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Legal Aspects of Human-Animal Chimeras and Hybrids:

Country Report Sweden

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1 Introduction

During the past three decades or so, legislators in Sweden as in many other parts of the world have be required to consider ethical, societal and legal implications of the development of biotechnology, in particular gene technology. A number of Swedish parliamentary committees and ministerial law commissions have dealt with these issues, sometimes from a comprehensive, overall perspective[2] and sometimes addressing more specific issues related to the protection of human rights and dignity, animal welfare or environmental values.[3] The investigations and public debate preceding Swedish legislation on biotechnology have addressed the justifiability and risks of genetic modification in humans as well as in animals and plants, but have rarely been focussed specifically on the mixing of animals and humans. It is mainly in relation to the debate on xenotransplantation that such matters have been discussed, primarily with regard to risks to public health and animal welfare.

Since the beginning of the new millennium, considerable developments have taken place in Swedish law concerning the regulation of research involving humans and further use of human biological material, as well as the use of gene therapy and genetic testing. New provisions and statutes have thus been enacted in a number of fields. Important contributing factors have been the aim to ratify the European Convention on Human Rights and

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[2] For example the Ministerial Report Hybrid DNA technology under control (*Ds U 1978:11 Hybrid DNA-tekniken under kontroll)*, the Parliamentary Report Genetic Integrity (*SOU 1984:88 Genetisk integritet*), the Parliamentary Report Gene technology – a challenge (*SOU 1992:82 Genteknik – en utmaning*) and the Parliamentary Report Crossing boundaries – the possibilities and risks of biotechnology (*SOU 2000:103 Att spränga gränser – bioteknikens möjligheter och risker*).

[3] For example the Ministerial Report Gene technology – plants and animals (*Ds 1990:9 Genteknik – växter och djur*), the Parliamentary Report From one species to another – transplantation from animal to human (*SOU 1999:120 Från en art till en annan – transplantation från djur till människa*), the Ministerial Report Ethics review of research involving humans (*Ds 2001:62 Etikprövning av forskning som omfattar människor*), the Parliamentary Report Legal regulation of stemcell research (*SOU 2002:119 Rättslig reglering av stamcellsforskning*), the Parliamentary Report Ethics review of animal experiments – genetics and biotechnology applied to animals (*SOU 2003:107 Etisk prövning av djurförsök. Genetik och bioteknik på djur*) and the Parliamentary Report Genetics, integrity and ethics (*SOU 2004:20 Genetik, integritet och etik*).

Biomedicine,[4] which Sweden signed in 1997, and the necessary implementation of various EU directives, for example Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials.[5] In this process, Sweden has also demonstrated a strong ambition to assert itself as one of the leading research nations in the area of biomedicine, not least in stem cell research. Upholding such ambitions, coupled with a liberal approach towards research, while at the same time applying the precautionary principle and protecting human rights and animal welfare, can constitute quite a challenge.

At present, there is no Swedish legislation explicitly regulating on the mixing of humans and animals, not even with regard to xenotransplantation. In the absence of any legal rules specifically addressing the creation and use of human-animal chimeras and hybrids, this report on Swedish law will be based on an analysis of the implications of more generally applicable legislation.[6] There is thus general legislation related to genetically modified organisms. Furthermore, most research projects involving humans or human biological material is governed by statutory law, and so is research on animals. More specific rules apply to the use of human ova and genetic modification. Commercial aspects and property law will only be touched upon very briefly. Section two below will provide an overview of the relevant laws and regulations, followed by an application of the provisions to measures where animal and human material is mixed, in section three.

2 Relevant legislation

2.1 Provisions on medical interventions involving humans

Starting with general legislation on transplantation, it should be noted that despite its name, the Swedish Transplant Act (1995:831) does not regulate transplantations as such, but only the *taking* of human biological material for transplantation or certain other medical purposes. The Transplant Act is thus primarily aimed at the protection of *donors*, whereas the rights and safety of transplant recipients are protected by more general rules in the Health and Medical Services Act (1982:763) and the Act (1998:531) on Professional Activities in Health and Medical Services, complemented by certain provisions issued by the National Board of Health and Welfare.[7] These provisions apply to the transplantation of whole organs, tissues or cells as well as the transfer of DNA. However, since statutory law contains only general rules laying down prerequisites for the provision of good health care, specific risks or problems related to transplantation are not really addressed. In addition to general legislation on

[4] Council of Europe Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine (ETS No. 164).
[5] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
[6] For an overview in English of some relevant Nordic statutes (although not fully updated), see also *Legislation on biotechnology in the Nordic countries – an overview*. The Nordic Committee for Bioethics 2005, available at: http://www.ncbio.org.
[7] E.g. the National Board of Health and Welfare Code of Statutes (SOSFS 1994:4) on measures against the transmission of infectious diseases at the transplantation of tissue or organs.

pharmaceutical products and medical devices,[8] special regulations are being introduced, concerning safety issues regarding certain types of biological materials for use in humans.[9]

If a certain transplantation intervention does not constitute an established treatment method in keeping with science and proven experience, it should normally be considered as research. The legal prerequisites for research on humans must then be met.

Only a few years ago, Sweden introduced comprehensive legislation on research involving humans.[10] Before the entry into force of the Act (2003:460) on Ethics Review of Research Involving Humans, the system for ethics review was legally unregulated and such review in many cases formally voluntary. One exception concerned clinical trials for medicinal products and medical devices, where a legal requirement for ethics review existed also previously. Furthermore, a statutory requirement for ethics review had been introduced with regard to research on certain biological samples that could be traced to an identifiable donor, under the Biobanks in Medical Care Act (2002:297).[11] This Act regulates how human biological material may be collected, stored and used for certain purposes, with due respect for the personal integrity of the individual.[12] It covers biobanks that are established as a part of a health care provider's professional medical activities, as well as banks consisting of samples that have been released from a health care provider biobank for storage and use by another legal entity (for example a research institution).[13] Special rules apply to the use of certain types of human biological materials, such as human ova and tissue from aborted foetuses.

With the new Act on Ethics Review, ethics approval became a mandatory requirement for many types of research involving humans or human material. The purpose of this Act is to protect individual humans and respect for human dignity in research.[14] However, the Act only covers such biological material as can be traced back to an identifiable human. This means that although ethics approval is required for research on most human biological material, regardless of whether the Biobanks Act applies or not, all de-identified samples may be used for research without any ethics review. The more precise criteria defining concepts like traceability or identifiability of human biological material still remains a question unanswered in Swedish law, and no European consensus would seem to exist.[15] Since the interpretation of these concepts determines the scope of both the Biobanks Act and the Act on

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[8] Medicinal Products Act (1992:859) and the Medical Devices Act (1993:584), with complementing ordinances and regulations. For English versions of certain regulations issued by the Medicinal Products Agency, see the Codes of Statutes at the webpage http://www.mpa.se.

[9] See for example the Government Bill 2007/08:96 Implementation of the EC Directive on human tissues and cells *(Genomförande av EG-direktivet om mänskliga vävnader och celler*) concerning Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[10] Government Bill 2002/03:50, based on the Ministerial Report Ethics review of research involving humans (*Ds 2001:62 Etikprövning av forskning som omfattar människor*). The following description of this Act is based on Rynning, E. "The Swedish System for Ethics Review of Biomedical Research and Processing of Sensitive Personal Data". *RECs, Data Protection and Medical Research in European Countries* (eds. Beyleveld, D. Townend, D., Rouillé-Mirza, S. & Wright, J.). Aldershot: Ashgate Publishing Ltd 2005, pp. 245-270.

[11] Chapter 2, Section 3 and Chapter 3, Section 5 of the Biobanks Act.

[12] Chapter 1, Section 1.

[13] Chapter 1, Section 3.

[14] Section 1 of the Act on Ethics Review.

[15] Rynning, E. "Public law aspects on the use of biobank samples – privacy versus the interests of research", in *Biobanks as resources for health* (eds. M.G. Hansson & M. Levin), Uppsala University 2003, pp. 91- 128, at pp. 110-111.

Ethics Review, the present legal situation must be considered somewhat uncertain in this respect.

The Act on Ethics Review provides a system of six regional review boards, with one central board reviewing appeals and cases that are referred by a dissenting minority of a regional board.[16] The Central Board for Ethics Review also has a supervisory function. The regional boards each have a judge as a chairperson and fifteen other members, all appointed by the Government. Ten of the members shall have scientific qualifications and the other five represent public interests.

The Act on Ethics Review lays down a number of basic principles for justifiable research, which must be met in order for a research project to be approved. These principles include traditional requirements concerning respect for human dignity, risk-benefit-assessment, informed consent etc. It is thus explicitly required that the research can be carried out with respect for human dignity, and that human rights and fundamental freedoms are observed.[17] However, it is underlined that the interest of new knowledge that may be developed by research must also be taken into consideration. Nevertheless, the wellbeing of humans shall be given precedence over the needs of science and society. In the *traveaux préparatoires*, it is stressed that respect for human dignity involves not only protection of the interests of research subjects directly concerned by the research, but also consideration of the further implications of the research, e.g. to future generations.[18] Such deliberations could speak both in favour of the research and against it. Unfortunately, the considerations that could be called for with regard to the protection of human dignity are not exemplified in the *traveaux préparatoires,* and no known legal cases clarifying the issue exist.

A basic requirement is also that the research must be scientifically sound. The project must have the potential of generating well-founded and important knowledge, by the use of reliable research methods.[19] It must be expected that the results of the research could be useful to society and humanity as such. This assessment of the scientific soundness and expected value of the research is necessary for the subsequent balancing of risks and benefits related to the project, which is considered to be one of the most central elements of the review, alongside the evaluation procedures for informed consent.[20] Section 9 of the Act on Ethics Review thus prescribes that research may only be approved if the risks it may involve, with regard to the health, safety and personal integrity of the research subject, is counterbalanced by its scientific value.[21] Furthermore, the research must not be approved if the expected results could be achieved by other means, involving less risk to the health, safety and personal integrity of the research subjects.[22]

As regards research projects involving physical interventions or the use of human biological material, explicit informed consent will normally be required. The main rule, under Section 17, is thus that the research subject himself or herself should freely consent to participation in

[16] Sections 24-33 of the Act on Ethics Review.
[17] Sections 7 and 8 of the Act.
[18] Government Bill 2002/02:50 p. 98.
[19] Government Bill 2002/02:50 pp. 98-99.
[20] Government Bill 2002/02:50 p. 99.
[21] It should be noted that this risk-benefit-assessment does not mention the possible risks to society or future generations. Such considerations are only indirectly regulated by the more general prerequisites laid down in Sections 7-8.
[22] Section 10 of the Act on Ethics Review.

the project, after having received information in accordance with Section 16.[23] It is required that the consent be explicit and specified to certain research. Normally, consent should be given in writing, but if for some reason it is given orally, it must be appropriately documented by a sufficiently competent researcher taking part in the project.[24] When it comes to using previously collected samples for a new research related purpose, however, the board for ethics review is authorised to decide on a different standard for information and consent.[25] If the review board in such a situation finds this justifiable, with regard to the general provisions on risk-benefit-assessment, respect for human rights and human dignity etc, consent may even be waived completely.

Consent may at any time be withdrawn, under section 19 of the Act on Ethics Review. If the withdrawal concerns biological material that is covered by the Biobanks Act, however, the principal of the biobank is allowed to choose de-personalisation of the samples instead of destroying them, regardless of the wishes of the donor.[26] Even so, if the de-personalisation as such is to take place for research purposes, it would seem that this measure must also be subject to ethics approval.

2.2 Measures involving human gametes

Sweden introduced legislation on assisted human procreation in the mid- to late 1980's, first on insemination and sperm donation, later also on IVF.[27] From the outset, the legislation was rather strict and egg donation was not allowed until 2002.[28] It is still a requirement for assisted procreation that if the egg is not the woman's own, then the sperm used for fertilization must come from her husband/co-habitant partner.[29] Half of the future child's genetic heritage must thus come from one of the legal parents.

Although assisted procreation was clearly an area of research from the very start, research involving gametes was not formally regulated until the introduction of the Act (1991:115) Concerning Measures for Purposes of Research or Treatment Involving Fertilised Human Ova.[30] The provisions of this Act have now been incorporated in the new Act (2006:351) on Genetic Integrity, which today regulates also assisted procreation. The 1991 Act originally addressed only activities regarding *fertilised* eggs, but was changed in April 2005, to cover also measures with human ova that have been subject to somatic cell nuclear transfer (SCNT).[31] The creation of human embryos for research purposes, both by way of fertilisation and by SCNT, may thus be lawful under certain conditions. This means that at a future ratification of the European Convention on Human Rights and Biomedicine, Sweden will have to make a reservation against Article 18.2 of the Convention, which prohibits the creation of embryos for research.

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[23] With regard to minors and incapacitated adults, special provisions apply.
[24] Government Bill 2002/03:50 p.132.
[25] Section 15 of the Act on Ethics Review.
[26] Chapter 3, Section 6 of the Biobanks Act. See also the Government Bill 2001/02:44, p. 44.
[27] The Insemination Act (1984:1140) and the In Vitro Fertilisation Act (1988:711), both of which have been replaced by the Act (2006:351) on Genetic Integrity.
[28] See for example Burrell, R. *Assisted Reproduction in the Nordic Countries – A comparative study of policies and regulation*. Nordic Committee of Bioethics 2005, pp. 8-17, available at http://www.ncbio.org. See also Saldeen, Å. "The Childrens Ombudsman, Adoption by Homosexual Partners and Assisted Reproduction." *The International Survey of Family Law 2004 Edition* (ed. Bainham, A) Bristol: Family Law 2004, pp. 439-449, at pp. 444-449.
[29] Chapter 7, Section 4 of the Act on Genetic Integrity.
[30] Government Bill 1990/91:52.
[31] Now regulated by Chapter 5, Section 1 of the Act on Genetic Integrity. See also the Government Bill 2003/04:148, pp. 43-47.

Justifiable research with human ova, under the Act on Genetic Integrity, is not restricted to certain research areas or purposes, but is to be assessed on a case-by-case basis, by the competent regional board for ethics review. The period during which research may take place is restricted to the first 14 days after the fertilisation or SCNT procedure, not counting time during which the eggs have been frozen (normally no more than five years).[32] After this time limit, the eggs must be destroyed in order to prevent any further embryonic development. An egg that has been subject to experimental measures must not be implanted in the body of a woman, and the same applies if the sperm has been experimented on before the fertilisation.[33] Reproductive cloning is thus indirectly prohibited.

Furthermore, the Act on Genetic Integrity explicitly prohibits any research entailing genetic modifications that can be inherited by human, as well as any treatment aimed at achieving such modifications.[34] The 1991 Act contained a similar, but stricter prohibition, ruling out also the *development of methods* for introducing hereditary genetic modifications.[35] Since the old provision only covered measures involving human ova that had been fertilised or subjected to SCNT, the restrictions were not applicable to experiments with sperm, unless the sperm was later used to fertilise a human egg. Nor did the prohibition apply to experiments with human eggs that were not later used to create an embryo in vitro. The new prohibition, on the other hand, is generally applicable and not restricted to measures with human ova. Nevertheless, it should be noted that it only covers "genetic modifications that can be inherited by *human*". Research aimed at developing methods for introducing hereditary genetic modifications may be lawful also with regard to human gametes and embryos, as long as they are not actually used for human reproduction.

As opposed to certain other European countries, Sweden does not require embryo research to be authorised by any special central agency. Such research projects only need to be approved within the ordinary system for regional ethics review. If a certain minority of the regional review board does not agree with a majority approval, or if approval is denied, the case may be transferred to the Central Board for Ethics Review, by way of referral or appeal. A regional board should also consult with the Swedish Council for Research and other agencies concerned, if a proposed research project gives rise to new ethical issues on matters of principle. Such agencies could include for example the National Board of Health and Welfare and the Gene Technology Advisory Board. Otherwise, the project will only be subjected to regional review. As has already been mentioned, if a research project were to involve human gametes or embryos that cannot be traced to any identifiable donor, the Act on Ethics Review would not be applicable. This means that no ethics approval or similar authorisation of the research would be required. Even so, the restrictions laid down in the Act on Genetic Integrity would still apply.

2.3 Protection of environment and animal welfare

General provisions concerning genetically modified organisms can be found in Chapter 13 of the Swedish Environmental Code (1998:808), complemented by the Ordinance (2000:271) on Contained Use of Genetically Modified Organisms and the Ordinance (2002:1086) on

[32] Chapter 5, Section 3 of the Act.
[33] Chapter 5, Section 5 of the Act.
[34] Chapter 2, Section 3-4 of the Act.
[35] Section 2 of the Act (1991:115) Concerning Measures for Purposes of Research or Treatment Involving Human Ova. For comments on the original and the new wording, see Government Bills 2003/04:148 and 2005/06:64.

Intentional Release of Genetically Modified Organisms in the Environment.[36] Originally, the rules were introduced in the now repealed Act (1994:900) on Genetically Modified Organisms. Since 1994, Sweden also has a special agency, the Gene Technology Advisory Board, which monitors developments in genetic engineering, reviews ethical issues and gives advice on the uses of genetic engineering.[37]

The purpose of the Swedish Environmental Code is to promote sustainable development which will assure a healthy and sound environment for present and future generations.[38] This entails *inter alia* the preservation of biological diversity as well as the protection of human health against damage and detriment. It is a general requirement under Chapter 2, Section 3 of the Environmental Code, that persons who pursue an activity, take a measure or intend to do so, shall implement protective measures, comply with restrictions and take any other precautions that are necessary to prevent, hinder or combat damage or detriment to human health or environment ass a result of the activity or measure.

The Swedish Environmental Code thus prescribes that prior to the contained use or deliberate release of genetically modified organisms, an investigation shall be carried out, in order to provide a proper basis for an acceptable assessment of the damage to health and the environment that the organisms are liable to cause.[39] Special attention shall be paid to ethical concerns.[40]

The definition of an *organism* in Chapter 13, Section 3, of the Environmental Code, is a biological entity capable of replication or of transferring genetic material. This means that all animals as well as human beings in principle qualify as organisms under this legislation. A genetically modified organism is an organism in which the genetic material has been altered in a way that does not occur naturally, by mating or natural recombination.[41] Under Chapter 13, Section 5, *contained use* shall mean any activity in which organisms are genetically modified, cultured, stored, used, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population or the environment. *Deliberate release*, on the other hand, shall mean any intentional introduction of genetically modified organisms into the environment without containment.[42] Both contained use and deliberate release of genetically modified organisms are subject to special provisions on mandatory prior notice or authorisation etc.[43] However, it is explicitly stated that the provisions in Chapter 13 of the Environmental Code on deliberate release are *not* applicable to genetically modified humans.[44]

With regard to the use of genetically modified animals, the Swedish Board of Agriculture has issued special regulations.[45] It is prescribed *inter alia* that the precautions required under the

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[36] Implementing Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.
[37] See Chapter 13, Section 19 of the Environmental Code and the Ordinance (1994:902) with Instructions for the Swedish Gene Technology Advisory Board.
[38] Chapter 1, Section 1 of the Environmental Code.
[39] Chapter 13, Section 8.
[40] Chapter 13, Section 10.
[41] Chapter 13, Section 4 of the Environmental Code.
[42] Chapter 13, Section 6.
[43] Ordinance (2000:271) on Contained Use of Genetically Modified Organisms and Ordinance (2002:1086) on Intentional Release of Genetically Modified Organisms in the Environment.
[44] Section 4 of Ordinance (2002:1086).
[45] The Swedish Board of Agriculture Code of Statutes SJVSFS 1995:33 (as revised by SJVSFS 2003:28).

Environmental Code shall include an assessment of the scientific value and public interest in the production and use of the genetically modified animal, in relation to a) risks to human health, b) risks to animal suffering and health, and c) ecological risks concerning genetic depletion and unintended dispersion.

General animal welfare aspects in research were made subject to legal regulation already in the late 1970's,[46] and have recurrently been on the political agenda ever since. At present, animal experiments are regulated by the Animal Welfare Act (1988:534) and the Animal Welfare Ordinance (1988:539), complemented by various regulations issued by e.g. the Swedish Board of Agriculture and the Swedish Animal Welfare Agency.[47] The overall aim of the animal welfare legislation is that animals shall be treated well and protected from unnecessary suffering and disease.[48] As of 1 April, 2006, it is explicitly stated in the Animal Welfare Act that the rules on animal experiments also apply to the production of genetically modified animals, by the use of gene technology, chemicals or similar methods.[49]

The Swedish definition of animal experiments is comparatively wide, including not only measures that could involve animal suffering, but all situations where animals are used for scientific research or education, the diagnosis of disease, the manufacture of drugs or chemical products or other similar purposes.[50] Any experimental use of animals, including breeding for the purposes mentioned, must be authorised by the Swedish Board of Agriculture.[51] There is also a mandatory requirement for ethics approval from a committee on animal experiments.[52]

The present Swedish organisation for animal ethics review consists of seven regional ethics committees, each with fourteen members appointed by the Swedish Board of Agriculture.[53] The chairman and vice chairman shall be impartial and have legal training. Half of the other members shall be lay members and the rest include research workers and representatives of the personnel who handle laboratory animals. The lay representation is thus larger than in the boards for ethics review of research involving humans.

Under section 19 of the Animal Welfare Act, three basic prerequisites must be met if animals are to be used for research etc. It is thus required a) that the purpose of the activity cannot be attained by any other satisfactory method that does not entail the use of animals, b) that the animals are not subjected to greater suffering than is absolutely necessary and c) that no other animals than animals bred for the purpose are used in the activity.[54] When considering the ethical justifiability of a research project, the animal ethics committee shall weigh the importance of the experiment against the suffering inflicted on the animal.[55] This means that perceived human benefit is balanced against expected animal harm, primarily in the form of pain and suffering. A recent study shows that very few applications concerning the production

[46] See Government Bill 1978/79:13, regarding changes in the 1944 Animal Welfare Act.
[47] The Animal Welfare Agency was introduced on 1 January, 2004, as a national public agency with numerous tasks in the field of Animal Welfare, including animal research. As of 1 July, 2007, the Agency is closed down and the tasks have been returned to the Swedish Board of Agriculture.
[48] Section 2 of the Animal Welfare Act (1988:534).
[49] Section 1 b, see also Government Bill 2004/05:177.
[50] Section 19 of the Animal Welfare Act.
[51] Section 19 a.
[52] Section 21.
[53] Sections 41-44 of the Animal Welfare Ordinance.
[54] As of April 1, 2006, a fourth prerequisite is introduced, concerning the use of as few animals as possible.
[55] Section 49 of the Animal Welfare Ordinance

and use of genetically modified animals are directly rejected by the animal ethics committees, whereas additional information from the applicants is often required.[56]

2.4 Property rights and commercialisation

With regard to commercialisation, there are obvious differences between the approach to humans and human biological material on the one side, and animals or animal material on the other. In principle, there is no legal obstacle to trade in animals or biological material from animals. Trade in human beings, on the other hand, is long since abolished, and the Act on Genetic Integrity also prohibits a number of measures with human biological material, with a view to financial gain.[57] It is thus unlawful to take, deliver, receive or distribute biological material from a living or deceased human, or tissue from an aborted foetus, with a view to gain. The criminalisation also applies to those who knowingly use or take charge of biological material that has been subject to such unlawful commercial activities. It is explicitly stated in the Act that human ova, as well as cells and cell lines from human ova, constitute human biological material. There are, however, certain exemptions from the prohibition, one of which concerns de-identified cell lines from human ova that have been fertilised or subjected to SCNT. [58] Nor does the prohibition apply to blood, mother's milk or teeth.

It should also be noted that it is the human material *as such* that must not give rise to financial gain. If human material for example is used as a component in a pharmaceutical product, this product may still be sold. Appropriate remuneration for services such as the taking, storage, processing or transport of the material is also accepted.

Sweden has implemented Directive 98/44/EC on the legal protection of biotechnological inventions,[59] by introducing a number of changes in the Swedish Patent Act (1967:837). [60] The new provisions entered into force on 1 May, 2004. This means that whereas animal varieties and essentially biological processes for the production of animals are not patentable, microbiological or other technological processes for such production may be so, as well as the product of such a process.[61] With regard to humans, there is no similar patentability of processes or "products" since this would be contrary to basic ethical principles.[62] However, although the human body, at the various stages of its formation and development, cannot constitute a patentable invention, an element isolated from the human body or otherwise produced by means of a technical process may be patentable.[63] Section 1c of the Swedish Patent Act copies Article 6 of the Directive, on inventions which shall be considered unpatentable, due to the fact that their commercial exploitation would be contrary to *ordre public* or morality. Examples of such inventions thus include processes for modifying the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to causes them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

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[56] Nordgren, A. & Röcklinsberg, H. *Genetically modified animals in research: an analysis of applications submitted to ethics committees on animal experimentation in Sweden*. Animal Welfare 2005, 14: 239-248.
[57] Chapter 8, Section 6 of the Act. A similar provision could previously be found in Section 15 of the Swedish Transplant Act.
[58] Government Bill 2005/06:64 p. 178-181.
[59] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[60] Government Bill 2003/04:55.
[61] Section 1a of the Patent Act.
[62] Government Bill 2003/04:55, p. 58.
[63] Section 1b of the Patent Act.

The implementation of the Directive did not escape criticism, in the public debate and some consultation opinions.[64] Even though the changes in the Patent Act were considered to constitute a codification of the already established legal situation, the Government declared that the rapid development in the area of biotechnology made it necessary to follow also the legal developments more closely, in order to facilitate an appropriate balancing of the various private and public interests concerned.[65] A Parliamentary Committee was therefore appointed in January 2005, with the task to follow certain aspects of the legal development and evaluate the effect of the new provisions.[66] The final report of this Committee is expected by the beginning of March, 2008.

3 Creation of human-animal chimeras and hybrids

3.1 Transplantation of animal material into living humans

In Sweden, xenotransplantation is not governed by specific legislation. Interventions where biological material of animal origin is transplanted into a human being have been taking place for many years, but these materials have mainly been without living cells (for example the use of so-called catgut made from sheep intestines and heart valves from pigs).[67] The use of *living* biological material from animals raises more difficult issues, and in 1999 a Swedish parliamentary committee presented the report "From one species to another – transplantation from animal to human being". According to the report, Sweden at this time held a strong position in research on xenotransplantation.[68] Swedish researchers had performed transplantations of insulin producing cells from pig foetuses, extra-corporeal perfusion (dialysis) by the use of pig kidneys, and had also joined a European project intended for transplantation of nerve tissue from animals to patients suffering from neurodegenerative diseases.

The report identifies a number of risk factors related to different types of xenotransplantation, in particular risks concerning the health of recipients and the general public,[69] but also risks to animal wellbeing,[70] as well as psychological, social and cultural aspects.[71] In a study ordered by the committee, however, a clear majority of the informants claimed that they would be positive to receiving a kidney or a hart from an animal, provided the result and risks would be no different to those involved if the donor were a human.[72] With bigger uncertainty and risks, however, the positive group dwindled considerably.

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[64] See for example the opinion of the Swedish national Council for Medical Ethics 2002-02-25, No 30/2001 (English version available at the webpage http://www.smer.se).
[65] Government Bill 2003/04:55, p. 127.
[66] See the terms of reference provided by the Ministry of Justice (*Dir 2005:2 Uppföljning av patentskyddet för biotekniska uppfinningar*). One report has already been published, dealing with absolute product protection of genetic inventions (*SOU 2006:70, Oinskränkt produktskydd för patent på genteknikområdet*).
[67] Parliamentary Report From one species to another – transplantation from animal to human (*SOU 1999:20, Från en art till en annan – transplantation från djur till människa*), p. 61.
[68] Parliamentary report pp. 147-148.
[69] Parliamentary report pp. 89-132.
[70] Parliamentary report pp. 133-142.
[71] Parliamentary report pp. 271-277.
[72] Parliamentary Report, Appendix 4, pp. 496-498.

The conclusion of the Swedish Xenotransplantation Committee was that although the perceived risks involved in xenotransplantation did not motivate any permanent or even temporary prohibition, there was call for certain safeguards, based on the cautionary principle. Several pieces of new legislation, directly aimed at various issues related to xenotransplantation, were proposed. Under this legislation, xenotransplantation would only be allowed in clinical research, subject to the authorisation of a new agency, the Xenotransplantation Board. Such authorisation would not be granted unless the project had been approved by an ethics committee for research on humans, as well as an animal ethics committee. The proposed legislation also introduced a number of additional safeguards for control and follow-up of donor animals, human recipients and third parties, including the creation of a special biobank and a registry for recipients.

The consultation period for opinions concerning the xenotransplantation report expired in May 2000, but so far no legislation has been prepared by the Government. Accordingly, this type of transplantation is still only covered by more general legislation. Research projects on xenotransplantation have decreased in the new millennium, researchers having voluntarily agreed to abstain from clinical studies for the time being.[73]

Since transplantation of biological material from an animal to a human being is not an established treatment method, in accordance with science and proven experience, such interventions are considered to constitute research. They thus require ethics approval under the Act on Ethics Review, involving assessment of the perceived scientific soundness, risk-benefit ratio, informed consent requirements and, not least, the justifiability of the project with regard to respect for human rights and human dignity. It is difficult to foresee the outcome of such an evaluation by a regional review board, of an individual project involving transfer of animal material into a human being. At the present time, however, it is not very likely that such a project would be approved, due to the uncertainty regarding the risks involved.

The use of animal material for xenotransplantation research would also require the approval of an animal ethics committee, as well the Swedish Board of Agriculture, as has been described above. This would entail an assessment of the perceived importance of the experiment in relation to the suffering inflicted on the animal.

3.2 Transplantation of human material into living animals

Also experiments involving the transplantation of human biological material (organs, tissue, cells or genes) into animals would fall under the Swedish animal welfare legislation. Such research thus requires animal ethics review and authorisation by the Swedish Board of Agriculture.

If the human material used for the transplantation could be traced to an identifiable donor, the Act on Ethics Review of Research Involving Humans would also apply and, depending on the origin of the samples, possibly also the Biobanks Act.[74] This means that additional prerequisites would have to be met, in order so safeguard human interests concerning e.g. scientific soundness, risk-benefit ratio, conformity with respect for human rights and human dignity, and normally the informed consent of the donor. If the human material were de-

[73] Parliamentary Report Ethics review of animal experiments – gene technology and biotechnology applied to animals (*SOU 2003:107 Etisk prövning av djurförsök – genteknik och bioteknik på djur*) pp. 74-75.
[74] The applicability of the Act on Ethics Review of course presupposes that the use of human biological material is part of a *research* project and not a standard procedure.

identified, however, these requirements would not apply. It should be noted that if the human material had been previously obtained for some other purpose, it would seem lawful under the Biobanks Act to have it de-personalised and then used for e.g. transplantation into an animal, regardless of the wishes of the donor. If the de-personalisation were to take place as *part* of the research project, however, with the purpose of using the samples for transplantation to animals, ethics review would be required and thus, most likely also the consent of the donors. If on the other hand the biological material used were de-personalised already at the outset, e.g. taken from a bank of un-identifiable samples, there would be no requirement for ethics review or consent.

3.3 The creation of chimbrids from embryos with mixed human-animal genetic material

Although the matter is not explicitly addressed, it must be assumed that the provisions of the Act on Genetic Integrity make it unlawful to use any form of assisted reproduction to produce a creature of mixed human-animal genetic make-up who could be defined as *human*. This presupposes that such measures for mixed reproduction would be considered to constitute genetic modifications that could be inherited by humans, under Chapter 2, Section 3 of the Act. Although embryo experiments for the purpose of *developing methods* for introducing hereditary genetic modifications may well be lawful within the 14-day-limit, this is not the case with research aimed at actually achieving such hereditary genetic modifications.

On the other hand, unless the creature produced could be defined as human (or could at least procreate with humans), even experiments directly aimed at the creation of human-animal hybrids or chimeras would not seem to be prohibited, provided the research does not involve the direct use of human ova that have been fertilised or subject to SCNT.[75] For example, procreation by the use of human sperm to fertilise egg cells from animals, or the use of genetic material from human somatic cells for a SCNT procedure with animal ova, would not necessarily be unlawful, depending on how the creature produced is defined. Similar legal uncertainty would pertain to experiments involving transplantation of gamete producing tissue from animals to humans or vice versa, as well as some varieties of inter-species gestation. Ethics approval would of course be required, at least with regard to animal welfare issues. If the human material used could be traced to an identifiable donor, the research would also fall under the Act on Ethics Review of Research Involving Humans.

Organisms created by fertilisation *in vitro* are not considered as genetically modified under the Environmental Code, unless the procedure has entailed the use of hybrid DNA or an already genetically modified organism. If the creature produced does count as a non-human genetically modified organism, certain additional precautionary considerations will be required, including authorisation by the Swedish Board of Agriculture.

4 Concluding remarks

Although the creation of human-animal hybrids or chimera has not been explicitly addressed in Swedish law, there are many provisions in more general legislation, which would be applicable to such measures. Certain types of interventions and methods would thus seem to be completely prohibited, whereas others would be subject to requirements of mandatory

[75] Such human ova will have to be destroyed at the 14-day-limit, see Chapter 5, Section 3 of the Act on Genetic Integrity.

ethics approval and/or the authorisation of other special agencies. The number of Swedish authorities sharing responsibilities in the field of gene technology is in fact so high and the regulatory system so complex, that a special website has been constructed to provide some overview.[76]

In the areas of health care and medicinal products, a number of general and specific legal requirements exist, in order to guarantee the safety of patients and consumers. When interventions are not part of an established treatment method, however, the boundaries of lawful activities are primarily regulated by provisions defining justifiable research.

There is separate legislation on research involving humans and animal research, both requiring ethics review. If human ova are used or the intervention entails genetic modification that can be inherited by human, additional legislation will also be applicable. The criteria for ethically justifiable research differ, depending on whether humans or animals are concerned. Scientific soundness and perceived value of the research is important in both cases, but the animal ethics committees balance these aspects with animal suffering of various types, whereas the review boards for research involving humans are concerned with risks to the health, safety and privacy of human research subjects, as well as more general risks to human rights and human dignity. However, review of research with human biological material is only required if the material used can be traced to an identifiable donor.

Whereas the actual and intended achievement of hereditary genetic modifications is completely prohibited with regard to humans, no such prohibition exists concerning animals. On the other hand, the intentional release of genetically modified animals falls under the restrictions prescribed in Chapter 13 of the Environmental Code, whereas the release of genetically modified humans does not. When applying the precautionary principles laid down in the Environmental Code, the primary aim is a sustainable development that will ensure also future generations a sound and healthy environment. Risks to human health are important, and so is biological diversity.

Also with regard to commercial aspects and patent law, the distinction between humans and animals is of significant importance. As in most other areas of law, provisions concerning animals are more liberal than those related to humans.

Despite the clear differences between the legal rules applicable to humans and those applicable to animals, there is no definition of "human being" as opposed to "animal" in the relevant Swedish legislation. It would seem to have been considered self-evident what we mean by this concept. Although legal discussions concerning the scope of human rights and respect for human dignity have drawn attention to the unclear legal status of unborn human foetuses (and even premature newborns),[77] the possibility of future part-humans does not appear to have been seriously considered. The borderline between human and animal is thus hard to define in terms of the law, but it is at the same time highly relevant. We may think that we are still very far from a society where for example assisted reproduction includes the possibility of having a human foetus carried by an animal,[78] but biomedical science moves

[76] See the official website of the Swedish gene technology authorities, http://www.gmo.nu.
[77] Rynning, E. "Åldersgräns för mänskliga rättigheter? Om rätten till hälso- och sjukvård vid livets början" (Age limits for human rights? On the right to health care at the beginning of life.) *Barn och rätt* (eds. Olsen, L. & Nygren, R.) Uppsala: Iustus Förlag 2004, pp. 149-180.
[78] Welin, S. *Reproductive ectogenesis: The third era of human reproduction and some moral consequences.* Science and Engineering Ethics (2004) **10**, 615-626.

quickly and it is clear that there are already areas of research where traditional boundaries between human and animal are being crossed. The ethical, legal and social consequences of this development must be addressed.