offspring	18 great-grandsons and 135 great-granddaughters in the nucleus and 27 great-grandsons for breeding finisher pigs	~91,154	~91,334

Source: Wageningen University

Figure 9. Sire and dam lines of a porcine breeding system using AI

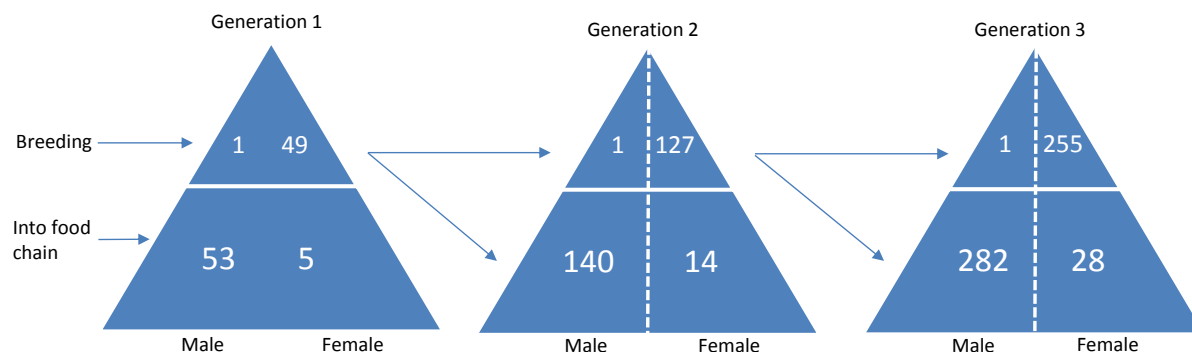


Source: Wageningen University

4.3.3 Ovine and caprine animals

On average a breeding ram produces 108 offspring, assuming natural mating (since AI is rarely used in this sector). One son and 49 daughters will be used in breeding and they will produce 282 second generation offspring. The third generation comprises 566 progeny (from 1 grandson and 127 granddaughters). Within three generations (i.e. 12 years) an average breeding ram produces 956 progeny (i.e. the total of all offspring in the first, second and third generations).

Figure 10. Illustrative breeding structures for ovine sector (natural mating)



Source: Wageningen University

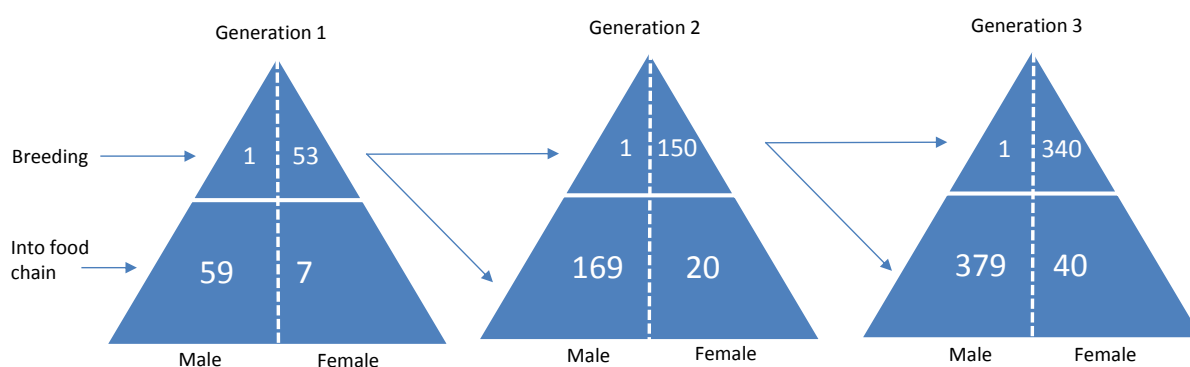
Table 4. Illustrative example of ovine breeding with natural mating

	Number of breeding animals	Number of non-breeding animals	Total
1 st generation offspring	1 son and 49 daughters	~58	~108
2 nd generation offspring	1 grandson and 127 granddaughters	~150	~280
3 rd generation offspring	1 great-grandson and 255 great-granddaughters	~310	~566

Source: Wageningen University

Caprine breeding is similar in structure to the ovine example but with fewer progeny at each generation, as illustrated below. Across the EU, about 5% of the dairy goats are offspring of a breeding buck in an AI centre. A breeding buck produces on average 120 offspring; 1 son and 53 daughters will be used in breeding and they will produce 340 second generation offspring. The third generation comprises 760 progeny (from 1 sire and 150 dams).

Figure 11. Illustrative breeding structures for caprine sector (natural mating)



Source: Wageningen University

Within three generations (i.e. 10 years in goat breeding) an average breeding buck produces 1,220 progeny (i.e. the total of all offspring in the first, second and third generations). The number of descendants of a natural-mating buck is considerably different from an AI buck, so the variation from buck to buck is substantial.

Table 5. Illustrative example of caprine breeding with natural mating

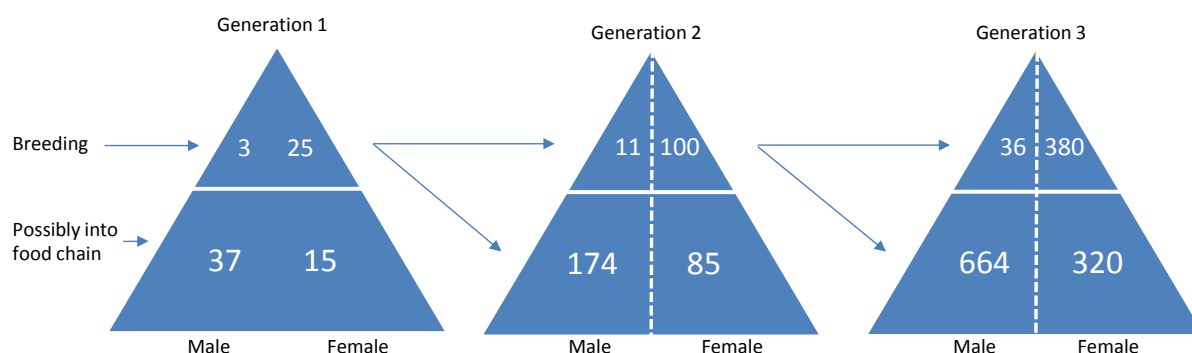
	Number of breeding animals	Number of non-breeding animals	Total
1 st generation offspring	1 son and 53 daughters	~66	~120
2 nd generation offspring	1 grandson and 150 granddaughters	~189	~340
3 rd generation offspring	1 great-grandson and 340 great-granddaughters	~419	~760

Source: Wageningen University

4.3.4 Equine animals

On average a breeding stallion produces 80 direct offspring where AI is allowed; three sons and 25 daughters will be used in breeding and they will produce 370 second generation offspring. The third generation comprises 1,400 progeny (from 11 sires and 100 dams).

Figure 12. The number of equine animals produced by an average breeding sire using AI



Source: Wageningen University

Table 6. Illustrative example of equine breeding

	Number of breeding animals	Number of non-breeding animals	Total
1 st generation offspring	3 sons and 25 daughters	~52	~80
2 nd generation offspring	11 sires and 100 dams	~259	~370
3 rd generation offspring	36 great-grandsons and 380 great-granddaughters	~984	1,400

Source: Wageningen University

Within three generations (i.e. 25-30 years in horse breeding) an average breeding stallion has 1,850 progeny (i.e. the total of all offspring in the first, second and third generations).

There is large variation in these figures. A popular sire might have 800 progeny of which 15 sons and 250 daughters become parents themselves. By the third generation, this sire might have 25,000 descendants – over ten times more than the average breeding stallion.

4.3.5 Differences between species

The differences between species in the number of offspring produced have biological and management causes. The number of progeny per litter varies from one for bovine animals to 14 for porcine animals. The number of litters per female varies from two for dairy goats to four for beef cattle. The number of females mated to a breeding male is strongly dependent on the use of AI and the need to control inbreeding.

For porcine and caprine animals the number of doses per semen collection is about 20. An AI bull could theoretically have hundreds of thousands of direct offspring, as in excess of 400 doses can be produced from a single collection of semen. A natural mating bull on the other hand can only serve a few hundred cows in its lifetime.

The number of progeny for purebred breeding is generally restricted to minimise the rate of inbreeding in the purebred populations. This is not a concern for producing crossbred

porcine animals for meat production, hence the much larger number of potential offspring.

4.3.6 Implications for a clone offspring labelling obligation

The implication of the analysis above is that, for any given definition of clone offspring, the number of animals that would be classified as clone offspring (and the amount of derived product in the food chain) would vary significantly (Table 7). Where used, clone genetics would be propagated more rapidly in bovine dairy and porcine sectors than in (for instance) the caprine sector.

Experts stress the variation possible within each breeding sector. This variation is illustrated by Table 8 which contrasts the number of first generation offspring generated by a 'typical' sire and the number that may be achieved by very high value / high performance animals.

Table 7. Illustration of the differences in number of progeny after three generations across different livestock species for a typical animal

	Bull (bovine dairy)	Bull (bovine beef)	Boar (porcine)	Ram (ovine)	Buck (caprine)	Stallion (equine)
Total number of progeny after three generations	4,625	240	122,279	956	1220	1,850

Source: Wageningen University. See text for caveats and assumptions.

Table 8. Comparison of the typical and outlier numbers of first generation offspring of dairy bull, beef bull, boar, ram, buck and stallion

	Average number of lifetime offspring	Maximum number of lifetime offspring
Dairy bull	500 (artificial insemination)	>500,000 (artificial insemination)
Beef bull	40 (natural mating)	>500,000 (artificial insemination)
Boar	300 (artificial insemination)	25,000 (artificial insemination)
Ram	100 (natural mating)	360 (natural mating)
Buck	120 (natural mating)	1,400 (artificial insemination)
Stallion	80 (artificial insemination)	2,000 (artificial insemination)

Source: Wageningen University

4.4 Extent of animal ancestry recording

An effective system of ancestry recording is needed if the clone ancestry of animals is to be recorded and verified for the purposes of labelling animal products. This section provides a description of existing practices within the EU for recording ancestry information of breeding animals and for all slaughter animals for the five species.

4.4.1 Summary of the current situation

There is no compulsory system for ancestry recording in the EU. However, pedigree recording systems are used by breeding organisations to record parentage information, for breeding animals that are entered in herdbooks. The current situation for the five species of interest can be summarised as follows:

- The majority of the total population of animals in the EU (including breeding and food production/slaughter animals) across the five species **are not** pedigree recorded, therefore identifying the ancestry of most of these animals is not possible at present;
- For most dairy cattle and horses **ancestry information is available for at least both parents** (*but not necessarily the grandparents, i.e. information is not recorded cumulatively*).

4.4.2 Current recording of breeding animal ancestry

Breeding organisations are associations of animal keepers that share a common goal to improve or conserve a particular breed. The membership is the voluntary decision of each individual.

The EU legislative framework on zootechnics²⁵ regulates purebred breeding animals of the bovine, porcine, ovine, caprine and equine species and hybrid breeding pigs.²⁶ The aim of this legislation is to provide harmonised standards for Member States in order to remove obstacles to the free trade in breeding animals and their reproductive material in the EU. The rules also take into account the objective to ensure 'the sustainability of breeding programs and preservation of genetic resources' (European Commission, 2014b). The legislation governs the recording of the parentage of pedigree animals in breeding books and on pedigree certificates for:

- purebred animals of the five species and their reproductive material;²⁷ and
- hybrid²⁸ porcine animals and their reproductive material.

The legislation ensures that certain minimum requirements are met by any association keeping breeding books in the EU. This system of parentage recording is voluntary and is not systematically used by all farm animal keepers. Individual breeders decide whether or not it is important or useful for them to participate in a breeding programme. The registration of animals in breeding books is understood to be restricted to 'a small

²⁵ Science concerned with the domestication and breeding of animals (Collins Dictionary, 2015).

²⁶ There are four Directives with the basic principles on purebred breeding animals for each of the following species: bovine animals (Council Directive 2009/157/EC), porcine animals (Council Directive 88/661/EEC), ovine and caprine animals (Council Directive 89/361/EEC), and equine animals (Council Directive 90/427/EEC). For each of the five species there are separate legislative texts with the specific rules regarding breeding animals, including rules for the recognition of breeding organisations, criteria for entering animals in breeding books, details to be provided in pedigree certificates, methods to performance and genetic evaluations of animals, and rules on the acceptance for breeding purposes of purebred breeding animal. In 2014, the European Commission presented a proposal for a regulation on zootechnics (European Commission, 2014b). The aim of the proposal is to combine the EU zootechnics legislation in one regulation, and to remove inconsistencies from existing rules.

²⁷ It is also possible to register non-purebred animals of the five species in a supplementary section of breeding books.

²⁸ These are defined as crossbreeds between purebreds, a purebred and another crossbreed, or two crossbreeds (Council Directive 88/661/EEC).

percentage of the total farm animal population in the EU' (European Commission, 2013a). However, pedigree recording is a basic condition in nucleus breeding populations.

Estimates of the percentages of each species recorded in breeding populations and in the total population of animals are provided in the following sub-sections.

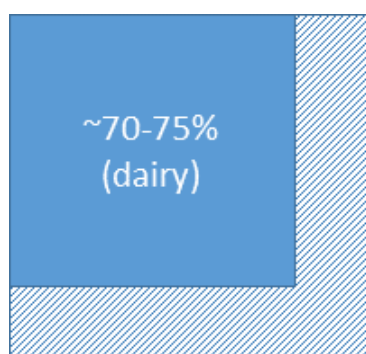
4.4.3 Bovine animals

Recording of ancestry information is more prevalent for dairy animals than for beef production animals.

Across the EU as a whole 70-75 per cent of dairy cows are estimated to have information on at least the sire and dam recorded. Consultations suggests that ancestry recording for male dairy calves that are destined for use for beef or veal production is much lower and comparable to that of beef herds. In dairy breeding systems in some EU countries (e.g. Denmark, Finland, Sweden, the Netherlands, France, and UK), ancestry information (at least the sire and dam) is recorded for nearly 100 per cent of the nucleus breeding population. In Denmark, Finland and Sweden this system extends beyond the core breeding sector. The prevalence of ancestry recording in breeding programmes in these Scandinavian countries is estimated to be as high as 80 per cent. In other EU countries, only 20-30 per cent of the reproductive herd may be pedigree recorded.

Figure 13. The majority of dairy cows have ancestry information recorded

Percentage of dairy cows for which ancestry information is recorded

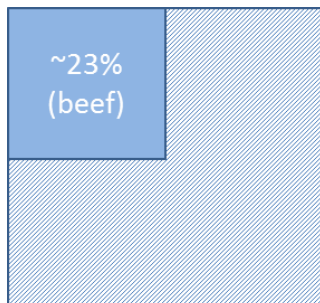


Source: ICF, based on expert consultation. Ancestry recording rates for male dairy calves are typically lower.

Ancestry recording practice for beef cattle varies. In Member States where beef production is based on a purebred breeding system (e.g. France, the Netherlands and Belgium), a similar percentage of animals are pedigree recorded as in dairy systems (i.e. nearly 100 per cent of the nucleus breeding population and approximately 80 per cent of all animals). But in countries where beef production is based more on crossbreeding (e.g. UK), the percentage of pedigree recorded animals is much smaller. There is therefore significant variation around the EU average. The significant variation among Member States in breeding and ancestry recording practice, and the lack of centralised data on herdbook usage, makes it more difficult to establish an EU average figure with confidence. Consultations with beef cattle breeding associations and experts in Member States that account for 66% of the EU beef herd suggest that ancestry is recorded for around 23% of those animals.

Figure 14. Ancestry is recorded for less than a quarter of beef cattle though there is sizeable variation among Member States

Percentage of beef animals for which ancestry information is recorded



Source: ICF, based on expert consultation

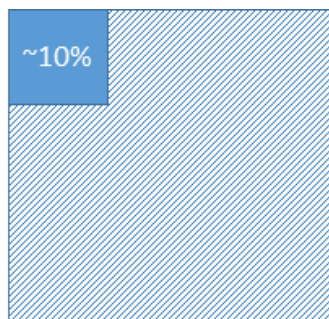
Note: the solid area of the figure represents the proportion of all animals, both breeding and slaughter / food production animals with ancestry information available for at least both parents; the shaded area of the figure represents the proportion of the population without information for at least both parents.

4.4.4 Porcine animals

Expert advice is that ancestry information is available for 10 per cent of the EU pig population (Figure 15).

Figure 15. Ancestry information is not recorded for most porcine animals

Percentage of porcine animals for which ancestry information is recorded



Source: ICF, based on expert consultation

Pig breeding companies maintain their own ancestry records. Nucleus herds have ancestry information recorded (sire and dam) at a rate of 90-99 per cent in the nucleus population (in Denmark 100 per cent of the elite nucleus herd and the multiplier herd is pedigree recorded). Ancestry information recording is sometimes also undertaken at the multiplication stage under contract with the breeding company; approximately five per cent of crossbred sows have ancestry records covering at least both parents.

In most cases, however, ancestry information is lost through crossbreeding when the pig becomes part of a 'batch' at the multiplier stage through mixed weaning of all litters. The effective ancestry recording of 'finishing pigs' (food production/slaughter animals) is zero (ancestry information is recorded for 0.01 per cent of animals to inform breeding programmes at the top of the pyramid).

4.4.5 Ovine and caprine animals

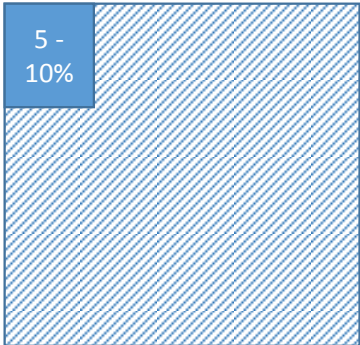
Consultations with experts in major sheep producing countries (e.g. France) indicate that ancestry information is available for at least both parents for around 5 per cent of the

EU's sheep population and 5-10 per cent of the goat population. For sheep this is likely to also include both sets of grandparents (i.e. a full pedigree record).

100 per cent of sheep in a nucleus herd are pedigree recorded, but these nucleus herds represent only five per cent of the total population. Pedigree information is estimated to be available for nine per cent of the goat herds in Spain (expert consultation). In the Netherlands and France only about five to ten per cent of dairy goats have a pedigree record, and recording is mostly done by hobby breeders rather than commercial farmers (expert consultation). Ancestry information is available for very few meat production animals.

Figure 16. Ancestry information is not recorded for most ovine and caprine animals

Percentage of ovine and caprine animals for which ancestry information is recorded



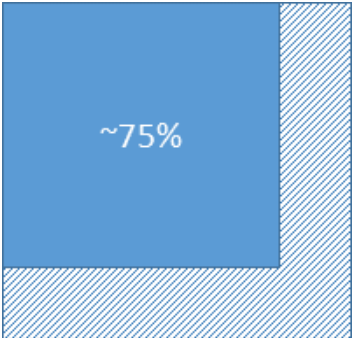
Source: ICF, based on expert consultation

4.4.6 Equine animals

Most (about 75 per cent of) equine animals in the EU are individually registered. These data include ancestry information about both parents.

Figure 17. Approximately 75 per cent of equine animals are individually registered with information about both parents provided

Percentage of equine animals for which ancestry information is recorded



Source: ICF, based on expert consultation

4.5 Individual animal identification

For the labelling of products derived from clone offspring to be possible, each individual animal needs to be linked to its ancestry information. The animal's identity would need to be passed with the animal through the supply chain. This section describes the current situation with regard to individual animal identification and how that varies by species and sector.

4.5.1 Individual animal identification

All bovine animals in the EU are individually identified throughout their whole life²⁹. Bovine animals imported into the EU are individually identified from the point of entry into the EU.

The majority (at least 80 per cent) of porcine animals are not individually identified. Animals are identified on a batch basis during movements³⁰. At each stage in the supply chain, it is only possible to identify the name of the holding and country of origin, as well as the last holding from which an animal has come. Breeding animals are individually identified but these account for a small fraction of the overall population (10-15 per cent according to experts consulted).

Around 68 per cent of ovine animals are likely to be individually identified, based on the size of the breeding herds relative to the total population size. For caprine animals, around 80 per cent are likely to be individually identified.³¹ EU law³² requires individual identification of ovine and caprine animals with a derogation for animals that are slaughtered within 12 months of birth where these do not enter intra-EU trade. Since the typical slaughter age is between six and nine months (for sheep) and four weeks to eight months (for goats), several Member States make use of this derogation to identify slaughter lambs on a batch basis. For example, in Spain, which is one of the EU's main goat meat producers, all animals intended for meat production are slaughtered before 12 months and identified on a batch basis.

Expert consultation indicates that up to 75 per cent of horses are individually identified. EU law³³ has required individual identification of horses and a single lifetime document (passport) since 2000³⁴. Horses sent to slaughter before six months are not required to be individually identified.

4.5.2 Availability of ancestry information with individual animal identification

EU law (Regulation (EU) 2015/262) requires information on the dam and sire for registered equidae (that represent 75 per cent of the total equine population). For bovine animals, Regulation (EC) No 1760/2000 requires the recording of the dam, but not the sire. Parentage recording is not required for porcine, ovine or caprine animals.

The current arrangement for equine animals provide for individual animal identification and the recording of ancestry information of the kind needed to support a clone offspring labelling system. For all other species further development of existing systems would be needed.

²⁹ Basic provisions on the identification of bovine animals are laid down in Regulation (EC) 1760/2000.

³⁰ Basic provisions on the identification of porcine animals are laid down in Council Directive 2008/71/EC.

³¹ In 2014, there were an estimated 85 million sheep and 12 million goats in the EU. Around 68 per cent of the EU sheep population comprised ewes and ewe-lambs put to ram (Eurostat, 2014). This figure may be an over-estimation if not all of the lambs slaughtered (within a year of their birth) are captured in the annual standing population size. The risks of over-estimation are, however, smaller than for other animals as there is typically only one, seasonally-concentrated lamb crop per year. Similar estimates for the proportion of animals individually identified are applicable to caprine animals. Over 80 per cent of the standing goat population in the EU is made up of breeding goats.

³² Basic provisions on the identification of ovine and caprine animals are laid down in Council Regulation (EC) 21/2004 amended by Commission Regulation (EC) No 759/2009 and Commission Regulation (EC) 506/2010

³³ Rules are laid down in Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC.

³⁴ Rules are laid down in Commission Decision 2000/68/EEC and Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC.

4.6 Traceability of animal food products to the individual animal

This section describes the current traceability in the food supply chain between the live animal and the food produced from it. It explains how existing traceability systems do not, as a general case, allow products of animal origin (meat or milk) to be traced back to an individual animal (European Commission, 2013a).

Businesses handling products of animal origin are required under the General Food Law³⁵ to provide information that includes a reference that identifies the batch or consignment. Information must be available one step forward along the supply chain and one step back: each operator must know where the product came from and be able to pass information to the next operator that will allow it to do the same. In case of any incident that requires a piece of meat to be traced back, this can be done to a batch of animals processed together and the holdings these animals originated from. In the case of milk, traceability would allow the processing dairy to be identified and, from there, the group of farms from which the milk originated.

Regulation (EC) No 853/2004 on the hygiene of foodstuffs specifies that products of animal origin must have an identification mark noting the approval number and last approved establishment and country in which the product was prepared. Imported food products must be accompanied by a health certificate submitted at the EU border. This does not include information that enables the product to be linked back to an individual animal.

Under current arrangements, the link between the product and the individual animal of origin is broken well before the product reaches the consumer. In the dairy sector the link between liquid milk and the individual animal is lost at the first point in the production process as the milk from different animals is mixed on farm during the milking process. In meat production the link can be broken:

- before slaughter, such as for porcine animals (and most ovine and caprine animals) which are not individually identified when they arrive at the slaughterhouse; or
- at and immediately after slaughter, such as for bovine animals, when the carcasses are cut into primal cuts and combined into new batches of meat products. Even if individual animal identify was retained through to the primal cuts, it would be lost under further processing (such as for minced meat and meat preparations/products).

In an average-sized slaughterhouse, between 100 and 1,000 slaughtered bovine animals are combined into a lot (batch), which is then processed into cuts (e.g. steaks). Multiple lots (batches) may be delivered together to a supermarket. This means that a piece of beef can be traced back to a group of individual animals with confidence (European Commission, 2012), but not to the individual itself even though the identification numbers are recorded when cattle are slaughtered (in accordance with Regulation (EC) No 1760/2000). For pigs, cuts are combined into a batch that can contain meat from 2,000 animals. Depending on the size of the batch these may have come from 20-100 different holdings.

Linking animal products to the individual animals from which they originate would therefore require further development of traceability systems. The alternative, in the context of a labelling obligation for products derived from clone offspring, is segregation of clone offspring and derived products from the rest of the supply chain.

³⁵ Regulation (EC) 178/2002.

4.7 Current requirements for labelling

As a general principle of EU food law³⁶, information provided to consumers should enable them to make informed choices and should not be misleading. New rules on food labelling in the EU have been in force since December 2014 under the so-called 'Food Information to Consumers' (FIC) Regulation³⁷. The aim of the legislation is to improve the clarity, completeness and accuracy of information provided to consumers through food labels³⁸.

The FIC Regulation sets out information which must be included on food labels. Examples of such information are: the name of the food; ingredients; allergens; quantities; 'use by' date; storage/use instructions; the name of the supplier; country of origin; alcoholic strength by volume (if over 1.2%); and, nutrition information.

The rules on nutritional information will be fully implemented from 13 December, 2016. They will require all prepacked food to carry nutritional information covering: energy; fat, of which saturates and carbohydrate, of which sugars; protein; and, salt. Unprocessed products comprising a single ingredient (such as a cut of meat) are exempt from this requirement. For food that is not prepacked, the provision of nutrition information will be voluntary.

Fourteen specific allergens (and their products) must be identified³⁹ in the list of ingredients.

Also, it is now mandatory to state the country of origin for fresh, chilled and frozen meat of beef (already in place), swine, sheep, goats and poultry. The Commission has assessed the possibility to extend mandatory origin labelling to milk and milk used as an ingredient in dairy products, to meats from other species and to meat used as an ingredient, but no further legislation has been brought forward.

There is a clear difference in the rationale for, and objectives of, including the different types of information required by EU labelling provisions. Allergen and nutrition labelling is provided for health reasons, to allow the consumer to avoid foods which will provoke an allergenic reaction and to make an informed choice between different products which have different nutritional profiles. Origin labelling, in contrast, is an attribute which allows consumers to select the products they prefer in a context where there may be no difference in the products' food safety, animal welfare, etc. This labelling also prevents consumers from being misled as to the origin of the food.

The FIC Regulation makes a distinction between providing information on a mandatory or on a voluntary basis. As recital 17 notes, "*the prime consideration for requiring mandatory food information should be to enable consumers to identify and make appropriate use of a food and to make choices that suit their individual dietary needs*". Recital 18 adds, "*any considerations about the need for mandatory food information should also take account of the widely demonstrated interest of the majority of consumers in the disclosure of certain information*". The mandatory origin labelling for

³⁶ Article 16 of the General Food Law (Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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).

³⁷ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

³⁸ The general objective of the FIC Regulation is stated as follows: "The provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations".

³⁹ Cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites, lupin and molluscs.

beef and beef products was introduced following the bovine spongiform encephalopathy (BSE) crisis and the Commission's impact assessment which confirmed that the origin of meat was a prime concern of consumers. The extension of country of origin labelling to other meat species followed impact assessments which demonstrated strong consumer interest. The FIC Regulation also highlights the importance of striking the right balance in providing information for the benefit of the consumer, as *"experience shows that in many cases voluntary food information is provided to the detriment of the clarity of the mandatory food information"*.

There is no requirement under origin labelling for any linkage between individual animals and the derived meat or livestock products (such as milk). This means that the current rules on labelling do not put a framework in place that could be used to facilitate the labelling of food products derived from the offspring of clones.

5 The implications for livestock breeding and production

Section summary:

The obligation to label clone offspring would require individual identification and ancestry registration for all animals of the concerned species. In the case of cattle, pigs, sheep, goats and horses there would be around 273 million additional animal identity registrations a year, most of them porcine animals. There would also be around 310 million additional ancestry records generated each year.

Additional costs that could reach beyond EUR 800 million a year would be incurred, mostly by livestock producers, in applying electronic identification tags, recording identity and ancestry, and recording movements on an individual basis. More than 80% of these costs would fall on the pig sector due to the number of animals affected by the switch to ancestry recording and the move from batch identification. If the manager of each EU livestock holding spent a total of 5 hours understanding its obligations under the new rules and preparing for their implementation, the sector could see 46.6 million person hours absorbed in familiarisation, time worth in excess of EUR 363m. Further preparatory costs are likely in equipping farms, markets/assembly centres and slaughterhouses with enough electronic tag readers to support the new system. There would also be ongoing training costs.

Substantial investment would be needed, probably by public authorities in the first instance, to develop the information and communication systems required. The design, testing and implementation of such systems would take time. Overall system operating costs would rise beyond what they are at the moment due to the need to accommodate (or integrate with) consolidated ancestry records, and the increased number of animal registrations and movement records.

The obligation would affect trade in reproductive materials; supplying countries would need to introduce measures to satisfy EU requirements on clone ancestry.

The costs identified above would be incurred even if there were no clone genetics in the EU livestock production sector or those of its trading partners, and are insensitive to both the definition of clone offspring and the number of animals that fall within it. They are the price of acquiring the capability to identify any animal as a clone offspring in a context where healthy animals from anywhere in the breeding system may enter the food supply chain.

Accidental or deliberate mis-assignment of identity or ancestry could not be detected via the documented approach outlined above. DNA sampling, profiling and recording arrangements might provide a verification mechanism for a system that would otherwise be vulnerable to fraud, albeit at a cost in excess of EUR 9.3 billion a year to the EU sector on the basis of the assumptions used. The DNA sampling and storage or profiling system would be without precedent in scale.

This chapter describes the type and scale of the changes required to 'close the gap' between the current practice in individual animal ancestry and identity recording (as described in Chapter 4) and the comprehensive approach that would be required for both domestic production and imported reproductive materials, live animals and derived products (as described in Chapter 3).

5.1 The need for universal recording of identity and ancestry

Once a labelling obligation came into force, all animals would need to be identified and their ancestry recorded. As shown in Chapter 4, animals from anywhere in the breeding pyramid can be sent to slaughter and enter the food chain. Any animal received at a slaughterhouse could potentially be an offspring of a clone. Only with a comprehensive

ancestry and identity system would it be possible for the slaughterhouse to confirm that each animal received was not an offspring of a clone. The same would apply in the dairy supply chain – once an obligation to declare clone status was in place then it would be necessary for each link of the supply chain to be able to confirm whether the milk was not derived from the offspring of a clone in a context where any animal might be a clone offspring.

The requirement for universal ancestry and identity recording would apply even if there were no clones or clone offspring in the food chain: the identity and ancestry requirements are insensitive to the number of clone offspring present.

The recording of ancestry and identity of all animals in the EU would be required even if the definition of clone offspring adopted covered only the first generation offspring (i.e. the direct descendants of the clone). Changing the definition of clone offspring to include more animals would not, therefore, change the number of animals affected by this requirement, or the scale of the costs associated with it. All the additional costs are incurred even if there are no clones in the system.

The definition of clone offspring adopted would have implications for those exporting reproductive materials to the EU. If the definition covered the first generation offspring only then it would be sufficient to record the clone status of the donor animal (animals produced in the EU from the semen or ova could then be identified as clone offspring). If the definition was extended over more generations then the ancestry records in the third country would need to be extended sufficiently for it be possible to make the appropriate declarations to EU authorities and importers.

If the definition covered two generations of offspring (i.e. to include the 'grandchildren' of the clone), the requirements on third countries with regard to meat and dairy products would be more extensive. Imports of reproductive materials from clone offspring could yield second generation clones in the EU that might then enter the food chain. In the absence of alternative authorised measures, comprehensive identity, ancestry and traceability systems in the EU would be needed to confirm the clone heritage status of all animals from the species within scope of the legislation to ensure that food was appropriately labelled.

5.2 The impacts of a move to universal ancestry and identity recording

As current systems do not provide universal ancestry and identity recording, further development of those systems and changes in recording practice by actors along the length of the food chain would be needed under a clone offspring labelling obligation (whatever the definition of clone offspring adopted).

The implications vary by species because current law and practice varies. For the bovine dairy sector, in which animals are individually identified and for which recording of the dam is required (and more extensive ancestry recording is common), the impact would be less dramatic than in pig production, where most animals are not individually identified and ancestry recording of production animals is uncommon.

Table 9 describes the changes required for each species and provides an estimate of the number of animals each year that, based on current production levels, would be affected by those changes. For each species there is a particular combination of the following:

- Extension of individual identity from part of the population to all animals;
- The recording of clone status against animal identity;
- The linkage of the identity record to an ancestry record for each animal;
- The extension of ancestry recording from a subset of the population to the entire population;
- The extension of ancestry recording from dam only to both sire and dam;
- The transfer of ancestry records from private systems to a central public register;
- The capture of identity and clone status for imported reproductive materials and live animals.

5.3 Determinants of the number of clone offspring covered by the obligation

The number of animals classified as 'clone offspring' would be determined by:

- The frequency of use of cloning techniques;
- The number of generations specified in the definition of clone offspring;
- The breeding structure of each species.

The absolute number of clone offspring recorded would be affected by the scale of use of the cloning technique in livestock production. If clones remained very uncommon then, clearly, fewer animals would have a clone offspring status than if it became a common breeding technique.

If clones are present in the system then the more generations that are covered by the clone offspring definition, the more animals would, over time, have a 'positive' clone offspring status. The scale of this effect varies across species, as was illustrated in 4.3.6.

5.4 Animal ancestry recording and identity recording systems

Investments would be needed in databases and supporting communications infrastructure and related services for recording identity and ancestry. This would involve enhancements to the processing and storage capacity of existing systems, or the replacement of existing systems by larger, robust information systems and supporting infrastructure and services.

For some species there would be very substantial increases in the number of animals that would need to be registered. Systems for porcine, ovine and caprine animals would require significant further development to support individual identity recording and the extension of ancestry recording beyond existing use of herdbooks to the full population. Systems for tracking animal movements through the supply would all require development and investment.

The registry would also need to be able to hold a record of whether or not each animal was a clone or an offspring of a clone. Offspring would need to be identified by the system having the capability to trace back through the generations (via the unique animal identity numbers) as far as was required by the definition of clone offspring that had been adopted in law.

The system would also need to have the capacity to relay information on the clone status of each animal on request. For example, a slaughterhouse would electronically submit a batch of animal identification numbers to the system and receive, in response, notification of the clone offspring status of each animal. This response would need to be provided immediately to avoid delays and cost in the supply chain. The implication of the extensive trade in livestock within the EU is that the system in any Member State would need to be able to confirm the clone offspring status of any animal born in any other Member State. It would also need to be able to indicate the status of animals produced from imported reproductive materials.

Table 9. Implications of clone offspring labelling by species

	Individual ID required	Ancestry recording required	Necessary adaptations for clone offspring labelling	Estimated number of animals affected by changes each year
Bovine	Yes, all animals (Reg'n 1760/2000)	Compulsory only dam (Reg'n 1760/2000) Private breeding org. 70-75% of dairy cows ⁴⁰ ~23% of beef cattle ~47% of total cattle population	Extension of compulsory ancestry recording to both parents Ancestry record linked to identity record Ancestry records held in public database rather than private systems Clone status attached to identity record Identity and clone status of imported reproductive materials recorded Clone status of live animals imported to the EU recorded	Ancestry recording extended to both parents for ~ 16 million ⁴¹ animals per year Identity, ancestry records and clone status required for an ~ 10 million doses of imported semen doses each year, principally from US and Canada ⁴²
Porcine	No Minority of animals (<20%) individually registered	Private breeding organisations ~10% of pig population ⁴³	Individual identity assigned to all animals Ancestry recording compulsory throughout the breeding and production system Ancestry records held in public database rather than private systems Ancestry record linked to identity record	Individual identity would be required for ~239 million animals per year ⁴⁴ Ancestry recording to 246 million more animals a year and all records transferred to an alternative system

⁴⁰ Based on expert consultation. Lower rate applies for male calves channelled into meat production.

⁴¹ Derived from Eurostat data (2014) on annual slaughterings. UK herd replacement rates were used as proxy for EU (ADHB, n.d.).

⁴² Based on Eurostat 2014 data on imports of bovine semen from third countries.

⁴³ Based on expert consultation.

⁴⁴ Nucleus herd populations assumed to be 1.5% of total herd, with 90% annual nucleus herd replacement rate. Multiplication herd assumed to be 11% of total herd, with a 44% multiplication herd replacement rate. Values adapted and derived from expert consultations, and annual slaughtering data (Eurostat, 2014).

	Individual ID required	Ancestry recording	Necessary adaptations for clone offspring labelling	Estimated number of animals affected by changes each year
			Clone status attached to identity record Identity and clone status of imported reproductive materials recorded Clone status of live animals imported to the EU recorded	Imports of porcine reproductive materials and live pigs from third countries are negligible
Ovine	Yes (but derogation for young slaughter lambs below 12 months of age) (Reg'n 21/2004) Estimate of 68% ovine & 80% caprine animals registered	Private breeding organisations 5% of sheep population ⁴⁵	Individual identity assigned to all animals without option of derogation Ancestry recording compulsory throughout the breeding and production system Ancestry records held in public database rather than private systems Ancestry record linked to identity record Clone status attached to identity record	Individual identity assignment to an additional 31 million sheep per year ⁴⁶ Ancestry recording to 44 million more animals a year and all records transferred to an alternative system ⁴⁷ Imports of ovine reproductive materials and live sheep from third countries is negligible
Caprine		Private breeding organisations 5-10% of goat population ⁴⁸	Identity and clone status of imported reproductive materials recorded	Individual identity assignment to an additional 2.5 million goats per year ⁴⁹ Ancestry recording to 3.9 million more animals a year

⁴⁵ Based on expert consultation.

⁴⁶ Values adapted and derived from expert consultations, and annual slaughtering data (Eurostat, 2014). A UK ewe replacement rate of 20-25% was assumed for the EU (Eblex, n.d.).

⁴⁷ Ibid

⁴⁸ Based on expert consultation

⁴⁹ Ibid. Breeding herd replacement rates (20-25%) from the ovine sector were used as proxies for those in the caprine sector.

	Individual ID required	Ancestry recording	Necessary adaptations for clone offspring labelling	Estimated number of animals affected by changes each year and all records transferred to an alternative system Imports of caprine reproductive materials and live goats from third countries are negligible
Equine	Yes (Reg'n 2015/262 etc.)	Private breeding organisations 75% of horse population ⁵⁰	Ancestry recording compulsory for all horses Ancestry record linked to identity record Identity and clone status of imported reproductive materials and live animals recorded	Ancestry recording extended to 54,000 more animals a year ⁵¹

⁵⁰ Based on expert consultation

⁵¹ Figure includes information on ancestry and clone status of live imported horses from third countries slaughtered in the EU.

The obligation would require a register that was accessible to the food chain and regulators for the purpose of checking clone offspring status by tracing ancestry. Independently operated, paper-based systems operated by breeding organisations in some Member States would not be adequate or efficient in a context where the ancestry of each animal needs to be recorded, its clone status logged and that status be accessible to system users.

Member State authorities and herdbook administrators would need to work together on fit-for-purpose technical solutions, and address the data ownership and access issues associated with the transfer of information from privately administrated databases to systems that would service the requirements of a clone offspring labelling obligation. It seems likely that a single register, integrated with the identity register, would need to be constructed for each species in each Member State and those registers be linked together at EU level.

The transition to a single register may have wider implications for managers of herdbooks. The maintenance of the herdbooks can be a core part of these organisations' function and can also have a financial significance to them. In some Member States there has already been some consolidation of ancestry recording (multiple breed associations use the same recording system rather than each operate their own). In those cases the changes required to accommodate clone offspring labelling would be less extensive.

In some cases ancestry records are currently held by companies in private systems (e.g. in much of the pig sector). These systems would not provide the access, independence and transparency required for a regulatory system built for public purpose. Either new systems would need to be constructed or Member States would need to work with the owners of existing registers to introduce arrangements that opened up the access to existing data as far as was required for the purpose of the labelling obligation, and ensure that the systems were robust and reliable.

To make it possible to confirm the identity and ancestry of animals traded within the EU the national databases would need to be inter-operable, or a complete set of EU data compiled regularly from data sourced at Member State level and that composite dataset be accessible to system users. This integration would add very significant complexity, and add to cost.

Research has provided estimates of the costs of the development, system administration and support of animal database registry database that vary very widely. Case studies provide data that illustrate system establishment costs. The Netherlands, for example, built an information system for registration and tracking of bovine animals that was established at the end of 2006 and cost approximately EUR 8.5 million. Enhancing the system to accommodate ovine and caprine animals in 2010 cost a further EUR 5 million (both costs are inclusive of the cost of engagement with the livestock sector and their recruitment onto the system).

Consultations suggest that IT system development costs for individual countries cannot readily be quantified without detailed study of the current arrangements in each Member State and the transition required (for some Member States and some species systems are already well-developed and would require little adjustment, in other circumstances there would be a need for much more extensive investment). Extended ancestry recording (e.g. via integration with herdbook records) would be a challenge for all. The scale of the systems would according to the size of the herd/flock of different species across the Member States. Providing EU-level inter-operability/integration so as to enable the clone status of animals that are traded within the EU to be checked would add an additional level of complexity.

The available evidence suggests that extension of ancestry and identity systems to meet the requirements of clone offspring labelling would trigger extension and upgrade costs measured in the tens of millions of euros for the EU-28 as a whole, and possibly in the hundreds of millions of euros. These development costs are likely to be

incurred in the first instance by public authorities, though in practice public-private arrangements might be adopted. Ongoing costs may fall to the taxpayer or food chain – current practice varies among the Member States.

These enhanced systems would require maintenance and administration. There would be additional activity due to the large number of animals registered, movements recorded, etc. Consultations with registry operators in several Member States with significant livestock sectors suggest that they have 40-50 staff and operating budgets of several million euros, though species coverage varies. With each identity record being accompanied by an ancestry record, and the scope of identity, ancestry and movement recording all being extended (albeit to different degrees for different species), it seems likely that the scale of these operating costs will increase significantly. There are some estimates in the literature on operating costs per animal⁵², and other estimates were provided by consultees but the range of cost ranges (and range of changes required by species and by Member State) is too wide for a detailed operating cost analysis to be feasible.

The incidence of these costs would depend on the cost recovery strategy adopted by the Member State. In some instances registry services are provided at no direct cost to the food chain, in others there is a cost recovery strategy by which livestock producers and other food chain businesses face a tariff structure that reduces the burden on general taxation.

5.5 Additional obligations and costs imposed on livestock producers and traders

The clone offspring labelling obligation would impose additional obligations and costs on livestock producers and traders. The principal elements would be:

- The costs of familiarising themselves with the requirements of the legislation;
- The costs of assigning and maintaining individual identity for animals where that is not currently required (elements comprising the purchase of the electronic ear tag, fitting of the tags, registration, re-tagging where tags are lost);
- The cost of recording both parents in an ancestry recording system where at present there is either no such recording or records are kept for the dam only;
- Recording animal movements on individual basis where it is currently conducted on a batch basis.

5.5.1 Familiarisation

Livestock producers, markets and assembly centres, and slaughterhouses would incur costs in understanding and preparing for compliance with the legislation relating to labelling of products derived from the offspring of clones. There would be wide variation in scale of the implications for individual businesses, and in the time and resources that they would need to invest in understanding those obligations and putting in place such arrangements and systems as would be required to secure compliance. Businesses in sectors where there is already individual identification of animals and ancestry recording is common (e.g. breeding of pedigree herds of dairy cattle) would see little impact. By contrast, large scale pig producers would face significant changes in operating practice.

Preparatory studies and impact assessments make *ex ante* assumptions about the scale of learning and adjustment costs incurred by businesses when new legislation is introduced into the food chain, but it is very rare for these assumptions to be checked, through targeted research, against the actual costs incurred. Adopting the same time

⁵² For example: Saa et al. estimated that for Spain average operating costs were EUR 0.15/animal/year; one consultee estimated EUR 1/animal/yr.

assumptions as were used in a previous study on a similar issue⁵³, the total time requirement could reach 47 million hours. There are various methodological issues associated with valuing the time of a group that comprises many self-employed farmers (see section 2) but on the basis of the approach used here this would have a value of around EUR 363 million.

The EU's trading partners would need time to adjust to the requirements placed by the EU on imports (whether of reproductive materials or animals). This would include the time needed to establish arrangements, e.g. segregated supply chains, and develop registries and similar arrangements to support claims for clone offspring status.

EU-based breeding organisations and importers of reproductive materials would also need to understand the requirements. The principal trade-related cost would fall on exporters in third countries. It can also be expected that there would be costs to the EU budget in working with trading partners on explanation, support and system development.

In addition to the initial costs of familiarisation there would be ongoing costs relating to training in the procedures required for compliance with the legislation.

5.5.2 Tagging

It is here assumed that under a clone offspring labelling obligation animals would be tagged with an electronic identification tag (EID) to support more rapid processing and reduce the error rate in data capture, such as at slaughter. The EID tag would be used together with a conventional tag. For costing purposes the additional components of the obligation are therefore assumed to comprise one EID tag for each additional animal that needs to be tagged plus an appropriate applicator and the time taken to apply the EID tag.

An indicative additional cost of EUR 475 million/year has been estimated. The distribution of this across species is indicated in Table 10.

The tagging would need to be done as soon as possible after birth. This may pose a risk of negative animal welfare impacts (e.g. ear tagging of very young goats).

Research suggests EID loss rates have been falling and reliability improving as designs and technology have improved over the years and livestock producers have gained more experience. Some loss of tags and loss of functionality is however, inevitable. Where a tag is lost or the number is no longer picked up by a reader the farmer needs to order a replacement tag and spend time fitting it.

Modelling of replacement costs has been undertaken assuming a loss rate of 3% (i.e. 3% of additional EID tags fitted would need to be replaced before the animal was sent to slaughter). This is towards the low end of the rates used in other studies, but reflects the fact that most of the animals individually identified as a consequence of the cloning obligation would be food production animals destined for slaughter within a year. Data on time required for ordering and fitting replacement tags are scarce so the cost, EUR 30 million, should be regarded as indicative.

The additional tagging costs would fall on livestock producers in the first instance. They would result in some additional revenue to ear tag suppliers and their supply chains.

⁵³ 5 hours per holding and 10 hours for each market/assembly centre/slaughterhouse as used in *Study on the introduction of electronic identification (EID) as official method to identify bovine animals within the European Union*, Food Chain Evaluation Consortium, for DG SANCO, European Commission, 2009.

Table 10. Indicative additional tagging and re-tagging costs, EUR m/yr

	Bovine	Porcine	Ovine	Caprine	Equine	Total
Tagging ⁵⁴	-	440	31	4	-	475
Re-tagging	-	28	2	0.3	-	30.3
Total		468	33	4.3	-	505.3

Source: These figures are based upon estimates of the number of additional animals that would require electronic identification, costs for purchase of ear tags and assumptions on the time taken to fit tags. Cost estimations are explained in detail in Annex 4.

No additional provision has been made for electronic tag readers on the assumption that farmers and the supply chain already have some access to this equipment. However, in some sectors (e.g. pig production and slaughter) upgrades of reading equipment is likely to be required to realise the economies of scale on offer from fixed readers. The cost of such equipment is falling over time. Some existing activities would become redundant once EIDs were in use (e.g. the application of slap marks⁵⁵ or other holding identifiers to slaughter pigs). Savings in time and materials currently spent on those activities would offset the time and resources allocated to EID tagging.

5.5.3 Identity and ancestry registration costs

The number of additional animals requiring individual identity registration is the same as used for EID tagging. It is assumed that Member States establish enhanced online systems for identity recording of the animals and that alternative (e.g. paper-based or voice-based) systems are provided as an alternative for those farmers who do not have internet access.

The number of animals for which ancestry would need to be recorded is different to the additional identity registrations. There is no additional effort required for animals currently pedigree recorded in herdbooks (indeed the time required for these animals may actually ultimately reduce where new, more efficient registration systems are introduced). For other animals the clone offspring labelling requirement would involve additional registration of one (e.g. where only the recording of the dam is required under current law) or both parents (for animals where parentage is not currently recorded).

It is assumed that identity and ancestry recording would be done as part of the same operation. Reasoned assumptions have been made about the average time required per animal for the ancestry recording operation but wide variation is likely depending on the scale of the operation – large economies of scale would be expected. The sophistication of the ancestry/identity database's user interface would also have a significant impact on time required (e.g. batch registrations). Indicative cost estimates are provided in Table 11.

These costs would fall on livestock producers. The administration of the registration by the database operator is discussed at section 5.4.

⁵⁴ It is assumed that no additional tagging costs would be incurred for bovine and equine animals as they have to be individually identifiable under existing legislation.

⁵⁵ A slap mark is a permanent ink mark of the herdmark is applied on each front shoulder of a slaughter pig in lieu of an ear tag.

Table 11. Indicative incremental annual costs by sector for registration of identity and ancestry, EUR m/yr

	Bovine		Porcine	Ovine	Caprine	Equine	Total
	Dairy	Beef					
Registration ⁵⁶	-	-	60	6	0.4	-	66.4
Ancestry	1	12	207	29	2	-	251
Total	1	12	267	35	2.4		317.4

Source: The estimates are based on estimates of the number of additional animals for which (i) individual identity and (ii) ancestry would need to be recorded plus assumptions on the average cost of time and time required for each operation. Cost estimations are explained in detail in Annex 4. Some figures have been rounded to the nearest EUR m.

5.5.4 Movement records

The clone offspring labelling obligation would require animal movements to be recorded on an individual basis rather than the batch basis currently permitted in certain circumstances, e.g. for porcine and ovine animals under 12 months travelling to be slaughtered. At the slaughterhouse, the registration process would need to provide the operator with information on the clone offspring status of animals so that clone offspring could be segregated as needed. This status might also be indicated by the supply chain on accompanying documentation (e.g. as a requirement of contract).

There is no central EU registry from which the data needed to build a fully accurate estimate of the number of individual animal moves affected could be taken. Estimates have been developed based on data requested from the registries of certain Member States and figures gathered from the literature. These collectively enable the construction of ratios that can be applied to livestock production figures to derive an estimate of the number of additional moves per year that would need to be recorded. Variation in the number of moves in an animal's lifetime can be expected due to differences in industry structure, trade, etc. Estimates developed for this study suggest that around 435 million individual animal movements a year within the EU could be affected.

The operational impact of requiring individual recording of movements needs to be considered in the context of the animals being tagged with EIDs. When compared to manual reading of plastic slaughter tags, reading of electronic identification is faster. The value of time savings at markets and slaughterhouses, where economies of scale can be realised, can be significant⁵⁷: a well-equipped slaughterhouses would be able to scan many more animals per minute than a sole farmer with a handheld reader. The additional cost of EIDs to farmers has been a barrier to uptake of the technology but if legislation on clone offspring labelling obligation mandated use of EIDs then there are circumstances in which time savings along the supply chain would be available as a 'co-benefit' of the investment. The baseline situation in use of EIDs varies by species and by Member State. Time required varies by species, context and type of reader. Overall it is not feasible to establish whether there is an overall saving or a net cost.

Savings in capturing animal data associated with use of EIDs would be offset by the additional time taken to submit movement data to the authorised registry on an individual animal (rather than batch) basis. The literature on the time taken for such activities is scarce. The time implications will vary from case to case according to the

⁵⁶ It is assumed that no additional registration costs would be incurred for bovine and equine animals as they have to be individually identifiable and registered under existing legislation.

⁵⁷ An example is provided by the UK Government's impact assessment of the adoption of EIDs for slaughter lambs (Defra, 2013).

scale of the holding or market operation, the design of the information system, the farm's access to the internet, etc. For operators that are able to exploit economies of scale and make best use of technology, the cost per animal is likely to be low.

Facilities (e.g. slaughterhouses) receiving animals would need to check the clone offspring status of the animals, e.g. to ensure animals were allocated to the correct segregated system. If confirmation of animals' clone heritage status was not possible in real time then there would be the potential for delays in processing animals (and hence additional costs).

5.6 Modification of existing breeding and production practices and supporting systems

For some parts of the livestock sector implementing individual identification and ancestry recording would imply more than added administrative burden and inconvenience - it would force more fundamental changes in practice.

For example, extensive livestock systems may not be compatible with the ancestry recording arrangements required for clone offspring labelling. Assigning the paternity of each young animal to a single sire would not be possible where there is more than one male animal and it may be difficult to assign a given young animal to a specific dam with full confidence⁵⁸.

The change would also affect some intensive farming practices. For example, in porcine production, in some Member States (e.g. Denmark) it is common for semen from 3 to 10 boars to be mixed for use in AI to improve the farrowing rate (Carr, n.d.).⁵⁹ Where semen is mixed, the ancestry of the offspring is not known - i.e. the practice is incompatible with individual ancestry recording. The practice is not universal, mixed semen is not allowed in the Netherlands⁶⁰ for instance.

The logistics (and thus costs) of assigning identity, re-tagging etc. would also - in practice - vary significant across sectors. Re-tagging pigs confined indoors is likely to be less time-consuming than re-tagging the same number of upland sheep.

5.7 Verification of documentation and labelling

A labelling system for food derived from clone offspring could be constructed using documented systems only⁶¹ but there would be no means of verifying claims made for the clone offspring status of specific animals. If the claims made on labels about the clone heritage of the products cannot be verified then the system will be more vulnerable to error and to fraud. The greater the negative (or positive) economic value attached to an individual animal's 'clone offspring' status, the greater the incentive for malpractice. If the labels cannot be relied upon then consumers may be misled, public confidence in the system eroded and food business operators face legal challenges. Even without incentives for fraud, errors in ancestry recording could be sufficient to discredit a system that lacked a verification mechanism⁶².

DNA profiling could, under certain conditions, provide verification. A DNA profile for an animal is built by looking at the DNA markers at particular points in its genome. By comparing the profiles of two animals it is possible to confirm parentage with a high degree of confidence⁶³. The technology is established. DNA profiling can, for instance, be used by a farmer to confirm parentage of a bovine animal for the

⁵⁸ Studies reported in Kilgour & Dalton (1984) suggested that 6 - 18% of lambs can be 'stolen' from their dam by another ewe. This would result in the wrong dam being recorded and probably the wrong sire.

⁵⁹ Number of matings divided by the number of litters produced (farrowed) (Abell et al., 2012)

⁶⁰ This biosecurity measure was introduced following a major outbreak of Classical Swine Fever in 1997.

⁶¹ 'Documented' here encompasses electronic data recording, storage and retrieval systems.

⁶² Research involving DNA profiling of pedigree sheep and goats has found comparatively high levels of mis-assigned parentage.

⁶³ The result of a parentage test is expressed as a probability, rather than as a definitive yes/no answer.

purposes of the animal passport, with the DNA of the dam and calf being sampled and compared by an accredited laboratory.

By itself a DNA profile could not distinguish a clone offspring from a natural offspring of the donor, but the combination of DNA records and documented records would provide a much more robust control regime than either approach when used alone. Relationships cannot be confirmed across several generations through a single test but if samples are systematically taken from all animals then parentage could potentially be confirmed back through successive generations. This process could go back as far as is required by the definition of clone offspring adopted in law.

At present DNA samples are not regularly taken for the livestock species assessed in this study. Where they are taken, it is primarily for selective verification purposes to meet the demands of a particular operator. A DNA-based verification scheme would require, for each animal, a DNA sample to be taken, the sample despatched to an authorised facility, a test to be conducted, and the results recorded on an appropriate information management system. All animals would need to be sampled. If the status of a particular animal is challenged it is unlikely to be feasible to find and profile its parents (which may have been slaughtered and consumed, or be located in another jurisdiction) – the profile needs to be on the system already.

The sampling might be undertaken alongside regular animal identify assigned and registration activities. There are EID ear tags available on the market that are designed to integrate tissue sampling for DNA profiling with the application of the ear tag. When the tag is applied to the ear a tissue sample is deposited in a tube that is pre-labelled with the identification number present on the ear tag. The tube can then be despatched to a DNA profiling facility or storage.

The profiling of the samples and record management and storage would also be additional activity and would imply an additional cost. Development and standardisation of profiling protocols would be required. Significant investment would be needed in facilities equipped to conduct the baseline DNA profiling at the scale required, to log the results on a system linked to the identify and ancestry records, and to support enquiring about the ancestry of particular animals. The system would need to be able to process samples from hundreds of millions of animals a year in Europe alone. It would be without precedent in its scale.

Researchers for this study were quoted prices starting at EUR 25 per test (i.e. per animal) and rising to over EUR 100/test. Reductions in price through economies of scale, technological improvement and automation might be expected over time.

The illustrative cost estimates shown in Table 12 have been prepared based on a sampling EID tag cost of EUR 3.50 (so an incremental cost of EUR 2 over conventional EID tag), and reasoned assumptions about the time taken for preparation, documentation and despatch, packaging costs, and a test cost of EUR 25. The total cost on the basis of the assumptions made is in excess of EUR 9 billion a year. Of this total most (87%) would be testing costs. Costs fall mostly the porcine (EUR 7.1bn) and ovine (EUR 1.3bn) sectors.

Table 12. Illustrative costs of DNA sampling and profiling, EUR m/yr

	Bovine	Porcine	Ovine	Caprine	Equine	Total
Beef	Dairy					
183	545	7,156	1,272	139	6	9,301

Source: The estimates are based on estimates of the number of animals for which DNA samples would need to be obtained and estimates of the unit cost of the sampling equipment, time incurred by the livestock producer and the cost of the tests. Cost estimations are explained in detail in Annex 4.

An additional cost of this scale would have very significant impacts on sector profits, output, employment, exports, etc. A key issue would be how far unit costs could be reduced through innovation, automation and economies of scale.

The countries that are the principal source of EU's meat and dairy imports do not have verification systems of this type for confirming clone offspring heritage. If they were required to have equivalent systems to support the verification of claims made under labelling obligation then those that chose to continue trading with the EU would incur additional costs in system establishment and maintenance.

Placing such a requirement on imports would address the competitive disadvantage that EU domestic producers would otherwise face in the EU market. The additional costs of verification would, however, make it more difficult for EU exporters to compete in world markets against producers that do not face equivalent costs.

5.8 Impacts on third countries supplying animals and reproductive materials

5.8.1 Direct effects on imports would arise from regulatory requirements

Imports of live animals and reproductive materials (embryos and semen) to the EU from third countries will be affected by the labelling requirement.

If 'clone offspring' is defined to include only the first generation offspring of a clone, then breeders in third countries would only need to identify whether the reproductive materials exported to the EU were from a clone or not. If they were the product of a clone, it is likely that the breeder in the third country would be aware that the animal was a clone and information should be easy to provide in the export records, where provision is made for this information to be recorded on the documentation. Very little in the way of additional work would be required and therefore little additional direct cost. Live animals could similarly be designated as a clone for export to the EU with little effort. Appropriate information would be needed for ancestry records and arrangements made (within the EU) to accommodate such imports within the identity/ancestry recording system.

If the definition of clone offspring was extended to include second generation offspring (or beyond), it would become more difficult for a breeder in a third country to be certain of the clone status of the donor animal (for reproductive materials) or the live animal. This is because most third countries do not require tracing of cloned animals or their reproductive materials. Breeders would need to put in place additional systems to check and verify the status of the reproductive materials they use in their breeding programmes, and therefore the status of the breeding animals that produced reproductive materials for export to the EU in their own company/organisation. The additional costs would be most significant in Canada and the US, with New Zealand and Australia also affected. If DNA-based verification mechanisms were required as discussed in section **Error! Reference source not found.** then the impacts would be significant. If third countries were not required to meet verification standards equivalent to those applied within the EU then it could reasonably be argued that EU producers were being put at an unfair disadvantage by EU law.

5.8.2 Indirect impacts could arise from behavioural response to the labelling obligation by the EU food chain and by exporters

Imports to the EU could be indirectly impacted as a result of behavioural responses by the EU food chain once labelling of products derived from clone offspring was required. Specifically:

- If exporters were unwilling or unable to meet EU requirements then the EU could lose access to the high quality genetics that are currently imported;
- If a definition of clone offspring spanning several generations was adopted and cloning was practised in the exporting country such that a significant share of the reproductive materials was classified as clone offspring, then EU importers

may stop using imported reproductive materials in response to the market dynamics discussed elsewhere in this report.

The impact of such responses would be most significant in the bovine dairy sector.

5.9 Summary of the impacts on the EU livestock sector

Based on the analysis undertaken and associated assumptions, a clone offspring labelling obligation would trigger additional operating costs of over EUR 800 million per year for the EU livestock sector.

This system would deliver a document-based system that would potentially be vulnerable to fraud and error. Application of a DNA-based verification system could theoretically provide security against fraud but would add substantial further costs, potentially of EUR 9.3 billion a year, and itself involve significant technical and logistical challenges.

There is uncertainty about the magnitude of the cost factors, but the analysis provides a useful indication of the likely order and distribution of the impacts. The distribution of these costs by activity and species/sector is shown in Table 13. The distribution of annual operating costs (excluding familiarisation) by species is shown in Figure 18.

Table 13. Indicative operational costs of a clone offspring labelling system to the livestock production sector, EUR m/yr

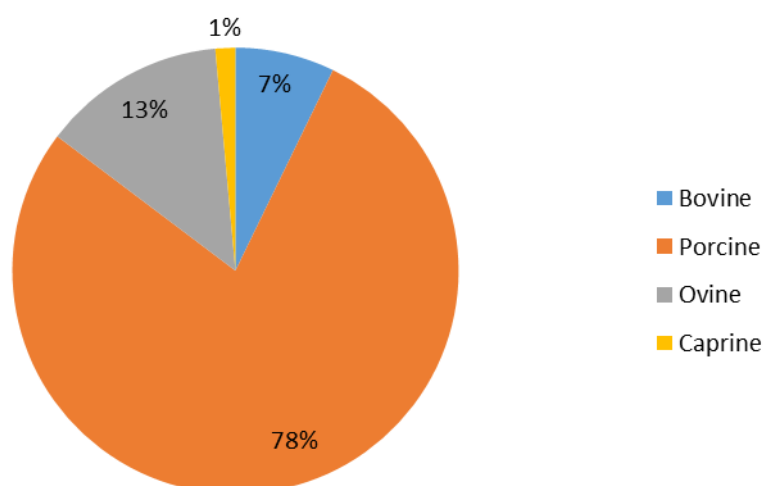
	Bovine		Porcine	Ovine	Caprine	Equine	Total
	Dairy	Beef					
Tagging	-	-	467	33	4	-	505
Identity & ancestry	1	12	267	35	2.4	-	317
Sub-total	1	12	734	68	6.4	-	824
Verification (option)	183	545	7,156	1,272	139	6	9,301
Total	184	557	7,890	1,340	145	6	10,125

Source: ICF estimates. Excludes development costs of databases and associated systems. Also excludes ongoing training costs associated with the obligation.

The scale of costs is sufficient to suggest that income and output levels in EU livestock production would be affected. The implications for domestic production and the new market equilibrium that would emerge cannot easily be predicted.

These costs would be incurred even if there were no clone offspring in the livestock sector, and irrespective of the definition of clone offspring adopted. They arise from the requirement for full identity and ancestry recording for all livestock, and the need to secure the capacity to attach a clone offspring status to any animal and retain that link from birth to slaughter. Excluding clone offspring from the food chain or establishment of segregated supply chains based on production from clone offspring would not, therefore, mitigate these impacts of the legislation.

Figure 18. Distribution of incremental operational costs by species



Source: Based on ICF estimates. Equine costs are less than 1% of the total so an equine label is omitted from the figure. Excludes development costs of databases and associated systems. Assumptions and caveats are detailed in Annex 4.

The table below sets these operational costs in context, referencing them to the production value of the sectors concerned.

Table 14. Operational costs as a percentage of the economic value of livestock production sectors

	Bovine	Porcine	Ovine & Caprine	Equine
Tagging	-	1.33%	0.70%	-
Identity & ancestry	0.04%	0.76%	0.70%	0.004%
Verification (option)	2%	20%	26%	1%

Note: operational costs are assessed against the production value at basic prices of the livestock sectors using Eurostat data (2014). Separate production value data for sheep and goat sectors were not available.

The obligation would also require enabling investment in information infrastructure to support the transmission of clone offspring information through the supply chain and across Europe, linking identity to ancestry, and accommodating trade within the EU and with third countries. These costs, which would be measured in the tens – if not hundreds – of millions of euro across the EU as a whole, are assumed to fall to Member State governments in the first instance.

For some species the infrastructure established by the obligation could potentially provide benefits in terms of supporting more sophisticated breeding and performance management systems, though the sector bearing the largest share of the expected costs of the obligation (pig production) is already well-served in this regard.

6 The implications for food supply chains

Section summary:

A clone offspring labelling requirement would call for changes to traceability systems at markets, assembly centres, slaughterhouses and meat processing plants to facilitate information on individual animals being carried through to the primary products. Identity (and ancestry) information is lost when product from different animals is mixed (in forming product batches) so the 'clone offspring free' / 'clone offspring' status would need to be established at a batch level for such products. If there is no 'clone offspring' product on the market then the practical impact is limited.

A clone offspring labelling requirement would prompt segregation of 'clone offspring free' and 'clone offspring' dairy supply chains since identification of milk from an individual animal is not technically feasible within modern supply chains. This segregation would lead to additional costs to the supply chain only if clone offspring milk was collected or placed on the market.

Under the negative labelling assumption specified for this study (i.e. products being labelled as 'not derived from clone offspring', not just as 'derived from clone offspring'), all meat and dairy products not produced from clone offspring would require modified labels. Under current (and projected) market conditions, this would mean labelling changes for all products on the market across all five species.

Consultations with the supply chain suggest an obligation to indicate the clone offspring status of products would result in the active exclusion of clones from the livestock production and the food chain by retailers, food producers, and animal breeders. This is primarily because companies believe consumers would not purchase products labelled as being derived from clone offspring and firms would be reluctant to place such products on the market.

Clone offspring, where present, would trigger segregation costs without creating additional revenue (in the form of higher prices) to compensate. In those circumstances the supply chain would incur the costs of acquiring the capability to trace and label products, and incur the cost of modifying labels to indicate the products' 'clone offspring free' status, but no segregation costs would arise as there would be no clone offspring derived products to segregate.

A clone offspring labelling requirement would require third countries that export relevant products to the EU to invest in traceability systems or establish segregated supply chains. The additional costs associated with either strategy are expected to be added to export prices, and so increase the cost to the EU of imported food products. This would alter the EU market equilibrium in ways that cannot easily be predicted. Food costs to consumers would, however, be expected to rise and net incomes to producers fall.

To the extent that the labelling requirement increased costs to EU producers this would be expected to reduce the competitiveness of their products in global food markets until such time as there is a market premium attached to information about clone offspring status.

This chapter examines the implications that a clone offspring labelling obligation would have for the processing and packaging of products derived from animals, and their delivery to the consumer.

6.1 Changes to animal product traceability systems and supply chains

For information on the clone heritage status of individual animals to be carried through to the labels of the food products derived from those animals there needs to be the

appropriate internal traceability systems in place at intermediate meat handling operations, such as slaughterhouses, cutting and processing plants.

Existing traceability requirements in the EU do not, in general, extend to linking individual animals with their food products beyond the carcass level and there is no forward transmission of information on individual animals with their products.⁶⁴ Even for bovine animals, for which individual animal identification is well-developed, the link to the individual animal is broken when the animal is slaughtered. For milk products, the problem occurs even earlier in the supply chain when milk from many animals is mixed together on the farm.

The clone offspring labelling requirement impacts differently on the meat and dairy supply chains. In the meat supply chain it is possible to identify additional requirements that would facilitate labelling. Similar solutions are not available for dairy because milk from different animals is already mixed on farm. A segregated supply chain would be required for farms with milk producing animals that were clone offspring.

The supply chain would incur familiarisation costs, and ongoing costs in the training of staff in the additional procedures required by the obligation. There would be a requirement for the further development of information systems to support the passage of information of clone heritage status from source through to consumers.

The text below explores the practical implications with reference to bovine animals. The same issues will apply to meat production in porcine, ovine, caprine and equine animals and to milk production from ovine and caprine animals (the bovine dairy supply chain is dealt with separately). The traceability systems for such species are more limited and will need to be upgraded to the level of bovine animals and new capabilities would then be required to enable individual animal traceability for primal meat cuts.

6.1.1 Meat production

To label the food produced from clone offspring, information on identity and clone offspring status would need to be carried over from the slaughtered animal to the food products derived from that animal. The information would then need to be passed *forward* through the supply chain to facilitate the appropriate labelling of the product for the final consumer.

One theoretical option is to segregate the supply chain for each individual animal carcass, but this introduces major changes to the current operation of slaughterhouses and would create significant inefficiencies. The modern meat supply chain operates on a commodity basis. Carcasses are broken down and the different cuts of meat are separated into batches of product types and uniform sizes/weights for specific cuts to serve different markets and food outlets.

If the slaughterhouse was able to carry the animal identity through the slaughter process to the whole cuts of meat then it would be possible (via the identity database) for the slaughterhouse to notify clone status of those cuts to the next stage in the supply chain. This retention of identity on whole cuts would not help for minced meat and other products that require the mixing of raw materials from more than one animal. For such products, each batch would need to be recorded as being free of clone offspring or containing clone offspring and that information transmitted forward through the supply chain.

⁶⁴ France appears to be a special case in that there is a system in place which allows primal meat cuts sold in retailers to be linked back to a specific carcass through a bar code. For minced meat and lightly processed products such as beef burgers the link is made to a group of animals, from which links to individual animals can be made. This system is passive, in that the information is not actively used, but the system can be called upon if there is a need to trace the origin of the meat.

Assembly of batches of products derived from clone offspring could not easily be done if clone offspring were rare and randomly distributed. Some consolidation of clone offspring production would be required, potentially leading to a segregated supply chain for clone offspring and derived products. This would, however, require a scale of operation and investment that goes well beyond that associated with individual farmers making use of clone offspring reproductive materials and other reproductive materials interchangeably. Consultations with the supply chain indicate that such investment is unlikely. Batch-based management of clone offspring meat would add costs for slaughterhouses and cutting plants.

Systematically keeping track of the clone heritage status of meat ingredients in the downstream stages of the supply chain (i.e. those following slaughtering) would pose significant operational challenges. These would become more serious in the case of:

- Small-scale operations.
- Continuous production processes.
- Mixing of meat ingredients from multiple sources, combined with frequent changes in the mix of suppliers.

The implementation of a segregated supply chain through the addition of a dedicated 'clone offspring' production line (including dedicated storage facilities) would be extremely difficult in small-scale operations, as throughput is less likely to reach the volumes required for an efficient and economic operation of the line itself, irrespective of the nature of the process (continuous or batch-based). Net returns from the required investment are likely to be unsatisfactory, also considering that the products labelled as being derived from clone offspring are not expected to attract a price premium on the market.

The possible alternative, i.e. thorough cleaning of production lines/storage facilities after processing/storage of any batch of clone offspring meat ingredients, would result in inefficiencies - the necessary downtime would negatively impact the utilization of process capacity. Thorough cleaning of production lines and storage facilities would be even less sustainable in case of continuous production processes, irrespective of the scale of operations. In such conditions, the addition of a dedicated 'clone offspring' production line (together with dedicated storage capacity) would be the only option. Considerations on the minimum size of throughput and on the net returns from investment in a dedicated 'clone offspring' line are even more critical in case of continuous production processes.

When meat ingredients sourced from multiple suppliers that change frequently over time are mixed in the production process (a situation which is far from being an exception in the EU food industry), systematically keeping track of the clone heritage of meat ingredients becomes even more challenging, irrespective of the solution adopted (dedicated production lines or thorough cleaning). These challenges would have to be overcome even for simple processed meat products, such as minced meat, sausages or burgers.

If the labelling obligation was applied to all animal food products – i.e. including by-products of slaughtering, such as offal - then there would be further challenges for the supply chain in establishing segregated systems and end markets for them. These are not high value-added products: net returns on any related investment are more likely to be unsatisfactory. Examples are the pig offal, trotters, ears, etc. that are often exported.

It is the systematic nature of recording of clone heritage status of any batch of meat ingredients entering the process, which has to be repeated through every stage of the process up to the inclusion of meat ingredients in products for final consumption, which poses the most serious challenges. The implementation of such a traceability system is much more demanding than the 'one step forward, one step back'

traceability currently required for food safety purposes in the EU. The link between individual items sold to final consumer (e.g. burger or sausage labelled as not being derived from clone offspring) and the individual animal(s) or homogeneous batch(es) of animals (i.e. documentation that all the animals in the batch are not clone offspring) must be established and kept for any item marketed. This link must be maintained over its entire production process if the information on clone offspring status is to be communicated through product labelling. This is more demanding than what is used to support retrospective traceability back up the supply chain when problems arise (typically a food safety problem).

Verification and enforcement of the labelling system would vary depending on the type of meat product involved. DNA profiling is technically feasible only for carcasses / meat cuts – i.e. where samples of the DNA of an individual animal can be obtained. DNA profiling would only be able to verify claims (e.g. labelling meat as clone free) if samples could be compared to DNA profiles held on a reference database that held the DNA profiles of all relevant animals, including those in third countries. That system would need to be linked to records of identity, ancestry and clone status. DNA profiling cannot be used to identify individual animals in compound meat products (Raymer, 2005, cited in ICF, 2012). Determining the number of animals represented in a DNA mixture of randomly selected animals is impossible when the mixture contains DNA from more than five or six individuals (Dodds and Shackell, 2004, cited in ICF, 2012). Individual identification is even more difficult; testing can only identify whether an individual animal may have contributed to the mixture. A pack of minced beef could contain meat from more than 1,000 animals (Hu *et al.*, 2012)).

Given the trade within Europe in meat products, information systems supporting verification would need to be integrated and accessible to all control authorities and business operators in the EU. To accommodate meat and meat products imported from beyond the EU, the systems would need to integrate with matching systems built and maintained by third countries. It seems unlikely that this would be feasible.

6.1.2 Dairy production

Tracing back to individual animals from dairy products is even more complicated than for meat. The first complication arises as soon as cows are milked because the milk from a number of different animals is collected and mixed in tanks. This mixing precludes any traceability back to individual animals.

Milk is then collected by a tanker⁶⁵. In countries such as the Netherlands, where the milk producing sector is extremely concentrated, one tanker can be required per farm. In others, tankers collect milk from several farms. For example, in Denmark tankers typically collect milk from 3-5 farms. In Bavaria, where farms are smaller in scale, 100 farms may be required to fill one tanker; it is not uncommon to have tankers collect from 50 farms. In some Member States smaller tankers are used to collect milk that is then transferred to larger tankers for distribution to dairies.

At this point it is clearly no longer possible to link milk to the farm of origin (unless a single farm is the source of all the milk in a tank); however, the link to all farms of origin is still possible, for example if there is need to trace back for food safety purposes. The tankers deliver milk to dairies where it is stored in silo tanks which, in some larger milk producing countries such as Denmark, typically hold between 100,000 and 300,000 litres (i.e. milk from up to 50 individual farms). In other Member States dairies hold milk in one silo from a greater number of farms. Dairies have multiple silos and total capacities of up to two million litres are common.

Even tracing milk products back to the country of origin is complicated. There is a sizeable trade in raw milk within the EU. For example, around one third of raw milk

⁶⁵ A tank will typically have a capacity of 18,000 to 25,000 litres, although in Denmark (and other major milk producing countries/regions) 30,000 litre capacity tankers are common.

from the Czech Republic is processed in Germany. A considerable volume of raw milk from Italy is also processed in Germany. There is an added stage in the supply chain in the UK where milk is sometimes bought by traders who then sell it on to dairies.

At the dairy the milk may be processed into skimmed milk, cream and whey which may then go to different dairies for further processing where it will also be mixed in silo tanks of between 100,000 and 300,000 litres. Around 90 per cent of the raw milk becomes skimmed milk and around 10 per cent becomes cream. Around 10 kg of milk is required to produce one kg cheese. A one kilogramme block of cheese may therefore be derived from milk from very many farms.

The complexity of the supply chain is illustrated by an internal calculation provided by the European Dairy Association which showed that, due to the mixing of milk, one pack of butter could potentially contain milk from up to 10,000 farms. Dairy products are used as ingredients in many other products and this involves further mixing of products from many animals, farms and countries.

The possibility to track the individual animal producing milk is therefore lost from the very beginning of the process. The only way to trace milk to the individual animal would be to stop mixing milk from different animals into the same tank. This would require milk to be collected from individual animals and then transported separately to dairies for processing. Clearly this would not be commercially viable and the modern milk supply chain would no longer be possible. Given that the production of cream, butter and cheese requires substantial quantities of raw milk, achieving economies of scale in the production of these commodities would no longer be possible.

The only technically feasible way to supply a clone offspring labelling requirement in the dairy sector would be to use a batch tracing system within a segregated supply chain. This would be similar to the approach taken currently for organic production.

The Danish organic dairy sector is used to illustrate how this segregation operates. Around one third of all drinking milk consumed in Denmark is from certified organic production. Most dairies in Denmark operate segregated organic and non-organic supply chains (there are only two larger and 2-3 smaller dedicated organic dairies in Denmark and all are small and medium sized enterprises). The two supply chains use the same infrastructure, but at different times. Identity preservation is maintained by processing organic milk first and then conventional milk. This means that there is no requirement to clean between batches as the presence of some organic milk in conventional milk is not considered to be an issue (whereas conventional milk in organic milk would be a problem). Before the system is next used for organic milk the delivery tankers, pipes and silos are thoroughly cleaned.

If traceability to identify milk from clone offspring were introduced, at dairy level, it would be necessary to operate this as a third system (i.e. an additional supply of milk to the current conventional and organic production systems). Organic milk would be followed through the system by conventional milk ('clone offspring free' milk) which would then be followed through by milk from animals with clone heritage.

At farm level, individual farms would need to use only cows guaranteed not to be from cloned reproductive material (according to the definition of offspring used) if the milk (and derived products) was to be labelled as 'clone offspring free'. If this guarantee could not be provided, their milk would have to be processed as if it were produced by clone offspring. The production sector would therefore need to be divided into organic, conventional and clone offspring segments and it would be necessary to add a third round of milk collections from farms (if there was any production from animals with clone heritage). This would require changes to collection routes and additional cleaning time. The cost of this would be different for each dairy.

The need to use batch processing will impact on the downtime required. For example, in Denmark organic cheese may be produced for 2-3 days a week with the rest of the week devoted to the production of conventional cheese. Some dairies producing milk

powder may run for a few weeks continuously; they also operate 365 days a year. Others operate one or two shifts per day. As a general rule, smaller plants stop more often for cleaning than large ones. Stopping for cleaning in a continuous system requires downtime and so there is also an opportunity cost to add to direct labour and production costs.

The magnitude of costs to the supply chain of segregating product derived from clone offspring would depend partly on the proportion of processing time devoted to each milk market segment. Greater use of batch processing will increase the costs. If there was no milk production from clone offspring there would be no need to change existing schedules and no change to operating costs (beyond information transmission and, where necessary, verification).

Operators using liquid milk and/or dairy products (butter, milk powder, cheese, etc.) as ingredients have the same options as discussed in section 6.1.1 to systematically keep track of the clone heritage status of such ingredients:

- investing in dedicated production lines and storage facilities, in order to implement a fully segregated supply chain;
- perform thorough cleaning of production lines and storage facilities after any batch of “clone-related” raw materials has been processed/stored.

The practical implications for operators, and the related operational challenges, match those discussed above for meat production. As with meat production, frequent mixing of dairy ingredients from different suppliers is common practice in the EU food industry, and in the current context adds to the operational challenge.

It is not possible to use DNA profiling to determine the individual animals that produced milk and its derivatives due to the mixing of milk in the supply chain. The only information which can be extracted from DNA analysis concerns the animal's breed, which is of no interest for identifying individual animals (Blasi, 2004). It is also difficult to extract DNA from products obtained by processing milk. In particular, it is difficult to obtain DNA of sufficient quality to conduct traceability analysis from hard paste and long ripening cheese. These constraints are additional to the inherent constraints of identifying the DNA of cloned animals/offspring from that of their parents, as discussed above.

6.2 Labelling changes

Adoption of a negative labelling policy, as specified for this study by the Commission, means that all animal products would need to indicate the clone status of the animal from which they are derived. The costs associated with label redesign and acquisition of the capacity to indicate the clone status of the product would therefore be incurred under any definition of clone offspring and with any level of presence of clone offspring in the food chain. Even if there are no clones in the food chain (and so no clone offspring) the label on every stock-keeping unit (SKU) on the EU market that contains animal products would need to be changed to indicate that the product were not derived from clone offspring. This would include all meat and dairy products for the species concerned, and a very large number of processed food products.

Labelling products as not being derived from clone offspring could be seen to be misleading consumers if there was no known use of cloning in the food chain for that particular species.

The number of individual packages carrying a ‘positive’ label would be affected by the scale of use of the cloning technique and the definition of clone offspring adopted (both parameters affect the number of animals with clone heritage in the system).

Under a positive labelling policy (in which only products that were derived from clone offspring were required to carry a distinguishing label), then product labels would need to be changed only for those items that are derived from clone offspring. If there

were no such products on the market, there would be no additional labelling costs for the food business operators. The obligation is still likely to trigger expenditure on advice and supply chain audits (to confirm absence, modify contracts, etc.), but labels would not need to be changed.

The literature suggests that design and printing costs for a new label formulation would be small compared to the other costs triggered by the obligation. Previous studies have examined the costs of labelling changes, mostly in the context of EU country of origin labelling requirements. A study conducted by the European Commission found that design and printing costs for a new label formulation vary depending on the type of change involved. Small changes may cost in the range of EUR 2,000-4,000, while a full re-design may cost EUR 7,000-9,000 (European Commission, 2008). A 2010 study in the UK estimated that the average cost of a label change was EUR 3,800 per single SKU⁶⁶ (Balazs-Horvath et al., 2010). Costs are influenced by factors that include the notice period provided (which influenced the number of stocked labels that have to be written off (EAS, 2004)).

Companies may need specialist legal advice to ensure that labelling requirements are met. The costs of this would depend on the complexity of the product and precise labelling requirements. Estimates available in the literature vary widely. For example, a UK Food Standards Agency study on administrative burdens collected estimates for Member States on the administrative burdens associated with familiarisation and understanding legislation (Leatherhead Food International, 2006). Labelling requirements were estimated at between five per cent (in Denmark) and 13 per cent (in the UK) of total administrative burden costs.

Where the change is expected to have a negative impact on consumer perception of the product (as is likely in the case of a label identifying a product as derived from clone offspring), an operator may look at reformulating it. The associated costs – of assessment and potentially of reformulation – may be considered indirect costs of the labelling obligation.

6.3 Supply chain responses to clone offspring labelling obligation

There is no known use of clones in livestock breeding for the food chain in Europe, and for most species considered in this study cloning is very uncommon. Consultations for this study and the previous ICF study for the European Commission suggest that a clone offspring labelling obligation is likely to prompt firms to take steps to exclude clones (and clone offspring) from the EU food chain. This is because:

- In dynamic breeding systems, clone-derived genetics do not confer a performance advantage over and above advanced genetics from conventional sources;
- No positive product proposition / attribute (and potential price premium) is conferred on the product by virtue of its clone offspring origin;
- The segregation required for supply chains using clone offspring would create additional cost that would not be compensated for by higher prices;
- Consultees believe EU consumers would be unwilling to buy products labelled as having been derived from clones (evidence supported by Eurobarometer findings);
- Companies in the food chain would be unwilling to place such products on the market because of the expected consumer response and unfavourable economics.

Without a labelling obligation, use of clone offspring has no direct effect on the supply chain. The labelling obligation has the effect of imposing increased cost on all production – in the retention of identity and ancestry records, segregation, labelling –

⁶⁶ The reported cost was GBP 3,260, converted using the ECB reference rate for 2010 on 29 May, 2015 using a conversion rate of 1 GBP = 1.39168 EUR

whilst also (in the view of consultees) reducing expected demand for the specific products of interest (i.e. those derived from clone offspring).

If clone offspring are excluded no segregation costs are incurred in the EU food chain – no production would be derived from clone offspring. The food chain in the EU and in trading partners would, however, still bear the cost of relabelling all products with the information that they are not derived from clone offspring (as per section 6.2), and the costs of establishing the capacity to identify and trace clone offspring status.

The clone offspring labelling legislation would need to consider how to handle clone offspring in the EU livestock production sector at the time when the legislation came into force. The review of the use of cloning provided in section 3.4 indicated that the cloning technique is not in use in the EU and is uncommon elsewhere so this is unlikely to be a major issue, but if those circumstances change it could be.

In many parts of the livestock production sector the identity and ancestry recording systems needed (together with information on cloning events) to identify such animals would not have been in place. Retrospective determination of the clone heritage of animals in such circumstances would often not be feasible, even if the cloning technique had been used. There may be areas, e.g. bovine dairy, where identify and ancestry recording was extensive enough for at least some of any clone offspring present to be identifiable. As shown in section 4.3, the use of artificial insemination can lead to an individual sire having many thousands of descendants. If a definition of clone offspring was adopted that spanned many generations, then – under certain conditions - a large number of animals could potentially be identifiable as clone offspring. In such circumstances, if those animals were retained in production, additional costs would be incurred in establishing segregated supply chains or batch processing the derived products.

6.4 Implications for trade in food products

6.4.1 Imports

A clone offspring labelling requirement is expected to have impacts on EU food imports as operators in countries exporting to the EU will be obliged to comply with requirements relating to labelling of products derived from clone offspring and doing so will result in them incurring additional costs.

The size of the impacts affecting imports and exports of food products will depend on the definition of clone offspring (and therefore the type and number of animals affected). If the definition applies to the first generation of clone offspring only, then nucleus breeding animals are the most likely to be affected and it would be easier to exclude these animals from products destined for the EU in third countries. A second generation offspring definition will be more challenging and costly.

Trade partners would need to develop traceability systems sufficient to support declarations to the EU authorities and supply chain about the clone status of food products. This would be a significant undertaking. The EU has the world's most advanced traceability system. To meet a clone offspring labelling requirement for meat and dairy products, third countries would need to adapt their food production systems in all of the ways outlined in this study, but with additional measures to compensate for the lack of, for example, individual animal traceability and ancestry information.

The labelling requirement may result in the development of segregated (clone offspring free) supply chains to serve the EU market. These would need to be supported by sufficiently robust documentary systems to satisfy the EU that products derived from clone offspring were not being shipped to the EU.

There are too many unknown factors and too much variation among trading partners, and by species, for it to be feasible to estimate the additional costs that would be incurred by EU trading partners in establishing the systems that would be needed to

support a clone offspring labelling obligation. It can be expected, however, that they would be substantial.

The additional costs incurred by third country suppliers would be expected to be reflected in prices offered to the EU market. The higher cost would, to some degree, be passed through to EU consumers. Some suppliers may stop serving the EU market and there would be no demand for imported product if the additional costs increased the price beyond that for domestic EU product; this would apply upward price pressure in the EU market which would impact on consumers.

Effects on imports are most likely to occur for beef, with trade valued at EUR 1.6 billion in 2014 (Eurostat, 2015). The EU's main trading partners for beef are Brazil, Argentina and Uruguay, Australia and the US, all countries where there are records of the cloning technique being used in livestock production. The sheep meat trade would also be affected (and the EU's principal partners in this trade, New Zealand and Australia).

6.4.2 Exports

A clone offspring labelling requirement would affect EU meat and dairy exports insofar as EU production costs increase and these cost increases affect the EU operators' ability to compete in international markets for meat and dairy products. There is currently no market in 'clone offspring free' products and so no price premium for products with this status. Increases in production costs will therefore reduce the profit margins on exported products. The market is likely to adjust dynamically in ways that are difficult to predict with accuracy.

The distribution of impacts arising from a labelling requirement will vary by species and product type. Effects on exports are most likely to occur in the following sectors:

- Bovine dairy products, of which the EU is a net exporter, with trade worth an estimated EUR 10.2 billion in 2014 (Eurostat, 2015); and
- Pork products, which are the EU's most significant meat export, with trade worth an estimated EUR 4.9 billion in 2014 (Eurostat, 2015).

7 Conclusion

The research undertaken for this study has found that a clone offspring labelling obligation would have a significant impact on the production of meat and dairy products in the EU and in the countries that export such products to the EU. Substantial additional costs will be imposed on the food chain even if, as at present, there is little or no use of the cloning technique in livestock production in the EU.

Consultees see no prospect of use of the cloning technique in the breeding of animals for food production in the EU increasing significantly in years ahead. However, imports of reproductive materials and live animals from countries where the technique is used for certain species could lead to there being clone offspring in the EU livestock population even if the cloning technique is not used within the EU itself.

The definition of clone offspring adopted in the legislation would determine the number of animals that fall within its scope. If clones are used in livestock production, the number of animals classified as clone offspring rises very quickly as the number of generations covered by the definition is increased, particularly for species where artificial insemination is commonly used. A single porcine boar, for instance, may have more than ninety thousand descendants after just three generations.

The labelling obligation would require individual identity, ancestry recording and individual movement recording to be extended to all animals in order to document where or not they have clone heritage. Additional annual costs to the EU livestock sector for identity, ancestry and movement record could reach over EUR 800 million per year. These impacts would be concentrated on the pig and sheep sectors.

The claims made under a system based on recording identity, ancestry and movements alone could not easily be verified since there are no tests that enable clone offspring to be distinguished from the natural offspring of the same animal. This makes a clone offspring labelling obligation vulnerable to error and fraud: consumers could be misled. If a DNA sample was collected from each animal and attached to its identity and ancestry records, it would theoretically be possible to check ancestry claims. This verification mechanism would require a DNA profiling system that covered all animals in the EU in the scope of the legislation. It would need to reach beyond the EU if imports were also to be covered. There are no precedents for animal DNA registries of this scale. On reasoned assumptions used in this study the annual cost to the EU livestock sector of verification could exceed EUR 9.3 billion. All livestock sectors would be affected but the largest share of costs would fall upon pig producers.

Retaining the identity of dairy products from individual animals is not feasible in modern production systems due to the mixing of milk on farm and further down through the supply chain. Segregated production systems for clone offspring and derived products would be required, analogous to those for organic products. The segregation would need to extend from the farm through collection and primary processing at the dairy through to production of the final product and packaging.

Individual animal identity is currently lost at the point of slaughter in most instances. With process modifications and investment, identity might be retained through primary processing such that whole cuts of meat could be labelled based on the clone heritage of the original animal. However, where material from different animals is mixed, such as minced meat, individual identity cannot be retained and products derived from clone offspring would need to be managed via segregated supply chains. The supply chain would also have to amend its systems to carry information about the clone offspring status of forward to the point of final packaging.

The costs of product labelling would be modest compared to the other costs associated with the obligation. A policy in which foods had to be labelled as not being derived from the offspring of clones would, however, mean all dairy and meat product labels would have to be changed regardless of how many clone offspring there were in the food chain.

The information infrastructure needed to support the obligation would cost EU public authorities tens, and possibly hundreds, of millions of euro in total. National databases would need to be inter-connected to enable the clone offspring status of animals traded within Europe to be checked.

There is no indication, at present, that consumers would be prepared to pay the premium required to compensate the supply chain for the costs associated with providing products derived from clone offspring. It is deemed likely that the obligation would prompt food business operators to exclude clone offspring and derived products from the market.

Exclusion would avoid the costs of segregation but not most of the other costs of the obligation. The additional costs of full individual identity, ancestry and movement recording, verification and labelling would still be incurred. Businesses would also bear the costs of familiarising themselves with the legislation's requirements, training staff and adjusting systems, contracts and processes to accommodate the new law. The investment in constructing the data collection and management systems would still be needed. Countries exporting reproductive products, live animals and meat and dairy products to the EU would need to make similar investments to be able to meet EU requirements. Additional costs in livestock and food production would put upward pressure on consumer prices.

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