



NEDERLANDSE VERENIGING VOOR RECHTSVERGELIJKING
NETHERLANDS COMPARATIVE LAW ASSOCIATION

Legal Limitations on Genetic Research and the Commercialisation of Its Results

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1. Introduction

Developments in genetics hold a strong promise for future possibilities in the cure of diseases and the prevention of health hazards. Research by Groningen University has e.g. brought to light that presently unknown mutations of alleles on the fifth chromosome make children susceptible to the adverse effects of passive smoking. Further research is done to identify the specific alleles and to find out how to influence the processes set in motion by the mutation. This kind of research and its results give rise to many legal and ethical questions. The example described above seems rather innocent in this respect but even here moral issues can rise. Should parents that smoke have their children tested on the presence of the mutation? Should they only test the children if there are more concrete indications for doing so? Should they stop smoking if their child carries the defect? Are these only ethical questions or can they also become legal questions and if so, under what conditions? These are difficult questions that are not always easy to answer, drawing from existing laws and regulation.

This report deals with the legal limitations to genetic research. The emphasis in this report is mainly on human genetics. Within this subject, three themes will be addressed. The first theme addressed is transparency. More than with any other technology, in biotechnology it is difficult to imagine what the positive or negative effects of research will be. Also the choices in what to research are very great. In such circumstances, transparency with respect to (intended) research requires explicit attention. Transparency can take away unnecessary fears and renders decision-making more democratic. Transparency does, however, not come by automatically. It may be burdensome and might place research in a less favourable light than would have been the case if other choices with respect to transparency had been made. In short, there is ample reason to address transparency in this report. As a second theme, this report will address the limits to freedom of research. Freedom of research finds its limits in other values and interests at stake in genetics. We will see that the Dutch government has devised a framework for describing the relevant values, interests and norms in

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genetics. This framework will prove useable in dealing with the limits to freedom of research. Finally, in order to influence (research) behaviour regulation is necessary. The existing regulatory instruments are however not always as effective as may be desired. Genetic research does not neatly fit in regulatory pigeon holes. Genetic research does also not stop at the state frontier. Regulation of genetic research at the national level has therefore definite shortcomings. At the international level, a national government is only one of many players. It is difficult to influence international regulation in such a way that it sufficiently reflects an individual country's moral preferences. In short, the relation to international regulation and shortcomings of traditional regulatory means is the last theme addressed.

2. Transparency

The promise of the undiscovered and unexploited potential inspires researchers to move the frontier of the state-of-knowledge and the state-of-art further towards the presently unknown. The progress of genetic research has many and profound societal implications. In the (near) future important decisions have to be taken. Modern biotechnology is, however, not a technology as any other. On the one hand, the technical aspects are complicated. Without explanation by experts it is easy to misunderstand modern biotechnology or its applications. On the other hand, biotechnology has potentially far reaching effects upon society and touches upon controversial moral issues. The combination of both characteristics makes that the understanding of biotechnology and its societal implications are vulnerable to misconceptions and biased views.

In view of the foregoing, the Dutch government recognises the relevance of a public debate on societal aspects of biotechnology. It is therefore not surprising that the Dutch government tries to stimulate the public debate on modern biotechnology by taking the initiative to debate.¹ Transparency – brought on by a debate – has many beneficial effects, e.g.: taking away fears and prejudices, enabling members of the public to specify their objections to developments, enabling them to exercise their democratic rights in an informed way, gaining support from the several fractions of the public for new scientific developments, etc. A debate bringing by these advantages has however not yet materialised. The debate is confined to limited fractions within the public and has not been picked up in wide circles. The debate is furthermore complicated by the fact that different stakeholders may want to adjust the public image of aspects of biotechnology in a way that is favourable to their own purposes.

With respect to transparency, a special responsibility rests on the shoulders of scientists. They have the knowledge of the newest developments and are best suited to inform the 'public' in an objective way, but even for scientists, this is not an easy task. It requires an extra effort to visualise biotechnological developments for a layman. To communicate with the public about biotechnological research is still a formidable challenge. In the research program 'The Societal Component of Genomics' (which is funded by the Dutch government) funding is explicitly made available for the imagination of 'hard' biotechnological research and its results.² In fact, it is one of only three legs of the research program. Since the first projects within this program only got the green light at the end of 2004, it is too early to report about any findings.

¹ *Kamerstukken II 2000/01, 27 428, nr. 2 (Nota biotechnologie)*, p. 21-23.

² See <<http://www.society-genomics.nl/>>.

Transparency concerns not just the core technology itself but also the applications with which the public is confronted. In 2003, the Rathenau Institute – a prominent Dutch research institute of the social sciences – formulated recommendations on food genomics, amongst which was a recommendation on transparency:³

‘The government must, via institutes or the flow of money, etc., ensure the scientific independence and provision of information in the public domain with regard to the track records of producers and products, healthy nutrition patterns and the role of functional foods therein, and the risks that are associated with it’.

The existing structures for the understanding of food safety are no longer adequate for dealing with functional foods. There is a practical need to educate the public – functional food that is good for me may not be so for you. There is also a need to enable the public to decide in an informed way on the acceptability of the products of food genomics. Researchers play in this respect an ever increasing role as a source of – hopefully – objective information.

3. Limitations to the Freedom of Research

Freedom of research does not bestow researchers with an unlimited freedom to pursue their research interests. There are other values and interests that may conflict with the exercise of research freedom and set limits to objects and methods of research.

The Dutch government devised a general framework for the assessment of biotechnological developments. This framework provides a neat structure for describing regulation governing (or limiting) genetics and genetics research.

3.1. The Framework for the Regulation of Biotechnological Developments

For a basic understanding of the framework, it is necessary to recognise that in argumentation with respect to biotechnology two types of ethics can be discerned. On the one hand, there are the ethics of consequences. Here, the consequences of an act are considered and on the basis of the consequences it is decided whether the act leading up to the consequences is desirable or not. This type of argumentation often amounts to the result that the most luck for the greatest share of the people is the best. On the other hand, argumentations may build on the ethics of principles. The ethics of principles assume that there are principles that may not be violated, independent of what the consequences of an act are. The difference between the two types of ethics has a high explanatory value in modern biotechnology. This can be easily demonstrated with the help of the four main values involved in biotechnology, which the Dutch government distinguishes. Biotechnology research has to respect the following four types of values:

- Sustainability: the processes that are decided upon now must not shift costs to the future. We do not want to leave the world to later generations in worse state than it is now. Decisions in this field often involve ethics of consequences.

³ Gremmen *et al.* 2003, p. 148.

- Welfare, health and safety: these are basic values. They are a precondition to materialise other values. Issues involving these values are decided on the basis of ethics of consequences.
- Human dignity and the intrinsic value of the animal: humans and animals have a value in themselves and are worthy of protection, irrespective of any conditions. An animal deserves e.g. protection irrespective of whether it is useful to man. Decisions in this field are governed by ethics of principles.
- Freedom: humans are able to reflect upon their own lives and make choices that affect their lives. Such choices presuppose the freedom to choose. For the exercise of such freedom, information is essential. These values are governed by ethics of principles.

The government considers these four values to be the core values that are at issue in the application of biotechnology. Apart from those values, there are many interests involved in biotechnology. The government mentions e.g. the freedom of science and economic interests as specific interests. For the purpose of this report, the core values can be viewed as the principal limitations to the freedom of research.

The discerned values and conflicts between them are governed by norms. The norms may take a type of organism as their object, e.g. a micro-organism, plants, animals or humans. With micro-organisms and plants often ethics of consequences will govern decisions. With animals and even more so humans ethics of principles will enter the equation as well. Alternately, the norms can take an act as their object, e.g. research with human subjects.

Norms can also be categorised according to their source and the way in which they operate.

With respect to the source, self-regulation and government regulation can be distinguished. Although this straightforward distinction is valuable for analytical purposes, in practice many intermediate forms of regulation exist, such as self-regulation that is instigated by the government or self-regulation where the government specifically channels or sanctions regulation by the actors involved. With respect to the way in which rules operate, substantive norms and process norms can be distinguished. Hereinafter, I will shortly touch upon pure self-regulatory norms concerning research. Subsequently, I will address government and intermediate regulation governing research. With respect to these forms of regulation, I will address substantive and process norms separately.

3.2. Self-regulation of Research

The values and interests involved in genetic research do often warrant government regulation. Since government regulation cannot cover all aspects of the field, specially where technical developments take place at great pace, there is a role for self-regulation. The Dutch biotechnology association (*Nederlandse Biotechnologische Vereniging*) has devised a professional code for biotechnologists. Some twenty prominent biotechnology firms have acceded to the code. The code has been the basis on which the European Federation of Biotechnology has set up the EFB Code of Conduct for Biotechnologists.⁴

⁴ See <http://files.efbpublic.org/downloads/EFB_CODE_OF_CONDUCT.pdf>.

The Dutch medical sector of course has its own code of professional conduct. The Dutch government sees only a limited role for self-regulation in biotechnology, because of the fundamental values involved. One could question whether this is justified. However, the Dutch government has defined self-regulation in a restrictive way. In the section about process norms, we will see that governmental process norms give the scientists an important role in the decision making process with respect to research.

3.3. Substantive Norms and Research

According to the Dutch government, a government should only establish substantive norms if they embody the undisputed way to deal with undisputed values. In the field of human genetics, the Dutch Embryo Act of 2002 (hereinafter: DEA or Embryo Act) provides a few examples. Certain acts are forbidden because they go against well established fundamental values. The Embryo Act forbids e.g. reproductive cloning (Art. 24 sub f DEA). It also bans the intentional modification of the genetic material of human germ cells, with which a pregnancy is to be brought about, or as it is often termed: change the genetic identity of humans (Art. 24 sub g. DEA). Both considerations of safety and of protection of the human dignity have inspired this ban.

The Embryo Act also forbids gender selection on non-medical grounds (Art. 26 DEA). The argument of the government for the prohibition is that gender selection must not become purely an object of the wishes and desires of the parents. Procreation would thus become instrumental in character. Strangely the Embryo Act is silent on other eugenic interventions. Of course, the prohibition of modifying human germ cells comes some way, since such modification could conceivably be used for eugenic purposes. However, eugenic interventions, such as selection of embryos on characteristics such as the colour of the hair, body length etc, are not dealt with. Apparently, the government chooses to await technical developments and to act when more clarity exists with respect to the future technical possibilities.

The Embryo Act forbids creating embryos specially for scientific research or for other purposes than bringing about a pregnancy (Art. 24 sub a. DEA). 'Specially created' embryos may also not be used for non-pregnancy purposes (Art. 24 sub a. DEA). With the latter ban, the Embryo Act makes the use of embryos imported from abroad illegal, at least for the indicated purposes. The implication of the ban is that scientific research into the development of therapeutic cloning is illegal. Therapeutic cloning is the creation of an embryo that is genetically identical to a patient, in order to breed tissue from the stem cells of that embryo for the therapy of the patient.

The Embryo Act does however not foreclose all research with embryos. Under certain conditions, the Embryo Act allows scientific research with embryos left over after IVF treatment. This is further governed by process norms and will be dealt with below.

Furthermore, it is noteworthy that there is a statutory provision (Art. 33.2 DEA) for the lapse concerning the ban of Article 24 sub a DEA. The government can determine by decree the moment at which the ban lapses. The provision guarantees parliamentary involvement in the proceedings leading up to the decree causing the lapse of the ban (Art. 33.2 DEA). The parliament can even require that the ban be lifted by a 'normal' statute, and not merely by a decree. If the government wants to lift the ban, it must however come forward with its plan before 1 September 2007. The present government has already indicated that it has no intention to do so. If this government finishes its term, the ban will certainly not be lifted using the expedited procedure of Article 33.2 DEA.

The decision to include the possibility to terminate the ban in the – at that time – Embryo Bill was taken by the – then – government after it weighed several values and interests involved in assessing the admissibility of the special creation of embryos.⁵ In short, the government considered the human dignity, the progress of medical science, the support within society and the legal situation in other European countries. It found that there was no broad support in society for the creation of embryos for scientific research and that most European countries disallowed it. Given these facts and the value of human dignity, it decided to forbid special creation, but it did not want to close the door completely. It did not rule out that support in society might grow as time passes and the discussion about the subject progresses. It did also not rule out that foreign legislation may become more liberal. The government has therefore designed a framework which allows quick reaction without unnecessarily hampering medical research.

A question is how to evaluate this legislative technique? In my view, the government – with this technique – found a smart way to channel the discussion about the subject. Would no statutory ban have existed, embryos might have been created for scientific purposes. If public discussion would have risen as a result of a public outcry about such incident, discussion would have been much more polarised. Such discussion – if at all – takes place in parliament before any embryos are created. At the same time, a strong signal is given that biotechnology and discussion about the implications of its application is in constant flux and that the statutory ban may not be the final word on the matter. Such signal is important, because a normal statutory ban has, to some extent, the effect of fixing the *status quo*. That does not do justice to the constantly changing biotechnological reality and the discussion of its societal implications. Nonetheless, it is questionable, whether a lift by the expedited procedure would have done justice to the issue. Would the parliament not anyway have chosen for a real statute for dealing with the issue?

It is striking that human dignity is playing a smaller role than might be expected on the basis of the framework described above. It seems that the weight accorded to human dignity is indirectly determined by such issues as public opinion and other countries' laws.

The government creatively deals with its own starting point that a substantive norm should only be brought about if discussion about the way to deal with the interests and values involved has led to a less or more stabile conclusion. Here, the rule is used to channel the discussion process and not so much as a codification of the results of discussion. In the end the views on the issues involved proved more stabile than the government anticipated. The division between substantive norms and process norms is less straight forward than the theory of the framework may imply.

That reality is always more complicated than theory is also illustrated by the implementation of a Biotechnology patents directive into Dutch law.⁶ On instigation of the Dutch parliament, the government has appealed to the European Court of Justice with the aim of annulling the directive. The proceedings before the Court took a long time and in the end, the Court rejected the Dutch appeal.⁷ The government had, in meantime, set the process of implementing the directive into Dutch law in motion. The Dutch parliament had not laid its opposition against the directive to rest after the

⁵ *Kamerstukken II* 2000/01, 27 423, nr. 3, p. 24-30.

⁶ Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions, *OJ L* 213, 30-7-1998, p. 13-21.

⁷ ECJ October 9, 2001, *Jur.* 2001, p. I-7079, C-377/98.

Court's ruling had been handed down. It is said that some members of parliament perceived the implementation trajectory as a second chance to water down the effect of the Directive.⁸ During the parliamentary proceedings of the implementation bill, many amendments to the bill were introduced. A number of these amendments cast doubt about the correctness of the Dutch implementation. One such amendment – introduced by Mrs. Witteveen-Hevinga e.a. – declared the commercial exploitation of patents relating to animals or plants contrary to *ordre public* or morality.⁹ The directive does not exclude patentability of animals and plants in such a general way. Based on Article 4 Directive only plant and animal *varieties* are not patentable, nor are essentially biological processes for the production of plants and animals. Subject to certain qualifications, Article 6 of the Directive only declares the process of modifying the genetic identity of animals contrary to *ordre public* or morality. The Amendment did not make it in the end, but this was only after the government exerted much pressure. With respect to other amendments the government was less successful. There is e.g. the amendment by Member of Parliament Stellingwerf.¹⁰ He introduced an amendment declaring processes endangering the life or health of humans, animals or plants or that cause serious prejudice to the environment contrary to *ordre public* or morality. According to Stellingwerf, the text closely resembles the text of Article 27.2 of the TRIPs Agreement. He failed to acknowledge that the TRIPs Agreement excludes such processes from patentability only where they are at all times contrary to *ordre public* or morality. A patent on such a process may not be excluded merely because its exploitation is prohibited by law. Nevertheless, the amendment has been maintained. As a consequence, an overbroad exclusion for dangerous processes is now enacted by and part of the Dutch Patent Act of 1995.¹¹ A second amendment that made it into law but that was not the fruit of careful reflection was the amendment by Poppe concerning the delicate relation between patents and biodiversity.¹² The amendment declares unpatentable inventions by which Article 3, Article 8 sub j, Article 15 section 5 and 16 section 5 of the Convention on Biodiversity are being infringed upon.¹³ The directive does not contain an obligation to include such restrictions in national law. According to recital 55, Member States must merely give 'particular weight' to the provisions of the Convention when implementing the directive, but they are certainly not obliged to codify them explicitly. On the contrary, recital 56 of the directive indicates that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights ... and the Convention on 'Biological Diversity' ...'. This relation between patent and biological diversity is still subject to discussion. It is

⁸ Van der Kooij 2003, p. 215-228.

⁹ *Kamerstukken II* 1999/00, 26538 (R 1638), nr. 11 (Amendment).

¹⁰ *Kamerstukken II* 1999/00, 26 538 (R 1638), nrs. 16 and 37 (Amendment).

¹¹ See art. 3 section 2 sub. e DPA 1995.

¹² *Kamerstukken II* 1999/00, 26 538 (R 1638), nr. 23 (Amendment).

¹³ Article 3 of the Convention on Biodiversity concerns States' responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction. Article 8 sub j concerns States' 'obligation' to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Article 15 section 5 provides that access to genetic resources shall be subject to prior informed consent of the State providing such resources. Article 16 section 5 requires states to cooperate in order to ensure that patents and other intellectual property rights are supportive of and do not run counter to the objectives of the Convention on Biodiversity.

therefore undesirable to foreclose discussion by enacting explicit legislation on this subject. Here again, it is doubtful whether substantive norms only come about as the result of finished discussion.

Patents on genes and gene sequences are a continuing source of discussion. According to proponents they are nothing new under the sun. They are patentable just like other compositions of matter are patentable. According to opponents they give too wide a protection to the patentee. The Dutch government defends the patentability of genes and gene sequences on practical grounds. In the first place, the abolition of their patentability as compositions of matter would immediately generate questions about the patentability of many other chemical compounds, such as proteins and protein derivatives that can be conceived as products from metabolic processes that are governed by gene sequences. Secondly, a limitation to process patents would burden patentees with problems of evidence. If a subject matter is found in the possession of a third party, the holder of a process patent can only substantiate a claim of infringement if he can prove that the subject matter was produced using a patented invention. That may not be so simple.

Here you see that substantive norms can become less rooted in *communis opinio* through technical developments.

The Netherlands does not have a national biobank.¹⁴ The Dutch Forum Biotechnology and Genetics has made a first exploration of the opportunities and possible pitfalls of setting up a national biobank. The Forum defines a biobank as a collection of body tissues for diagnostics or research, often also containing related data. A national biobank contains a large collection of materials of all citizens, or a representative fraction of the population (ill and healthy persons) that may be used both for prospective and retrospective scientific research. The government takes the viewpoint that it is up to researchers in the field to take the initiative to create a (national) biobank. The government merely provides suitable framework conditions. In this respect, it is worth mentioning that the government is preparing a bill on control over body tissues. A first draft is expected to be ready in 2006. The bill will also contain provisions on biobanks.

This section shows that there are many situations in which substantive norms are less rooted in *communis opinio* than would theoretically be desirable. Sometimes this is intentional, as we saw on the ban on the special creation of embryos. In other situations this comes about through forces from outside. Substantive norms can be overtaken by the reality of autonomous technical development. Also, holders of contrary views may just be a little bit more successful in influencing the lawmaking process.

3.4. *Process Norms and Research*

Research projects in genetics are subject to preventive oversight. Concentrating on the field of human genetics, the oversight is subdivided along the lines of values involved: environmental protection, health, and human dignity. A relatively recent development in Dutch legislation is the coming about of the Embryo Act of 2002 (hereinafter: DEA or Embryo Act). It specifically deals with sex cells, embryos and fetuses (which are defined as embryos inside women's bodies). The Embryo Act mainly concentrates on the values human dignity and freedom.

¹⁴ See <<http://www.forumbg.nl/werkgroepen/biobanken/Signalering%20biobanken.pdf>>.

Scientific research involving sex cells and embryos which are outside the human body is subject to review by the Central Committee on Research Involving Human Subjects (hereinafter indicated by its Dutch abbreviation: CCMO).¹⁵ As we have seen above, for scientific research, no use may be made of an embryo that has been created through transplantation of a cell nucleus specifically for scientific research (Art. 24 sub a DEA). Under certain conditions the Embryo Act allows scientific research with embryos left over after IVF treatment. These conditions concern both the way in which the embryos became available for research and the research itself.

The embryos must have been made available for the purpose of scientific research (Art. 12 DEA). When making the sex cells or embryos available, the donor may indicate that his or her cells may only be used for scientific research after he or she has been informed about the goal of the research and after he or she has given his or her explicit consent (Art. 6 DEA).

The research itself is judged on the basis of a research protocol that describes the intended research in its entirety. This protocol requires a positive judgement by the CCMO (Art. 3 DEA). The CCMO may only approve of a protocol if it meets five criteria (Art. 10 DEA): 1. it is plausible that the research will yield new insights in the domain of medical science, 2. it is plausible that the same results cannot be reached through other forms of scientific research than research with embryos and that they cannot be reached through research of a less far reaching nature, 3. the research conforms to the requirements of an adequate methodology of scientific research, 4. the research is being executed by or under the supervision of persons that are experts in the applicable domain of scientific research, and 5. the research conforms to other requirements that it should reasonably meet. If the embryos involved in the research are destined to be used for bringing about a pregnancy, stricter rules with respect to the consent and the approval of the research protocol apply (Arts. 16-17 DEA).

In 2003, CCMO allowed a research group to generate embryonic stem cell lines from embryos that were left over after IVF-treatment. This was a first for the Netherlands.

Medical trials involving humans are governed by the Act on medical-scientific research involving humans (hereinafter: AMR; in Dutch: WMO). Research protocols must be reviewed by a medical-ethical review committee (hereinafter: MERC; in Dutch: METC). From the decisions of a MERC, appeals can be lodged with the Central Committee on Research involving Human Subjects (known by its Dutch abbreviation as: CCMO). Certain research proposals must however in the first instance be reviewed by the CCMO. This is the case with scientific research in which the genetic material of human body cells is intentionally being modified and with scientific research involving sex cells.¹⁶

The CCMO can only approve of a protocol if it meets eight criteria. Five of these criteria closely resemble the five criteria mentioned in the Embryo Act (see above). There are three additional criteria: 1. the plausibility of a reasonable relation between the interest served by the research and the risks involved for the subject., 2. the plausibility that compensation to be paid to the subject has not influenced the consent for participation in the research in an undue manner, and 3. it is indicated in the protocol to what extent the scientific research may be beneficial to the subject. Apart from the approval of the protocol, the AMR contains elaborate rules on the subject's

¹⁵ Articles 10-18 Embryo Act.

¹⁶ Article 4 WMO and Article 1 Besluit centrale beoordeling medisch-wetenschappelijk onderzoek met mensen (Decree on central review of medical-scientific research involving humans).

consent and the researcher's of his principal's liability and obligatory insurance. The CCMO is competent to review proposals for gene therapy. In 2004, a proposal about gene therapy with respect to prostate cancer received approval. No new proposals for gene therapy were submitted to the CCMO in 2004. In the same year, 9 incidents involving gene therapy were reported to the CCMO, but none of these have led to the withdrawal of CCMO's approval.

If modified organisms are being used in human genetics there can be a risk that the organisms find their way into the environment. If such risk exists, the pertinent research is governed by the 'Decree genetically modified organisms Act environmentally hazardous substances'. Subject to some exceptions, research requires a permit from the Minister of Housing, Country Planning and Environmental Control. When deciding on an application for such a permit, the Minister can request the Commission on genetic modification (in Dutch: Cogem) to provide advice on the matter. The decision is governed by ethics of consequences. The decision on the application mainly hinges on a as precise as possible assessment of potential consequences.

Also in the sphere of the exploitation of research results, process norms apply. An example is the compulsory license in patent law. If the public interest requires such, the Minister of Economic Affairs can grant a compulsory license for the application of an invention. At the request of the Dutch parliament, the government has surveyed the use of compulsory licenses in patent law. In her letter of august 18, 2005, the Secretary of State for Economic Affairs indicated that the use that is currently made of the instrument is limited, but that she expected its use to increase in the future, not in the least, because of the decision of the WTO to allow compulsory licenses for the production and export of pharmaceutical products to (developing) countries that have insufficient production capacity to cover their internal needs.¹⁷ The effect of substantive norms (of patent law) is thus being reduced because process type norms gain importance.

4. Relation to International Regulation and Shortcomings of Traditional Regulatory Means

In the previous section, legal rules with respect to biotechnology were discussed and sometimes found lacking. The suitability of legal rules as an instrument of regulation was questioned. This section contains some observations in this respect.

A shortcoming of regulation is that it is (or seems?) to be lagging behind the development of technology. Regulation is always to a certain extent predetermined by the current state of technology. In the context of research in human genetics this is all too apparent. In the Netherlands, the oversight over research is e.g. fragmented, as we have seen above. Several bodies are each responsible for oversight with respect to partial aspects of research projects. This does not only burden researchers, it may also give rise to unclarity with respect to final responsibility. In the Netherlands, the first tentative steps are being set to a streamlining of oversight of research in human genetics. The governmental bodies involved in the assessment of gene therapy research formed a working group. The aim of the working group was to devise a common working method in which the different assessment procedures are better attuned to each other and overlap is avoided. The efforts of the working group have led to the creation of a single counter system for all involved bodies. At this counter a

¹⁷ *Kamerstukken II 2004/05, 27 428 & 27 543, nr. 65.*

single common application form is used for requests for the assessment of clinical research involving gene therapy.

The single counter does, however, not take away that the statutory competencies and responsibilities of the bodies have remained unaltered. A situation in which it may be unclear what governmental body bears what responsibility for the approval of research is thus continued. The Central Committee on Research Involving Human Subjects (hereinafter indicated by its Dutch abbreviation: CCMO) has indicated that it is a proponent of statutory reform, so that one body will carry the final responsibility for the assessment of research projects.¹⁸

The autonomous development of biotechnology creates its own challenges. Research and its results do not always fit in with existing regulation. This is e.g. the case with food genomics. Food genomics cannot be dealt with adequately under both regulation of food and medicine. The Rathenau Institute – an independent research institute – has called upon the government to create a suitable regulation framework for approval and testing of health claims for food.¹⁹

New developments are at the forefront of science. Often only a few experts exist that can assess the contents and implications of intended research. This enhances the suspicion of scientific incrowds. The persons deciding on the admissibility of intended research have excessively close ties with the research or researchers they have to judge. This situation is enhanced by the often close ties that exist between university research groups or professors and biotech companies. The Rathenau Institute has e.g. called for greater distance between the two in the context of genetically tailored foods.

The international character of developments calls for a suitable regulatory framework. Three expert committees on biotechnology have drawn up a trend analysis of biotechnology.²⁰ In their analysis, they find that globalisation diminishes the national discretion to stop ‘undesirable’ developments at the border. Biotechnological developments that are not in accordance with ‘the’ Dutch vision will materialise elsewhere.

A self-evident reaction to that would be to escalate to regulation on an international level. Indeed, the three expert committees on biotechnology that drew up the trend analysis propose that as a reaction, a proactive strategy could be developed in order to influence international developments in a direction favourable to the Netherlands. An example could be to start negotiations in an early stage with *inter alia* national governments in order to come to common viewpoints that can also be sustained in the WTO-context.

The government is on the same track. Where national regulation seems little useful, unless it is embedded in international regulations, the Netherlands strive for the creation of international norms through the various organs in which the Netherlands participate. This is e.g. the case with the research exception in patent law. According to the Dutch government, clinical genetic research is not inhibited by the patent system, in so far as the research does not involve commercial acts that take

¹⁸ See CCMO, Annual report 2004 (in Dutch), p. 25, <http://www.ipfier2.nl/hipe/uploads/downloads_catc/ccmo-jv2004.pdf>.

¹⁹ Gremmen *et al.* 2003, p. 148.

²⁰ CBD, CCMO & COGEM 2004. Trends in de biotechnologie en hun mogelijke betekenis voor de maatschappij, Gezamenlijke notitie van de Commissie Biotechnologie bij Dieren (CBD), de Centrale Commissie Mensgebonden Onderzoek (CCMO) en de Commissie Genetische Modificatie (COGEM), <http://www.bvfplat.form.nl/nieuws_en_archief/Trendanalyse_Biotechn_2000.pdf>.

place in the exercise of a profession or trade. The government admits that the border between scientific research and commercial exploitation of an invention is not always clear-cut and that the issue needs further clarification, but it does not take action on a national level. Since the European Commission is active on this subject, the government participates in the relevant European committees and awaits developments. Another example is the grace period in patent law. Dutch patent law does not allow for a grace period. According to the Dutch government a grace period should only be introduced as part of global harmonisation agreements.²¹

Although regulation on an international level seems an adequate answer to the globalisation of biotechnology, the national level has not lost its relevance. On the contrary, to some extent the national level has gained in relevance. An important asset of national law is the speed with which it can be brought about. It allows gaining experience with regulation in a relative short run. Early national regulation can confer upon a state the role of a guide-state. The Dutch regulation of genetic modification of animals is in a number of respects further reaching than the relevant EU-regulation. The prohibition in the Dutch Animal's Health and Welfare Act of performing biotechnological acts with animals without permit is for the time being unique in Europe. The Danish parliament has ordered that specific legislation on genetic modification of animals should be created. The Danish government, faced with the task of drawing up a bill, has requested information from the Dutch government about the way in which genetic modification of animals has been regulated in the Netherlands.

The forum biotechnology and genetics mentions in its exploration of biobanks three reasons why a policy should be formulated on a national level:

- without significant national initiatives and a national best practice the voice of a smaller member state is simply not heard;
- if on a European level regulation must be formulated for a young branch of activities that are relevant to the communities and that have a strong potential, the tendency is to suppress possible excesses through the instrument of stringent regulation.
- the national implementation of European directives yields better results if a well developed national practice exists. In the implementation process, the national practice can be spared.

In conclusion, international regulation is often preferable, but it is by no means a panacea. There are very good reasons to regulate nationally, even though the problem that is regulated is international in character.

5. Conclusion

The Dutch government has grappled with the question of how to regulate genetics. It has devised a framework that gives some basic indications of how to deal with genetics. There are, however, no easy answers to the societal issues raised by genetics. It is too simple to think that cross border effects of genetics research merely require a strengthening of international regulation. It is too simple to think that regulation of substantive issues by statute could be confined to situations where *communis opinio* exists on the values and on the way to solve conflicts of interests and values. The

²¹ *Kamerstukken II* 2003/04, 27 428 and 27 543, nr. 43, p. 8-9.

government recognises this itself; it stresses the fluidity of the framework and necessity of constant change and awareness of changing circumstances.

As concerns developments that are just around the corner, early 2006, the Dutch government will present a bill on authority over body materials. Genetic research is a field that will remain interesting, for the near future and later.

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Cite as: M.H.M. Schellekens, *Legal Limitations on Genetic Research and the Commercialisation of Its Results*, vol. 11.1 ELECTRONIC JOURNAL OF COMPARATIVE LAW, (May 2007), <<http://www.ejcl.org/111/article111-19.pdf>>.