REGULATORY ASPECTS OF GENOMICS, GENETICS AND BIOTECHNOLOGY: An Orientation on the Positions of Germany, the United Kingdom and the United States

M.H.M. Schellekens and J.E.J. Prins[1]

Abstract

The human genome that is inside the nucleus of every cell of the human body contains codes that form a blueprint for the entire human being. In recent years, these DNA codes have to very large extent been uncovered. Within the framework of the so-called Human Genome Project, important work has been carried out in this respect. The next step will be to grasp the meaning of the codes. Biotechnologists are only beginning to understand the codes, although they are making good progress and have already a profound understanding of the 'meaning' of some small, isolated parts of the genome. The knowledge about the genome opens up unprecedented possibilities. The progress of life sciences has, e.g., brought knowledge about genetic predispositions, early diagnosis and even 'diagnosis' before a condition shows itself. It will, e.g., become possible to mend defective genes (aka genetic therapy) and to improve xenotransplants. Furthermore, life sciences are not confined to the human genome; they also focus on animal and plant genomes. The knowledge in these fields has even led to technically further reaching applications, such as genetically modified (GM) food, such as GM soybeans and GM maize, which is resistant to, e.g., damaging insects and plant diseases. As a last example, the cloning of animals such as the - already dead - sheep 'Dolly' can be mentioned.

The new knowledge and its applications are bound to give rise to legal questions. The purpose of this article is to provide an insight into the legal questions that arise as a consequence of the developments described above. In order to gain a first understanding of the questions that have already been raised, the laws in Germany, the United Kingdom and the United States have been studied. Furthermore, it has been investigated whether these questions exhibit a need for legal intervention. In this respect the authors have discerned four themes that may serve as a basis for structuring the discussion about intervention.

1. Introduction

As is the case with the development and use of many other new techniques and technologies, the introduction of genetics, genomics and, more in general, modern biotechnology gives rise to many new legal questions and challenges. For various reasons, these questions and

---

[1] Maurice Schellekens is senior researcher with the Centre for Law, Public Administration and Informatisation, Faculty of Law, Tilburg University, the Netherlands. Corien Prins is Professor of Law and Informatisation at the centre.

challenges appear highly complex. They may vary between the *development* of the technology and the *use* of the technology. Also, they may differ when it comes to the products of genomics and modern biotechnology on the one hand and the relevant process (means) and the reasons (interests) on the other hand. Thus, the interrelation between law and genomics is a highly complex issue, and seeing and knowing the full implications of this issue will require years of discussions, research and policy-making.

Not only given the recently claimed developments in the area of human cloning, but also in the light of various legislative initiatives, it seems good to gain an overview of the key issues at stake as well as the main legal developments in countries prominent in this respect. Several documents have indicated that a further understanding of the legal aspects of genomics as well as a better look at the research area of law and genomics are required. Such an understanding could also shed a light on the question whether and to what extent genomics is essentially different from other modern technologies, such as information and communication technologies. This article aims at providing a first impression of the legal developments and key issues at stake.[2] The text was originally written as an essay for a research programme of the Dutch Scientific Council (NWO) that focuses on the societal implications of genomics.

Before elaborating on the exact position and scope of this essay within the domain of law and genomics, we will go into the legal relevance of the distinction between genetics, genomics and modern biotechnology. As mentioned above, the NWO programme is centred around the societal implications of genomics. The research conducted for this essay as well as discussions with experts in other countries showed that developments in the field of technology and regulations in relation to genomics can, to a large degree, be compared to (earlier) developments in the field of biotechnology. Hence, although the distinction between genomics, genetics and biotechnology is relevant outside the legal domain, a legal division of the three (in the present way of thinking) hardly plays a role. Many similar legal questions arise: privacy, the ownership and commercial exploitation of human data, issues on accessibility, intellectual ownership rights, distribution of risks and consumer protection, to name a few.

Furthermore, it is anticipated that many of the legal questions will be answered through international circles. In a policy document on biotechnology the Dutch government stated that the Dutch legislation on biotechnology would be determined, to a large extent, by international treaties, European directives, etc. The anticipated influence from international developments implies that these developments will be instrumental in solving many of the legal questions at the national (Dutch) level. The policy developments indicate that over the last ten years a whole range of international initiatives have been developed regarding genomics and modern biotechnology. As early as 1990, the Council of Europe issued a recommendation regarding prenatal genetic diagnostics and screening according to which fourteen principles were to be laid down to be included in national legalisations. A European bio-ethics treaty was debated in the nineties.

The development of particularly a European set of measures does not mean that national policy-makers are merely awaiting the international measures to be issued. In the case of the Netherlands, a report was published five years ago by the Dutch Data Protection

---

[2] The text of this article was finalised in November 2002.

Authority.[3] In other countries, the legal issues are also addressed at policy level. After all, although there is an important amount of international steering, there is still enough room for policies at the national level as far as the regulation of genomics is concerned. In addition, the legal regulation debate at the international level will also be fed with, or at least influenced by, national opinions and developments introduced by the representatives of several member states.

In view of this statement, the question arises what the position of the Netherlands is in relation to other countries. Which legal issues have been addressed in other countries' policy documents and, at policy level, how do they relate to the issues being discussed in the Netherlands at present? After all, in order to take a national position in an (international) debate on technology and regulation of genomics, it must first be clear what the international trends and developments are. Also, in order to draft a national research agenda on law and genomics, one should be aware of developments in other countries and possible lessons to be learned.

As mentioned above, when considering the interrelation between law and genomics, a very large and complex research area emerges. It covers a variety of legal domains and concerns several fields (environment, agriculture, health care, etc.) and summons a range of normative, ethic, social and economic questions which, in turn, have an impact on legal implications and developments. It is not possible to make an analysis of all possible implications. Thus, this essay presents an overview from a specific perspective on the domain. In the light of what has been said above, the restriction lies in the aim to determine the legal issues which are prominent on the policy agenda of three countries. In other words, this essay is not an attempt to provide an analysis of legal issues given all possible normative, ethic, social and economic questions that arise when it comes to the development and use of genomics and biotechnology. This essay tries to provide insight into the manner in which other countries look upon legislation and regulation, and the normative considerations that have influenced them. In addition, it attempts to distill from this insight options for further - more in-depth - research into the domain.

Developments in three countries have been researched: the United States, the United Kingdom and Germany. Germany was chosen because it was one of the first countries to introduce legislation in the field of biotechnology, whereby its position and, thus, policy was quite restrictive. In contrast, the United Kingdom has over the past few years chosen a generally more liberal approach to its biotechnology legislation. Finally, the United States provides a good basis for this essay because of its long tradition of research into and use of biotechnological results. At an early stage, the US was confronted with the question how and to what extent biotechnology should be subjected to regulation. In order to put the developments in both Germany and the United Kingdom into their European perspective, the relevant measures of the European Union are also discussed.

An attempt will be made to answer the following more specific questions:
- What are the legal issues on the policy agendas of the countries investigated?
- Do governments intervene as regards the effects of genomics and, if so, in which fields/domains (health care, food, etc.)?
- Can - on the basis of the domain-by-domain synthesis - broader themes or dilemmas representing certain interests be discerned?

---

[3] *Gegeven: de genen. Morele en juridische aspecten van het gebruik van genetische gegevens*. See <http://www.cbpweb.nl> (accessed: November 2002).

- What instruments of legal intervention are used in regulating these themes or dilemmas?
- To what extent do governments make use of the instrument of public education and discussion in directing the course of developments in genomics and biotechnology? And to what extent do they provide the legitimacy required of certain legal measures?
- Do the answers to the above-mentioned questions allow for the tentative formulation of certain research themes and questions in the domain of law and genomics?

In order to answer these questions, section 2 will introduce the key legal issues. The overview presented is based on an analysis of documents pertaining to the three countries researched. On the basis of this overview, section 3 will show, by country, which of these issues are dealt with and why. Both chapters provide the necessary material for answering the first two research questions. Section 4 places the discussion at a more general level (which is abstract from the domain perspective), aiming to formulate answers to the remaining questions. All research material has been collected on the basis of desk research, contacts with researchers in the countries investigated and a workshop held on 5 September 2002 in Amsterdam, The Netherlands. Section 5 contains our concluding remarks.

2. Legal implications: A first impression of the key issues at stake

2.1 Introduction

When looking at the various policy documents as well as scientific discussions in the three countries investigated, it is clear that biotechnology raises many and diverse questions that have a profound legal impact. This chapter provides an overview of the most compelling legal issues to which biotechnology has given rise. It identifies from a general perspective the issues at stake and thus sets the framework for the discussion in the next chapter on specific regulatory developments in the European Union, Germany, the United Kingdom and the United States. We start with developments on genetically modified products that appear primarily risk related and give rise to the need for transparency. Subsequently, we touch upon developments related to the genetic modification of animals and human beings. Here the questions at stake are not only risk related, but also focus on dilemmas related to the ‘success’ of the technology. Issues at stake then deal with the legal dimensions of power, access, knowledge, transparency and integrity.

2.2 Genetically modified material: The environment

The genetic modification of plants raises various legal questions, specifically with respect to the environment. The key issues addressed by regulatory instruments appear to be the following:
- To what extent and under what conditions may genetically modified organisms be made available?
- How does one balance the risks against the benefits and how can the balancing be made transparent?

Applications such as biological pesticides, genetically modified organisms (GMOs) with increased resistance against diseases, etc., require them to become available. This also holds for research into (and thereby creating) such GMOs. The availability of GMOs does,

however, entail risks since little is known about the interaction between GMOs and nature. One of the larger risks lies with biodiversity, which may become impaired.

In order to limit the risks involved in the availability of GMOs, rules that make such availability dependent upon authorisation seem to be in place. Authorisation generally depends upon a balancing of the expected benefits of the research, the (in)availability of less dangerous alternatives (subsidiarity) and an assessment of the risks involved in releasing the GMOs. A key difficulty consists in the fact that even the most meticulous assessment cannot bring absolute certainty about the real risks involved. For this reason, authorisation systems in Europe are governed by the precautionary principle. However, too stringent restrictions have their drawbacks: scientific progress and innovation are slowed down, and the freedom of scientific inquiry may be reduced.

Assessment of the risks involved requires specialised knowledge (and thus a strong involvement of specialists), while at the same time important public interests are at stake. This raises the question how and to what extent the general public is to be informed and may become involved. The European Union leaves the issue of informing the public to the Member States (e.g. in Directive 90/220/EC). Article 9 of (new) Directive 2001/18/EC, however, provides for public consultation.[4] The Directive does not deal with the consequences of such a consultation (e.g., what if the general public objects to certain developments?).

2.3 Genetically modified material: Food and feed

Genetically modified material is also used in food-related products. The legal dimensions seem to focus on risk, transparency and choice:
- There may be a health risk involved in the consumption of genetically modified foods. The consumption of GM food may, e.g., bring about the transmission of diseases to animals and humans. This requires assessments comparable to those mentioned in the previous section.
- The consumer wants to be able to choose between traditional food and GM food; the same holds for farmers who want to have a real choice as regards feed. In order to afford the consumer and farmer such a choice, legal requirements for the labelling of food and feed are needed.

2.4 Genetic research

As mentioned above, the issues related to genetic modification of animal and human genetics are not only risk related, but also focus on dilemmas related to the ‘success’ of the technology. Issues at stake deal with power, access, knowledge, transparency and integrity. Ethical considerations and decisions based on balancing the relevant considerations play a key role here. As was mentioned in section 1, we will restrict the discussion to the legal issues that are at present on the policy agenda. Human genetics appears to be the key topic to be addressed.

2.5 Human genetics

---

[4] These and other European directives are discussed in section 3.

The application of (the results of) genetic research to humans gives rise to a wide range of legal questions. Below, the analysis is structured along the lines of four coherent themes: 1) genetic testing; 2) genetic therapy; 3) cloning and 4) research on human genetics.

2.5.1 Genetic testing

With respect to genetic testing, various moments bear a special legal significance: the decision to undergo a test, the access to the results of the test and the use that is eventually made of the test results.

2.5.1.1 The decision to undergo a genetic test

The decision of a patient or - prospective - parents to undergo or to have their offspring undergo a genetic test must in principle be taken voluntarily and based on all relevant information. Informed consent is the key principle here. Nevertheless, there are a number of considerations and developments that make the principle less obvious and may cause decisions to be made involuntarily. Mention can be made of the following examples:
- The care for the health of future human beings may inspire a government to make preconceptual, preimplantation or prenatal testing compulsory for certain risk groups. Making tests compulsory would serve to make parents aware of the seriousness of a condition. Theoretically, a government could also take action, for example by having the embryo treated on the basis of the test results, but such a compulsory intervention with respect to the unborn embryo would come into conflict with the fundamental rights of the mother to privacy and physical integrity.
- Forensic testing can take place in the course of criminal investigations or legal proceedings, for example, genetic fingerprinting and paternity testing.
- Testing may be made a condition for access to certain services or facilities, such as insurance or employment. People may unwillingly be confronted with information about their genetic predisposition.
- Even if the taking of a test is not a requirement for access to insurance or employment, a general obligation may exist to give the insurer or employer all the relevant information that is available. Such an obligation may have adverse effects on the willingness of a person to undergo a genetic test for therapeutic purposes. People will become hesitant to undergo testing for therapeutic purposes, fearing that they will be required to inform insurers (or employers) of the test results. Such hesitation, however, also keeps people from the advantages that may be gained from knowledge that is derived from genetic testing.

On a more fundamental level, the key question to be asked here is how the above restrictions relate to the principle of individual autonomy, the principle of respect for one’s personality, dignity and privacy and the prohibition of discrimination. In legal literature, the concept of the right ‘not to know’ has been suggested as an instrument to resolve the tension between the principles on the one hand and the arguments in favour of or forces towards forms of non-voluntary testing on the other hand. The question is, however, what the precise content and scope of such a right should be: Which of the forms of compulsion mentioned are to be counteracted, and under what circumstances?

Aside from the fundamental legal problem of balancing individual autonomy and general interests, decisions concerning the taking of tests may have more practical legal

consequences, for example in the field of liability: a doctor, failing to advise or offer an available test (in preconception, preimplantation or prenatal counselling), while the doctor is aware of a family history of hereditary disease or an older child that suffers from a hereditary disease, may have to face consequences in the sphere of liability.

2.5.1.2 Access to the results of genetic testing

Genetic testing may yield important information about a person's genetic predisposition. The knowledge resulting from such information may be a psychological burden. Should someone be burdened with such knowledge against his or her will? The right not to know is advocated as a phrase that highlights the negative side to this question. The right can be considered to be a form of respect for one's private life. Informing somebody against his or her will may be considered to be a form of intrusion on someone's private life. However, the acceptance of such a right is not without problems. The right seems to be at odds with the duty that rests on a doctor to cure where possible; or to formulate it in terms of the law of liability, to prevent damage where he can (easily) do so. What does a doctor do when he knows of a condition that can be alleviated by timely measures, but which cannot be cured? Informing the patient may be an intrusion on his private life; not informing the patient may be negligent.

Another problem is that genetic conditions are often not confined to one person, but may be present or latently present in members of the family to which the person tested belongs. Does a person have a duty to pass on the information gained from genetic testing if it concerns members of his or her family too? Does a doctor have the duty to inform family members? How does this relate to his duty of professional secrecy? Legal literature has advocated the necessity of a reevaluation of traditional notions of privacy in health care.

Apart from access by the person whom it concerns, problems may arise with respect to access by third parties. Should insurers and employers, e.g., be prohibited from gaining access to test results? There is a strong argument in favour of this position: insurance and employment should be available to everybody. Access by an insurer to (disadvantageous) test results may give rise to exclusion. On the other hand, it is argued that insurers, who have no access at all, are put in a disadvantageous position since the insured person, who does have access to his own test results, may in a calculated way compose his insurance cover. Solidarity, as one of the mainstays of insurance, comes under pressure.

2.5.1.3 Use of the results of genetic testing

Information that becomes available in the case of preconception, preimplantation and, to a lesser degree, prenatal genetic testing may prove to be very 'usable' because of the early stage at which it becomes available. Information about the medical condition of the foetus enables, e.g., parents to make better, informed decisions about the commencement and continuation of a pregnancy. As such, the tests may very well become a desirable service. If the genetic tests desired prove to be expensive, the question arises whether they will be available to everybody and, if choices have to be made, what tests will and will not be covered by health insurance.

Apart from medical reasons for intervention, parents may also want an intervention for other reasons. Parents may, e.g., want to determine the gender of their child. At present, the Convention on Human Rights and Biomedicine does not allow the use of techniques of medically assisted procreation for the purpose of choosing a future child's sex, except where

a serious hereditary sex-related disease can be avoided.[5] In future, the capability to 'predict' characteristics of a 'future' human being may very well be much broader. This may open the discussion on whether it is desirable to broaden the prohibition to other grounds for selection. Intervention on non-medical grounds is, after all, still 'suspect', because it carries a connotation of eugenetic intervention.

Apart from genetic testing in the early stages, postnatal genetic testing and the use of the results thereof also raise legal questions. Legal implications seem to relate mainly to insurance and employment. If insurers and employers are given access to data, it is likely that they will use them in their decisions regarding the acceptance of prospective policyholders or employees. Problems may arise because it appears to be far from easy to interpret the test results with a view to actuarial significance or suitability of a certain employee to fulfil of certain job. Does the government have a role in guiding or even determining what information can be derived from test results and what use can be made of test results? In criminal law questions with respect to the principle of *ne bis in idem* and the time limit after which a suspect is immune from prosecution, are in discussion. Since the ever-advancing possibilities of forensic genetics bring the resolution of 'cold cases' in the realm of the possible, discussion arises on the question whether, with respect to certain serious crimes, the legal obstacles to prosecution and conviction should not be lifted as well.

2.5.2 Genetic therapy

Genetic therapy consists of the modification, replacement or insertion of genes in cells with defective genes. The cells with respect to which genetic therapy may take place are either somatic cells or germ cells. Therapy with respect to somatic cells affects only the person to whom the therapy is applied; in the case of germ cell therapy, the modification of the genes is passed on to future generations. Since somatic cell therapy is still in its infancy, the question arises whether somatic gene therapy should be considered to be a therapy or a medical experiment involving humans. Because of its experimental character, qualification as the latter seems at present to be the most appropriate.

As little knowledge is available about the long-term effects of somatic gene therapy, setting the conditions under which somatic gene therapy should be allowed under law requires a complicated balancing of the risks and benefits. At least, the following factors seem to be relevant from a legal perspective: the seriousness of the disease, the lack of alternatives, the expectation and seriousness with respect to the health damage that could occur and the expected health gains. Also, somatic gene therapy requires informed consent. What information duties then rest on the therapist?

As regards germ cell therapy, most countries have banned the alteration of germ cells within the human body or with the fertilised human egg cell. The question is whether this prohibition is founded in ethical considerations or merely stems from the fact that little is known about the 'medical' consequences of germ cell therapy, thus leaving open the possibility of a reassessment once science has progressed enough to assess the consequences. The consequences both concern the risks involved for the patient to whom the therapy is administered and the consequences that a germ cell therapy may have for future generations.

---

[5] Art. 14 of the 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, Oviedo 4 April 1997, ETS no. 164.

If the modification of germ cells is to take place on a large scale, the question of the diversity within the human genome pool becomes relevant.

2.5.3 Cloning

Generally, a distinction is made between reproductive and therapeutic cloning. Reproductive cloning is aimed at the creation of an identical human being. International consensus that reproductive cloning should be forbidden is growing; in many countries, it is in fact prohibited. It is considered that human dignity does not allow reproductive cloning.

2.5.4 Research on human genetics

Genetic research with respect to human beings or involving human material (IVF, cell nuclear replacement, embryonic germ cells, neonatal stem cells) raises a number of questions with legal implications.

A first question is under what conditions human material may be taken. The right to physical integrity requires the informed consent of the person from whom material is taken (including the mother/parents in the case of gametes or embryos). This consent may not only concern the 'taking' of the materials but also their use. The question is whether such a disposition and use can be governed by subjective property rights or whether circumstances develop under which they should be governed by personality right.

A second question relates to the admissibility of certain research, for example research with embryonic stem cells requires a balancing of the purposes of research and its legitimacy against the means. Therapeutical and fundamental research aimed at the discovery of the way in which cell differentiation takes place may qualify as legitimate purposes. Reproductive cloning and the modification of germ cell lines on the other hand are considered to be non-respectable purposes. Against the purposes and their legitimacy, the means and their acceptability have to be balanced. Most attention is, of course, drawn by the acceptability of the use of embryos for research purposes. The means used have to be subjected to a subsidiarity test. In the case of the use of human embryos, it has to be ascertained that less far-reaching means such as the use of laboratory animals do not form a viable alternative. The result of the balancing of the research interests against the interests of embryos and the protection of their human dignity has led to different outcomes in the countries that have been researched.

2.6 Patent protection

It may be clear that the system of patent rights is a key instrument in the progress of biotechnology. A patent is granted in order to enable the inventor to recoup his investment with the help of the exclusive patent right. In this way, 'society' stimulates new research that could yield new inventions. Without an exclusive patent right, an inventor may choose not to invest in research:
- he would have to compete against third parties that (commercially) use his invention without having had the burden of the investment, or
- he keeps his invention secret in order to safeguard his position in the market.

In the latter case, society has no knowledge of the invention, and development could be seriously hampered. After all, scientists stand on the shoulders of their predecessors. In the

field of biotechnology, these traditional ideas with respect to patenting may, however, conflict with other interests:
- Patenting the human body or parts thereof could be in conflict with fundamental values, such as the inalienable character of human material that is part of human dignity or the integrity of the person.
- Patenting may severely restrict the possibilities of analysis, diagnosis and healing, in that they are not allowed, are substantially more expensive or may only be performed by licence holders without substantial influence on the conditions under which they take place.
- The freedom of scientific inquiry may be at stake if a patent right covers the use of the material that is the subject of research. Especially patents on genes or gene sequences or parts thereof may restrict access to the basic data for research; think, e.g., of patents on ESTs and SNPs.
- Development is hampered because the requirement of novelty delays the publication of research results.
- Plant genes that are patented are often found in Third-World countries. The governments of these countries observe the patenting of their plants by Western companies with disappointment; after all, it concerns 'their' natural resources.

3. National legal measures and developments

The overview presented in the previous chapter provides a general basis for a more specific analysis of the developments at the national level of a specific country. This section will show by country which of the issues mentioned above are being dealt with and why. But first, the relevant developments at the European level are discussed because they determine to a large extent the situation in Germany and the United Kingdom.

3.1 European developments regarding the environment and products

European Union legislation is what could be called 'genomics specific'. The main reason for the introduction of specific legislation in Europe is the need to provide a harmonised regulatory framework and the protection of human health and the environment.[6] Below, an overview of the most important EU legislation is given. The European rules mainly focus on the relation between GMOs and the environment and products (mainly food and feed).[7]

Directive 90/219/EEC regulates the contained use of GM microorganisms (GMMs) in order to minimise their potential negative effects on human health and the environment.[8] The

---

[6] See European Communities Committee 2nd Report, Session 1998/99, EC Regulation of Genetic Modification in Agriculture, HL Paper 11, 15 December 1998, para. 39.

[7] Directive 90/220/EEC about deliberate release of GMOs into the environment will not be dealt with here because on 17 October 2002 it has been repealed by Directive 2001/18/EC.

[8] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, OJ L117, 08/05/1990, pp. 0001-0014.

Directive has been amended by Directive 98/81/EC.[9] The contained use of GMMs is classified into four groups according to the level of hazard. A user planning to make contained use of GMMs must submit a notification to the authorities enabling them to ensure that the proposed installation can be used without danger. With the notification, information is supplied to the competent authorities; this information comprises inter alia a summary or copy of the assessment of the risks to human health and the environment that the user has carried out.[10] The user must adhere to certain principles of safety and health. The Directive gives a number of provisions for accidents, covering subjects such as emergency response plans, informing the competent authorities and the European Commission.

A subsequent measure is the Novel Food Regulation 258/97, the rationale of which is to warrant the safety of consumption of novel food and informing the consumer. Environmental aspects are not considered and left to other legislation, such as Directive 2001/18/EC on the deliberate release of GMOs. The Regulation creates a preventive admissibility regime for novel food, i.e. foods or food ingredients that have hitherto not been used for human consumption to a large degree within the Community (and that fall in one of the designated categories).[11] The application of the Regulation is therefore not restricted to food that is produced with the help of genetic modification. The regulation also provides for labelling rules; under these rules, a consumer must be informed of the presence of a genetically modified organism in a novel food. Producers do, however, reluctantly adhere to the labelling rules and seek for ways to avoid labelling.[12]

Directive 2001/18/EC on the deliberate release of GMOs into the environment replaces Directive 90/220/EEC.[13] The Directive is an elaboration of the precautionary principle and imposes a duty on Member States to take all appropriate measures to avoid adverse effects on human health and the environment which might arise from the deliberate release or marketing of GMOs. The Directive aims to make the procedure for granting the consent more efficient and transparent. The public is to be consulted, about a proposed release (Article 9) or marketing (Article 24). Consent is limited to a period of ten years, with a possibility of renewing it. Labelling and monitoring of the GMOs are compulsory. Registers have to be established about the genetic modifications in GMOs and the location of the GMOs. Furthermore, the Directive provides for mechanisms for modifying, suspending and terminating the release if new information becomes available about the risk.

---

9 Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms, OJ L330 , 05/12/1998, pp. 0013-0031.

10 In the case of class 1 contained use, the user may commence after notification (Art. 8), in the case of class 2, he may proceed 45 days after notification in the absence of an indication to the contrary from the authorities (Art. 9) and in the case of class 3 and 4 uses, the users must await written consent from the competent authorities (Art. 10).

11 Regulation (EC) No. 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L43/1, 14 February 97.

12 S.J.R. Bostyn, E.J. Dommering, J.K.M. Gevers and B.M. Vroom-Cramer, *Moderne biotechnologie en recht*, Serie Recht & Praktijk no. 85, Deventer: Kluwer 2001, pp. 81-83.

13 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 and repealing Council Directive 90/220/EEC, OJ L 06, 17 April 2001, pp. 1-38.

In July 2001, the Commission published two new proposals for regulatory measures:[14] on genetically modified food and feed[15] and on traceability and labelling of GMOs and food and feed products produced from GMOs[16]. The former proposal is the consequence of the thought that environmental and consumer aspects of GMOs are strongly interrelated, and that food and feed questions are interrelated. It provides an integration of the different aspects and procedure (based on the one door - one key principle). In order to give the consumer and the producer (farmer buying feed) a real choice, the labelling rules for GMOs are expanded. Not just food and feed that contain GMOs, but also food and feed that is derived from GMOs but in which those GMOs are no longer detectable need to be labelled. This arguably gives rise to an enforcement problem. The second regulation proposed is instrumental in countering this enforcement problem. The proposed measures establish a framework for the traceability of GMOs from farm to table, so that in all stages of placing the food and feed on the market information is available and thus enables correct labelling. Thus, at any moment an information trail should be available that facilitates the identification of the source of GM food and feed.

Despite the above two initiatives presented by the Commission, no new GM foods have been approved in the EU since 1998. Certain Member States refuse to participate in the approval process until a regime for the traceability and labelling of GM food is in place. This de facto moratorium may be discriminatory against products produced by means of GM technology and could therefore constitute a trade barrier that might provoke WTO action against the EU. The European Commission therefore hopes for an expedient implementation of Directive 2001/18/EC and a timely finalisation of the two proposed regulations. The far-reaching traceability requirements of the latter regulation may, however, have trade implications themselves.

3.2 European developments regarding patent protection

The European Patent Convention (EPC) was established in 1973. It allows companies to obtain a bundle of European national patents by filing a single application. Some provisions are more especially relevant for the patentability of biotechnological inventions. Article 52(4) EPC relates to patents for medical diagnosis and therapy: ‘Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.’ The impact of this provision is, however, limited in that instruments and medicines used can be patented (provided they meet the

---

[14] In July 2002, the Commission issued a press release stating that the proposals were favourably received in the European Parliament, including the extension of labelling requirements to products in which GMOs are no longer detectable.

[15] Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed, Brussels, 25 July 2001, COM(2001) 425 final, 2001/0173 (COD).

[16] Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, Brussels, 25 July 2001, COM(2001) 182 final, 2001/0180 (COD).

requirements for patentability): 'This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.'

According to Article 53(a) EPC, patents will not be granted if the publication or exploitation of the patent is contrary to *ordre public* or morality.[17] The question of morality came up in case T 19/90 about the patentability of the 'onco-mouse', i.e. a mouse that developed cancer after genetic modification.[18] The Board of Appeal of the European Patents Office considered that moral considerations such as the suffering of mice and the risk to the environment must be weighed against the possible benefits resulting from research into human cancer. The Examining Commission had granted the patent.[19] The ethical dimension of patenting biotechnological inventions was, furthermore, the subject of an opposition proceedings before the (Opposition Division of the) European Patents Office in July 2002. The procedure resulted in an amendment to a patent that was awarded to Edinburgh University in 1999.[20] The patent describes a method to single out stem cells from a more differentiated culture, so that a pure stem cell culture is obtained. The patent concerns animal stem cells, but the word 'animal' does not exclude application to human stem cells. The Opposition Division considered this to be in contravention of, inter alia, Article 53(a) and Rule 23d(c) EPC. Rule 23d(c) states that uses of human embryos for industrial and commercial purposes are excluded from patentability. The amendment to the patent excludes human and animal embryonic stem cells from the patent. The patent still covers adult animal and human stem cells.

Finally, it should be mentioned that a European patent is not granted in respect of '[p]lant or animal varieties or essentially biological processes for the production of plants or animals; this does not apply to microbiological processes or the products thereof' (Article 53(b) EPC).

Within the European Union, a Directive on the legal protection of biotechnological inventions was adopted in 1998.[21] Biotechnological inventions previously also were patentable, but the Directive brings further clarification in the legal protection of biotechnological inventions.[22] With respect to the question of the patentability of human genes and gene sequences, Article 5 of the Directive is relevant: 'The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or

---

[17] The provision of Art. 53(a) is mitigated in that it states that a case of exploitation will not be deemed to be contrary to the *ordre public* or morality merely because it is prohibited by law or regulation in some or all of the Contracting States.

[18] T19/90 Harvard/Onco-mouse OJ EPO 1990, 476.

[19] OJ EPO 1992, 589.

[20] See <http://www.european-patent-office.org/news/pressrel/2002_07_24_e.htm> (accessed: August 2002).

[21] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L213, 30 July 1998, pp. 13-21.

[22] See 4th recital Directive 98/44/EC.

partial sequence of a gene, cannot constitute patentable inventions.'[23] This fundamental position is, however, mitigated by the inclusion of paragraph 2 of Article 5 Directive 98/44/EC: 'An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.' Of course this does not alter the fact that such an element for being patentable needs to comply with the usual requirements for patentability such as novelty, inventiveness, industrial application and sufficiency of disclosure. For the requirement of industrial application, this is expressly repeated in paragraph 3 of Article 5 Directive 98/44/EC: 'The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.'[24]

3.3 Germany

3.3.1 General

The German government holds the view that international agreement is of paramount importance in addressing issues of biotechnology. In his address to the 55th UN General Assembly, German Foreign Minister Joschka Fischer stated that a global consensus is the only way forward in dealing with biotechnology (*Gentechnik*).[25] He suggested that an international convention be drawn up that promotes biotechnology, ensures the freedom of research and of its fruits, defines a sound ethical basis and guarantees protection against abuse. As a direct result of this position, Germany and France decided to broaden their dialogue on bioethics. The German–French coordination is seen as a first step towards a broader coordination on the European level.[26] The international perspective is also prominent in a document published by the Federal Ministry for Education and Research (*Bundesministerium für Bildung und Forschung*). In this document on guidelines for a research policy concerning biotechnology, the ministry observes that European legislation is

---

[23] The Dutch government has sought the annulment of Directive 98/44/EC inter alia on the ground that Art. 5(2) of the Directive reduces human living matter to a means to an end, undermining human dignity. In October 2001, the Court of Justice of the European Communities dismissed the application. The Court considered that the Directive provides sufficient protection to human dignity in its statement that the human body at the various stages of its formation and development cannot constitute a patentable invention (Art. 5(1) Directive 98/44/EC). Court of Justice 9 October 2001, Case C-377/98 (The Netherlands v. European Parliament and Council of the European Union).

[24] In January 2002, the Commission published a report about the failure to publish, or late publication of, papers on subjects that could be patentable and the implications thereof for basic genetic engineering research. Report from the Commission to the European Parliament and Council, An assessment of the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions, COM(2002) 2 final, Brussels 14 January 2002, [SEC(2002) 50].

[25] See <http://www.auswaertiges-amt.de/www/de/infoservice/presse/?bereich_id=11&type_id=3&like_str=&archiv_id=309&detail=1> (accessed: May 2002).

[26] See <http://www.bundesregierung.de/top/dokumente/Artikel/ix_63572.htm> (accessed: May 2002).

gaining importance.[27] Nonetheless, the Ministry thinks that EU biotechnology law has to become less bureaucratic, without sacrificing the existing high level of protection of humans and the environment.[28]

Although the speech was not confined to biotechnology-related environmental issues (it concerned environmental policy in general), mention must be made of the views expressed in December 2001 by German minister Trittin, when he spoke about the role of the national government in international environmental policy.[29] The minister acknowledged that the German nation is merely a small player in the international arena; that, nonetheless, it would be important that some nations take a leading role, not as world powers, but as examples of successful policies at the national level. Furthermore, he stated that it is the task of national governments to establish global environmental rules that are stronger than rules that address a nation's individual concerns; that the German government therefore strives to turn the UNEP into a 'world environmental organisation'.

3.3.2 Environment and products

When looking at the policy initiatives on specific matters of biotechnology and genomics, a first point of attention is the implementation of the European directives mentioned above. Directives 90/219/EC and 90/220/EC about 'contained use' and 'deliberate release' have been implemented in the *Gentechnikgesetz* (*GenTG*).[30] Germany chose to deal with biotechnology in specific legislation, hence it did not incorporate the directive in existing legislation. The later Directive 98/81/EC on the contained use of GMMs has not yet been implemented in Germany. The government's proposal for an amendment to the *GenTG* met with criticism from experts who believe that the proposal does not do enough to simplify the procedures that companies have to follow when making contained use of GMMs.[31] In the procedure for authorisation of class 3 and 4 contained uses or deliberate releases, the principle of public participation is adhered to, by holding a public enquiry (*Anhorungsverfahren* of Article 18 *GenTG*).[32]

In 2001, the Federal Ministry for Education and Research (*Bundesministerium für Bildung und Forschung*) started a programme aiming to make research (supported by the

---

[27] Bundesministerium für Bildung und Forschung, 'Rahmenprogramm Biotechnologie – Chancen nutzen und gestalten', Bonn, April 2001.

[28] Idem, p. 9.

[29] Bundesumweltminister Jürgen Trittin, 'Die Rolle des Nationalstaats in der internationalen Umweltpolitik', presented at the Conference 'Global Environmental Change and the Nation State', Free University Berlin, 8 December 2001. See <http://www.bmu.de/fset1024.php> (accessed: May 2002).

[30] The *Gentechnikgesetz* was amended by the *Gesetze* of 24 June 1994, *Bundesgesetzblatt* I, p. 1416.

[31] See <http://www.bundestag.de/aktuell/hib/2002_076/03.html> (accessed: August 2002).

[32] J.L. De La Cuesta Arzamendi, 'Environment Protection and Manipulation of Microorgansims', in: C.M. Romeo Casabona (ed.), *Biotechnology, Law and Bioethics Comparative Perspectives*, Brussels: Bruylant 1999, pp. 299- 330, at p. 312.

Ministry) about biological safety more transparent to a broader public.[33] The portal http://www.biosicherheit.de is the central element in this promotional programme. The portal opens up the so-called *Sicherheitsforschungs-Datenbank* (*SiFo Datenbank*), which contains easy-to-understand information about on-going and finished research projects in Germany on genetically modified plants.

3.3.3 Animals

On 17 May 2002, the German lower house adopted a bill that incorporates animal protection into the German Constitution.[34] It protects both individual animals and animals as a species. According to the explanatory memorandum to the bill, the sensitivity and receptiveness of higher developed animals to suffering and the state of research and development, which even enables the cloning of animals, necessitate a moral minimum standard for human behaviour.

3.3.4 Human genetics

3.3.4.1 Genetic testing

The German government plans to have a broad public discussion about the use of genetic testing by employers and insurers.

3.3.4.2 Cloning

The German Constitution protects human dignity. The *Embryonenschutzgesetz* regulates the ethical boundaries of biomedical research and its applications. This statute bans, e.g., the cloning of humans and the genetic modification of human germs (the modifications in germs will be carried over to next generations).[35] The German government aims to have the high level of protection guaranteed by these statutes accepted in the international context.

3.3.4.3 Research

The use of adult stem cells for research purposes has not been controversial in Germany. Research with embryonic stem cells is, however, controversial. The *Embryonenschutzgesetz* forbids the creation of embryos for research purposes, but does not deal with the importation of stem cells from countries in which stem cell creation by way of cloning or the extraction of

---

33 See <http://www.bundesregierung.de/dokumente/Bericht/ix_76907.htm> (accessed: April 2002).

34 See <http://dip.bundestag.de/btd/14/088/1408860.pdf> (accessed: May 2002); Drucksache 14/8860 of the German Federal Parliament. If the bill is enacted, the text of Art. 20a *Grundgesetz* will read as follows: 'Der Staat schützt auch in Verantwortung für die künftigen Generationen die natürlichen Lebensgrundlagen *und die Tiere* im Rahmen der verfassungsmäßigen Ordnung durch die Gesetzgebung und nach Maßgabe von Gesetz und Recht durch die vollziehende Gewalt und die Rechtsprechung.' Italics (by the present authors) indicate the amendment of the provision introduced by the bill.

35 See Arts. 5 and 8 *Embryonenschutzgesetz* and H. Nys, 'Human Gene Therapy', in: C.M. Romeo Casabona, *Biotechnology, Law and Bioethics Comparative Perspectives*, Brussels: Bruylant 1999, pp. 93-115, p. 110.

stem cells from embryos is allowed. On 30 January 2002, the German federal parliament voted for a principled ban on the importation of human stem cells; importation for research purposes is, however, admitted on very stringent conditions.[36] From the address of Prime Minister Schröder to the federal parliament the following considerations for the decision can be derived.[37] In the first place, Germany should not distance itself from research standards in other countries. Several reasons underlie the position against a 'distancing':
- Stem cell research takes place in other countries anyway. Here, the fact that in other *European* countries stem cell research is allowed and conducted is given extra emphasis. (Perhaps the unspoken argument is that Germany would miss out on an opportunity for economic growth).
- Joining other countries in their research standards would place Germany in a better position to have its voice heard in international research and policy-making, and thus in a better position to adjust or approximate international standards to German perceptions of responsible research.
- If stem cell importation (and stem cell research) were to be banned entirely, difficult questions could arise on the use of therapies and medicines that have been derived from 'responsible' foreign research with stem cells. Since their use will not be forbidden, an ambivalent situation could arise.

Apart from the considerations mentioned above, the Prime Minister presented other considerations as well. The freedom of science and research would be impinged on, if stem cell importation and thus research were to be banned altogether.
Furthermore, the decision expressly aims at clarifying the law on this issue - thus as if the position was laid down in the *Embryonenschutzgesetz*. (This Act does not explicitly ban importation.) This timely provision of legal security was necessary since scientists voluntarily postponed stem cell research pending the political decision. This situation could, of course, not be stretched too long.

3.3.5 Patent law

---

[36] Before its decision, the national investigation commission 'Recht und Ethik der modernen Medizin' published its reports on stem cell research and importation: the Second Interim Report of the Commission on Law and Ethics in Modern Medicine - Subject Report on Stem Cell Research (12 November 2001), and the Supplement to the interim report on stem cell research focusing on importation problems 'Research in Imported Human Embryonic Stem Cells'. The commission did not reach unanimity and declared itself against importation by majority. See <http://www.bundestag.de/gremien/medi/2zwischen.pdf> (in German), Drucksache 14/7546 of the German Federal Parliament, and <http://www.bundestag.de/gremien/medi/2zwisch_engl.pdf>, both visited in May 2002. The National Ethics Council published its report, 'Stellungnahme zum Import menschlicher embryonaler Stammzellen', on 20 December 2001. See <http://www.ethikrat.org/presse/pm/200103.html> (accessed: May 2002). On 22 March 2000, the German Federal Parliament created the national investigation commission on 'Recht und Ethik der modernen Medizin'. The task of this (and in fact any) *Enquete Kommission* is the preparation of legislative decisions about sizeable and significant issues. To that end, the commission determines the state of fact, regards developments as they unfold, lists arguments (relevant in the discussion) and, if relevant, defines the goals and instruments for governmental action. See <http://www.bundestag.de/gremien/medi/index.html> (accessed: May 2002). On 2 May 2001, the German Federal Government decided to install a National Ethics Council (*Der Nationale Ethikrat*), which is to be a forum for dialogue about ethical questions on life sciences. See <http://www.nationalerethikrat.de> (accessed: May 2002).

[37] See Bundestag Drucksache Plenarprotokoll 14/214, pp. 21209-21210; <http://dip.bundestag.de/btp/14/14214.pdf>.

In October 2000, the Federal Government issued the *Gesetzentwurf zur Umsetzung der Biotechnologierichtlinie* (Directive 98/44/EC).[38] The bill has been published on the Internet.[39] The German government declared that the European patent law does not provide the final answers to all patent-related challenges of biotechnology. Therefore, the government initiated a process aimed at changes at the European level. The government will do its utmost to bring about the necessary improvements and clarifications. Its concern is primarily directed at the examination of the conditions for patentability of genes, gene sequences and parts thereof that are derived from human or animal beings, plants or microorganisms.

A working group consisting of representatives of German and French ministries examines various questions regarding the future of patent law and, in particular, questions relating to biotechnology. The outcome of the work of the working group will be presented to the European Commission and to the European Patent Office.[40]

Mention should also be made of the report issued by the *Enquete Kommission* of the German federal parliament. The report - published in January 2001 - deals with the protection of intellectual property rights in biotechnology and was.[41] In it, the committee identifies a number of mainstays for the regulation of bio-patents. The government is called upon to take the mainstays into account in implementing the biotechnology directive and to initiate action at the European level to improve the patent law. The following mainstays relevant to biotechnology have been identified: patenting matters is an inadequate means to protect intellectual property in living systems; the interest of freedom of research must be accommodated for in the implementation; compulsory licensing has to be made easier in the medical domain; the patentability of biotechnological inventions is to be limited by the *ordre public*; the protection of the personality right of persons from whom materials are taken for biotechnological inventions must be strengthened; the origin of plant or animal material for biotechnological inventions must be indicated in the patent application and the compliance with bio-safety protocols has to be ensured. Indirectly related to biotechnology issues, the following are important: in the title of a patent application, the subject and scope of the application must be made clear to the interested public; appeals against a patent granted on the basis of infraction of the *ordre public* must be possible at any time.

3.4 The United Kingdom

3.4.1 General

Contrary to Germany, the UK government policy is characterised by quite a liberal position in legislating on biotechnology, in particular when one considers the position on human genetics. However, it also seems that the protests against biotechnology and its applications

---

38 See <http://www.bmj.bund.de/images/10239.pdf> (accessed: May 2002).

39 See <http://www.fuente.de/bioethik/Biotechnologierichtlinie_Umsetzungsentwurf.htm> (accessed: August 2002).

40 See <http://www.bundesregierung.de/dokumente/Artikel/ix_63572.htm> (accessed: May 2002).

41 See <http://dip.bundestag.de/btd/14/051/1405157.pdf> (accessed: May 2002).

are more intense in the UK when compared to other countries.[42]

3.4.2 Environment and products

The issues arising in the context of environment and products are too a large extent determined by developments at the European level. As a consequence of the de facto moratorium, GM crops are only cultivated in research settings. In the UK, these are primarily the so-called Farm Scale Evaluations (USE), which aim at a further understanding of the effects of the commercial cultivation of GM crops on biodiversity. Having made progress with labelling and traceability legislation at the European level, the end to the moratorium seems near and thus the commercialisation of GM crops comes within reach. However, even when the moratorium is lifted, there is probably no point in growing GM crops if the current polarisation in the public opinion about GM crops persists. Therefore, the government plans to stimulate the public debate on the commercialisation of GM crops. The Agriculture and Environment Biotechnology Commission (AEBC) produced the report *A Debate about the Issue of Possible Commercialisation of GM Crops in the UK*,[43] which formulates a number of suggestions for setting-up the public debate. The AEBC recommends that the debate should be held at an arm's length from the government because the public does not see the government as neutral (which may have to do with the BSE and foot-and-mouth disease crisis). In addition, the AEBC recommends stimulating independent scientific research and review of information, because most research into GM crops is funded by organisations promoting or opposing the new technology. With respect to the results that the proposed public debate may have, some reservation is shown.[44] The views held are often so deeply entrenched that one cannot realistically hope for a consensus. The public may merely get better informed, which seems an important step in the right direction.

The House of Lords Select Committee on the European Union published a report on the proposed European regulations on GM food and feed (COM(2001) 425) and the traceability and labelling thereof (COM(2001) 182).[45] The Select Committee points out that the exclusion from labelling requirements of food for the production of which GMOs as producers of proteins have been used, does not take into account persons who for ethical reasons object to GM technology.

Furthermore, the Select Committee questions the feasibility of the audit trail. GM

---

[42] See, e.g., the BBC news item 'GM crop protestors released' as recently as 19 August 2002; <http://news.bbc.co.uk/1/hi/england/2203220.stm> (accessed: August 2002).

[43] AEBC, Public Attitudes Group, *A Debate about the Issue of Possible Commercialisation of GM Crops in the UK*, 26 April 2002, <http://www.aebc.gov.uk/aebc/public_attitudes_advice.html> (accessed: August 2002).

[44] House of Commons, Environment, Food and Rural Affairs Select Committee, Session 200-02, Fifth Report, 'Genetically Modified Organisms', HC 767, 18 June 2002, <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmenvfru/767/767.pdf> (accessed March 2003).

[45] House of Lords, European Union Select Committee, Session 2001-02, Twenty-Second Report, 'Labelling and Tracing of GM Food and Animal Feed: Informing the Consumer', HL 117, 30 April 2002, <http://www.publications.parliament.uk/pa/ld200102/ldselect/ldeucom/117/11701.htm> (accessed March 2003).

soybeans and maize are, e.g., imported from the USA as bulk commodities. An audit trail back to the farm is impossible because of the way in which bulk commodities are traded: the commodity flow system does not distinguish between GM and non-GM crops. The batches that arrive in Europe are mixed. The Committee points out that there are alternatives. It is, e.g., possible to maintain the current labelling regime (food with detectable GMOs must be labelled) and supplement it with a GM-free scheme. GM-free food is kept apart from the bulk trade and can thus be guaranteed to be GM free. GM-free food does, however, need to be sold at a premium price because of the extra costs involved.

3.4.3 Human genetics

3.4.3.1 Genetic testing

The potential use of genetic test results for insurance purposes has raised concerns in the UK. From the report of the House of Commons Select Committee on Science and Technology it becomes clear that the public fears that genetic testing will lead to new forms of discrimination.[46] As a consequence, people may be deterred from taking a genetic test, even if it is beneficial to their health or for research purposes, for fear of being unable to get affordable insurance cover. It is also mentioned that insurers have concerns about the risk of adverse selection; people with adverse test results will take more insurance cover in the expectation of an early claim and a substantial payout. Finally, people fear that insurers may assign predictive qualities to genetic test results, which are not justified by the research.

The Select Committee takes the position that commercial insurance companies should have access to the same information as applicants, where it is relevant and reliable, but only if there are no adverse consequences for society as a whole, such as the discouragement of people from taking genetic tests. The government does not go further than to state that it recognises that the current system of insurance contracts depends upon the disclosure of relevant information by both parties. It also recognises the adverse consequences for society if people refrain from taking genetic tests for fear of consequences in the sphere of insurance. At present, the government considers legislation denying insurers access to all genetic test results to be inappropriate.

In October 2001, the government and the Association of British Insurers (ABI) reached an agreement on a five-year moratorium on the use of genetic tests by insurers.[47] The mainstays of the moratorium are the following:

- a five-year moratorium on the general use of DNA genetic test results by insurers from 1 November 2001, except in circumstances detailed below;

---

[46] House of Commons, Science and Technology Select Committee, Session 2001-02, Fifth Report, 'Genetics and Insurance', HC 174, 3 April 2001, <http://www.publications.parliament.uk/pa/cm200001/cmselect/cmsctech/174/17402.htm> (accessed March 2003).

[47] See <http://news.bbc.co.uk/hi/english/business/newsid_1615000/1615397.stm>, <http://www.abi.org.uk/newsreleases/default.asp?display=month&year=2001&month=10> and <http://www.doh.gov.uk/newsdesk/archive/octo2001/4-naa-23102001.html> (accessed: June 2002). A. Milburn, Secretary of State for Health, 'Putting Britain at the Leading Edge of Advances of Technology', Speech at the international conference 'Genetics and Health: A Decade of Opportunity', <http://www.doh.gov.uk/speeches/jan2002milburngenetics.htm> (accessed: June 2002).

- continued use of genetic test results by insurers only when authorised by the government's Genetics and Insurance Committee (GAIC) for life policies of over GBP 500,000 and other insurance policies of more than GBP 300,000;
- a review of these financial limits after three years;
- an impartial and independent complaints mechanism;
- monitoring by the ABI of companies' compliance with its Code and moratorium, with annual publication of the ABI's compliance report.

The period of the moratorium buys the government and all stakeholders time to develop consensus on what should replace the moratorium. The ABI will monitor the compliance to the moratorium by insurance companies. Health Minister Lord Hunt pointed out that the government is prepared to enforce the moratorium through legislation if there is evidence of serious and persistent non-compliance by the insurance industry.[48] Furthermore, the government believes that there should be independent supervision of the use of genetic tests by insurers. The GAIC is to be entrusted with this task. Furthermore, the GAIC will be given a task in resolving conflicts about the handling of applications by insurers under the moratorium. If the GAIC is unable to solve the problem, it will be brought before an independent tribunal (established under the ABI Code of Conduct), which has wide-ranging powers, such as the imposition of (unlimited) fines.

3.4.3.2 Cloning

On 4 December 2001, the Human Reproductive Cloning Act received the royal assent. It explicitly bans human reproductive cloning in the UK. According to Article 1(1) of the Act, 'a person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence'.

3.4.3.3 Research

Research with human embryos is regulated in the Human Fertilisation and Embryology Act 1990. It primarily regulates the practice of in vitro fertilisation. The Human Fertilisation and Embryology Authority is entrusted with the evaluation of intended research projects and may grant licenses for projects with diverse research purposes. From January 2001, the scope of the Act has been further widened by the Human Fertilisation and Embryology (Research Purposes) Regulation 2001. The Authority now can also grant licenses for the following (additional) purposes:
- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease; or
- enabling any such knowledge to be applied in developing treatments for serious disease.
The above means that the extraction and study of embryonic stem cells, including the use of therapeutic cloning, is allowed in the UK, in order to develop treatment and knowledge about

[48] See <http://www.doh.gov.uk/newsdesk/archive/octo2001/4-naa-23102001.html> (accessed: June 2002).

the development of embryos.[49]

Mention should, finally, be made of BioBank UK. This is an initiative to create a national resource for scientists studying the interaction between genetic, environmental and lifestyle risk factors in the development of the common diseases of adult life. Issues of confidentiality, security of data and informed consent will be addressed by the government.[50]

3.4.4 Patent law

The Patents Act of 1949 first allowed for patents on new chemical substances as such. The patent claim could not extend to the substance 'when found in nature'. But this has been interpreted as 'as found in nature', meaning that a substance could be patented once it was isolated from its natural environment. In 2000, the Patents Act 1977 was amended in order to comply with the European Directive on the legal protection of biotechnological inventions.[51]

In July 2002, the Nuffield Council on Bioethics presented an elaborate report on the ethics of patenting DNA.[52] The Council suggests that the problems or perceived problems regarding the patentability of genes and gene sequences is something for which to a large extent a solution can be found within the application of the existing criteria for patentability, primarily the inventiveness and utility or industrial application.

3.5 The United States of America

3.5.1 General

The United States' attitude towards biotechnology policy can be characterised as very open. If it comes to deciding about the use of biotechnology, the United States tends to ask 'Why not?', whereas in Europe rather the question 'Why?' is raised. This attitude is visible in their legislative traditions: the US legal system is based on a risk-taking culture, whereas the systems in the European countries are based on a risk-avoiding legal culture. This contrast in attitude is, e.g., at the basis of the American irritation about the European moratorium on approval of new GM foods that blocks the European market for American GM food. Within the US, the open attitude is, however, subject to increasing criticism. With respect to the ethical issues of human genetics, the US policy is surprisingly conservative.

In the past decade, numerous legislative texts and amendments to existing laws have

---

[49] See 'Report Examines Stem Cell Research Legislation in the EU Member States', *Cordis Focus*, no. 197, 20 May 2002, p. 2.

[50] Milburn, 'Putting Britain at the Leading Edge', <http://www.doh.gov.uk/speeches/jan2002milburngenetics.htm> (accessed: June 2002).

[51] Patents Regulations 2000, Statutory Instrument 2000 No. 2037.

[52] I. Kennedy et al., 'The Ethics of Patenting DNA: A Discussion Paper', London: Nuffield Council on Bioethics 2002.

been proposed. Few of them, however, were adopted.[53] In addition to federal legislation, several states have issued additional rules. The rules of the states vary considerably regarding scope, definitions used, etc. Experts differ in opinion on the question whether the legislative involvement should be intensified. Some claim that a first priority appears to be public awareness, informed consent as well as labelling initiatives, whereas others stress the need for new legal institutions.[54]

3.5.2 Environment and products

In the 1970s, the Recombinant DNA Advisory Committee (RAC) was asked to determine the need for the regulation of DNA technology. The main need the RAC identified was the regulation of laboratory practices. This resulted in the National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules, which still hold today.

In the 1980s, it became apparent that a more comprehensive reflection on regulation was needed. In 1984, the Reagan administration released the Coordinated Framework for Regulation of Biotechnology, which became final in 1986. According to this framework, a product of biotechnology needs to be regulated according to its composition and intended use (or characteristic and novel features), rather than by the method to produce it. New biotechnology products are thus regulated under existing federal regulation. This is based on the belief that the use of existing health and safety laws provides more immediate regulatory protection and legal certainty than is possible with the adoption of new legislation which is specific to biotechnology.

Under federal legislation, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the US Department of Agriculture (USDA) are the authorities that deal with products of biotechnology. Of these, the Animal and Plant Health Inspection Service of the USDA (APHIS) and the FDA are the most relevant.

APHIS regulates the importation, interstate transport and field-testing of GM plants and microorganisms. In 1997, APHIS published an expedited procedure for the field testing of crops. Four years earlier, the same procedure had already been introduced for a limited number of crops. For GM plants that meet certain criteria, no formal application is required, merely a notification describing the genes, the location where the test takes place and the characteristics of the plant. Almost all applicants for GM crops use the expedited procedure.[55]

The FDA regulates food and drugs to ensure that they are safe. On the basis of the Federal Food, Drug, and Cosmetics Act, the FDA subjects new food additives to a 'premarket' determination of safety. However, if a substance in a food is 'generally recognised as safe' (GRAS), it is not covered by the legal term 'food additive' and, as a consequence, the safety assessment is not required. On this basis, GM foods can and in practice have appeared on the market without a premarket safety determination, viz. if they are considered to be 'substantially equivalent' to food that is already on the market and the

---

[53] An overview of the legislative texts can be found at the website of the National Humane Genome Research Institute, <http://www.genome.gov> (accessed: September 2002).

[54] See W. Vullings and K. Planque, 'Genoomonderzoek in de VS. Aandacht voor maatschappelijke aspecten', *Technieuws* 5 (2002), 26-41, at p. 37.

[55] Environmental Media Services, History of US Regulation of Genetic Engineering, <http://www.ems.org/biotech/regulation.html> (accessed: August 2002).

safety of which has long been established. The idea that GM foods can be seen as 'substantially equivalent' rests on the FDA's 1992 Policy,[56] in which the FDA sets out its view 'that there is unlikely to be a safety question sufficient to question the presumed GRAS status of the proteins (typically enzymes) produced from the transferred genetic material, or of substances produced by the action of the introduced enzymes (such as carbohydrates, fats, and oils), when these proteins or other substances do not differ significantly from other substances commonly found in food and are already present at generally comparable or greater levels in currently consumed foods.' In practice, many producers of GM food have extensive consultations with the FDA, during development and before marketing of the food. This is, however, done on a voluntary basis. Consumer watchdog groups have protested against the practice that many GM foods enter the market without prior safety testing by the FDA.[57]

In 2001, the FDA proposed a new policy in which a notification to the FDA prior to introduction on the market is compulsory.[58] In this notification, the manufacturer provides information about plant-derived bio-engineered food that is to be consumed by humans or animals. The information in the notification must enable the FDA to ensure that all market entry decisions by the industry are made consistently and in compliance with the law. The 1992 policy stating that substantially equivalent GM food need not be subjected to a test by the FDA is maintained, although the FDA expects that the advances in DNA technology allow for the development of food that differs more substantially from food in future. The chances of such food obtaining a GRAS status are proportionally smaller.

GM food is subject to the same labelling requirements as traditional food. This means that GM food need not be labelled as GM food. If, however, GM food has properties that are relevant for the consumer, the label needs to express this just, as would be the case with traditional food. If a new food is different from a traditional food to such a degree that the traditional name no longer describes it adequately, the naming of the new food must reflect this. If the new food raises an issue with respect to its use or the consequences of its use, if it has a significantly different nutritional property or if it contains an allergen that the consumer would not expect, based on the name of the food, these issues must be addressed in the label. In 2001, the FDA published draft guidelines for industry about voluntary labelling indicating whether or not foods have been developed using bioengineering.[59] The guidance is aimed at assisting manufacturers who wish to label in ensuring that labelling is truthful and not misleading. The labelling does, however, remain voluntary. The FDA considers the fact of bioengineering in itself not to be a relevant circumstance: 'We are still not aware of any data or other information that would form a basis for concluding that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a)

---

[56] US Food and Drug Administration, 'Statement of Policy: Foods Derived from New Plant Varieties', Federal Register, 29 May 1992, vol. 57, pp. 22984-23005.

[57] See <http://www.cnn.com/2001/FOOD/news/01/11/biotech.marketing/index.html> (accessed: August 2002).

[58] FDA, 'Proposed Rule: Premarket Notice Concerning Bioengineered Foods', Federal Register, 18 January 2001, vol. 66, pp. 4606-4738.

[59] FDA, 'Draft Guidance for Industry: Voluntary Labeling Indicating whether Foods Have or Have Not Been Developed using Bioengineering', Federal Register, 18 January 2001, vol. 66, pp. 4839-4842.

and 201(n) of the act.'[60]

3.5.3 Human genetics

The legal debate that arises in relation to human genetics centres around the issues of privacy and discrimination, and the commercialisation of genetic information (patents).

3.5.3.1 Genetic testing

Several bills are pending in the Senate or in Congress, banning discrimination in employment and insurance on the basis of the results of genetic testing.[61]

3.5.3.2 Cloning

In November 2001, the US company ACT created a human embryo through cloning techniques. The embryo was allowed to grow to a six-cell embryo.[62] In January 2002, Senator Brownback introduced a bill in the Senate that bans all forms of human cloning: not just reproductive cloning, but also research cloning of human beings.[63] The bill has the support of President Bush.[64] In a call on the Senate to back the cloning ban, the president gave three reasons for the all-encompassing ban: first, an ethical reason - anything but a total ban may lead to human life being exploited or extinguished for the benefit of another; second, a partial ban would be virtually impossible to enforce; third, the benefits of research cloning are highly speculative. In April 2002, Senator Dorgan introduced another bill in the Senate, which bans only reproductive cloning.[65] Both bills are referred to the Judiciary Committee of the Senate.

A ban on cloning may be unconstitutional if it infringes the right to make reproductive decisions, which is protected under the constitutional right to privacy and the constitutional right to liberty.[66]

---

[60] 'We' refers to FDA and 'the act' refers to the Federal Food, Drug, and Cosmetic Act, source: 66 FR 4840.

[61] Genetic Nondiscrimination in Health Insurance and Employment Act (Introduced in House) [H.R.602.IH], Genetic Information Nondiscrimination Act of 2002 (Introduced in Senate) [S.1995.IS] and Genetic Nondiscrimination in Health Insurance and Employment Act (Introduced in Senate) [S.318.IS].

[62] See <http://www.cnn.com/2001/TECH/science/11/26/human.cloning.reax/index.html> (accessed: August 2002).

[63] Bill leading to Human Cloning Prohibition Act of 2001, S.1899; see <http://thomas.loc.gov/cgi-bin/query/z?c107:S.1899:> (accessed: August 2002).

[64] See <http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html> (accessed: August 2002).

[65] Bill for the 'Human Cloning Prohibition Act', introduced by Senator Dorgan on 12 April 2002, S.2076.

[66] L.B. Andrews, 'Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning', *Harvard Journal of Law and Technology*, summer 1998, 643-680.

3.5.3.3 Research

With respect to research, the US maintains a sharp distinction between publicly funded research and private research. Private research is largely unregulated, whereas publicly funded research is governed by various funding conditions. On 9 August 2001, President Bush determined the conditions under which federally funded human stem cell research is allowed.[67] Federal funds may only be used for research that uses stem cells of one of the more than sixty stem cell lines that are already in existence at present. The destruction of additional human embryos will not be sanctioned nor encouraged with federal funds. In addition, the existing stem cell lines may only be used if they were derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors. The National Institute of Health (NIH) will determine which of the over sixty stem cell lines meet these criteria.

3.5.4 Patent law

At the outset, it should be noted that the US patent law not only differs in a number of respects from European patent laws, but also is the expression of a different view on the reasons for patent law altogether. In the United States, patent law is primarily seen as a means to protect investments.

The patentability of biotechnological inventions has long been accepted. In *Merck v. Olin* (1958), a patent on isolated natural products was granted.[68] In *Diamond v. Chakrabarty* (1980), the patentability of living organisms produced by genetic engineering was confirmed.[69] The American criteria for patenting are broader and interpreted in a more flexible way than is the case under the European Patent Convention. Fewer requirements with respect to obviousness (in Europe, inventiveness) and utility (in Europe, industrial application) are set. According to the USPTO guidelines for the examination of applications for compliance with the utility requirement, the utility requirement is satisfied if a utility is 'credible', assessed from the perspective of a person of ordinary skill in the art.[70]

Apart from the broader criteria for patentability, the US patent law also lacks a number of exemptions that are usually made in Europe.[71] There are, e.g., no exemptions for diagnosis and therapy, nor exemptions on ethical grounds. The US Patent Act does not provide for an

---

67 See <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html> (accessed: August 2002).

68 Merck & Co., Inc. v. Olin Mathieson Chem. Corp., (1958) 253 F.2d 156, 161, 163.

69 Diamond v. Chakrabarty, 447 US 303, 206USPQ 193 (1980).

70 See Department of Commerce, United States Patent and Trademark Office, 'Revised Utility Examination Guidelines: Request for Comment', Federal Register, Vol. 64, No. 244, 21 December 1999, pp. 71440-71442.

71 A bill introduced in Congress in March 2002 pertains to amend the Patent Act in that it provides for non-infringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing and to require public disclosure of such information in certain patent applications. See the bill for the Genomic Research and Diagnostic Accessibility Act of 2002 H.R. 3967.

exemption for academic research either.[72] Many research centres, however, have agreements with patent holders allowing them to use the subject of their patents.[73]

Mention should finally be made of the joint statement of British Prime Minister Blair and US President Clinton of 14 March 2000, summarizing the patenting-and-research dilemma: 'To realize the full promise of this research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere . . . Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health discoveries around the world and enhance the quality of life for all humankind . . . intellectual property protection for gene-based inventions will also play an important role in stimulating the development of important new health care projects.'

4. Synthesis

The previous section provides an answer to the first two research questions posed in the introduction. Analysis of the three countries shows that genomics influences and challenges the law in a great variety of ways. The domains where implications are particularly felt include agriculture, the environment, animal rights, food and feed, pharmaceutics, health care, forensics, intellectual property and privacy. The subsequent question to be answered is whether on the basis of the domain-by-domain synthesis some broader themes can be distilled. For addressing the challenges of law and genomics on the basis of a mere (isolated) domain-by-domain synthesis appears not very fruitful: the isolated study of the issues in different domains may lead to a divided legal response to the issues, without the full comprehension of possible general themes and dilemmas. The synthesis below therefore structures the domain on a more general level, thus creating overarching links between the problems in the different domains.

4.1 Structuring the field

Surveying the domain of law and genomics in the three countries analysed, four central themes can be distinguished:
1. safety risks: genomics and its applications represent safety risks for society; the law has a function in protecting society against such risks;
2. individual autonomy, responsibility and privacy: the application of genomics with respect to individuals may have far-reaching consequences for them. The principles of individual autonomy and privacy imply that they have a say in the application of genomics *vis-à-vis* their person, and the consequences of such applications;
3. access and property: genomics give rise to the production of material and immaterial goods (information). Since there may be competing claims with respect to them (e.g. when it comes

---

[72] See, e.g., Art. 53(3) Dutch Patents Act 1995.

[73] European Group on Ethics in Science and Technologies (EGE), Opinion no. 16, 'Ethical Aspects of Patenting Inventions involving Human Stem Cells', 7 May 2002, <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf>, s. 1.12 (accessed March 2003).

to the commercialisation of such goods), the law has a function in the allocation of those goods;
4. integrity and intrinsic value: human and probably animal life is considered to have an intrinsic value. Furthermore, the integrity of the environment, plants, animal and human life and processes and products of nature (such as procreation and food) may be considered a value worth protecting, which can e.g. be infringed upon by genetic modification (think of crossing the species boundaries). The law may have a function in protecting against infringements on these values.

The above list only gives a rough indication of the four themes; below, we will elaborate on them in more detail.

4.1.1 Safety risks

Risks are especially relevant when it comes to the development and use of biotechnology and genomics. Many legal issues arise when applications of genomics fail to perform correctly. In the context of genomics, risk or harm is a concept that has to be construed widely. Risks of course concern physical harm to the environment, to animals and to humans. Risks in the environmental sphere include loss of biodiversity, decreased resistance against damaging insects and herbs, etc. With respect to animals and humans, risks concern health and life. Health may be deteriorate through illnesses, loss of the function of a part of the body, shortened life expectancy etc. Apart from these more or less objective harms, risk is also applicable to more or less subjective harms such as pain.

4.1.2 Individual autonomy, responsibility and privacy

Individual autonomy and the extent of this concept appears to be a key theme. Are individuals allowed to determine that applications of genomics are not used with respect to their persons, or can such applications be forced upon them? The principle of individual autonomy holds that individuals have a say in such an application. Here the function of law is twofold. On the one hand, the law may have function in enabling individuals to exercise their autonomy. If food does, e.g., not contain labels informing consumers about the presence or absence of GMOs, a right to choice becomes meaningless. So law has to provide for compulsory labelling. If a genetic test or therapy is to be applied to a person, individual autonomy requires the doctor to acquire informed consent from the individual. On the other hand, law also has a function in regulating infringements on individual autonomy. Law indicates, e.g., under what conditions DNA material can be taken from a suspect in the interest of the investigation and prosecution of criminal offences.

Individual responsibility often depends on the possibility of attributing behaviour to a person. Such attribution is often based on the presumption of a free will. Knowledge about a person's genetic predisposition may, however, change the prevalent views about the freedom with which somebody can exercise his will and may thus have consequences for individual responsibility.

4.1.3 Access and property

'Producers' in the field of genomics have to invest in order to be able to put a product on the

market. By marketing the product, they hope to recoup their investments. The user of the product may to a large extent be dependent upon the product, e.g. for his health or livelihood (think of the farmer and GM seeds). The exclusivity of a product may, however, lead to a situation in which the interest of the producer prevails too much and the interests of the consumer are set back. Especially if the products are relevant for the consumer's health, there may be a strong argument in holding that they should be available to everybody who is need of such products. Such competing interests with respect to the products may mean that the law has to intervene in the distribution of these goods.

4.1.4 Integrity and intrinsic value

Above, it was mentioned that safety risks arise from genomics or its applications failing to function in the way they ought to function. Apart from this, issues may arise from genomics functioning in the way they were intended to function. Especially if such intended use would be shifting borders, making new things possible, questions may arise as to whether this should be allowed. Here questions arise in relation to the *success* of the applications.

On the one hand, questions arise as to the result of the application of genomics: Do we want clones, genetically modified organisms and children that are the result of preconception, preimplantation or prenatal selection? On the other hand, there are questions about the way in which the result is obtained: May human or animal embryos be used for utilitarian purposes? May they even be created for such purposes? Both in the product and in the process approach questions arise about integrity (Should we divert from nature?) and intrinsic value (Is such a product or process compatible with the respect with which organisms ought to be met?)

4.2 The form of legal intervention

As we have seen above, the reasons for legal intervention may be broadly described in terms of four themes, each representing a type of interest: the prevention of risks, the realisation of individual autonomy, responsibility and privacy, access and property and integrity and intrinsic value. The question that subsequently arises is what instruments of legal intervention are used in the three countries in regulating the issues at stake.

4.2.1 Risk prevention

The prejudicial effects of materialising risks warrant far-reaching intervention by a government (the precautionary principle). In most countries, prior permission from the government or a government agency concerning applications of modern biotechnology that involve risks for the environment and health is the prevalent form of regulation. For the regulation of safety issues, most countries have taken a process approach.[74] The US takes a product approach as regards food.[75]

Uncertainties about the risks of the application of technology appear to be shifted to

---

[74] For Germany, see the *Gentechnikgesetz*; for the UK, Genetically Modified Organisms (Deliberate Release) Regulations 1992 and 1995 (SI 1992/3280 and SI 1995/304), Environmental Protection Act 1990, and the Health and Safety at Work Act 1974.

[75] See FDA Statement of Policy: Foods Derived from New Plant Varieties (1992).

an agency that has the task to decide on the permission, and is supported by a committee that advises the agency on technical and other issues. The use of self-regulation by committees of experts is increasingly considered to be too light an instrument given the risks at stake.

4.2.2 Individual autonomy, responsibility and privacy

This theme is characterised by the fact that all related questions directly and prominently concern an individual person. On the one hand, the regulation in this field is aimed at enabling a person to take his or her responsibility for issues that affect his or her person. In this respect, duties to provide information appear important: the requirement of informed consent for medical diagnosis and therapy and labelling and traceability requirements for GM food and feed. Mention should also be made of the information duties listed in the European data protection framework. Sometimes, autonomy may require information not to be provided to the person concerned: the right not to know.

On the other hand, the law has to regulate lawful restrictions to personal autonomy and privacy (against the will of the person concerned). Such restrictions have to be construed precisely in order not to prejudice the interests of individual autonomy more than is necessary. Mention can be made here of the relevant rules in the data protection laws as well as the requirements for taking DNA from a suspect.

In short, the interest of individual autonomy and privacy lead to general requirements that are directly imposed on those that interact with the person whose autonomy is at stake. There is, of course, a sliding scale from the situation where a person has complete control (informed consent for therapy) to the situation where control has shifted to another person (taking DNA materials from a suspect). Also, the principles of individual autonomy and privacy are themselves formulated in law as fundamental rights.

Does self-regulation appear an option in this theme? The situation in the countries discussed shows that here fundamental rights are at stake, which do not lend themselves for too much ‘self’. Self-regulation may, however, perform a function as an intermediary solution. An example can be found in the moratorium of British insurers on genetic testing.

4.2.3 Access and property

The law creates exclusiveness (property rights, intellectual property rights or freedom of contract) with respect to material and immaterial goods in order to safeguard their efficient use. This is in principle no different with respect to the goods that are the products of genomics. Material goods are, e.g., GM-modified seeds for use in agriculture or medicines that are produced with the help of biotechnological processes. Immaterial goods may be intellectual property rights such as patents or services such as genetic therapy. The allocation of goods under the influence of exclusive control appears to be generally considered adequate in the three countries. Nonetheless, there are circumstances under which this allocation is thought to be undesirable. There may, for example, be highly valued interests that imply that certain groups should have access to certain goods for certain purposes, even if the market under the influence of exclusiveness leads to a different allocation. The law may accommodate to such circumstances by reducing exclusivity. On the other hand, trade agreements such as the WTO limit the leeway to restrict international trade in goods derived with the help of modern biotechnology.

4.2.4 Protecting integrity and intrinsic value

More than any other theme, this theme appears influenced by ethical considerations. Regulation appears highly difficult because it concerns issues on which opinions largely differ. In those situations where regulations were introduced (cloning, germ cell modification, the creation of chimaeras), the rules were based on the relevant safety implications. Thus the safety implications at present form the underpinnings of the regulation in this field. This may imply that the underpinning of the rules is to a large extent dependent upon the state of technology. Once the technology is safe, the ethical discussion on - this time not the risk dimension but the success dimension of the technology - will gain a prominent position.

In some cases, risks and ethical considerations have such an impact that a total ban of the activity is in place. The reproductive cloning of humans is a case in point; it is banned in the three countries researched or bills for such a ban are in preparation (in Germany, the *Embryonenschutzgesetz* bans the cloning of human beings, in the United Kingdom, the Human Reproductive Cloning Act is in force and in the US bills are under discussion). With respect to such direct regulation by the legislator, questions in relation to the technology neutrality of the rules arise. Will we also want to ban reproductive cloning if technology has so far progressed that it can be done without (unacceptable) risks for the clone?[76]

4.3 The involvement of society

The above shows that in several instances the legislature has intervened in protecting relevant interests of a theme. As was mentioned earlier, legislative activity appears not to be the only instrument in regulating developments on genomics and biotechnology. In the US, experts differ in their views on whether priority should be given to law-making or to stimulating public education and public discussion. Hence, the question arises to what extent governments make use of the instrument of public education and discussion in directing the course of developments in genomics and biotechnology.

The reputation of biotechnology appears not to be all too positive. The emergence of the name ‘genomics’ can be seen as an attempt to shake off the stigma. With the public’s feelings against genomics, lawmakers are forced to listen carefully to public concerns regarding genomics and its applications. Thus, transparency seems to be a key factor. The far-reaching rules that the European Commission proposed concerning the labelling and traceability of GM food and feed should be viewed in the light of public scrutiny as regards genomics legislation. In the US, the public pressure seems to be less than in Europe, but is increasing. The proposed policies of the FDA about the labelling of GM food and the compulsory notification of new food are the clear exponents of this pressure.

It is clear that governments try to stimulate the debate about genomics and that such a debate should be accompanied by legislative involvement. Governments feel that the public is not sufficiently involved in the issues and lack an understanding of the - objective - facts of genomics. By organising public debate, governments hope to enable the public to make a more balanced judgement on the issues at stake, thus enhancing the legitimacy of legislation. Public discussion thus not only fulfils a useful role in educating the public on the issues, trying to make clear that consensus about certain issues (those where ethical considerations

---

[76] Admittedly, objections raised against reproductive cloning that concern the sorrow a clone might experience from having no normal line of descent may not be taken away by technology.

play an important role) may be difficult to find. Public debate is also a key instrument in generating the legitimacy of certain policy decisions as well as regulatory measures.

When looking at the specific initiatives taken in the three countries, we note that advisory bodies (think-tanks) have been created including participants from all walks of life, from various disciplines, etc. Examples are the German *nationaler Ethikrat* and the *Enquete Kommission Recht und Ethik der modernen Medizin*. In addition, the initiatives show that lay people can be involved in the discussion by organising discussion panels and using means of distant communication such as ICT (primarily the Internet) and television. The latter is used mainly for disseminating information about biotechnology, its applications and the difficult ethical questions it raises. Finally, mention must be made of the fact that in Germany the year 2001 was declared the 'year of life sciences' (*Jahr der Lebenswissenschaften*).

5. Conclusion

The previous sections provide an orientation on the complex interrelation between law and genomics. As with the development and use of many other new techniques and technologies (e.g. information and communication technologies), the introduction of genetics, genomics and, more in general, modern biotechnology gives rise to numerous new legal questions and challenges. Many of them arise not only from concerns about the failure (and thus risks) of the new technology, but also from its success. Legal questions arise in relation to the needs and opportunities of the technology and balancing the various interests. Questions also deal with institution building (Is there a need for new legal institutions? And, if so, what kind of institutions should these be?) and with respect to the implications for regulatory instruments of technological turbulence (the pace of new developments in the field). Also, dilemmas arise when it comes to developing the legitimacy and authority of (legislative) intervention. Finally, the decisions on the legal concerns may vary between the *development* of the technology on the one hand and the *use* of the technology. In short, the legal questions that we face when considering not only the products of genomics and modern biotechnology, but also the process (means) and the reasons (interests) appear vast and highly complex.

The analysis of the situations in the United Kingdom, Germany and the United States shows that four central themes need further consideration. The first theme deals with the safety risks of genomics. As became clear, genomics and its applications may present safety risks for society. From the legal perspective, these safety risks imply a role for regulatory measures in protecting society against such risks. A second theme deals with individual autonomy, responsibility and privacy: the application of genomics with respect to individual persons may have far-reaching implications for individuals. The principles of individual autonomy and privacy imply that people have a say in the application of genomics *vis-à-vis* their person and consequences of such applications. The third theme focuses on access and property. Competing claims arise with respect to the products and information that are rendered when applying genomics. Questions arise such as: Who owns the information and to what extent can the information be commercialised? The law has a role in the allocation of those goods. The fourth domain centres around legal issues in relation to integrity and the intrinsic value of human and animal life.

On these four issues, numerous questions will have to be answered. As regards the safety

risks, we need to rethink how and to what extent the public should be informed when it comes to the development and use of applications of genomics that carry safety risks. Is it possible or desirable to involve the public in the decision-making process on safety issues, and to what extent can and should this be realised by law? Another question relates to the international implications, for the effects of genomics and its applications are not confined to the territory of one state. What does this mean for the position of the national legislature? Is there an adequate international framework for governance dealing with cross-border risks (e.g. the risks of transgenic animals crossing borders)? A final example of a question under the issue of safety risks deals with liability. In view of the specific risks involved: Do we need special liability rules for the application and use of genomics?

When looking at the second issue - focusing on individual autonomy, responsibility and privacy - various questions require our attention. Insurers and employers, for example, may want to use genetic testing. The persons concerned, however, fear exclusion and discrimination. How should this conflict of interests be balanced and by means of what regulatory mechanisms (freedom of contract versus the availability of basic services and facilities for everyone; availability of information; commercialisation of information, privacy)? Another illustrative question here is whether there should be a legal right to the availability of non-GM food. Without such a right, the labelling of GM food may become pointless if GM food pushes non-GM food out of the market.

The third issue (access and property) relates, among other things, to patent issues. Is legal intervention required with respect to patents law, in view of the unease that exists with respect to Directive 98/44/EC? Does the directive reflect a desirable balance between the interests of producers and users of inventions in the field of genomics? In addition to these and other questions on patent and, more in general, intellectual and industrial property law, we face various questions related to access. Health-related applications of biotechnology may be expensive and not available to everybody equally. The inequality in this respect may entrench social differences. Thus, we need to answer the question whether and under what conditions a legal right to access such applications must be construed (or perhaps may already exist).

The final issue centres around integrity and intrinsic value. Here, due to the many ethical considerations and dilemmas that underlie the theme of integrity and intrinsic value, law and regulation itself cannot provide truly balanced answers. At present, these issues therefore have to focus on the legal framework within which the ethical discussion can and must take place. This leads to questions such as: Does international trade law allow for national states to have their own ‘ethical’ policies? More specifically: May restrictions be imposed with respect to products of genomics that are not acceptable for ethical reasons? As an example, the proposed European rules about labelling and traceability of GM food can be mentioned. Do such rules constitute a trade barrier under the law of the WTO?

The above shows that, when considering the interrelation between law and genomics, a very large and complex research area becomes visible, with numerous questions requiring our attention. Further, more in-depth research in this domain is therefore essential. With this essay, we hope to have provided an impression of the manner in which three key countries consider the position of regulatory instruments and the normative considerations that have influenced the introduction of the legal measures they have taken.