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Biotechnology: Ethical and social debates

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List of Abreviations

AFM: Association Française contre la myopathie (French Muscular Dystrophy Assocition)

APC: Animal Procedures Committee (UK)

BIO: Biotechnology Industry Organisation

Bt-Cotton: Bacillus Thuringiensis cotton, a variety of GM cotton.

CBD: Convention on Biological Diversity

CCNE: Comité Consultatif National d'Ethique (French National Advisory Ethics Committee)

DOE: Department of Energy (USA)

DPI: Disabled People International

ELSI: Ethical, Legal and Social Implications

ES Cell research: Embryonic Stem Cell research

FOE: Friends of the Earth

GE: Genetically Engineered

GM: Genetically Modified.

GMO: Genetically Modified Organisms

GuRT: Gene use Restriction Technology

HGA: Human Genetics Alert

ICBG: Internattional Cooperative Biodiversity Group

ICMR: Indian Council of Medical Research

IFPRI: International Food Policy Research Institute

INSERM: Institut National de la santé et de la recherche médicale

ISE: International Society of Ethnobiology

KRRS: Karnataka State Farmers' Association (India)

NIH: National Institutes of Health (USA)

NGO: Non-governmental Organisation

RAFI: Rural Advancement Foundation International

TRIPS: Trade Related Aspects of Intellectual Property Rights

UKDPC: United Kingdom's Disabled People's Council

WWF: The World Wide Fund

3R Doctrine: Doctrine concerning the Refinement, Reduction and Replacement of animals in research.

Executive summary

The development of biotechnology has triggered many ethical and social reactions from the public opinion, the media and non-governmental organisations. The aim of this document is to provide some insights into the ethical concerns, dilemmas and trade-offs that have been expressed concerning biotechnology in the last ten years. The paper focuses on six objects from the agriculture, industry and health sectors, whose procurement, production, storage and use by biotechnology has raised general attention: genetically modified organisms, biofuels, natural genetic resources through bioprospecting, transgenic and cloned animals, private genetic information and stem cells. Specific examples and international comparisons are drawn from a vast geographical scope: Brazil, Canada, China, Denmark, Finland, France, Germany, India, Italy, Japan, Mexico, Norway, Sweden, the United Kingdom, and the United States have all hosted some ethical debate, sometimes specific to these countries, other times shared by a more international public. Some key elements can be identified:

- The majority of the public is optimistic about the ability of biotechnology to improve our quality of life. There are, however, visible differences between global support when the aims are medical, moderate support when biotechnology aims at improving industry products, and low support or adverse positions against biotechnology used in agriculture.
- In the EU, the low public support for genetically modified food is an exception as compared to generally positive attitudes regarding science, technology and biotechnological progress. GM food is often seen as not useful, morally unacceptable and a risk for society. It remains unclear if technical progress could inspire more positive opinions. NGOs adverse positions, stemming from ethical concerns on health and environmental safety issues, have been influential in the 1999 EU moratorium on GM food and crops. The population from less-developed countries as India and China is interested in GM culture, perhaps less as a "humanitarian" means to "feed hungry people" than as an efficient tool chosen by farmers cooperating with industry to increase yield. Support hence depends on GM technical ability in the long term. So does belief that GMOs help respecting biodiversity.
- The public opinion is supportive of biofuels, though major national differences exist. Biofuels are linked with issues such as fighting global warming, preserving national security, and limiting dependence on foreign oil. European Green parties have an ambivalent position, while moslty vocal NGOs call for the preservation of wilderness and express adverse positions against the ecological, social and economic impacts of biofuels, such as the competition between fuel and food, detrimental environmental impacts, displacements of poor farmers and indigenous people, and global prices rises. Calls for more sustainable fuels are recurrent, and opposition to GM biomass is appearing.
- The Convention on Biological Diversity has produced a two-sided effect on bioprospecting. On the one hand, it has set a frame according to which the public opinion and media can consider bioprospecting, involving communities and benefit-sharing, is far from what NGOs call "biopiracy". On the second hand, however, a Mexican example shows that identifying legitimate local organizations' spokespersons has proven difficult, and that international NGOs have been influential in blurring the general scenery.
- Public support for transgenic and cloned animals is lower than that for transgenic plants. The use of such animals in medical research, though, receives strong approval. The welfare of transgenic and cloned animals used in research is not a major issue for the general public at the moment, except in the UK and Nordic countries. NGOs, however, are well-aware of specific animal welfare issues concerning transgenic and cloned animals, and have a strong influence on EU and other national policies.

- Public support for genetic testing is strong. It increased in Europe at a moment when the deciphering of the human genome was in the media focus. Non-medical uses of genetic information, however, inspire debates and adverse positions from NGOs, particularly in the USA where many consider health insurers' demand for genetic information hinders research and treatment. In the medical field, the future development of pharmacogenetics, which the public considers useful, morally acceptable and not very risky, could attenuate positions claiming genetic information is "exceptional" compared to other medical information. In all countries, medical professionals have important influence on the general regulation of genetic information.

- Public attitudes on adult and embryonic stem (ES) cell research are positive, as a great part of the public adopts utilitarian ethical positions. Human reproductive cloning is generally seen very negatively. Disease associations support ES research. Debates on the production of embryos through nuclear transfer techniques ("therapeutic cloning") are very intense in countries encoutering a high influence of religious groups, such as the Roman Catholic Church and American White Evangelical Protestants. Church members often adopt less rigid views than their organizations. In Japan, India and China, ES cell research and "therapeutic cloning" are not of religious concern.

As yet, the general public adheres to quite positive views on biotechnological innovations – but for GM crops and food. As the paper and annexed tables shows, however, NGOs, ethics committees and the media express concerns, together with high hopes, which participate in shaping public regulation. Major roadblocks and accelerators can hinder, orientate or facilitate the common development of these innovations in the long term. Such key elements are summarized at the end of the paper.

The Annex includes two set of tables:

- Synthetic tables on the NGOs involved in the debates and the media positions.
- Comprehensive tables on the debates and regulations that have been observed in each country in the last ten years.

Introduction

The development and regulation of biotechnology has triggered many discussions from different academic fields, such as economics, law, politics and even history. Specifically, however, the genetic engineering of living cells, plants, animals and human beings has brought ethical concerns and issues to the foreground. Mediatic announcements such as the creation of genetically engineered tomatoes or soya, the cloning of the sheep "Dolly", the deciphering of the human genome or research on "cloning" human embryos have been followed by many reactions in the name of ethics. Diverging views have been expressed, as representations of our "natural" world were being challenged.

The aim of this document is to provide some insights into the ethical concerns, dilemmas and trade-offs that have been expressed concerning biotechnology in the last ten years. The paper focuses on six objects from the agriculture, industry and health sectors, whose procurement, production, storage and use by biotechnology has raised general attention: genetically modified organisms, biofuels, natural genetic resources through bioprospecting, transgenic and cloned animals, private genetic information and stem cells. Specific examples and international comparisons are drawn from a vast geographical scope: Brazil, Canada, China, Denmark, Finland, France, Germany, India, Italy, Japan, Mexico, Norway, Sweden, the United Kingdom, and the United States have all hosted some ethical debate, sometimes specific to these countries, other times shared by a more international public.

The classical division between science and society does not seem to operate, when biotechnology is seen through an ethical lens. Science, indeed, could provide no adequate, technical answer to the questions that relate to moral values such as dignity, justice, autonomy, integrity and freedom or to notions considered absolute, such as nature, biodiversity, humanity, animal welfare, health, knowledge or individual interest. Quite often, ethical values conflict with one another, and produce dilemmas through which the public, researchers or regulators must find their own way. Though not pretending to be comprehensive or holistic, this study presents characteristic features, trends and snapshots on the state of public opinion and major ethical controversies regarding biotechnology.

I. Biotechnology and the public opinion

Public attitudes towards biotechnology and biotechnological research are quite varied within the geographic scope. Some common elements appear, however. To begin with, the majority of the

public is generally optimistic about the ability for biotechnology to improve our quality of life. Most of the EU 15 member States (Eurobarometer, 2005) have seen a rise in national public optimism[1] about biotechnology since 1999 (Fig. 1). The deciphering of the human genome was by then very much in the media focus - to such extent that, very probably, the public came to identify biotechnology less to GM crops and food, as it had done until then, and more to a promising part of the health sector. In Japan, where awareness of the word "biotechnology" is one of the highest in the world (Macer, 2001), interest and optimism have been generally higher than in European countries, although they have declined from 1997 to 2000 (Macer, 2000; Inaba & Macer, 2003).

Optimism in the USA and Canada have followed a similar trend, as, after a short optimism decline in 1997-2000 (Hornig Priest, 2000), it reaches around two-thirds of the US and Canadians citizens (Government of Canada's Canadian Biotechnology Secretariat, 2005)

Figure 1. Evolution of optimism in some European countries.

index score	1991	1993	1996	1999	2002	2005
Sweden	-	-	42	-	61	73
Italy	65	65	54	21	43	65
Denmark	26	28	17	-1	23	56
UK	53	47	26	5	17	50
France	56	45	46	25	39	49
Finland	-	-	24	13	31	36
Germany	42	17	17	23	24	33

The proportion of European citizens considering that biotechnology "will deteriorate things" was rather low in 2005 (12%) (Eurobarometer, 2005). Interestingly enough from an ethical point of view, however, there was a high proportion of respondents claiming they "do not know" how to answer such question for biotechnology (22%) and nanotechnology (42%), while much more

1 Optimism, here, is defined as the subtraction of the percentage of those claiming biotechnology "will deteriorate things" from that of those claiming it "will improve our way of life in the 20 years", divided by the combined percentage of the former and latter responses and of those claiming biotechnology will have no effect (Eurobarometer, 2005)

respondents claimed they knew if computers and information technology, mobile phones, solar and wind energies, space exploration and nuclear energy will cause an improvement, a deterioration or have no effects. The novelty of nanotechnology may explain claimed ignorance in this field, whereas answers regarding biotechnology could be partly explained by a common public feeling of ambivalence, as citizens seem to be able to identify some risks and benefits but not always confident enough to balance them (Eurobarometer, 2005). An indicator of the "bioethical maturity" of a society (Macer, 2004), this ability to identify and balance risks and benefits has extended to different degrees in Europe, America and Asia, and has been linked with awareness and general education (Iniba & Macer, 2003).

Awareness and familiarity, as a matter of fact, do not automatically inspire higher public support, but rather strengthen the different points of view and lower the proportion of respondents claiming ignorance. Genetically modified food, for instance, was a very-well known biotechnological innovation in Europe in 2005, yet its support remained generally low, even in countries such as Spain where GM crops had already been planted. Thus, in order to understand the evolutions of public opinion regarding biotechnology, it is useful to consider the ethical issues, public debates, media coverage and public policy decisions that specific technologies have inspired.

II. GM crops and GM food

II. 1. Public opinion: The GMO exception

Apart concerning GMOs, public opinion in Europe is certainly not a constraint to technological innovation, even in the field of biotechnology, as a Eurobarometer survey has established (Eurobarometer, 2005). Opinions, however, do not seem mostly grounded on immutable presuppositions about alleged undisputable benefits of scientific progress, nor on immediate negative reaction against rational science. On the contrary, the general public expresses diverse opinions on diverse innovations, instead of judging them as a whole. Typically, genetic testing innovations inspire stronger public support than GM organisms innovations.

Low support for genetically modified food (GM food) in Europe, indeed, provides no evidence for a general European opposition to science and innovation. Surveys show such a low level of support is much more an exception than the rule (Eurobarometer, 2005). European support for GM food has been following a constant decline since 1996 in some countries such as France and Germany. In France, it has fallen from 54% of citizens supporting it in 1991 to 29% in 2005 and in

Germany, from 56% to 30%. In other less risk-adverse European countries such as Finland or the UK, however, GM food received a more positive opinion between 1999 and 2002, declining again between 2002 and 2005 (Eurobarometer, 2005). In Japan the low level of public support for GM food started increasing later than in Europe, in the second half of the 1990s.

These low levels of support are likely linked to the media focus and the visible debates and affairs that have surrounded GM food and GM crops in each of these countries. They also depend on the trust the general public places in public authorities and biotechnological companies, as, for instance, such trust has been rather low in Japan when public support decreased. However, support mostly depends on a form of risk assessment. Indeed, in Europe, GM food is considered to combine three major negative perceptions (Eurobarometer, 2005): many consider it is not useful, morally unacceptable and a risk for society. National differences in public support for GM food lies greatly in these risk assessments, since, for instance, European citizens, and Canadian citizens, consider GM food much more risky and less beneficial than US citizens do (Eurobarometer, 2005). Biosafety concerns for the release of GMOs in the environment have been a major issue in the European public mind while, by contrast, they are of little concern to Asian consumers from China, Indonesia and the Philippines (Hoban, 2004). In 2004, over two-thirds of respondents from the United States, Colombia, Cuba, Dominican Republic, China, India, Indonesia, and Thailand considered that the benefits of GM crops are greater than the risks. Fewer than 40 percent of consumers agreed to this statement in France, Greece, Italy, Spain, and Japan (Hoban, 2004).

Such risk assessment, however, is not only utilitarian, because it combines individual, social and moral dimensions. Deciding which dimension should prevail is a matter of individual "bioethical maturity" (Macer, 2004) and could hardly be anticipated. Thus, one can only wonder whether countries where support for GM food is low would be more inclined towards GM crops and GM food if they considered them positive under one of these dimensions: ethically, as, for instance, it is claimed GM crops could help feeding poor nations, protect biodiversity by diminishing pesticide use or help develop new effective medicines and biofuels; socially, if they were considered economically useful for a nation, or if vitamin-supplemented GM food were deemed of public utility; individually, if consumers thought it implied lower cost, more flavourful food, or crops that are easier to sow. In all these cases, risk could be tolerated to a different extent.

II. 2. Public debates

The intensity of public debate and controversy between NGOs, scientists and public authorities, has played a major shaping role in many countries in the public's immediate negative reaction to GM crops and food. Institutional decisions have had an influence, as, for instance, the June 1999

EU Environment Council's *de facto* moratorium which halted the regulatory approval of GM foods certainly fuelled the feeling that there was something special concerning such food and the crops it derived from (Eurobarometer, 2005).

Indeed, fears have been expressed about GM field-trials and GM food since 1995 in the United States, following development of the FlavRSavR Tomato, and 1998 in Europe, after the first French authorization to cultivate GM Maize. European NGOs, as a matter of fact, had been forming coalitions and interest groups since US Bovine Growth Hormone producers had applied for a European licence in 1988 (Schenkelaars, 2001). Their mobilizations on GM food and crops benefited from these previous action networks. In India and Japan, opposition from NGOs gained importance at the turn of the century."Ethical" arguments were rapidly presented, from the idea that genetically modified organisms (GMOs) are not natural, to more precise issues concerning the safety of their release into the environment. Some associations, such as Greenpeace, also voiced the economic and social issue that a massive development of GM crops could lead to increasingly powerful biotechnology companies taking control of agriculture at the farmers' expense. Institutions and researchers, including the US Department of Agriculture, answered to the so-called "unnaturalness" of GMOs through the media, insisting that such definitions ignored history, as common fruits and vegetables all have been voluntarily genetically altered - thus highlighting continuity between traditional and modern biotechnologies. Institutions also presented evidence that biosafety and economic issues, while usually not considered specific to modern biotechnology, nor "ethical" in any sense, were addressed. When Australia, Luxembourg and Italy opposed in 1998 the voluntary dissemination of GMOs on safety grounds, however, effective group action from NGOs transformed the uncertain consequences of developing GM crops into a ripe topic for the media. NGOs also battled in favour of labelling GM food, in the name of the consumers' right to know exactly what they would buy, especially if their health could be at stake - a comment which would be often formulated throughout regulation processes, until most European NGOs eventually considered labelling and traceability were adequately addressed in the 2003 EU Directives. In the late 1990s, as the controversy expanded, European public research institutions, with the help of some elected officials, opposed NGOs by stating that uncertainties would be much better understood through a precise follow-up of open field GM crops. Fear and confusion in the public's mind increased with the media focus on the controversy over whether Bt-Maize would kill the monarch butterfly (Losey, 1999). Contradictory views within the scientific community gave even more strength to general opposition, which caused EU authorization of Bt maize import to freeze and a EU moratorium to be declared in 1999 on imports and cultivation of GMOs intended for

marketing.

The use of GMOs in developing countries became a very much debated issue since 1999-2000, following the EU moratorium (Nature, 1999). Two different aspects have prevailed: the idea that GM technologies might help feed hungry people (humanitarian argument), and the fact that individual farmers in less-developed countries such as India or China show a keen interest for GM culture.

The "humanitarian" argument is not new, yet it has become more influential as scientific progress seems to go in this direction, working on drought-resistant, climate-specific or vitamin-supplemented GMOs for instance. The media has given voice to the idea that "the Developing World Simply Can't Afford to do Without Agricultural Biotechnology" (Anderson, 2003) and that GM crops could alleviate hunger or malnutrition. In Asia, against such ethical arguments, NGOs such as Greenpeace, the Third World Network, and the Research Foundation for Science, Technology and Natural Resource Policy in India have argued that the real issue was not shortage of production, but the poors' incapacity to have access to existing food. According to the Nuffield Council on Bioethics, however, such considerations are not relevant, as it would be unethical to rely merely on a theoretical redistribution of goods to answer world food problems (Nuffield Council on Bioethics, 2003). Associations have also stressed that Gene Use Restriction Technologies (GuRTs) - coined "Terminator" technologies by the Canadian group RAFI (now the ETC Group) - aiming at creating sterile plants, "would deny the farmers their ancient right to save and exchange seeds from previous harvests" (The Corner House UK, 1999). This has lead to more classical economic arguments such as corporate control threatening farm livelihoods of the very poor. The “Terminator” argument has been very influential in countries such as India, where monopoly on a living organism is seen as unacceptable and where seeds saving, exchange and re-planting are identified as farmers' rights (De Castro *et al.*, 2003). Although GuRT techniques were still in the research phase, international NGOs, together with farmers associations and lobbies such as Karnataka State Farmers' Association (KRRS) - the Gandhian socialist farmers' league in India - used these techniques as their main argument against any GMO development.

Public opposition to Bt-Cotton in India, led to voluntary declarations from industry not to use GuRT there, and to the government eventually refusing applications for open-field Bt-Cotton agriculture in 2001 (Ramanna, 2006).

Such involvement from farmers and their representatives, which was observed throughout South Asia (De Castro, *et al.*, 2003) is, however, two-sided. In India, the government's decision to finally

approve commercial release of Bt-Cotton in March 2002, indeed, is a result of pressure from Indian farmers themselves, who concluded their first alliance with industry (Ramanna, 2006). The Kisan Co-ordination Committee, Liberty Institute, Confederation of Indian Industry and Federation of Farmer's Associations of Andhra Pradesh, claimed and managed to obtain recognition of the right for farmers to choose what they considered the most efficient seeds against recurrent pest attacks (Ramanna, 2006). Since then, confronted with farmers calling for freedom in agricultural choices, the national influence of international NGOs has been less important and innovative in India, as solid networks between industry and farmers associations have come into place.

The Cartagena Protocol on Biosafety, an international agreement on biosafety annexed to the Convention of Biological Diversity and aiming to protect biological diversity from the potential adverse effects of GM organisms entered into force in 2003 and the European moratorium came to an end, respect for biodiversity has become a more influential driver in the promotion of GM crops. The technical assertion that pest-resistant and other GMOs require less pesticides than conventional cultures has been expressed in developed as well as developing countries. The ecological impact, it is claimed, could be much less than that of conventional agriculture. NGOs have opposed this argument from a technical point of view, doubting that GMOs effectively have such capacity in the long term as pests grow resistant and evolve. However, they do not refute the logic in itself. Indeed, such an argument might gain influence as the public awareness of ecological issues grows and as GM crops are monitored to see if they fulfil their promise. There is, however, a trade-off between two aspects of biodiversity preservation. In 2004 Asian NGOs, together with Greenpeace, have reinterpreted in terms of respect for biodiversity, including the diversity of rice, previous calls to protect traditional food against genetic engineering. Biodiversity, as an argument, is thus called upon from conflicting views: both promoters and opponents of GM crops have referred to this ethical principle.

Biodiversity has also triggered active interest for the coexistence of neighbouring GM and non-GM crops, including organic cultures. Organic cultivators and organic food associations have accessed the GM controversy arena, and expressed their viewpoint both with NGOs already opposed to GM crops and within public institutions. In this frame of mind, keeping a watch on dissemination is less identified as avoiding possibly ill-controlled mutants to develop in the wild, than as ensuring that one's freedom to grow crops does not harm the land of other neighbouring farmers - perhaps a useful reinterpretation. Coexistence regulations, thus, create a major change in the representation of GM seeds, as debates on GM crops are transferred from the health and safety

sensitive domain to the more pragmatic world of free trade and economics. So as to be totally effective, however, this transfer should also mean ensuring farmers and consumers that all necessary safety issues have already been addressed.

It is not sure, however, whether co-existence provisions should be technical or social. Technically, indeed, the initial stated purpose of GuRTs is to be an environmental tool which allows GM planting without taking the risk to contaminate the environment. Defensors of GuRTs have been describing them as "coexistence techniques" and called for a re-evaluation of the Convention on Biological Diversity Recommendation (2000), which considered national regulators should not approve GuRT for field trial or commercial use. Past controversies concerning these technologies, yet, might make it difficult for them to gain public acceptability, even on coexistence grounds. Socially, on the other hand, one can observe the gradual implementation of coexistence regulations throughout Europe and Asia, including details on adequate distances between crops and eventual economic liability of the farmers responsible for contamination. This pattern is very diverse. Some countries have no effective measures yet adopted, and others have strict regulations like those adopted in Germany, where buffer distances between conventional and GM crops are high and GM farmers' economic liability for the contamination of non-GM crops is clearly addressed. It could be that public confidence would be raised if such regulations were more rapidly harmonized.

III. Biomass energy and biofuels

III. 1.Public opinion

In Europe, energy derived from biomass is the most favoured energy after solar, wind, hydroelectric and ocean energies, as 55% of EU citizens are favourable to its use in their country, against 8% opposed to it and 27% assuming balanced views (Special Eurobarometer, 2007). Opinions, however, are very diverse within EU Member States (Fig. 2), for instance 75% of Germans and only 35% of British respondents are favourable to energy derived from biomass in their country. There is a relatively high proportion of "don't know" answers, implying that more knowledge and more information could perhaps inspire more favourable opinions. Balanced views, however, are also expressed at different rates, not always correlated to the proportion of favourable opinions, and this could imply that citizens experience a tension as they balance benefits with costs. EU citizens also expect that the use of fossil fuels, particularly oil and gas, will drop within the next thirty years and be replaced by the use of renewable energy (Special Eurobarometer, 2007). The greatest progression expected, however, is in solar energy. Wind and biomass energies are expected

to rise by more or less six times the proportion each is thought to be currently at (from 7% to 40% for wind energy and from 3% to 19% for biomass energy). Finland is one of the three countries where biomass energy reaches the second or third step of the expected "most used energy sources in the thirty years" in one's country.

(Fig. 2(Special Eurobarometer, 2007): Opinions on the use of biomass in some European countries

Are you in favour or opposed to the different sources of biomass energy in (OUR COUNTRY)?	In favour (%)	Balanced views (%)	Opposed (%)	Don't know (%)
Germany	75	20	4	1
Denmark	70	25	4	1
Finland	64	34	1	1
France	59	27	7	7
Italy	40	33	10	17
UK	35	39	14	12
EU 25	55	27	8	10

Biofuel technology inspires general confidence from EU citizens, as a great majority (68%) would be certainly or probably "willing to buy petrol with added ethanol or biodiesel for [their] vehicle if it costs the same price as ordinary petrol/diesel" and 71% consider that "the biofuel industry should get tax incentives to allow it to compete with the oil industry" Europeans are divided, however, when it comes to paying more for a vehicle designed to run on biofuel, as 47% agree they would certainly or probably do so, against 37% who would certainly or probably not (Eurobarometer, 2005). In the United States, such tension between individual cost and public benefit is not so clear, since around 80% respondents or more are in favour of government support for the development of biodiesel or other biofuel, while between 61 and 69% express their willingness to pay slightly more for biofuels (BIO/Harris Interactive, 2006; National Biodiesel Board, 2004). Public concern about global warming and global climate change is increasing in the United States, and opinion polls reveal it is placed far ahead of any environmental issue in the public's mind (ABC News/Washington Post/University of Stanford Poll, 2007). However, such concern does not seem to be the major driver for biofuel support. In opinion polls concerning

biofuels, indeed, respondents' reasons for supporting biofuels appear rather pragmatic: the preservation of nature and biodiversity is not the main driver for such a promotion, but helping reducing US dependence on foreign sources of oil is to 80% of respondents (BIO/Harris Interactive, 2006). Other reasons include decreasing gas prices, creating jobs in rural areas, or providing potential health benefits to consumers (BIO/Harris Interactive, 2006; National Biodiesel Board, 2004). Such pragmatic views, as they combine political, economic and social interests are influential as they enable an effective acceptance and promotion of biofuels.

III. 2. Ethical debates

Since the turn of the century, many countries in Europe, America and Asia have been promoting biofuel development and use. Brazil government started supporting national biofuel development in the 1970s, while, more recently, the USA have been implementing major public policy decisions on biofuel promotion. Ecologic considerations, aiming at the reduction of carbon emissions, have been influential in these decisions, together with the political will to ensure national energy security by addressing concerns about the high price of oil, forthcoming energy supply shortages and national dependence on foreign fossil energy (Eikeland, 2005). In Europe, countries without domestic mineral oil resources have been politically more eager to create a market for domestic biofuel industries (Eikeland, 2005)

Many Green parties had advocated national commitments for biofuel use before they were implemented (European Green Party / EFGP, 2005), including in countries such as Germany (House of Lords, 2006) and Sweden where they played an influential role as coalition partners to other political parties. Such global public policy decisions to gradually increase the share of biofuel within transportation fuel in the years to come , however, have also raised awareness of specific environmental and ethical issues. Green parties have, more recently, highlighted such issues, in line with international and local NGOs. In many countries, such as France and Germany, this has lead to their rather ambivalent support for decisions usually presented as ecological to the general public.

One major concern is the competition between food and energy for agricultural resources. NGOs such as Friends of the Earth (FOE) have adhered to the view that biofuels triggered a "competition for food between cars and people" (Monbiot, 2004, 2005 and 2007). According to these associations, a compromise needs to struck, between reducing carbon emissions through political support for biofuels and bioethanol and protecting colossal tracts of agricultural land from being turned over to biofuels. Some economists agree stating that rising prices of common food in developing countries would eventually "starve the poor" (Ford Runge & Senauer, 2007). Moreover,

institutions such as IFPRI have acknowledged such tension between the need for energy and the need for food and feed, as an aggressive biofuel scenario could lead to massive rises in the world prices of commodities such as cassava, maize, oilseeds, sugarbeet, sugarcane and wheat (Rosegrant, *et al., 2006*).

Concerns have also been expressed that the global support for biofuels, leading to rising food prices, would create temptations for farmers to cultivate once virgin lands. In developed countries, environmental associations deeply involved in the conservation and management of wetlands and set-aside lands, such as Ducks Unlimited in the United States and Canada, Birdlife International and WWF have deemed there was a high risk that set-aside lands, vital for many bird species and benefiting from specific protections in Europe and Northern America, could be used to grow biofuel crops. Moreover, within developing countries from Asia and South-America, this has led to massive action networks from international and local NGOs, all opposed to what they consider to be the gradual destruction of primitive forests and wilderness. In Brazil, oppositions from NGOs have been very intense, as Brazil is extensively producing biofuel and promoting its use in transportation fuel. Most of these NGOs are international, benefiting from a worldwide coverage as the Gaia Foundation, and the World Rainforest Movement. Their influence has not been very effective yet.

Controversy has also taken place, on whether Europe's consumption of biodiesel was causing deforestation and the destruction of natural habitats in Indonesia and Malaysia, or whether palm oil production for biofuel was only marginal compared to the massive global palm oil production aimed at the food market (Commission of the European Communities, 2007) In Brazil also, it is claimed that the expansion of sugar cane crops to produce ethanol on lands once devoted to food production is causing food crop producers to move closer to Pantanal wetlands and Amazonian rainforest; this could have the same disastrous effects as, it is claimed, massive-scale soya production already reducing such wild environments. (Bravo & Ho, 2006). Such environmental damages, as European Green party representatives and Latin American associations have reported (Lucas, 2007), endanger the lives of indigenous people. In Brazil, indeed, international NGOs, including the Global Forest Coalition federates local Indigenous associations and give voice to such issues, as they defend the poverty of indigenous and forest-dependent people. The Landless Workers' Movement, the largest social movement in Latin America and Brazil, opposed to current land distribution, expresses fears against possible forthcoming displacement of food crop producers, and oppose to the US way of living, deemed excessively dependent on cars and fuel.

Deforestation, furthermore, is considered a major cause of climate change and global warming. The environmental impacts of massive-scale biofuel production would therefore be quite negative if primitive forests were to be destroyed in great part. The transition costs towards agricultural fuel, as well as its management costs, should be closely monitored from an environmental point of view. During the 1990s, indeed, as European authorities acknowledge, the economic and environmental impacts of biofuels were often evaluated in terms of carbon dioxide emissions, thus omitting important nitrous oxide emissions caused by fertilizer use and the cultivation of land (Commission of the European Communities, 2007). This caused some exaggeration concerning the positive greenhouse gas effects of biofuels. As regulatory institutions state, "it is clearly essential to design biofuel promotion policies so that they continue to contribute to sustainability in future, in particular if biofuel use is to increase by an order of magnitude beyond today's levels." (Commission of the European Communities, 2007)

Such willingness to ensure that carbon and other emission benefits outweigh environmental impacts has lead the French Green Party, for instance, to state agricultural fuels were not all "bio"fuels, as their impact on environment was rather negative. However, many associations consider biofuels can be part of the solution to climate change, and differentiate biofuels by their environmental and ethical performance, insisting "not all biofuels are created equal" (FOE, 2007). NGOs have therefore been opposed to target-oriented public policies aiming at increasing the general proportion of "biofuels" within national fuel consumption, in Europe, the UK and the USA (FOE, 2007), as long as these targets include biomass production that is less environmentally and ethically sustainable. NGOs share common views on the different forms of fuel. The most important international NGOs, including Friends of the Earth, see first-generation biofuels, such as ethanol derived from corn or cane or biodiesel from rapeseed oil as environmentally and ethically unfriendly, as it were. Development of third-generation biomass such as trees genetically engineered to produce more efficient fuel receives negative opinions from many associations, anxious about the biosafety implications of open-field release. The eventuality that such trees could reduce forest devastation does not convince NGOs from the STOP GE Trees Campaign, who have taken their arguments before the United States Commission on World Forestry. This large alliance of NGOs, including the Global Forest Coalition, and indigenous peoples associations call for the protection of biodiversity, wilderness, and rainforests, and against indigenous communities being endangered by the GM industry. Support for the use of second-generation "responsible" cellulosic biofuel, on the contrary, is generally high, as such fuel could be sustainably developed from the biomass waste of perennial crops instead of native soils. All concerned NGOs, it seems, would

support more research and development into such cellulosic fuel. Such views are quite in line with those of members of institutions such as IFPRI, who have drawn prospective scenarios on the use of biofuel between now and its probable impacts on feedstock prices (Rosegrant, et al, 2006). They have, indeed, provided evidence that such price expansion would soften, as it were, in case second-generation cellulosic conversion technologies were being used on a large-scale from 2015, and investments were made in crop technology to increase productivity over time.

Debates and decisions in Brazil need to be closely monitored. Among less-developed countries, indeed, Brazil combines a unique public policy regime promoting biofuel development, an exceptional environmental setting with rainforests and wild habitats in need for protection, Indigenous communities willing not to be endangered by biofuel production, and active mobilizations by international and Latin American NGOs.

IV. Bioprospecting

Since the early ages of humanity, medical science and industrial progress have greatly benefited from the observation of living organisms that could be found in nature. Throughout centuries, major scientists have also shown an acute curiosity for traditional natural medicines and healing techniques, in order to understand where the active ingredient was and why the technique worked so well. Modern techniques of investigation are making it easier to identify active molecular compounds and to replicate them. Although "bioprospecting" is a neologism, its definition often highlights the continuity between such past and present activity, as it is defined, for instance, as “the systematic search for genes, natural compounds, designs, and whole organisms in wild life with a potential for product development by biological observation and biophysical, biochemical, and genetic methods, without disruption to nature” (Mateo, Nader, & Tamayo, 2001). The modern expansion of the pharmaceutical market, however, often generating great benefits, together with modern trade-related aspects of intellectual property rights (TRIPS), which lays out minimum international standards for intellectual property rights, have given "bioprospectors" incentives for identifying natural compounds and traditional knowledge that possess potential economic benefits[2].

IV. 1. Bioprospecting and Indigenous communities

It is commonly considered that Tropical exploration and appropriation of natural resources have taken place, throughout history and until the latter half of the 20th Century, with little concern for

2 This paper will not include a discussion on the ethical and social debates behind patenting life and the surrounding Intellectual Property Rights issues. These debates are different from those involving the recognition of Indigenous rights. A more comprehensive overview would benefit from considering such issues.

collateral damages to ecosystems and societies, including slavery, forced relocation of populations, and genocides (Berlin & Berlin, 2004). The modern bioprospecting industry is certainly very far from such outrageous attitudes. Its economic aspects, however, have led to diverging ethical and social views on such issues as whether knowledge is being commoditised, whether it is acceptable to patent living organisms, innovations derived from traditional local knowledge and active ingredients from plants considered sacred, and whether the industry should share benefits with local communities that have served as stewards of these environmental resources and protected such organisms and knowledge for generations. Such debates have mostly involved private and public research and pharmaceutical institutions, political representatives from developing countries, local indigenous rights movements and international environmentalist NGOs. These issues have been raised to international fora and linked to the increasing concern of biodiversity preservation since the early 1990s.

The Convention on Biological Diversity (CBD), as it entered into force in December 1993, produced an ambivalent impression on international and local NGOs. On the one hand, the specific recognition of “knowledge, innovations and practices of indigenous and local communities" was deemed very positive by NGOs such as GRAIN (GRAIN, 1998), claiming "the objectives of the CBD are founded on the recognition of Community Rights". The promotion of an "equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices" (Art. 8(j)) was in line with the first meeting of the International Society of Ethnobiology (ISE) in 1988 and the Art. 4 of the Declaration of Belem which was at the founding of this international learned society specialized in understanding the relationships between indigenous people and their living habitats. (Berlin & Berlin, 2004). The consideration that States possess sovereign rights over their natural resource was received positively, highlighting the ethical necessity to obtain "the prior informed consent" of the State (Art. 15.5).

On the other hand, however, NGOs such as Rural Advancement Foundation International (RAFI) called for the recognition of "a right not to consent"[3], in order for consent not to be simply formal. Some felt "biopiracy", identified as the replacement of indigenous communities' rights on their genetic resources by the exclusive rights of commercial companies developing them, would still occur (Shiva, 1997). In Chiapas, Mexico, for instance, a local healers' NGO started opposing a US Government-sponsored project, the Maya International Cooperative Biodiversity Group (Maya ICBG) Project, aimed at using Mayan traditional knowledge and remedies for biotechnology research in exchange for prospective financial compensation, specific training and technology

3 RAFI, Bioprospecting/biopiracy and indigenous people: are weak agreements just legalized "biopiracy? 1994.

transfer in 1999. Such opposition lead, through international NGOs such as RAFI and the Global Exchange, to national opposition from Mexican intellectuals and the media, and finally put a halt to this research in 2001 (Hayden, 2003).

IV. 2. Difficulties in identifying legitimate spokespersons

Controversies regarding bioprospecting are highly dependent on anthropological and political considerations. As it highlights the necessity to obtain prior informed consent of indigenous people, the Convention on Biological Diversity seems to make the assumption that such communities are unified as a polity, following the model of representative centralized political structures (Berlin & Berlin, 2004). In Latin America, it has however been claimed that such political entities, are more an exception than the rule (Berlin & Berlin, 2004). It is thus not always elementary to determine which NGOs indeed represent indigenous people in such a way that their prior informed consent would appear as that of the indigenous people themselves. In the Maya ICBG Research Project, consent had been given from a general community assembly, the traditional decision-making group for indigenous communities in Highland Chiapas (Berlin & Berlin, 2004). Opposition from the Council of Traditional Doctors and Midwives of Chiapas (COMPITCH), however, consisted in claiming such community was not representative of the people and managing to convince international NGOs that the COMPITCH spoke for the local communities of the Highland (Berlin & Berlin, 2004)

Identifying a representative group, indeed, also raises many difficulties when different communities, sometimes across national borders, share a common traditional knowledge or use of medicines: Who has the right to sell access to national and indigenous resources? Should the company mainly obtain prior informed consent from the local communities it intends to work with? Should he refer to larger representative groups for "Indigenous People"? Should he consider that all "stakeholders" should give consent, including national or even international NGOs who claim to represent the general interests of the Indigenous people? (Berlin & Berlin, 2004) Moreover, as national sovereign rights over natural resources are recognized in the CBD, tensions have been expressed between local communities and States. Some indigenous associations, for instance, have rejected the idea that a government should possess national sovereignty over their resources and traditional knowledge (indigenous Peoples Council on Biocolonialism, 2004).

Oppositions between different NGOs, finally, have been observed on benefit-sharing. Local communities such as the Forest People's Fund in Surinam,have been interested in receiving proper technology transfer, capacity-building, training and obtaining future or present financial

compensation. Against such logic of individual rewards, international environmental organisations, on the other hand, have been reminding that the CBD's initial aims were to ensure sustainable use of biodiversity, benefit-sharing for communities and States, and conservation of biological resources. They have been calling, therefore, for increased compensation for the exploitation of nature linked to bioprospecting, and general participation in the conservation of biological resources. The 2002 Bonn Guidelines on access to genetic resources, as they list all these benefits in a non-exhaustive manner, do not encroach with the Nations' right to decide and negotiate benefit-sharing terms.

V. Transgenic and cloned animals and their welfare

The development of transgenic and cloned animals inspires concerns in the public mind. Biosafety issues, concerning the open release of these animals in the environment or their use in feed or food are commonly shared by genetically engineered crops and animals. Another concern is that such research could push humanity on a "slippery slope" and constitute the first step towards giving birth to transgenic or cloned human beings in a not so distant future. Applying modern biotechnology to animals, however, has also revealed original public concerns relating to animal welfare and animal integrity.

V. 1. Public concerns regarding animal welfare

In most countries, indeed, animals are generally considered by the public as quite different to simple organisms, thus implying special care. Within Europe, such considerations are most visible in the Nordic countries and the United Kingdom, and much less influential in more Latin cultures such as those of Spain, Italy, and, partly, France. In Japan, public concern for the welfare of animals started in the late 1940s, when numbers of stray dogs started wandering around fields and towns[4], and this interest increased in the 1970s when an ageing society with fewer children started caring for home pets. From then, many Japanese citizens claim they have a moral duty towards animals or that taking care of them implies subjective consideration close to love or familial attachment; animal welfare is therefore a very emotional issue in Japan (Kishida & Macer, 2003). Moreover, in countries such as India, respect for animal welfare is rooted in religious beliefs. However,

4 Akira Takeuchi, DVM, PhD Professor Emeritus, University of Tokyo, Tokyo, Japan, Amendment of Legislation for Animal Welfare in Japan, oral presentation at the 28th World Congress of the World Smal Animal Veterinary Association, Oct.24-27 2003, Bangkok, Thailand. http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2003&PID=6490&O=Generic

"Animals and birds are thought not only as Vahanas or Vehicles on which God rides, but much more useful as well. Over the centuries this has brought about a very healthy respect in the Indian mind for all forms of life. The cow is sacred not because it is a divine vehicle alone, but because it has an overall utility value. Buddhism and Jainism carry this attitude further, leading to vegetarianism and respects for all living beings. To the Sufis, steeped in equally considerate attitudes the prevalent Indian mind set was extremely acceptable. Thus, in the East, regardless of specific sects or religions, the attitude to other life forms was not exploitative, but appreciative. Even pigs, boars, buffaloes and monkeys are referred in holy books and the Indian mind set can become easily sensitive when it comes to these animals. These religious sentiments could be one major reason why the animal activism in this country has found firm roots, while in the West it may be because of the writings of some secular philosophers." (Indian Council of Medical Research, 2000)

It is against such background that research on and production of transgenic and cloned animals takes place. Developed in the United Kingdom, the "Three Rs" doctrine (Russell & Burch, 1959), raised awareness on the welfare of animals used in research, as it promoted the “Refinement” of research techniques in order to minimize animal suffering and distress, “Reduction” in the number of animals used, and “Replacement” of these animals where possible so as to avoid the use of animals in research. The United Kingdom, indeed, has developed a highly comprehensive framework for animal use. The Brambell Report of 1965 was highly influential in this matter, as it identified the "five freedoms" an animal should be recognized : freedom from hunger and thirst, from discomfort, from pain, injury or disease, from fear and distress, and freedom to express natural behaviour (Kaiser, 2005) Issues of animal welfare have gradually been voiced in the European political arena and elsewhere since the mid-1970s, and have been major issues in the European research policy since *circa* 1986, when the European Convention and Council Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes were adopted. Such issues also imply that animals' integrity should be protected, so that they can live a life as close as possible to natural life, in terms of mental state, capacity to withstand unfavourable fluctuations of the environment, express natural instincts and fulfil its natural activity. Animal welfare, thus, is not only a physiological consideration, but it involves a general philosophical notion of what an animal is, against which the use of animals for purposes such as research or farming is evaluated. The main principle for such evaluation is the principle of proportionality, such that research going against animal welfare should be clearly aiming at higher benefits for society. As legal regulation cannot fully detail the application of such a proportionality principle, best practice guidelines are deemed useful by many, as they make sure that research conforming to

public regulation can be considered moral as well (Nuffield, 2005).

With such a frame of mind, since the intense media coverage of the cloning of the sheep Dolly in 1997, many people express some defiance towards biotechnology applied to animals, disregarding the fact that classical animal breeding already constitutes a form of "biotechnological" production. . In the United States, for instance, Americans are much more likely to support the genetic modification of plants, than that of animals (Pew Survey, Nov. 2005). The greater part of the public worldwide, however, does not oppose to any experimentation on animals whatsoever, but is either indifferent to animals or would like animal welfare to be taken into account within such experimentation. Animal rights considerations have thus very little effect on the public opinion, while animal welfare issues concern some part of the public. In all cases, most of the public is willing to consider the purpose as it evaluates the engineering of animals. In Japan, leisure purposes have been generally deemed an insufficient justification for genetically engineering an animal, such as a "larger sports fish" (Inaba & Macer, 2003). Transgenic and cloned animals engineered for medical or research purposes have been met with more approval worldwide. Concerns have been raised, however, that, while the general number of animals used in research is going down, the proportion of animals used for cloning or transgenic research are quickly rising.

Animal designed for food and agricultural purposes do not receive general support from the public. Religious belief plays a role in the public acceptance of food from transgenic and cloned animals. Some Christians, on the one hand, object to the genetic engineering of animals as such, arguing it is equivalent for human beings to play God and goes beyond moral limits. Animal food is not their specific concern, but the modification of the Creation is. Hinduism, Buddhism, Judaism and Islam, on the other hand, do not refer to the 'Playing God' argument, but express more concerns about specific aspects regarding food, such as, for instance, whether genes have been introduced from animals such as pigs or cows (Kaiser, 2005). Arguments against GM animal farming, nevertheless, mostly relate to animal care and animal welfare considerations.

In Japan, animal welfare issues certainly plays a part in the fact that although support for GM crops and GM food is low, surveys since 1993 consistently show more support for genetic engineering of crops than that of animals producing less fatty meat or cows producing more milk (Inaba & Macer, 2003). Thus, even alimentary and agricultural purposes do not inspire high approval, as a part of the public shares an emotional sympathy for the animal and an indistinct but firm decision to no to eat what it considers "unnatural" food, be it derived from GM crops or GM animals. Regarding cloned animals, many advocacy groups have argued, from scientific reports, that, among the few cloned animals that survive a cloning process, many are deformed or have

significant abnormalities. As scientists have stated, the low-success rate and abnormalities appear, for the present time, "inherent to the cloning techniques", though technical improvement is nonetheless entirely conceivable (AFSSA, 2005). Animal welfare associations have been raising such issues in countries as the UK, and in India where "religious sentiments could be one major reason why the animal activism in this country has found firm roots, while in the West it may be because of the writings of some secular philosophers," (Indian Council of Medical Research, 2000). In such countries, however, the welfare of the animals is also advocated by national ethics committees, such as the Indian Council of Medical Research as it states that inducing heritable deviations in a species is also a form of violation against their living normativity (Indian Council of Medical Research, 2000)

Organizations promoting animal cloning for food, such as the US Biotechnology Industry Organization (BIO), insist there is nothing special in food derived from cloned animals. They promote ethical values such as the liberty of research, the freedom of rational thinking in "demystifying cloning", and the necessity not to issue useless, demagogic public regulation. In this setting, animal welfare, though important, is probably not the main concern. BIO's Comments to the European Food Safety Authority's Request for public comments on the “Implications of animal cloning on food safety, animal health and welfare and the environment” (May 29, 2007), for instance, call for extensive biosafety assessments, but do not raise issues such as animal welfare or animal integrity. It could be that industry would benefit from addressing such issues where possible, if it is admitted that the long-term economic success of biotechnology generally seem to depend on consumer acceptance (McCluskey, 2004).

V. 2. Public regulation issues

From this situation, public regulation is varied. In many countries, research on transgenic and cloned animals is not regulated as such, but wholly depends on the pre-existenting national frameworks adopted for the management of animal research, often in line with cultural and religious specificities. Transgenic animals in research settings do not often require specific legal provisions. Contained use and release are addressed as with any animals used in research. Animal welfare is often considered by specific advisory national commissions or ethics committees within the research institution. Some national legislation, however, explicitly applies to transgenic or cloned animals. The Norwegian Animal Protection Act, for example states that "It is forbidden to change the genetic make-up of an animal by use of biotechnology or traditional breeding techniques if: a) this makes the animal poorly equipped to engage in normal behaviour or influences

physiological functions negatively; b) the animal has to suffer unnecessarily; c) the modification triggers common ethical reactions' (Kaiser, 2005). Such is also the case in Asian countries such as Japan. However, even in the United Kingdom, inducing "morally objectionable changes" (Banner Committee, 1995) to an animal, for instance producing pigs of reduced sentience or disinclined to engage in activity normal to them, has never been rejected without proper consideration of the purpose of such modifications, in accordance with the principle of proportionality. Thus, the production and use of transgenic and cloned animals remains a very controversial issue. Consensus in regulation of biotechnology engineered animals is unlikely to happen within the European Union (CeBRA, 2005) or Asia. The presence or absence of national regulation on animal cloning is an indicator of such tension between incentives to accelerate medical and biological research, and the willingness, as embodied in the Danish Law on cloning, to consider that cloning is a moral issue calling for exceptional measures of regulation.

VI. **Private genetic information**

VI. 1. Public opinion

Following the first developments of genetic testing for late-onset monogenic disorders in the mid-1980s and the first identification of genes inducing higher susceptibility for familial breast cancer in 1994, genetic testing has grown dramatically. Clinical tests for more than 1000 diseases are now available. They help medical professionals diagnose genetic conditions, propose adequate treatment, predict the risk of a genetically-induced pathological disorder, and allow parents to make more informed decisions concerning their health and reproductive choices. Major issues, however, have been raised concerning the ethical implications of obtaining, storing and using genetic samples and information. These include respecting the autonomy of the person who submits to a test, ensuring his or her right to fully informed consent, privacy and confidentiality, accepting decisions to know and not to know, and the freedom to withdraw from research protocols at any time. There are also dilemmas surrounding the usefulness and benevolence of obtaining and providing information where no proper treatment is available, where it gives indications in terms of risk and probability in the long term and where it might induce persons in good health to change the representations they have of themselves and of their own abilities and future.

Optimism for biotechnology started progressing in 1999 in most EU 15 members (Eurobarometer, 2005). Such increase occurred at a moment when the deciphering of the human

genome was very prevalent in the media. One hypothesis for such optimism, therefore, is that the media coverage of human genetics has led the public to identify biotechnology less to GM crops and food and more to the major hopes that were raised in the health sector. The European public, indeed, is rather supportive of the use of genetic data for personal medical diagnosis, though important disparities can be observed within and across countries (Figure 3).

While French respondents, for instance, are very likely to "take a test to detect any serious disease that [they] might get", they are much less inclined to allow their "genetic information to go into a national data bank for research into the origins of disease". This might suggest that inclination for medical examination practices and trust for medical professionals are more influential than the desire to participate in genetic research, perhaps as one refuses the cost of participating to research when no personal benefit is in store, or perhaps because one might be anxious about how banked genetic information can be used or circulated. By contrast, respondents from Denmark, Finland and Sweden are much more inclined to participate to medical research progress that could be useful for the community, than to take to a genetic test for personal medical reasons. Nordic populations are also inclined to give genetic information to the police, quite in the same proportion as to research, perhaps from a general sense of community interest. Respondents from other countries such as Germany, however, show a relatively low support for any use or storing of genetic information.

Fig. 3 : Acceptability of uses of genetic data in some European countries (Eurobarometer, 2005)

% responding "Yes, Probably" or "Yes, Definitively"	Would take a genetic test for diseases	Would allow banking of my genetic information for disease research	Would give police access to genetic information	Would give government (social security agency) access to genetic information	Would give private insurance companies access to genetic info.
France	81	65	51	40	26
United Kingdom	69	64	72	27	19

Sweden	63	74	73	12	4
Italy	62	60	56	28	25
Finland	58	68	66	25	9
Germany	52	42	50	9	5
Denmark	50	76	76	40	6
Total EU 25	64	58		25	14

In the United States, general support for genetic testing for research and healthcare reaches a high level, approximating 90% from respondents according to some surveys (Genetics & Public Policy Center, 2007). In 2002, 69% of respondents have claimed very or somewhat likely that they would take “a comprehensive genetic test which would tell [them] about the likelihood that [they] might get several major diseases" if "it was not at all expensive" (Harris Poll, 2002). Cost, however, has been identified as a major issue, since, for instance, a significant proportion of women are less willing to take a genetic test for cancer if their private insurance company does not cover its cost (Gwyn *et al.*, 2003). Generally speaking, information is valued for its practical utility, as 79% of Americans consider they would be very or somewhat likely to take a free genetic test for a "very serious disease" if "there are treatments or other ways to greatly reduce [their] risk of getting it". Knowledge, however, is also valued for itself, even in the absence of clear practical medical implications, as 49% Americans are willing to take such test if there are "no know treatment or other ways to greatly reduce" their risk (Harris Poll, 2002).

In Europe, access to genetic data by government agencies in charge of social security or private insurance companies raises great opposition (Eurobarometer, 2005). In the United States, since the NIH-DOE ELSI Report of 1993 (1993, NIH-DOE), the possibility that health insurance companies could have access to private genetic information has raised much concern. It has inspired much opposition from the public and the media, who generally consider it more important for an individual not to be denied health coverage, than for the insurance industry to prevent fraud and identify risk as accurately as possible.

Current developments in pharmacogenetics seem to be leading the way to a shift in the discourse,

as the genetic profile of an individual, instead of being perceived mostly in a fatalistic view, is considered a useful element to tailor medication to his or her personal identity. At the same time, pharmacogenetics thus feeds a discourse highlighting one's responsibility to get information on one's genetic predispositions and manage one's health as best as possible. Thus, although the theory of individualised medicine is at stake since the beginning of genetic testing (Ruffié, 1993), it is gaining influence with pharmacogenetics. The public, as in Europe, often considers pharmacogenetics to be useful, morally acceptable and not very risky (Eurobarometer, 2005). While the technology of genetic testing has been mostly used clinically to assess the risk of late-onset genetic diseases that cannot yet be cured, pharmacogenetics, by contrast, would be entirely devoted to raising the efficiency of medication.

VI. 2 Regulatory aspects

Most issues on the common practice of genetic testing have been raised and resolved by the medical profession, without major input from public authorities. Ethical guidelines have been published, on international, national and local levels. The harmonization of these protocols is gradually taking place on such different levels since the 1990s, together with the recognition, that different health conditions can imply different protocols regarding, for instance, the ethical necessity for the patient to wait quite a long time before the obtention of a genetic result or ensure that a psychologist or a genetic counselor helps the individual to understand the probabilistic result of a test.

Public regulations have not always addressed the medical use of genetic testing. In countries such as Finland and Germany, for instance, the regulation requirements are the same as for other medical applications, and relies greatly on professional guidelines. In countries where specific legislation has been introduced on such medical uses, it usually implies minimal statements, commonly-agreed within the medical profession. In France, for instance, since the Bioethics Laws of 1994, the medical study of a person's genetic characteristics should be obtained only for medical practice and research, with prior consent, following a clear information on the nature and intent of the tests. Public authorities have also played a role, not only in funding research and medical genetics institutions, but also in ensuring professionals receive proper training relating to genetic testing. However it not always mandatory for the practitioner to have been trained in genetic counseling. In some countries such as Japan (Macer, 2003), guidelines from the medical profession are designed to help practitioners communicate in a non-directive manner the social, ethical, psychological

implications of a test.

Pharmacogenetics has inspired recurrent calls against the "exceptionalist" representation of genetic information and in favour of a more gradual approach. (McNally & Cambon-Thomsen, 2004). The "exceptionalist" representation implies that any genetic information, sample and test is highly sensitive and needs extra caution, as compared to other medical tests and information. As medical genetics started with the diagnosing and forecasting rare and serious diseases, this exceptionalist view seemed inevitable in many countries, as France. By contrast, however, most tests linked to pharmacogenetics would aim at identifying genetic individual profiles relating to common medical conditions, considered less psychologically damaging than neurodegenerative diseases. The UN International Declaration on Human Genetic Data states, "It is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned." (UN, 2003, Art.11). It is not clear, however, whether, according to such soft law, the common use of pharmacogenetic tests would need genetic counseling. National legislation is sometimes necessary to react to some developments of technological innovation; it should, however, be broad and flexible enough not to depend on representations of science and technology that could become outdated.

VII. Stem Cell Research

VII. 1 General public opinion

Since embryonic stem cell lines were first produced in 1998, ethical issues and controversies have been raised within the general public, influential groups and public policy arenas. Embryonic stem (ES) cell research has inspired specific concerns, while adult stem cell research has mostly raised scientific questions relating to its efficacy.

Interestingly, however, the public opinion is globally quite favourable to stem cell research, and adopts a utilitarian view, such that it seems an ethically acceptable trade-off to destroy embryos for the future prospect of saving human lives or curing diseases (Eurobarometer, 2005). Support, hence, depends largely on the belief, which seems to progress, that such research will have real benefits. In the USA, as in Europe, a clear majority supports this utilitarian view, while fewer than half supported it in 2001 (Pew Forum, 2005). By contrast, they generally tend to show low support for xenotransplantation, which could be considered a competing technology in addressing issues of

shortage in human organs and tissues (Hagelin, 2004; Martinez-Alarcon, 2005). Safety issues and fear of animal contamination play a role in such low support, but so does feelings and representations of a substantial gap between animals and humans. Regarding stem cells, surveys also show that public support is stronger with more informed and educated respondents (Eurobarometer, 2005).

Research on stem cells derived from embryos raise religious concerns linked to the status of the embryo. According to Islam and Judaism it is legitimate to accept research until the 40th day after conception. As the Talmud states, the embryo is considered "as if it were simply water" until such moment[5]. Moreover, in Judaism, embryos created for research purposes through nuclear transfer techniques could not be considered as "potentially humans" as long as they would be intended for implantation in a uterus. In China, Confusianist thinking commonly considers that a being becomes a human person at birth only; the manipulation of an embryo thus raises very few ethical issues within these religious frames. In other Asian countries, Buddhist thinking consider that products of human technology are not less "natural" than what humans have not produced, and frames the stem-cell issue from its oppositions to abortion (Promta, 2004) Christian public opinion is more concerned with using embryos in research or producing embryos for research purposes. It not certain, however, whether most Christian individuals are opposed to destroying embryos. Faced with a situation of supernumerary embryos since the development, legalisation and use of in vitro fertilisation techniques, indeed, many adopt a utilitarian view, such that religious belief does not preclude support for ES cell research (Eurobarometer, 2005). In the USA, the majority of Protestants and Catholics supports ES cell research, except for white Evangelicals; this group, however, has seen support for ES research massively progressing since 2002 (Pew Forum, 2005).

Although religious faith is influential on people’s attitudes towards ES cell research, these attitudes are not so strictly dependent on religious dogma and evolutions have been observed. On the whole, in many countries, stem cell research is a much more contentious issue for religious associations and public authorities than it is for the general public (Eurobarometer, 2005)

VII. 2. Influential religious groups

Protestant groups have diverging views on the moral status of the embryo. Some Protestant associations are relatively progressive and express support for embryo research. The French

5 Babylonian Talmud, Sanhedrin 72b, Hullin 58a, Yevamot. See Embryonic Stem Cell Research: The Jewish Perspective by Elliot N. Dorff, United Synagogue Review/Spring 2002. http://www.uscj.org/USCJ_ReviewSpring_205803.html Accessed on 28 April 2007.

Protestant Federation, for instance, considers that an embryo lacking any "parental project", i.e. not planned to be adopted by prospective parents, is not wholly a human being. In the USA, religious opinion is divided: while many Protestant associations agree to stem cell research under tight public regulations, many others are still pondering. Evangelical Christians with influence on public authorities have been opposing all ES cell research as it implies destroying embryos.

Christian groups, however, have largely been opposing stem cell research on embryos, arguing that life is a continuum and humanity does not appear at a precise moment during the development of the embryo. Pro-Life associations claim that the consent of parents to let research be conducted on embryos that no more enter "parental projects", i.e. that parents have clearly discarded and that no other person plans to adopt, is ethically unacceptable because the decision to protect human dignity cannot be made on a case-by-case basis, nor depend on the decisions of individuals. These opinions are particularly reflected by civil groups and political parties influenced by the Roman Catholic Church, as the Vatican's point of view on the embryo has stayed the same since 1987: the embryo is considered a human person from the moment of conception, who should neither be produced for other means than giving birth to a child, nor be killed[6]. Neither, they claim, should it be instrumentalized as a research element or therapeutics. In Italy and Brazil the influence of the Vatican and religious groups against utilitarian views remains high. The public regulation outcomes, however, differ in these countries. The religious Catholic beliefs of many members of Parliament in Italy might explain the very strict public regulation of ES cell research as a "transversal party issue" (Boggio, 2005). In Brazil, by contrast, the religious groups have not been influential enough to hinder political elites from voting in 2005 for a rather progressive Biosafety Law, which authorises ES cell research, though still prohibiting "therapeutic cloning".

VII. 3. Non-religious associations

Other organizations have actively campaigned to express non-religious issues on ES cell research. Quite visible in the UK, for instance, are different pressure groups such as H.G.A. (Human Genetics Alert), which aims at keeping a watch on genetic human engineering and opposes human "cloning" as such, considering therapeutic cloning to be the first step on a slippery slope towards human reproductive cloning. These groups actively campaigned to support the UN call for a ban on human cloning in 2005. They however only participate in political decisions from the outside. By contrast, disability associations and federations, such as the United Kingdom's Disabled People's

6 Congregation for the Doctrine of the Faith, Donum Vitae, Instructions on Respect for Human Life in its Origin and on the Dignity of Procreation, 22 Feb. 1987.

Council (UKDPC) or Disabled People International (DPI), enjoy genuine recognition and express specific concerns in national and international arenas. They, indeed, oppose the representations of disabled people that, they claim, stem cell scientists, political elects and the media convey. Disabled people, they claim, are scarcely then presented as individuals with their own history and their own personal will and ability to live a normal daily life, but more often as objects of pity, in order to gain support for stem cell research. They oppose such representation and to the idea that stem cell research must be conducted for eradicating handicaps "while ignoring the immediate social and economic inequalities that transform impairments into disability" (UKDPC, 2004).

Much more common, however is the support of stem cell research by associations and charities concerned by rare diseases and considering ES cell research as an ethical necessity. Eurordis, the European rare disease association, has expressed its support for ES cell research in Europe, while insisting a patient must keep the right not to participate in future research. Support from patients groups has sometimes even led to very positive networks between influential rare disease associations and national scientific institutions. The popular French Association against Muscular Distrophy (AFM), for instance, created in 2006 and co-funds the I-Stem laboratory, together with a national research institute (INSERM). Despite the public reactions that such decision triggered within Catholic groups and funding members, such institution have the potential to inspire even more support from the French and European public on embryonic stem cell research.

VII. 4. Regulatory considerations

The ethical and public debates regarding the public regulation of stem cell research highly depend on the source of these cells: adult cells raise issues in terms of good practice, that are left to researchers to handle. Embryonic stem cells, on the contrary, have been considered for specific public regulation. Among these, regulations often differ between embryos derived from fertilized eggs and embryos obtained from nuclear transfer techniques.

A crucial element is that taking stem cells from an embryo implies destroying the embryo, a voluntary act which some political authorities, as in Germany, Italy, and Norway have considered unacceptable from an ethical or religious viewpoint. In the United States, there is great tension between the Presidential opposition to federally funded embryonic research, the federal necessity to not to encroach with liberty of research within each State, and the decisions by some States such as California to legalize and promote embryonic stem cell research. Other countries, however, including the United Kingdom, Finland, Denmark, Sweden, Canada, Japan, China, India and Brazil,

since the fate of supernumerary frozen embryos left over from In Vitro Fertilization techniques was to disappear, have admitted that these could be used provided research aims at consequent medical improvement. According to the regulations of these countries, written informed consent from the donors must be obtained, embryos must have been left without no parental project supporting them and research cannot be conducted after the 14th day of the embryo. Such is also the case in France, although in a more ambiguous manner: in principle, ES cell research remains prohibited. In practice, however, derogations are issued by the Biomedical Agency to laboratories who must conform to the same deontological rules.

Countries opposing to stem cell research derived from supernumerary embryos face another issue, however: whether importing embryonic stem cells from other countries would match with the refusal to derive these cells from embryos on the national territory. Indeed, from a pragmatic point of view, it might appear unethical to kill an embryo, but not to study imported embryonic stem cells, even though such cells are necessarily derived from destroying embryos. Thus, while Italy has not considered the legitimacy and legality of importing ES cells but lets it happen, Germany and the United States have. Both consider it acceptable to conduct research (Germany) or federally fund research (USA) on imported ES cell lines, provided they have been cultured before national regulations were in place. These provisions might appear ethically coherent, as they avoid Germany and the USA from bearing responsibility for new embryo killing. Nevertheless, scientists have since then, in both countries, insisted on old embryos lines gradually loosing quality, creating difficulties both in international research competition and cooperation.

Nuclear transfer techniques, often referred to as "therapeutic cloning" is also the object of diverging regulatory views. All national regulations which prohibit ES cell research are opposed to nuclear transfer techniques for similar reasons including the commoditisation of the embryo. Within countries where deriving stem cells from supernumerary embryos is permitted, only some national regulations have authorized the use of nuclear transfer techniques to obtain human embryonic stem cells. In France, despite support from a part of the researchers, it has not been authorized by the Biomedical Agency. It is explicitly authorized and regulated in countries such as the United Kingdom, Sweden, Canada, some US States such as California, Japan, China and India, while it has not been forbidden in Finland. Interestingly, many national ethics committees have produced reports quite favourable to human nuclear transfer, years before the law became more flexible when it did. Such has been the case in France, Germany, Finland, Sweden, and the UK. The classic image of national ethics committees slowing down scientific progress and research do not

seem to operate in these cases.

Roadblocks and accelerators

The intent of this paper has been to describe the current ethical debates regarding GM crops and food, biofuels, bioprospecting, stem cell research, transgenic and cloned animals and the use of human genetic information. From there, it is possible to identify roadblocks and accelerators which can either impede the use of such innovations or facilitate it. One can notice that, in many cases, the general public, media and concerned NGOs do not oppose to the development of an innovation as such but rather to its ethical and social consequences. In other words, these arguments often provide orientations on how each innovation can or cannot gain public support and be commonly used. Roadblocks and accelerators are summarized as follows:

GM crops and food

Roadblocks

- Misinformed and overcautious public opinion. The public opinion is in great part ill-informed, both of what GMOs are and are not, and of the regulatory system adopted to ensure health and environmental safety. One source of the adverse positions against GMOs is as set of irrational representations concerning what they can or cannot do. Technical education is necessary, though neither the media, nor public consensus conferences have proven effective enough in the long term.

- Industry ignoring or underestimating local/national cultures and ethical values. As the intense debates in India have shown, the GM industry has suffered from ignoring or underestimating local/national cultures and ethical values. Indeed, in India, the temporary success of international NGOs between 1999 and 2001 could partly be explained by their ability to identify "the ancient right to save and exchange seeds from previous harvests" as a very efficient ethical theme. The cultural attachment to national products and typical local "terroir" food is also an element NGOs have insisted upon in Japan, Italy and France, and which limits GM development.

- Organization of political power. In countries where decisions are not national but can be taken by local or regional authorities, as in Italy, Germany or Japan, opposition to GMOs is not only based on economics, ethics and safety grounds but also on local interests and deals. Local elect officials might wish to satisfy their electors when they institute GM-free zones.

- Fears against new distributions of power. In European countries such as France and Germany, NGOs and small farmers consider that GM expansion would lead to massive corporate control of

agriculture. The politicization of the GM debate is not to be desired by GM producers, as it creates delays and often limits cultivation and marketing possibilities. However, when such political and social considerations undoubtedly affect the general public, technical education on GMOs cannot be the main answer to adverse reactions from the public.

Consensus conferences, as they happened in Nordic countries and the UK, have incidentally driven members of the public to explicit their views on society, what they desire from it and how freedom of trade and ethical concerns should be combined. In the UK, the 2003 conference has lead to positive views on GM organisms, which the media has been actively echoed ,

Accelerators

- Humanitarian arguments. Drought-resistant, climate-specific or vitamin-supplemented GM organisms inspire support from actors in developing and developed countries, such as the Nuffield Council on Bioethics in the UK. Developed countries are willing to fund and support research in GM organisms based on humanitarian prospects. In developing countries, national support depends on the ability of GM crops to fulfill their promises in the long term and convince farmers.

-Adequate public regulation. In many cases, public regulation is an asset in the development and marketing of GMOs. Provisions regarding health and environmental safety issues are most useful tools in ensuring public confidence. In the USA, trust in the FDA regulation system is an important element in the general public acceptability of GM food. In Europe, new coexistence provisions are reshaping the debate, from health and safety issues to the world of free-trade and liberal economy. All public regulation is not always well addressed. In China, for example, unrealistic coexistence provisions have detrimental effects both on public confidence and on the GM industry. By contrast, EU and US public regulations are the objects of discussions with stakeholders. Though such discussions do not accelerate the diffusion of GM organisms through time, they consolidate it into legal and reassuring frameworks in the long term.

- Building constructive alliances. In India, a constructive cooperation between farmers of Andhra Pradesh and the GM industry has reshaped the debate and led to farmers claiming their right to choose what they consider the most efficient seeds. Such cooperation is an asset for the GM industry in developed countries, as it avoids a politicization of the debate, and provides answers to fears of corporate control over agriculture.

Biofuels

Accelerators

- Ecological arguments. The public opinion is generally positive on biofuel development and often associates this energy with considerations of global warming and other ecological issues. As public concerns for such issues are expanding in the EU, USA and Canada, the biofuel industry actively promotes such mental association. In order to accelerate the implantation of biofuels in the transportation area, however, it would be useful to give it a more "sustainable" orientation. Research on cellulosic biofuel, for example, will raise more public support.

- Economics and national security. The current dependence on foreign oil is a major argument in the USA in favour of biofuel promotion. The general public is well aware of the economic and national security consequences of such dependence, and willing to see them reduced. The effectiveness of this argument, nevertheless, depends on whether the dependence on foreign oil will be eventually reduced by increasing the use of biofuel.

- Public policy promotion of biofuel. The current wave of public policies promoting biofuels in America and the EU is very positive, not only on economic terms, but also regarding public acceptability. Governments use biofuel promotion as a tool to convince that ecological issues, national security and economic dependence on foreign oil are addressed. This will certainly accelerate biofuel development in the years to come as long as the public and the media are convinced. Once again, orienting biofuel towards more "sustainability" will be very useful for its massive development

Roadblocks

- Cost for the consumer. Not all individuals take their decisions from ethical grounds or act as citizens of the world. Effective acceptability of biofuels depends on the price the consumer will have to pay. Where biofuels are seen as valuable for ecology or national security, individuals or national governments might accept to participate to a greater extent. Research is necessary on how much actors sharing such views may be willing to pay, in order to identify to what extent the price of biofuels is an effective roadblock for its implantation.

- GM development. There is great probability that a world-wide increasing demand for biofuels will lead to actively generating biomass through genetic engineering. NGOs are starting to consider this aspect, and many share an opposition against GM crops and foods and would certainly battle against such massive engineering. More importantly perhaps, the public opinion, already wary about GM food, would very probably react negatively to GM biomass .

- Ecological, economic and social negative impacts. First-generation biofuels inspire critics and caution from NGOs and European Green parties, for their possible or effective ecological, economic and social negative impacts. The media focus on these aspects is expanding. Awareness from the public opinion will take time, and will probably happen at a moment when biofuels are massively used. When this happens, will the public accept such negative impacts, as it has generally done with fossil fuels, or how negatively will it react? The competition between fuel and food might be attenuated by developing more eco-sustainable biomass derived from other sources than food crops. Such attenuation, though, needs early preparation, otherwise transition costs towards such sustainable biomass could be very high.

Bioprospecting

Accelerators

Through the Convention on Biological Diversity, the recognition of Community Rights positively leads to more equitable sharing of benefits and enables positive cooperation between industry and local/indigenous associations and populations. This leaves the possibility open for the media - and particularly the media from developing countries - to represent such research in a more positive manner.

Roadblocks

- Identifying proper indigenous and local stakeholders often proves difficult. Research has often been blocked by pressure groups whose legitimacy was unclear.
- Agreeing on benefit-sharing terms is often uneasy. This latter aspect, however, is a minor difficulty, as compared to the former.

Welfare of cloned and transgenic animals

Accelerators

- Health prospects. Respect for medical research is generally high, and most of the public is willing to delegate decisions to experts in this field.
- Integrating animal welfare advocates into regulatory institutions. In the UK, the Animal Procedures Committee (APC) includes members from animal rights associations to advise the Government on animal welfare issues. This provides valuable insights from NGOs and drives them to express constructive propositions much more than adverse vocal opinions.
- Cooperation with other NGOs: disease advocacy groups and associations. Disease associations,

benefiting from positive public opinion and media focus, are in favour of more research on cloned and transgenic animals. In France, the AFM has vigorously claimed more research was necessary, notwithstanding the necessity to ensure animal welfare when possible.

Roadblocks

- Increasing number of transgenic and cloned animals. Such massive rise, counterbalancing a general decline in the use of animals for research, has not yet gained much attention from the media. In countries where animal welfare is a very sensitive issue, as Germany and Denmark, one must communicate on the usefulness of creating and using transgenic and cloned animals. In most countries, respect for animal welfare rules (3 R Doctrine) is left in the hands of researchers, with little or no supervision from public authorities. Thus, these actors must be able to communicate on such topics when necessary.

- Ill-conceived regulation. With biotechnology issues, it is not unfrequent for governments to consider one situation as similar to another one because of its novelty and uncertainty. At times, this can lead to ill-conceived public decisions and create blockage for artificial reasons. In Italy, for instance, between 1997 and 1999, the merging of animal cloning and human cloning into a single ban has dramatically impeded research. Such abstract public regulation has had negative effects on the development of cloned and transgenic animals research and was not based on arguments specific to such research.

Use of genetic information

Accelerators

- Public confidence in the medical and research community. Public confidence is generally high. The public is keen on hearing about innovations in the genetic field of medicine.

- Incentives from disease associations. Many national and international rare disease advocacy groups are pushing for genetic tests more accessible and more affordable. Cancer associations are also promoters of genetic tests in the USA and less-developed countries such as India.

Roadblocks

- Ill-conceived regulation. Some public regulations, as the French Bioethics Laws, consider genetic testing or genetic information as exceptional in some ways, as compared to other medical tests and information. Although this is often the case for the moment, the expansion of pharmacogenetics will very probably make a great part of genetic testing and information more common and trivial. Thus, such over-protective regulation could hinder future research and

treatment and be detrimental to the general good.

- Non-medical uses. Debates on whether health and life insurance companies should access genetic information are numerous. Regarding health insurance, discussions in the USA are intense and strongly limit the interest of the public in genetic testing. In other developed countries, debates mostly concern life insurance access and premiums and do not clearly limit the public's willingness to take a test.

Stem cell research

Roadblocks

- Religious beliefs. Opposition to ES cell research happens mostly on religious grounds. Many religious groups, however, approve of ES cell research for medical purposes. Roman Catholics and US White Evangelical Christians are the two most influential groups against ES cell research. In developing countries, such research is usually not a religious issue, except with the Catholic church, whose influence is strong in Brazil. Thus, major progress in this field would more easily happen in countries such as China, India or Japan, depending mainly on scientific capabilities.

- Ill-conceived laws. Human reproductive cloning and human nuclear transfer are submitted to a general public prohibition in Germany, Italy, Denmark, Norway and Brazil, as if the two raised identical ethical concerns. Countries such as the UK, Finland, Sweden, Japan, India and China avoid such confusion and might attract and train highly qualified researchers.

Accelerators

- Media coverage. Apart from Germany, Italy and Norway - where media focus is quite differentiated - the media is usually in line with the public opinion, mostly considering the utility of such research and insisting on accomplishments and high hopes.

- Cooperation with disease associations. The French AFM advocacy group supports and funds I-Stem, a stem cell laboratory managed by public researchers from the INSERM. AFM benefits from positive attention in the media, credibility at the government level, and gives researchers an ideal opportunity for developing ES cell research.

- Proper close-to-date monitoring of scientific and technical progress and social needs. In the UK, the public regulation system is specifically open to new experimentations and discoveries. Researchers benefit from great freedom, as the general public regulation frame is able to dynamically adapt to progress and social needs.

Conclusion

Different fields of biotechnology research and development have inspired different reactions and decisions in the last decade. For each innovation, there are clearly more than one public opinion, ethical committee advice and national policy framework. Conversely, in each country, social mobilizations and political regulations do not only depend on general attitudes towards biotechnology, but in great part also on the specific matter of each innovation as it connects with proper national, local or individual issues. In this context, each biotechnological innovation is much more than one item of health, agricultural, and industrial biotechnologies, whose ethical and social issues would have been addressed once for all. On the contrary, in order to gain public confidence, regulatory authorities must, and often do, address the ethical, social and technical issues of each innovation as such. National evolutions of public regulations on these issues prove how difficult the task may be, as regulators are not only confronted with technical uncertainty, but also with major ethical dilemmas.

In considering these dilemmas, ethical committees and ad-hoc commissions have played a role in most countries of our study. Many have focused on matters of definition, not for formal legal considerations - such as knowing what is lawfully possible - but because the clarification of an issue often starts with the definition of its object. Studies and elaborations of definitions for an embryo or an animal, for instance, played a major role in the advices given by these committees concerning stem cells or transgenic and cloned animals. Committees have also helped identifying values at play in ethical issues. While they have usually adopted a rational universal stance, some committees, as the Indian Council of Medical Research or the Danish Council of Ethics, have also considered cultural and religious beliefs of society. In highlighting values, most ethics committees have and made clear that a simple cost/benefit calculation should not apply to the ethical issues of biotechnology: it could be unfair to flatly consider issues of general justice against an aggregate of individual benefits (Kaiser, 2005). Opposing such balance, committees such as the French National Advisory Ethics Committee (CCNE), for instance, have expressed defiance both against the general public, who must by times be protected against themselves, and particular groups and associations, sometimes deemed too partial. This role of "guardians of the body" (Memmi, 1996), however, did not hinder many committees from formulating progressive views on issues such as "therapeutic cloning". Committees, eventually, have been major actors of public regulation, sometimes calling for legal clarification, as in Finland for stem cell research, other times inspiring legal texts in their detail, as the French CCNE inspiring national Bioethics Laws. Yet, their institutional status being quite different, there is a risk that committees belonging to S&T institutions or dependence on

Ministers of Research and Biotechnology be used as "faire valoir" for biotechnology promotion or public policy decisions already taken. Ad-hoc committees, moreover, have been considered as instruments of depoliticization (Hoeyer & Tutton, 2005). Thus, for example, the UK Biobank initiative, it is claimed, had been submitted to very little political debate in its inception, although depending on the national health system, while an ad-hoc ethics committee gave assurance that ethical questions were addressed and that "ethics was here" (Hoeyer & Tutton, 2005).

Promoting public education and scientific risk communication is certainly vital for the peaceful development of biotechnology. Such actions do reinforce the general public trust in science and technology, and provide feed for eventual debate. This is all the more useful as most of the public adhere to a utilitarian view, such that effective consequent benefits facilitate public confidence. Public education, however, implies that benefits and uncertainties have already been identified, and that the public merely lacks such knowledge. Our international comparison, on the contrary, shows that citizens and groups are proactive in defining themselves the issues, risks, uncertainties and benefits. In such assessments, the aim of an innovation is not the only criteria for its evaluation, but unintended consequences are also taken into account. Public authorities can help shape the debate and ensure that proper objective scientific and technical information is provided, thus leaving room for ethical and social discussion to take place. The implication of the public in citizens fora, as has been frequently the case in Nordic countries, might enable the identification of highly sensible ethical issues. The results of such implications are certainly more useful than would be that of general public referenda, as they provide regulators with in-depth "lay expertise" on what could be done to facilitate the development of an innovation. One frequent result of these exercises, for instance, is the opinion that regulatory decisions are not sufficiently explained, and public policy action not transparent enough. Different decisions to make GM crops registers available to the public, as in France or Germany, are interesting examples of a move towards more transparency.

The participation of some NGOs and concerned associations may also be an asset in the general regulation of biotechnology. In a social context where many action groups refer to and raise ethical issues, public policy could certainly benefit from establishing more effective networks with associations deeply interested in aspects of biotechnology. The promotion of stem cell research, for instance, benefits from the ability of disease associations such as the AFM in France to identify needs and create national and European networks with research institutions. Public authorities could facilitate input from associations on these matters. The involvement of such groups, moreover, could be useful in soothing conflict and tension, and creating a working climate of trust and efficiency, such as is the case with the British regulation of animal welfare.

Many biotechnology innovations are claimed to match ethical needs. Biofuels should contribute to the protection of the environment, genetically modified food and crops could participate in a fight against hunger and malnutrition, genetic testing is an asset for the autonomy of the patient and would enable personalized and tailored medicine, engineered animals could improve medical knowledge and stem cell research save human lives. These innovations, however, could be used in unethical ways, as any instruments. Diverging views, therefore, should not be simply considered useless and temporary, or caused by deficiencies of knowledge or rationality. They often express the inner ethical contradictions of biotechnological innovations, as well as they reveal deeply-rooted ethical and cultural values which should not be brushed aside. Though some international harmonization is occurring, the development of biotechnology needs appropriate ethical debates to identify and match specific cultural and national concerns, and thus ensure public trust.

Annex A- NGOs and The Media

NGOs and The Media - Private Genetic Information

PRIVATE GENETIC INFORMATION	USA & Canada	Europe	Japan	Brazil, India, China
Typology of NGOs and associations (local, national, international), positions (positive, differentiated, adverse) and influences (vocal, weak, medium, strong). Regional differences	- National and Norht-American patients groups. Local or national strong influence. Positive concerning medical uses. Adverse positions on the employment and insurance use of genetic information. American Cancer Society Genetic Alliance Huntington's Disease Society of America Huntington Society of Canada - National and North-American advocacy groups. Vocal. Differentiated Public Citizens' Health Research Group. American Civil Liberties Union. Regional differences: universal insurance system in Canada makes it easier for genetic medical market to expand.	- European and National patients groups. Strong. Positive concerning medical uses. Adverse positions on the employment and insurance uses of genetic information. Eurordis European Huntington's Disease Network. National Huntington's Disease Associations Associations against Muscular Dystophy (Telethon): French AFM and Italian UILDM. -Regional differences: NGOs are most consulted and influencing in the UK (Genetics Interest Group, British Council of Disabled People, Liberty, Genewatch UK) and at the EU Commission level.	- National disease advocacy groups. Positive. Vocal. Japan Cancer Association Japan Huntington's Disease Network and other Rare Diseases Associations.	- Brazil: National rare disease assocations. Positive. Vocal. Huntington's Disease national association. Prader Willi Association Brasileira. - India: national disease advocacy groups. Positive. Vocal. Cancer Patients Aid Association (CPAA) Huntington's Organization Indian Cancer Aid Society - China: No major influential or vocal NGO.
Media intensity (weak, medium, strong) Media positions (positive, differentiated, adverse)	Medical aspects: medium to strong. Positive. Insurance and employment uses: weak to medium. Differentiated.	Medical aspects: medium to strong. Positive. Insurance and employment uses: medium. Adverse. Regional differences: In the UK, media reports are often technical on medical uses (availability of tests; organization within the national health system;..) and differentiated regarding other uses. In France, media position is mostly sensationalist: positive on medical uses and adverse on non-medical ones.	Medium. Positive.	Brazil: strong. Positive. India: medium. Differentiated (focus on sex selection) China: medium to strong. Positive. Chinese progress in research is emphasized by the media.

NGOs and The Media - Genetically Modified Organisms

Genetically Modified Organsims	USA & Canada	Europe	Japan	Brazil, India, China
Typology of NGOs and associations (local, national, international), positions (positive, differentiated, adverse) and influence (vocal, weak, medium, strong). Regional differences	- International. Adverse. Strong. Japanese and Korean NGOs have put US GM wheat development to a halt in 2004, and keep a watch. Greenpeace International. - National or North-American NGOs. Differentiated Vocal. Small NGOs. Campaign to Label Genetically Engineered Food. Regional differences: Canada: The ETC Group (former RAFI) is influential abroad. Adverse.	- National. Adverse. Strong and destructive. Peasants and Farmers' confederations. Green associations. - International. Vocal. Strong Greenpeace, FoE Europe. Etc Group (Canada-based) - National Green parties. Weak to strong influence. - National watchdogs. Mostly vocal. GMWatch UK, Inf'OGM France. Regional differences: - Green parties influences differ, from weak (France, Italy), to medium (UK, local implication) and strong (Germany) - Violence is strongest in France (Confederation Paysanne, ATAC) and Germany. - Some local elect officials take sides with NGOs against GMOs in Italy and France.	- National. Adverse. Strong. Consumers Union of Japan, No! GMO Campaign - International. Adverse. Vocal. Greenpeace, GRAIN, FoE Japan.	- International. Adverse. Vocal. FoE International, GRAIN. Regional differences: - China: No effective national NGO. - India: National, adverse, vocal: India Resource Center (IRC); National and local, adverse, strong: Gene Campaign, Andhra Pradesh Coalition in Defence of Diversity, KRRS. - Brazil: National vocal NGOs such as ActionAid, and local indigenous rights associations with weak influence at present.
Media intensity (weak, medium, strong) Media positions (positive, differentiated, adverse)	Weak intensity. Positive. Canada: media attention is among the lowest among the OECD countries.	TV focus: Weak intensity. Positive. Has expanded since the end of the EU moratorium. Press focus: medium intensity. Differentiated.	Weak. Differentiated.	- Brazil: Weak. Differentiated. - China: Weak. Positive on national GMOs. From cautious to adverse against foreign GMOs. - India: Intense and differentiated.

NGOs and The Media - Welfare of cloned and transgenic animals

Welfare of cloned and transgenic animals	USA & Canada	Europe	Japan	Brazil, India, China
Typology of NGOs and associations (local, national, international), positions (adverse, differentiated, positive) and influence (vocal, weak, medium, strong). Regional differences	- International. Vocal. Differentiated. WSPA - National. Vocal. Differentiated. The Humane Society. The ETC Group (former RAFI).	- EU-wide. Strong. Differentiated EuroGroup, umbrella organization. - International. Vocal. Differentiated WSPA -Regional differences National animal welfare NGOs are strong in Germany (Animal Welfare Foundation, DTSchB) and the UK(CRAE, FRAME). French AFM pushes for more biotech animal research. Positive. Influential.	- National NGOs show very weak interest for biotech animals. Japan Animal Welfare Society. - National learned societies is more influential. Positive. Japanese Society for Alternative to Animal Experiments.	No national or international NGO has considered the welfare of animals derived from biotechnology.
Media intensity (weak, medium, strong) Media positions (positive, differentiated, adverse)	Weak intensity, apart from very mediatic moments (Dolly cloning). Differentiated.	Medium intensity. Differentiated. Regional differences: Media focus in Germany is strong and sometimes adverse.	Weak. Globally positive, though more differentiated than on other biotech fields.	Very weak. Differentiated.

NGOs and The Media - Biofuels

BIOFUELS	US&Canada	Europe & EU	Japan	Brazil, India, China
Typology of NGOs and associations (local, national, international), positions (positive, differentiated, adverse) and influence (vocal, weak, medium, strong). Regional differences	- International. Vocal. Differentiated FoE International, WWF, Birdlife International. - North-American. Vocal and medium influence on wetland management. Differentiated. Ducks Unlimited. Regional differences: Canada's implication in biofuel is not old, which leads NGOs to express more proactive and less reactive views than in the USA.	- International. Vocal. Differentiated. FoE International, WWF. - National environmental groups. Mostly vocal. Adverse. - National Green parties. Weak to strong influence. From differentiated to adverse. Regional differences: - Green parties' influences differ, from weak (France, Italy), to medium (UK, local implication) and strong (Germany)	- International. Vocal. Differentiated. FoE International. - National. Vocal. Differentiated. FoE Japan, Global Environmental Forum, Biomass Industrial Society Network.	- International. Vocal. Mostly adverse. Sometimes differentiated. FoE International, GRAIN. - In Brazil: International, vocal, weak: World Rainforest Movement, Gaia Foundation. National vocal, weak NGOs such as ActionAid and the Landless Workers Movement. Local Indigenous movements federated in the international Global Forest Coalition. weak influence at present. - No effective national NGO in China. Weak influence in India.
Media intensity (weak, medium, strong) Media positions (positive, differentiated, adverse)	Medium intensity.Positive. Television is globally positive. The press is more willing to express diverging views.	Positive. Weak Intensity, expanding as biofuel cultivation develops. TV is more positive than the press. Negative impacts are now being highlighted.	Weak. Positive, following and describing governmental decisions. Concerns are expressed, but often not highlighted.	Mostly positive, but major regional differences: Brazil: Intense and differentiated. A long-past history of biofuel production drives national media to be rather moderate. Biofuel trade aspects are highlighted as a major asset for national economy. Indirect deforestation and social negative consequences are frequent arguments against President Lula's policy. China: Weak. Positive. the media unequivocally supports the political promotion of biofuel production. India: Weak. Evolving, since the end of 2006, from very positive views to cautious support.

NGOs and The Media - Stem Cell Research

STEM CELL RESEARCH	USA & Canada	Europe	Japan	Brazil, India, China
Typology of NGOs and associations (local, national, international), positions (positive, differentiated, adverse) and influences (vocal, weak, medium, strong). Regional differences	- National and North-American religious groups. Vocal. Local influences. Some Protestant associations: positive. Pro-Life Catholics and Evangelical Christians: adverse. - National and North-American disease associations. Positive. Medium. American Parkinson's Association American Juvenile Diabetes Association - Regional differences: Evangelical Christians have more influence on US governmental decisions than on Canada's.	- International and national religious groups. Vocal, sometimes influent. Protestant associations, incl. Nordic Lutherian Churches : most often positive. Jewish and Islamic Churches, positive. Roman Catholic Church and Christian Pro-Life associations: adverse - European and national disease associations. Positive. From medium to strong. Genetic Interest Group, UK Eurordis Finnish Juvenile Diabetes Research Foundation & French I-Stem laboratory (AFM/Inserm) - International and National. Differentiated. Medium. Disabled People International UK Disabled People's Council - National. Adverse. Vocal. Human Genetics Alert, UK. -Regional differences Religious adverse positions are most influential in Norway and Italy.	- No major influential or vocal NGO. No religious opposition.	- Brazil: National religious groups. Vocal and influential. Protestant Churches: mostly positive. National Council of Catholic Bishops: adverse - India and China: No major influential or vocal NGO. No religious opposition. No visible support from disease associations.
Media intensity (weak, medium, strong) and media positions (positive, differentiated, adverse)	Medium to strong Differentiated.	Medium intensity. Differentiated Regional differences: Media intensity is very strong in Italy and Germany: conflicting views. It is also strong in the UK, but less controversial, and follows institutional changes and new authorizations.	Weak. Positive.	Brazil: strong. Differentiated. India: weak. Positive. China: medium. Positive. Chinese progress in research is emphasized by the media.i

Annex B- Country Profiles

Country Profiles - Private Genetic Information

	Social Context	Obtaining, providing and using genetic information for clinical or research purposes	Obtaining, providing and using genetic information out of the clinical context	Genetic research + data handling and biobanks
France	Patients groups, starting with Huntington's Disease Associations in the 1980s, have been very keen on supporting genetic testing offered to individuals with familial risk. The National Ethics Committee (CCNE) supports and organizes public conferences and debates on these issues on a yearly basis (Journées annuelles d'éthique). The 2007 report on biometry called for public debate on the routine use of biological and genetic information. However, the public and the media show curiosity for sensationalist possibilities of abuse, much more than for concrete aspects of regulation. Effective discussion on regulation, quality and availability of medical genetic information happens with the medical genetics community. Orphan Disease Associations participate proactively. Since 2000, the creation of an umbrella organization, the Rare Disease Alliance (Alliance Maladies Rares), has made such participation all the more easy. Patients autonomy is also addressed through Orphanet, an information platform created in 1997 and now the EU information server. The Genethon biobank from the AFM muscular distrophy association plays a major role in genetic research since 1990.	Since 1994 Bioethics Law, genetic tests can only be conducted for research and medical purposes, provided genetic counselling is given and previous written informed consent is obtained. Consent can be revoked at any time. No precise definition of tests is given. Consultation is multidisciplinary. Only the medical doctor who has prescribed the test can inform the person - an encroachment to the general principle of patients' right to information, as formulated in the 2002 Law on Sick Person's Rights. In 2004, the revision of the Bioethics Law, following debates in the professional arenas, led to consider information is both individual and familial: in case of a positive test for a serious condition, the Biomedical Agency can inform family members of their risks. Confidentiality and medical secrecy are preserved, as the tested individual's name does not appear. Precise procedures are addressed by professional guidelines, often revised and harmonized. Profession also plays a role in availability and quality control issues, as they did with the 1999 White Paper from genetics associations from the ANPGM. The National Committee of Clinical Genetics oversees such issues at the Ministry of Health.	**Over the counter** testing is forbidden in France, but orphan disease associations and medical professionals worry about psychological damages of possible autotests obtained through internet. **Insurance**: requesting a genetic test or using genetic information is forbidden for disability and life insurance policies. Since 1994, the issue has been addressed both by the industry's moratorium (1994-2004) and public legislation (1994 Bioethics Law). The 2002 Law on Sick Person's Rights prohibits such "discrimination" - a very negative concept. **Employment**: any use is forbidden by law since 2002. Wide controversy (Conseil d'Etat, trade-unions, associations) is not yet settled, on whether some tests could be used as tools of prevention in high-risk environments. Parliamentary vote against insurance and employment use was unanimous, due to "ethical issues", though clearly containing ill-defined issues and little debate. 1995 National Ethics Committee (CCNE) Advice on genetic testing states the dilemmas of such use, and oppose to it.	**Obtaining samples**: the same rules apply as for conducting any research, including specific written consent. Debates on whether non-germinal samples with non-identifying genes, such as tumour cells, are submitted to consent revocation. Before research is conducted, Regional Committees on People's Protection (Comité de Protection des Personnes, CPP) check consents have been properly obtained and participants well informed, and produce advices on the ethical aspects of research (principle of proportionality, autonomy,...) **Storing**: In 1996, specific legal provisions had been issued in a May 1996 Law for genetic banks. Following disapproval from researchers, the 2004 revision of Bioethics Law has created a general unified regime for all samples - but for embryonic stem cell samples. Authorization (AFFSAPS) is required when reimpleantation is intended. For scientific purposes, notification to the Ministry of Research is sufficient, though obtaining advice from CPP is mandatory. Regulations mostly come from professional good practice principles The National Committee for Computers and Liberty (CNIL) may oversee information data respect privacy. 2003 CCNE Advice insists no third party should access information from a DNA bank, and calls for regulation "unifying" material and information regulation, without excessive exceptionalness given to genetic aspects. In 2004, the National Ethics Committee (CCNE) produced a common reflection with the German Ethics Committee (Ethikrat), calling for internationally harmonized regulation.
Germany	Oct 2002, German National Ethics	No public regulation specifically address genetic	**Insurance:**	No specific public regulations on Genetic Data

	Committee (Ethikrat) holds a public conference on biobanks. April 2001, Federal Ministry of Education and Research funds a "citizen conference" on gene diagnosis, "Bürgerkonferenz: Streitfall Gendiagnostik". Randomly selected citizens consider pre-implantation and prenatal genetic diagnosis, and genetic testing as diagnosis and prevention tools. They conclude on the need for public information, and consider only qualified practitioners should perform such tests. Also recommend the creation of a central certification commission regulating laboratories. Genetic information and samples must be secured against potential misuses by third parties, such as employers and private health insurers. 2001 Governmental Decree (DM 279/2001) establishes a national network for the prevention, surveillance, diagnosis and treatment of rare diseases. In 2003, governmental 5-year program to establish networks, including in the EU, on rare diseases.	testing or genetic information. Some directives from the Federal Joint Committee (Gemeinsamer Bundesausshuss), for instance on newborn screening[7]. Guidelines have been issued by professional associations, such as the Federal Medical Council in 1998. The German Society for Human Genetics issued a general Position Paper in 2000 and Statements for more precise situations since 1995. Nov. 1999 Advice from the National Ethics Committee (Ethikrat) highlights informed consent, right to know and not to know, cost-benefit analysis, the principle of equality of access to genetic services, and insists no test should be performed without an international agreement on its reliability. Molecular genetic testing is mostly conducted in private clinics. There is no specific licence procedure. The June 2000 Act ratifies the Directive 98/79/EC on In Vitro Medical Devices. The public Institutes of Health organizes a public laboratories database	No public regulation. The moratorium from the main German Insurance Association declares genetic testing will not be a prerequisite for health insurance, nor supplying private companies with the result of previous voluntary tests. The possibility of a Genetic Discrimination Act is a frequently debated question. **Employment:** No public regulation on the use of genetic information for employment purposes. Nov. 1999 Guidelines from the National Bioethics Committee consider it is ethically acceptable to screen for any predisposition to illness in the workplace, provided that te aim is the workers' health and autonomy of decision, beneficence, justice and confidentiality are respected. Testing for susceptibility to cancers triggered by asbestos or other carcinogenic substances in the workplace would therefore be acceptable in certain circumstances. March 2003, the Senate Commission on Genetic Research of the German Research Organization (DFG) confirms such position.	Protection. The Federal Data Protection Act and different data protection provisions in the different States are in place In 2004, the German National Ethics Committee (Ethikrat), set up by the Chancellor in 2001, provided a joint reflection with the French National ethics committee (CCNE) on biobanks for research purposes, calling for internationally harmonized regulation. Ethikrat highlights the role of patients and donors and their right to self-determination and information. The re-use of samples for new research calls for legal clarification. In 2003, at its 21st annual meeting, the Working Group from the Academy of Medicine could not reach an agreement, in what has been called a "manual for informed consent on the scientific use of blood and tissue samples and the personal data involved". Questions of time limit, consent when consequences are unknown, On March 2003, the Senate Commission on Genetic Research of DFG expressed a statement on biobanks and predictive genetic diagnosis. Considers broad consents from donors are ethically and legally justified.
Italy	Public debates on genetic information mostly concern its utility and acceptability for reproductive choices. The nation-wide debate on 2004 Law concerning medically assisted procreation, for instance, dealt indirectly with issues of personal genetic information. Discussion and regulation mostly come from the medical profession. Theleton Italia foundation supports genetic banking from the Galleria Foundation.	No public regulation. No legal requirement of genetic counselling. 1998 Guidelines on Genetic Testing by the National Committee for Biosecurity and Biotechnology and Nov. 1999 Bioethical Guidelines for Genetic Testing by the National Bioethics Committee (CNB) serve as general recommendations, addressing issues such as confidentiality, data protection, right to know and not to know, informed consent and the necessity of genetic counselling.	**over the counter:** Although none is currently sold, it is not forbidden by public regulation. Professional community opposes to them for ethical reasons, as it might deter persons at risk from taking tests. **Insurance and employment:** Nov 1999, CNB Advice considers different medical uses of genetic information, including insurance and employment. Considers the person should be protected against detrimental use of genetic testing leading	2003, Guidelines for genetic biobanks, from the Italian Society of Human Genetics (SIGU) and Telethon Foundation. No specific public regulation for the protection of genetic privacy. Privacy is legally addressed since the 1996 Law. 30 June 2003, Data Protection Act: processing genetic data is allowed exclusively after ad-hoc authorization from Minister of Health and positive advice from Higher Health Council. Informed consent is mandatory for processing

7 European Commission, Directorate General:Research (Directorate E, Biotechnology, Agriculture and Food), Survey on national legislation and activities in the field of genetic testing in EU Member States, Ed. Line matthiessen-guyader, 1 May 2005

	National. The National Institute of Health (ISS) coordinates the National Center for Rare Diseases a	A main source of precise guidelines and training is the Italian Society of Human Genetics (SIGU). SIGU also monitors national provision of genetic tests since 1987. ISS coordinates internal and external quality assurance, together with the Ministry of Health. Ministry of Health is responsible for approval and registration of new genetic tests.	to "discrimination".	"personal data" (=not anonymous)
UK	Deep involvement for government in the development of human genetics and its availability to the public. Patients advocacy groups such as the Genetics Interest Group, British Council of Disabled People are commonly involved in consultations for public and private regulation. NGOs such as Genewatch UK monitor general and specific aspects of genetic information and are often consulted by government and commissions, together with industry and experts. Liberty and GeneWatch UK raised issues about the implication of private companies into the UK Biobank project. Reports from the media are quite well-balanced, giving voice to hopes and concern without exaggeration, often from reflections on availability, national health organization and management of privacy issues through institutions.	Genetic counselling is not required by law, though advisory commissions consider it should be proposed for serious conditions. Since 2000, the Human Genetics Commission (HGC), an advisory non statutory body is responsible for advising Government on ethical and medical aspects of genetic information. The Commission followed the May 1999 decision to review the general framework for biotechnology, uniting commissions in activity since the 1990s (ACGT, HGAC and AGSAG) in order to avoid gaps, overlaps, fragmentation and with the aim to produce a more transparent framework, more rapidly able able to deal with new developments. The Medical Devices Agency is responsible for authorizing diagnostic devices for marketing. Most genetic testing is provided through the public sector (NHS). Following a 2003 White Paper from the Department of Health, education and information programs are provided for NHS professionals, including GPs, through the NHS Genetics Education and Development Centre and the National Electronic Library for Health.	**<u>over the counter:</u>** According to the voluntary system of compliance and monitoring framed in Jul.1998 by the ACGT, suppliers are invited to present the proposal to ACGT prior to its introduction. March 2003 Report from HGT recommends stricter controls on the quality of these tests, and consider most predictive testing should not be offered as direct genetic tests to the public. **<u>Insurance:</u>** Since 2001, professional self-regulation by the Association of British Insurers (ABI) - current " Concordat and Moratorium" ends in 2011. Insurers will not require genetic tests as preconditions for insurance policies. They will ask for results of tests already performed by the applicant, only when such tests are approved by the GAIC (Genetics and Insurance Committee, a non-statutory advisory body) and when application concerns very high value policies. As yet, GAIC only approved one test, in 2001. **<u>Employment:</u>** In 2005, on request of Science Minister, HGC report on the effective use of genetic testing in the workplace, which appears to be very infrequent. In June 2005, the Information Commissioner's Employment Practices Code assumes HGC's recommendation that HGC should be informed by employers of any plans to use genetic information.	2004: Amendments to the initial text have been provided against provisions potentially burdensome for research. Thus, the Human Tissue Authority (HTA) has the power to give "deemed consent" for tissues or DNA to be used for the benefit of another; no specific consent is required for using samples in research, training or education; HTA may inspect facilities, on discretion. Personal genetic information obtained through research is protected against insurance use, as insurers have agreed not to use or request such information. 1995, Nuffield Council on Bioethics Report on "Human Tissue: Ethical and Legal Issues" made recommendations on biobanks. May 2002, HGC Report recommends an independent oversight mechanism for all large genetic research databases, and considers consent, privacy, access, and ownership issues need further consideration. Since the early 2000s, the Medical Research Council, together with the Wellcome Trust, has identified genetic epidemiology as of strategic importance. Among major projects are the DNA Banking Network, and the population-wide UK Biobank since 2002. Frequent discussions on the necessity for broad or narrow consents to storage and research, within professional arenas.

Denmark	The Technology Council organized a lay person Consensus Conference in 2000, showing general positive expectations from genetic information. The Lay panel also expressed warnings on possibilities of stigmatisation or discrimination on genetic grounds. Most regulation is proposed by national and advisory commissions, including the Danish Council of Ethics.	No specific regulation on genetic tests and services, neither on quality assurance issues, nor on medical uses and procedures. Genetic counselling is not required by law. Following Jan.2001 parliamentary debate, the Ad Hoc Committee on Gene Technology is set by the Ministry of Science, Technology and Innovation. In its Report, the Committee recommends that the capacity for genetic counselling should match future demand. Laboratories do not need accreditation or licence, but individually take part in external quality assessments. Most ethical issues of presymptomatic genetic testing on healthy subjects have been expressed in 2001 Advice from the Danish Ethical Committee.	**Insurance:** In 1997, amendments to the Act on Insurance Agreements stipulates health insurance companies may not ask for, receive or make use of the results of a predictive genetic test. The amendment followed the 1996 Danish Council of Ethics (DCE) Advice on insurance, which called for provisions to protect "personal integrity" considered at stake with genetic information. Respect for integrity implied the right to refuse a test from being performed, and the necessity that insurance be not less available to those with possibly detrimental genetic mutations. **Employment:** In 1996, following two calls for legal action from the DCE in 1993, the Law on the Use of Health-Related Information prohibits employers from using or requesting genetic information obtained from predictive genetic tests. However, employer may offer testing where the work situation causes a known risk to people with a specific genetic disposition. In such case, the employer should not be informed of the result.	May 2004 Act amends the Act on the Legal Rights of Patients in order to address the self-determination of participants on the use of their samples. Specific consent is mandatory for each use of collected biological material, and participants and patierts have the right to "back out" from the national Central Register of donated biological material. The 2004 Act is a result from the 2002 Ad-Hoc Task Group Report settled by different ministries (Interior&Health; Science, Technology and Innovation; Justice) The institution of a biobanks is not addressed by law. Authorizations are on a case-by-case basis, through government orders and edicts and registration by national authorities. Regional and Central Scientific Ethical Committees on the exposition of research subjects checks informed consent is respected. As early as 1993, a Report from the DCE highlights the necessity to protect sensitive personal information. The DCE considered this imperative once more in a 1996 Report on biobanks, and acknowledged that specific and broad consent both raised different difficulties, as the civil right to privacy should be measured against researchers' need for knowledge. Role of the groups was to prepare suggestions for future biobank legislation, which occurred in Oct 96.
Finland	The general public is keen on participating to genetic research and considers medical genetics very positively. Genetic researchers have inspired the public with hope for and willingness to participate in national genetic banking. The whole development of such banking, while popular, has remained in the hands of genetic researchers and experts, with little involvement, exchange or "co-production" of knowledge from associations and lay public (Tupalesa, 2007)	No specific regulation on genetic testing. Genetic counselling is not required by law. No legislation for quality assurance or medical uses. No general quality assessment of laboratories. Public authorities, however, organize specific supervision and quality control, as for Huntington's Disease. 1998 Memorandum from the Working Group on Genetic Screening (Ministry of Social Affairs) recommended improvements in the assessment of quality assurance, monitoring, counselling and use of genetic screening. In response, the 1998 Opinion from National Advisory Board on Healthcare Ethics (ETENE) called for more public information and considered only genes for	**Insurance:** Health Insurance use of genetic information: No legislation, but an agreement with the insurance industry. **Employment: June 2001 specific law on Data Protection in Working Life: an employer cannot require a genetic examination or enquire whether an employee has undergone such a test (section 7&8), while the employer has the right to consult the data of an employee's state of health under certain specified circumstances and with the employee's consent.**	No specific legislation on the collection, storage, transmission or analysis of personal genetic information for research purposes or public health. Since 1999 Medical Research Act, any medical research within hospital must be assessed by a local ethics committee. Consent and human dignity are of utmost importance. Open or wide consent is not possible, under the Act. The Genome Information Center, still in its beginning, coordinates information while aiming at marketing knowledge for national healthcare funding. Most influential in its creation were the 2005 report from the National Technology Agency

		treatable diseases should be screened in the first place - a position reflecting the intense ethical dilemmas at that time, as technical progress started with ability to forecast untreatable diseases.		(TEKES) on the possible use of population data and a 2003 Report from the Academy of Finland The Information Center stems from 2003 parliamentary discussion (Committee for the Future) and efficacious calls from scientists to support the development of a population-wide gene bank monitoring Finnish-specific mutations.
Norway	Scarce implication from the public on genetic testing and biobanks. Administration and medical/research professionals are the main actors in the regulation process and debates.	Dec. 2003 Act revising the Aug. 1994 Act relating to the application of biotechnology in human medicine stipulates provisions for genetic testing. Genetic counselling and written consent is mandatory only for healthy individuals taking a carrier or predictive test. "Postnatal genetic testing" shall only be carried out for medical or research purposes, for a diagnostic or therapeutic objective. 2003 Law anticipates that the King may eventually make exceptions for written consent and genetic counselling for the use of pharmacogenetic tests. Since Aug. 94, genetic testing can only take place in institutions approved by the Board of Health and within hospitals. Genetic tests must obtain approval from the Ministry of Health, through the Biotechnology Advisory Board. Since 1994 Law, medical professionals may contact an individual's relatives if they are at risk and if the individual does not wish to inform them. Written consent from the individual is mandatory.	Dec 2003 Law: "outside the health service", "it is prohibited to request, receive, be in possession of or use information" obtained through predictive or carrier testing, as well as obtaining such information from systematic surveys of hereditary disease within a family (insurance "family status" forms). It is also prohibited to ask whether a genetic test or a family survey has been performed.	Specific legislation on biobanks: Feb. 2003 Law on biobanks is aimed at collecting, storing, handling, destroying in an "ethical manner" the materials contained in biobanks. Genetic biobank programs need approval from Regional Ethics Committees (REK) and Ministry of Health and Care Services. Since the 2003 Law, researchers from the Functional Genomic research platform have expressed in the media their opposition to the "bureaucratic" situation caused by the law. They claim it is unethical to hinder good medical research which causes no stress to participants. Norway Research Council funds Biobanks for Health in Norway (BioHealth), a national network of population-based health biobank studies.
Sweden	Trust in medical professionals and researchers is high. Virulent opposition from professionals has been observed when a hospital in Vâsterbotten county granted a private company (Uman Genomics) with exclusive rights to its samples and health information collected for a past study on heart disease. The difficulties encountered by UmanGenomics did not lead to its public disapproval. Controversy remained within the medical and research community.	No specific regulation of quality assurance or on use of genetic information in health care. Genetic counselling is not required by law. Since 1994, the Swedish Gene Technology Advisory Board provides recommendations on the ethical use and development of biotechnology in all sectors. The National Board of Health and Welfare (Ministry of Health and Social Affairs)I keeps a database on rare disease available on the internet, together with specific provisions and	1996 Memorandum by the Ministry of Social Affairs prohibits requesting and using "genetic information about an individual's susceptibility to a certain disease, which cannot be detected in any other way by any party other than that for which the information was obtained." Genetic information includes family history; pharmacogenetic tests could also be considered addressed by this memorandum. No legislation or private regulation,	Dec. 2002 Act on biobanks in healthcare applies to the public and private sectors, and to previously obtained samples as well. Samples which do not originate from the healthcare sector, such as from pharmaceutical or biotechnology companies and research institutions disconnected from healthcare, are not covered by the legislation. Provisions do not apply when samples are anonymous. National Board on Health and Welfare subsequently issued recommendations.

		guidance. The Swedish Society for Human Genetics keeps a database of genetic laboratories for public consultation. Nordic education program for genetic counsellors started at the turn of the century.	however, on the requirement of genetic data by employers. Since the 1996 Moratorium, the Association of Swedish Insurers issued a statement on Jan. 1998: insurers "will not inquire about results from genetic testing or take into consideration such results when assessing risk below SEK 250.000"	Dec. 2003 revision of the Act on Ethics Review of Research Involving humans: research using samples requires approval from the Boards for Ethics Review. 1991 Act concerning the use of gene technology in medical screening: study of DNA requires specific authorization when it is part of a screening program. The aim must be clear and medically justified, and information should be safeguarded. Written consent is a prerequisite. Other laws, including the Act on bioethics in research and the Act on the registration of personal data, provide a consistent ethical framework for research in biotechnology.
USA	No large-scale public debate on biobanks, while genetic testing in prenatal or clinical settings have been major mediatic issues. Disease advocacy groups (Genetic Alliance), cancer associations, and more general consortia (Genetics and Public Policy Center, Public Citizen's Health Research Group,...) have been actively networking for the promotion of more reliable and affordable tests respecting the autonomy of the patient. Insurance use of genetic information has been of great concern for the American public since the mid-1980s availability of tests for rare diseases. Most of all, however, public controversy expanded after 1994, when tests linked with familial cancer became available. The American Civil Liberties Union have considered issues of genetic privacy, including in the insurance and employment fields, and joined pressure groups in support of federal legislation.	No federal regulation specifically on the use of genetic tests for medical purposes. - Laboratories are certified under the Clinical Laboratory Improvement Amendments (CLIA) and inspected by the Health Care Financing Administration (HCFA), according to quality assurance criteria. CLIA does not informed consent, clinical validity and utility of tests, or genetic counselling provisions. - The FDA is responsible for pre-market approval for genetic tests sold as kits to multiple laboratories, thus considering the effective performance of a test. FDA, however, has chosen not to oversee "in-house" tests developed by laboratories for their own use. Molecular genetic testing is mostly conducted in private clinics. Ethical and deontological aspects are addressed through professional societies Guidelines. The American College of Medical Genetics constitute a national and international reference. The ELSI program (National Institutes of Health) also provides guidance on the use and implication of genetic information. SACGT (Secretary's Advisory Committee on Genetic Testing) 2000 statement on genetic testing highlights the necessity of prior informed consent and education of the public and healthcare providers. Genetic counseling should be mandatory for predictive tests with little or no treatment available. The analytical validity,	**over the counter:** FDA prohibits direct marketing of "in-house" tests to consumers. Genetic and non-genetic kits approved for direct marketing are listed on the FDA weblist. **Insurance and employment:** Associations and most medical societies, including the American Medical Association, have been very much mobilized, calling through the media for a federal ban against genetic discrimination. Non-Discrimination Bills have never been adopted by Congress. State regulations are a patchwork, insufficient to ensure patients are not deterred from taking a useful genetic test. Folowing an Apr. 2000 letter from the ACGT, Government Guidelines on the 1996 Health Accountability and Accountability Act (1996) state that genetic information is banned from group insurance policies. **Employment** Since Feb. 2000 Executive Order signed by President Clinton, federal agencies are prohibited from requesting and using genetic information in recruitment and Human Resources services. SACGT response to the Executive Order	No federal specific provisions for genetic research. Very diverse State laws on genetic privacy. The Office for Protection from Research Risks protects human research subjects in DHHS-funded research. So does FDA in research trials aimed at the elaboration of devices, drugs or biologics development - except "in-house" tests. Experimental protocols are reviewed by Institutional Review Board (IRB), balancing benefits and risks and ensuring informed consent is provided.

		clinical utility and social consequences of the tests should be assessed. The latter issues were already considered by the 1997 Report of the US Task Force on Genetic Testing promoting safe and effective genetic testing. Public and professional information and Education programs are in place, including with the NIH and the National Coalition for Health Professional Education in Genetics.	called for a general ban on genetic testing in all workplaces. Office of Technology (OTA) 1983 and 1990 Reports: genetic testing can be useful health-monitoring tool its use for conditions which are not employment-related is not appropriate. Screening for susceptibility to occupational illness is more problematic, as employers' and employees' rights to autonomy conflict. In all cases, susceptible workers might decide, as part of their autonomy, to continue risking their own health.	
Canada	No large-scale public debate on biobanks, or on the national CARTaGENE biobank. Genetic testing in prenatal or clinical settings have raised public support. No effective involvement from the public and associations on the regulation of genetic information and testing. Authorities and commissions such as the Canadian Biotechnology Advisory Committee and the Privacy Commission of Canada have expressed concerns for privacy issues, and medical professionals from public institutions have shaped genetic testing practice.	No specific law on genetic testing. Most regulations come from professional guidelines, such as from the Canadian College of Medical Geneticists (CCMG) on specific aspects such as conducting genetic testing on children and minors, proper prenatal testing, and testing for different conditions including cystic fibrosis. The American College of Medical Genetics also is an influential institution on good genetic practices in Canada. In 2001, Health Canada commissioned a Working Group on Genetic Testing for Late-onset Diseases. Mostly considers issues of availability and quality assurance of tests., and monitors the use of genetic testing for late-onset diseases in Canada"	**over the counter:** Genetic tests marketed as kits require pre-market approval by Health Canada. In 2002, Ontario Government recommended federal standards for approval, review and monitoring of such tests. Direct to consumer advertising is illegal in Canada, but US broadcast media and the internet is of no help. **Insurance and Employment:** Nov. 2002 Report from the Information Access Commission in Quebec considers Government should elaborate regulations addressing specifically employement and insurance use of medical information, and to legally prohibit them from using or requiring genetic tests and information. Exceptions, however, could be useful for employment situations involving specific risks to health or security, as well as for very high-value insurance policies. June 1995, Privacy Commissioner of Canada, report on Genetic Testing and Privace raised issues of information misuse and genetic discrimination.	No specific legislation on biobanks, but regulation through decrees, guidelines and recommendations. Feb.2003 Recommendation on genetic information banks from Quebec's Ethics in Science and Technology Commission. Recommend improved protection of participants, better communication between Research Ethics Committees and clarification of their role. Sept 2003 Report from the Council of Health and Welfare highlights the necessity to protect participants. Tri-Council Policy Statement (TPS). Since 2002 revision, one chapter on biobanks provides general ethical requirements for researchers funded by the three councils such as informed consent, right of access to results of research, access by third parties dependant upon individual consent, family information to be coded, access to genetic counseling when appropriate. Controversial aspects are acknowledged and Research Ethics Committees are left to assess each application individually. Nov. 2002 Report from Quebec Information Access Commission calls for government to increase transparency in the management of samples and information. Public education and information shoud be developed. Consent from the person or from an authoritative committee should be mandatory for every new use.

				Population genomic project: CARTaGENE project (Genome Canada & Genome Quebec). Its main regulatory text is in the Jan. 2003 Directing Principles established by the Applied Medical Genetics Network.
China	No public debate on the use of genetic information. Deep involvement from Government into medical genetic research. Researchers worry about "colonial science" from foreign research institutions, with no benefit-sharing in terms of results or training. Since 1998, such concern is a key driver in the regulation of genetic data.	Genetic services are mostly concerned with consumerist attitudes towards genetic testing as useful tools for reproductive choices concerning disability or sex selection. Genetic services lack funding and expertise and cannot cope with the large number of people with genetic conditions.	No legal or professional requirements have been issued for public information.	Genetic research has been given a new impulse since the launch of a Chinese Human Genome Project in 1994. Provincial health departments assess the ethics and safety of projects, with the help of local ethics committees when they do exist. Collaboration with foreign scientific organizations pushed the Government in the 1990s to issue the first law on the protection of human subjects in research, with advice from the Ethics Advisosry committtee to the Ministry of Health (MOH). Bioethicists from this committee such as Q. Renzong have reported difficulties in obtaining written consent from people willing to participate, due to Chinese historical political past. Since the June 1998 Interim Measures for the Administration of Human Genetic Resources, the Human Genetic Resource Administration of China is responsible for overseeing the collection and export of human genetic data.. The 1998 decree came from concerns about the absence of benefit-sharing from exported samples. Such concerns also explain the 2003 decision (Ministry of Health and State Administration of Quality Supervision, Inspection and Quarantine) that any exports of genetic data would need specific national permit application as a prerequisite.
India	No public debate on the use of genetic information or biobanks. The Media mostly focus on sex selection. Regulation happens through practice. Broad guidelines from the scientific and medical community serve as large frameworks. In 2004, ethical bodies and research council had complained that US and European research on Indian population happened	No specific regulation on the use of genetic testing. Clinical genetic services consider the ICMR 2000 Guidelines for biomedical research can be used as a soft regulatory framework in clinical settings. Clinical institutions have no ethics committee. 2002, National Bioethics Committee (NBC) (Ministry of Science and Technology, Department of Biotechnology) Report on the "Ethical Policies on the Human Genome, Genetic Research and	No legal provisions on non-medical uses of genetic testing. Detrimental uses are broadly considered in the 2002 NBC Guidelines: "Discrimination of any kind on the basis of genetic characteristics or information shall be prohibited.", as the "principle of justice" implies that "there should be no discrimination against individuals (born or unborn including embryo) or groups. No harm should be done and benefits should	2002 NBC Report details ethical principles for genetic research and biobanks, including consent and dissemination of research results. Written informed consent must be renewed when researchers wish to analyse samples obtained during clinical testing. Any new research needs to be approved by local ethics committees and competent authorities. The Indian Council of Medical Research (ICMR, national body funded by the Ministry of Health and Family Welfare) provides guidance for the

	without effective sharing of benefits with researchers or population.	Services". Focuses on research but also proposes guidelines for clinical genetic services, highlighting principles of autonomy, privacy, justice and equity. Up-to-date education and training - of laboratory professionals is provided by professional organizations - of medical professionals is provided by professional organizations and the Medical Council of India (Ministry of Health and Family Welfare national body established under the MC Act 1956) No official framework for approving use of tests in clinical settings or assessing new genetic tests. A list of genetic laboratories, clinics and public centers is provided through the internet.	be maximized." The guidelines also consider education against prejudices should be developed.	development and validation of new research, through a task force on human genetics and the Genetic Research Center (GRC), a permanent national research center managed by ICMR. These statements have been written in harmony with the ICMR 2000 Guidelines. ICMR 2000 "Ethical Guidelines for Biomedical Research on Human Subjects", including a "Statement of Specific Principles for Human Genetic Research". Respect for autonomy and personality are of major concern, through addressing privacy and confidentiality issues within families, "psychosocial" risks involved in genetic testing, the need for counselling, informed consent, and sex selection, which "denigrates the fundamental personhood of those yet to be born"
Japan	General public support for medical biotechnology is high. The participation of the public and associations, however, rather low, as most regulation derives from medical professional guidelines. Medical professional associations call for governmental regulation to assess laboratory procedures and to evaluate the validity and utility of tests.	No public regulation of clinical genetic diagnosis, but guidelines from learned societies, which are mandatory for all professional members of these societies. Nov. 2000 "Guidelines for Genetic Testing" by the Japan Society of Human Genetics (JSHG) Council Committee of Ethics, a revision of two 1995 guidelines on genetic counselling and genetic testing. This professional regulation goes far into detail and includes provisions for non-directive genetic counselling, obtention of informed consent, ensuring both rights to know and not to know. Genetic information should remain confidential, but individuals should be encouraged to inform their relatives of single-gene and multiple-gene disorders. Disclosing information to relatives against a person's wish is however acceptable where it would reduce their possible suffering and provided an ethics committee has agreed. In March 2001, eight learned societies, including JSHG, have issued common guidelines for clinical genetic testing. The 2003 update calls for public regulation assessing quality, accuracy, validity and utility of genetic testing procedures. Education of Geneticists and genetic counsellors should be promoted. Government-funded programs should	**over the counter:** Japanese medical genetics community worries about expanding number of Japanese companies offering genetic testing through the internet. Since 2000, professional guidelines have forbidden such advertisement, with little effectiveness. In 2000, the BioIndustry Association Report to Government asked for a general ban on genetic tests that are no requested by medical doctors and when result is not given only by these doctors to the patient. No initiative from government, however. **Non-medical uses:** Nov. 2000 JSHG Guidelines: genetic information and samples should not be used for purposes other than those intended by the individual.	Public authorities have considered the use of genetic testing in research settings, through three Ministry Guidelines, including provisions on written informed consent obtention, samples management, individual privacy: 1) April 200O, in conjunction with the "Millenium Project", the Ministry of Health, Labour and Welfare Taskforce on the "review and critical study of advanced medical technology" issues “Guidelines for Human Gene Research and Its Related Ethical Issues" 2) June 2000, the Bioethics Committee of the Council for Science and Technology (Cabinet office) issues "Fundamental Principles of Research on the Human Genome". Principles are the same as JSHG guidelines for genetic testing. 3) March 2001, inspired from the June 2000 principles, three Ministries issue "Guidelines for Research on the Human Genome and Genes", known as the common "Three Ministry Guidelines" (Ministry of Education, Culture, Sports, Science and Technology (MEXT); Health, Labour and Welfare; Economy, Trade and Industry).

		move forward. The Japanese Society of Human Genetics (JSHG) and Japanese Society for Genetic Counselling (JSGC) have developed a system of certitification for "genetic counsellors", medical doctors specifically trained. There are no public laboratory standards regarding specifically genetic testing. However, following the 2003 common initiative, the Japan Registered Clinical Laboratories Association have issued “Ethical Principles on Entrusted Genetic Testing" in 2001 Universities' websites inform the public of tests available in Japan and their location.		Professional societies have also issued more specific guidelines, such as, for the example, the 2000 “Guidelines for Genetic Testing and Research on Familial Tumours and Their Clinical Applications” by The Japanese Society for Familial Tumour.

	Social context	GM food regulation	Safety of contained & open-field use	Coexistence provisions
France	Many environmentalists and local elect officials express concerns against GM crops development. They frequently obtain support from public research scientists through articles, petitions and specific risk assessments - such as, for instance, the controversial CRIIGEN research in 2007 on MON863 Maize. Some large farm industries have supported GM development, for economic reasons. Many other, less industrialized farmers, often affiliated to the French and EU Peasant Confederations. identify GM industry as a threat to their economic independence, to democratic consumers choice and to typical national and local "terroir" food products. Mediatic prosecutions were useful in their winning public sympathy. In 2004, 1000 mayors signed petitions claiming GM-free status of their municipality. In Feb. 2002, a debate in public (though not a public debate) was organized by the Economic and Social Council (CEC) on open-field trials , with contrasted views from scientists (CGB), farmers (FNSEA), researchers (INRA), Biovigilance Committee and AFSSA. Feedback from the youth panel highlighted the difficulty to understand issues amidst *ad hominem* arguments. As conclusions were uncertain, they could not play their intended advisory role to the government. Following Nov.1997 approval of GM maize crops, the Government and the Parliamentary Commission on Technological Choice Assessment organized a Citizens' Conference in June 1998. Many members of the lay panel supported GM plant development with authorizations on a case-by-case basis. At the same time, the Conference was an occasion for NGOs and the Green Party to raise mediatic focus on GM crops, and to obtain high popular approval for a moratorium. The Conference enabled also the State-based risk expertise to gain public legitimacy.	EU regulations 1829/2003 and 1830/2003 on safety, labelling and traceability are the main regulatory texts. AFSSA is responsible for food safety tests in France, as an experts institution exchanging information with the European Food Safety Authority (EFSA) 2002 AFSSA advice, in response to a 1999 Ministry of Health, Agriculture and Consumption request, insists toxicological risks of GM food should be completely evaluated, though the principle of substantial equivalence might help in this assessment.	Contained use for research purposes: Since Governmental Decree of May 1989 and the Law of July 1992, the Genetic Engineering Commission (CGG) evaluates risks and proposes measures of containment. Provides advice to administrative authorities for the case-by-case assessment of applications for authorization. The Commission assesses applications on a case-by-case basis, on government request. Appointed by Ministries of Research, Environment, Health , Agriculture and others. Members include representatives from the agricultural industry, a consumers association, an environmentalist association, the GMO industry, as well as a representative for Parliament, a lawyer and eleven scientific experts. Open-field release: The Biomolecular Engineering Commission (CGB) was created by a 1986 Governmental Decree, implemented in the July 1992 Law. Research cannot be approved by the Ministries of Environment and Agriculture without CGB's positive opinion. Since 2003, the public is invited to express its views on each open-field trial application, through an open e-mail system. Most answers from interested citizens do not consider specific risk issues and express too general negative views to influence CGB decision. Since 1999 Law, a Biowatch Committee (comité de biovigilance) provides advice to the Agricultural and Environment Ministers has been created to monitor and control the dissemination of GM organisms from open-field crops.	Feb 2005, 5 French regions sign the 25 European regions chart on GMO coexistence with organic and traditional cultures. In March 2007, in order to settle conflict with EU Court of Justice, two governmental decrees implementing 2001/18/EC Directive on environmental release of GMOs. They require notification of culture, leading to national register with information on parcels' surface and location. Precise location, however, remains confidential. Ministry of Agriculture's communication to the press concerning this Decree added that Gm maize growers must inform their neighbours of their culture and keep a buffer distance of 50 meters. These requirements, however, are an anticipation of the requirements of the Law, still to be adopted in Parliament though voted in March 2006 by the Senate. The Maize Grower Association (AGPM) expressed favourable views on GM maize since 1995. Its current very much involved in coexistence regulations, calling buffer zones of less than 50 meters. and opposing to the idea that neighbours should be individually informed.

			Only commercial-led culture is on MON810 Maize (EU authorization in 1998, and French Governmental consent on the same year)	
Germany	Strong public resistance against GMOs, viewed in great part as a threat to "nature" - German forests constitute a popular image of nature. NGOs have been active since the beginning of the 1980s - much earlier than in most EU countries. Intense opposition to factory farming (*Agrarfabriken*), including biotech farming, from promoters of alternative agriculture. GM field destructions led Ingenta to move its open-field trials to the USA. Throughout the 1990s, the polarization of the conflict did not evolve. Following 2001, impulsed by a Red-Green government coalition, debate became more rational. The 2005 Act has been praised by environmentalists (Greenpeace) and criticized by the farmers Union (DBV), researchers (Max Planck Institute) and industry (BIO Mitteldeutschland GmBH). DBV Statement expresses the view that the Law will shackle research and development necessary "to assess in an objective way this green genetic technology".They assert that planting GM crops has thus become an economic risk. As research is a constitutional right in Germany, the State of Saxony-Anhalt has filed a complaint on the constitutionality of the Act.	EU regulations 1829/2003 and 1830/2003 on safety, labelling and traceability are the main regulatory texts. Together with EFSA, the Federal Institute for Risk Assessment (BfR) assesses food and feed risk, mainly from applying the principle of substantial equivalence. Provides opinion to BVL, who is also responsible for labelling.	The Central Commission for Biological Safety (ZKBS, Robert Koch Institute) has been established in 1978 to issue proper procedures on dealing with in-vitro recombinant nucleic acids. With the 1990 Gene Technology Act, ZKBS is the main advisory body to the Government concerning genetic research and manipulation. Members represent trade-unions, occupational health bodies, the industry, research institutions, environmental protection groups. The Feb. 2004 revision of the 1990 Gene Technology Act implements the EU Directive on release of GM organisms into the environment. According to the Act, the Federal Office of Consumer Protection and Food Safety (BVL) is the competent authority in authorizing open-field trials, marketing and contained use, and receives advice from ZKBS. (The Aug. 2000 revision of the Act had addressed implements the EU Directive on contained use of GM organisms.	In 2001, following the BSE crisis, the Minister of Agriculture (Green Party) initiated the *Agrarwende*, promoting sustainable agriculture, consumers interest and informed choices. "Peaceful coexistence" was at stake. Since Jan 2005 (voted Nov 2004) Gene Technology Act on the cultivation of GM plants, all new GM crops should be noted in a public register by BVL. Only interested parties, however, such as possible neighbouring farmers, can have access to specific information on the location of GM crops. March 2007 Amendment to the Gene Technology Act: GM Maize crops must respect a 150m distance from conventional crops. The 2005 Act had considered species-specific distances, including 20 meters for maize, following test plantings, in order to remain below 0,9% contamination. The 2007 revision of the Act was hotly debated. Once adopted in Lower House (Bundestag), rejected by the opposition parties of the Upper House (Bundesrat), and voted by a short majority at the second and decisive vote of the Bundestag. Farmers' liability has evolved: 1) Strict liability, in the 2005 Act: Farmers growing GM plants are economically liable for the contamination of non-GM crops. Compliance with eventual guidelines is not taken into account. Contamination in general is considered as a decline in the value of crops, no figure being given by contrast to the 0,9% threshold in EU coexistence guidelines. 2) March 2007 Amendment announces Guidelines of Good Farming Practice. Only non-compliance with these guidelines could imply farmers' economic liability. The Act also establishes the common liability of GM farmers in a same region, hence their common participation to a mutual fund.
Italy	No effective political will to promote GM food and crops. Political opposition to GM development does	EU regulations 1829/2003 and 1830/2003 on safety, labelling	Following Feb. 1992 Law, the Italian National Committee for Biosafety and	Since the early 1990s, the promotion of local agriculture by a network of Green parliamentarians

	not only come from the Green Party, as it is mostly a transversal issue. Popular opposition to GM development. Opponents mostly aim at protecting national and local traditional food (*prodotti tipici).* Green parliamentary elects adhere to this protectionist frame. 15 out of 20 political regions have banned GM crops. Tuscany coordinates the European Network of GMO-free Regions. Opposition from farmers is strong, except from FuturAgra, an association regrouping more industrialized farmers from the North of Italy. 15 Nov 2000, Pope John-Paul II expressed the view that using GM crops to increase yield productivity goes against God's will; one should "resist the temptation of high productivity and profit that work to the detriment of the respect of nature", because "when [farmers] forget this basic principle and become tyrants of the earth rather than its custodians (...) sooner or later the earth rebels."	and traceability are the main regulatory texts. 2003 Law implementing the EU Deliberate Release Directive 2001/18: GM crops must be kept compatible 'with the need to safeguard the agro-biodiversity of agricultural systems and the agricultural production chain, with particular reference to typical [local], biological, and high quality products'. 2005 governmental decree raises concerns that open-field trials impacts negatively on public confidence for local food products. National protectionist strategy on Italian and local food against GM food, is accepted by all parties.	Biotechnology (CNBB) is created, to implement both EU Directives on contained uses ('90/211/EEC) and deliberate release (90/220/EEC). The Committee does not only advise the Presidency of the Council of Ministers on risk assessments of GM contained use and deliberate release. It also participates to the general coordination and harmonization of activities in the biotechnological field and may deliver advice and recommendations on national laws and EU regulations. Under the committee, a National Monitor for Biosafety and Biotechnology maps the location of biotechnology structures and activities, and creates a database on biotechnology.	and regional elects has led to consider GM development may constitute a threat. In March 2006, the Italian Constitutional Court ruled that the Coexistence Law voted by Parliament in Jan. 2005 was unconstitutional: Government had set a very general framework and considered no GM crop cultivation should be authorized in regions which would have not established their own coexistence rules. The Court considered that the law was against the region's autonomy to decide alone on these matters. The Coexistence Law was aimed at replacing the Italian 2000 ban on GM crops, maintaining the possibility for regions to stay GM-free. Indirectly, however, the Court's ruling should drive all regions to implement coexistence rules following EU Recommendation 2003/556/EC. Until then, theoretically, farmers would have the right to sow GM seeds. FuturAgra has been pushing for the establishment of effective coexistence policies. Since 1994 Law, the Biosafety Clearing House (BCH) provides the general public with internet-based information on GM crops and contained use. Location of the crops, however, is not available.
UK	Government has proactively supported public debate and information. This included initiatives to assess public acceptability of GM, such as the 2003 public debate "GM Nation" (AEBC) and a Citizen's Jury on the question: « Should GM food be available in the UK? » (FSA). In the jury, 9 out of 15 citizens considered GM food should be available, technology developed and education promoted, and expressed confidence in safety measures and labelling provisions. Perhaps even more than in other EU countries, the 1996 "mad cow" crisis inspired important concerns for the safety of food products. Opposition against large factory farming and industrialized agriculture found arguments in this crisis, upon which it still relies. UK farmers have been expressing ambivalence since the early 1990s. The National Farmer's Union immediate support, based on economic grounds has been gradually more limited.	EU regulations 1829/2003 and 1830/2003 on safety, labelling and traceability are the main regulatory binding texts. Food Standards Agency (FSA, created in Apr.2001) works with EFSA in ensuring food is safe and respects consumers choice, openness and transparency through labelling and traceability. FSA issues Voluntary guidelines on notification for approval. Case by case application review imply detailed consideration of potential for toxic, nutritional and allergenic effects. FSA Consumer Committee also consistently monitors public concerns and attitudes. Two representatives from consumer	Contained uses of genetically modified micro-organisms, plants and animals within laboratories and factories are regulated by the Genetically Modified Organisms (Contained Use) Regulations 2000 and its 2002 and 2005 amendments.. All premises must be notified to the Health and Safety Executive (HSE). Notification and application for authorization are mandatory for activities, depending on their risk level. A public register of GM premises and of certain activities is maintained. Deliberate release for research and marketing purposes are subject to Part VI of the Environment Protection Act 1990, and the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended in 1995 and 1997) open-field cultivation of GM seeds fall in the remit of the DEFRA (Department of	No specific legislative framework. Defra is still in the elaboration process of specific coexistence regulations. The Defra proposals for consultation stem from work it had requested at the NIAB (National Institute of Agricultural Botany) on different threshold levels and separation distances. March 2004 Environment Secretary's statement to the House of Commons: Farmers growing GM crops should comply with a code of practice to ensure that unwanted GM presence in non-GM crops does not exceed the 0.9% EU labelling threshold; options for providing redress should be available to non-GM farmers who, through no fault of their own, suffer financially because a GM presence in a non-GM crop exceeds the 0.9% labelling threshold. These positions were well received by the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), the main UK farm supply chain developing in GM crops.

	In 2004, 44 areas in England and 35 councils in Whales had approved a GM-free resolution. Nuffield Council 2003 statement on GM crops in developing countries: "The moral imperative for making GM crops readily and economically available (…) is compelling", as GM technologies match agricultural need specific to these countries. Biotechnology could be part of the solution against hunger and malnutrition in developing countries.	associations and one ethicist provide input on issues of acceptability. Until 2003 EU Directive on labelling, Greenpeace shopper's guides on GM and GM-free food were published, as part of a campaign promoting consumers freedom of choice.	Environment, Food and Rural Affairs). This governmental consent for release implies low risk to human health and the environment. Advice on approval and risk management is provided by the ACRE (Advisory Committee on Releases to the Environment) on each application. The Agricultural Biotechnology Council unites the agri-biotech industry in a commitment to increase public interest and confidence. Its first report was issued in Feb. 2002. The Agriculture and Environment Biotechnology Commission (AEBC) had been set up in June 2000 to provide independent strategic advice on the developments of biotechnology. It had been wound up in April 2005.	SCIMAC is involved in GM crops stewardship since 1998 and published guidelines in 1999. Controversy remains on whether to lower the threshold below 0,9%: SCIMAC would not agree to bear the cost of marketing standards decided by non-GM farmers. By contrast, associations such as FOE oppose to the figures and technical evaluations of GM farmers associations, as they consider GM contamination should not be higher than 0,1%. This notion of general "contamination" was already expressed in mediatic declarations by the Soil Association in 1998. Since Jul.2006 Defra is exploring whether a threshold below 0,9% is necessary and consulting on options for compensation.
Denmark	NGOs have questioned GMOs since the mid-1980s - earlier than in most EU countries. Sustainable agriculture was the main focus, implying concerns about herbicide-resistant crops. In 1987, NGOs obtained funds to organize a Consensus Conference on gene technology and agriculture. Trade-unions also quickly organized information and conferences on GM crops in relation to monoculture and sustainable agriculture. Danish Board of Technology funded Consensus Conferences in 1992 and March 1999 on GM food, crops and animals. In 1992, citizens insisted the "farmer's privilege" to keep his own seed for the next crop should be respected, and called for involving more lay participation in regulation. In 1999, citizens have fallen short of calling for a moratorium, but advocated strict regulation, control and labelling . Sept. 2005, Minister for the Environment request the Danish Council of Ethics to develop some reflection on " the concept of utility as seen in relation to genetic engineering research and application": "There is no requirement that demands an evaluation of the utility of the genetically modified organism, yet this plays a large part in the public debate on the use of genetic engineering." "Much has been said and written about risks, but far less about the more intangible topics that mean so much in the public	EU regulations 1829/2003 and 1830/2003 on safety, labelling and traceability are the main regulatory texts. These aspects are overseen by the Veterinary and Food Association (Ministry of Family and Consumer Affairs) and the Minister of Food, Agriculture and Fisheries. 2003 Report from a Task Force of the Danish Board of Technology on genetically modified crops in developing countries. GM crops represent one of the technologies that may contribute to the problem of food supply. As genetically modified crops are already being disseminated, the report highlights initiatives which good strengthen the ability of the poorest populations to obtain most benefits from GM crops. Danish aid through supporting GM crops does not conflict with Danish development aid policy.	1986 Biotechnology Act nearly banned the environmental release of GMOs while emphasizing "sustainable development". Since the 1980s, environmental policy are implemented to limit agrochemical use in agriculture, so that ground water could be used as drinking water. Under NGO pressure, this has led the Environment Ministry to finally adopt broad risk-assessment criteria for open-field GM crops. 2002 Danish Law on Environment and Gene Technology: the Minister of the Environment must hear relevant authorities, organizations and citizen when approval for GM release into the environment is sought for.	Denmark has issued a specific Law on coexistence, in force since Dec.2005, following 2003 Report by an expert group combining experts, administration and stakeholders. April 2005 Ministerial orders on the compensation with neighbouring farmers in case of economic loss due to GMO admixture has raised great controversy, both nationally and internationally. Guidelines for stakeholders and inspectors have been issued. Public register of GM crops with location is being kept on the internet. Cultivation distance depend on each GM material, and must be calculated so that no more than 0,5% GM seed should be found in neighbouring fields. GM farmers must inform their neighbours of their cultures. Farmers are liable for economic losses when they do not comply with the rules and GM seeds exceed 0,9% in a field exceeding 1,5 times the minimum cultivation distance, provided GM material is the same. However, organic farmers are guaranteed compensation if they suffer a loss because of GM seeds in their organic seed. Compensation is financed by the GM farmers' fund created since 2005 Law.

	debate". DCE report is in progress.			
Finland	The public is accepting the idea of GM crops development quite positively. High latitude climate, however, means very few GM crops varieties could develop. Political elites have express positive opinion on GM crops and food.	The Ministry of Social Affairs and Health is responsible for issues of genetic technology that are related to human health, including food. The Ministry of Trade and Industry steers the control of foodstuffs, GM foods included, under the Food Act. The National Food Agency and Novel Food Board provide experts advice to these administrations.	Since the 1995 Gene Technology Act, the Board for Gene Technology advises the Ministry of the Environment, responsible for fighting and preventing environmental damages, and the Ministry of Health, responsible for potential damages to human health. Both contained uses, thus, are considered by this Board, which must also consider ethical issues.	Co-existence legislation is in preparation, administrative reflexions since 2002 and Expert Working Group recommendations in 2005. Interim report is available in Finnish. 2004 advisory Memorandum from the Advisory Board for Biotechnology discusses minimum separation distances. Legislation could imply compensation from GM-farmers and from State to a certain extent.
Norway	Lay panels at Consensus Conferences (1996 "Fast Salmon and Techno Burgers" and its 2000 follow-up) have highlighted scientific controversies and uncertainties and called for moratoriums on GM food products.. GM aid program in developing countries: The Norwegian Agency for Development Cooperation (NORAD), under the Norwegian Ministry of Foreign Affairs, is responsible for assisting developing countries in their efforts to better understand and regulate GM risk, and to better control GM imports and exports. NORAD believes GMOs can participate in the fight against malnutrition and hunger, if capacity building and regulatory advices are provided, and not only unregulated GM seeds. NORAD is very much involved in Zambia, since Zambia's Aug. 2002 decision to refuse blunt GM food aid from the USA.	Since 1999, it is legal to sell GM food, which must be authorized by government. The practical supervision of GM food is carried out by the Federation of Norwegian Food and Drink Industry and the National Veterinary Institute. March 2000 Law has eventually forbidden GM food with antibiotic-resistant genes.	Containment uses of GMOs is regulated by the April 1993 Gene Technology Act. Containment is administered by the Ministry of Health and Social Affairs and the National Institute of Public Health. Release into the environment: April 1993 Gene Technology Act. Under the responsibility of the Ministry of Environment and Directorate for Nature Management. **The Advisory Committee on Pesticides (ACP)** gives advice when approval is required under the pesticides legislation to apply a particular pesticide to a genetically modified pesticide-resistant crop.	On co-existence, legislation is in preparation since 2004. An official draft was expected mid-2007. Danish rules have been a positive sting and model since a 2004 report to the Norwegian Scientific Committee on Food Safety.
Sweden	Due to general consumer opposition, farmers started rejecting GM crops in the second half of the 1990s. Following the 2000-2001 active campaign from the Swedish Society for Nature Conservation (SSNC), farmers adopted a common moratorium on GM crops, of which the government was supportive, and eight local communities declared they were GM-free, on SSNC's proposals. In 2006, livestock farmers started abolishing the ban, partly because of the increasing price of GM-free soy beans. 2007 Report from the Swedish Institute for Food and Agricultural Economics (SLI, a government agency	EU regulations 1829/2003 and 1830/2003 on safety, labelling and traceability are the main regulatory texts.. The Food Administration is responsible for monitoring these issues.	No cultivation of GM crops to date. EU Directives have been implemented through the 2000 Genetically Modified Organisms (Contained Use) Ordinance and the 2002 Genetically Modified Organisms (Deliberate Release) Ordinance National Board of Agriculture establishes regulations, in accordance with recommendations from the Gene Technology Advisory Board, which was created in 1994 to advise on human and animal health issues and promote an ethically defensible and safe use of gene technology.	On co-existence, inspired by Danish rules and following EU 2003 recommendations, a draft cultivation legislation was in preparation at the National Board of Agriculture in 2007 (rules expected in 2008), following scientific assessment of gene flow and GM cultivation. Information and cultivation distance would therefore soon be legally addressed. Draft might state that GM seeds in neighbouring conventional fields should not exceed 0,2%.

	providing economic insights in agriculture, foods and fishing): cultivating GM crops would be economically profitable for Swedish farmers.		GTAB makes statements on applications for consent to develop and release GM plants. However, GM Forest Trees intented for timber production depend on the Board of Forestry.	
USA	As GM crops and GM food on the market have expanded rapidly since the mid-1990s, many farmers and consumers have accepted these products with no specific concerns. Public acceptability does not only stem from the consumers' unawareness that some food is GM. Trust in FDA regulation system, and governmental education programs on GM food have been influential on more informed citizens Some NGOs, networking on the "Campaign to Label Genetically Engineered Food", call for mandatory labelling. The centralized and administrative regulation, however, does not involve associations very much, as it considers most GMOs do not raise specific issues, and labelling are economically detrimental when safety issues are addressed.	There is no mandatory labelling provisions, for GM food presenting the same characteristics as its non-GM equivalent (principle of substantial equivalence), since a statement from the Department of Health issued in 1992. Companies must notify the FDA at least four months before they intend to bring new bioengineered food to market. During assessment, the scientific description of the product is published on the internet for review. Companies can also decide voluntarily to label their products, in accordance with FDA guidelines on how biotech-derived food and ingredients can be described: "genetically modified" is excluded, as it leads consumers to believe inner characteristics are different. "Genetically engineered" or "made through biotechnology" is deemed more adequate. In 2001, the FDA issued guidelines for industry on mandatory and voluntary labelling.	The EPA is responsible for regulating toxic substances under the Towic Substances Control Act (TSCA). Genetically engineered micro-organisms fall into the definition of TS and are regulated as such. Safety issues from the environmental release of GMOs in the USA triggered attention from the public and political elects since the end of the 1980s, as stated in a 1988 Report from the US Congress Office of Technology Assessment (OTA). Ecological risks of GM crops are evaluated by the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). EPA also regulates pesticides created through biotechnology, according to the Federal Insecticide, Fungicide and Rotendicide Act (FIFRA). Since Nov. 2004, open-field crops must comply with mandatory FDA safety assessment guidelines.	Since Nov. 2004 Farmers planting Bt GM corn (insect resistant are required to sign and implement every year an insect resistance management plan (IRM), including separation distances, to contribute to minimising the possibilities of target pests developing resistance to the Bt trait. Compliance with IRM could facilitate coexistence. If farmers are found to have failed to comply with the IRM for two consecutive years , they risk losing access to the technology in the third year. Seeds suppliers are required to inform farmers of the IRM and provide them with Technology and Crop Stewardship Guides. Biotechnology industry is responsible for compliance annual surveys However, critics have considered the Nov. 2004 FDA rules are too easy to comply with and make "contamination" too easy. Since 2002, organic growers and crops need USDA certification. Although its standards prohibit the use of GM technologies, the USDA considers the presence of GM residues is not an issue if the organic grower has taken reasonable steps to avoid contact with such product.
Canada	As in the United States, there is a *de facto* public acceptance of GM foods. Surveys tend to show that a majority of citizens would approve mandatory labelling. Reports, such as that the Royal Society Expert Panel in 2001, have highlighted the necessity for Canadian officials and administration to maintain a neutral	Canadian regulations are close to US regulations. All the more as NAFTA rules imply free-flow of products between the two countries. Prior notification of any "novel food" product is mandatory under	The CFIA carries out environmental assessments of plants with novel traits (PNTs) under the Seeds Act. CFIA is also involved in post-approval inspection. Royal Society 2001 Report called for funding research to monitor long-term effects of GM crops.	Organic growers within the National Standards for Organic Culture are provided with guidance on buffer zones between organic and GM crops. Organic association have also issued self-regulation guidelines. CropLife, representing the manufacturers, developers and distributors of GM crops, has issued a "Coexistence Best Management Practices Guide",

	stance in the public debate, and have also urged for more transparency in the regulatory process, including safety assessments.	the Food and Drugs Act. No specific mandatory labelling legislation is required for GE food. As with any food, however, labelling is mandatory when food presents allergens or safety risks, or when it has been significantly altered in its characteristics. Health Canada is responsible for conducting safety risk assessments and mandatory labelling when necessary. The Canadian Food Inspection Agency (CFIA) is responsible for voluntary labelling supervision, which had been recommended in an Aug. 2002 Interim Report of the Canadian Biotech Advisory Committee (CBAC) in the name of consumers' right to make informed choices. 2001 Royal Society Expert Panel Report: uncertainty in scientific assessment calls for a "precautionary approach", against a too simple application of the "highly controversial principle of substantial equivalence." Risk assessments should also be more transparent and peer-reviewed. Government's response: while the latter principle is "the most appropriate strategy for safety and nutritional assessment" of GM food, it should not become a "decision threshold": all food, whether GM or conventional, should be thoroughly assessed.		to help farmers maintain the viability of their chosen production system. Autonomy and freedom of trade are main principles. The guide aims at enabling farmers to choose the production system that best suits their needs without infringing on the ability of their neighbours to do the same. According to CropLife, coexistence is not a health and safety concern, as the GE products involved have been rigorously tested and approved.
Brazil	Despite past virulent opposition to GM crops from the Workers' Party (PT), the federal government actively supported GM technologies after Da Silva (PT) presidential election in 2002.	Biosafety Law March 2005, voted by a large majority in Congress, regulates many aspects of biotechnology, including the planting and marketing of GM	In 1998, following CNTBio authorization to grow five GM soya varieties in open-field, a federal lawsuit was filed by the consumer association IDEC, leading to a temporary court injonction against commercial release	Bollgard Cotton authorization in 2005 has been followed by many opposition from farmers anxious about crossing with conventional cotton. Coexistence provisions, however, have not yet been

	Deep governmental and political interest in GM biofuel production (Sugar Cane EST Genome Project (SUCEST, Sao Paulo State research agency) Environmental groups are very much concerned by such developments. April 2001, first Citizens' Jury in Fortaleza, organized by the charity ActionAid. The panel of farmers and urban consumers unanimously considered that GMOs cannot contribute to solving hunger in the world and Brazil, that there is insufficient safety evidence to authorize release, and that public regulation lacks caution, transparency and public participation. NGOs and political parties have filed judicial complaints in opposition to GM development, since 1997 Greenpeace Brazil's unsuccessful court action against GMO importation. Many small farmers oppose to GM cultivation and importation. In July 2000, farmers attacked a ship containing GM maize from Argentina. Impulse came from the Landless People's Movement (MST). Following July 2000 actions, GM-free campaigns gained public and media attention. Since 2002 most large soya bean farmers have moved to GM soya..	Organisms. Since Jul. 2000 Presidential Decree, authorizations all depend on Brazil's Biosafety Commission (CNTBio, created in 1997). Some officials, including the Minister of the Environment, have expressed regrets that other public bodies (Agriculture, Fishing, and Health) are leftwith only a very secondary role on GM regulation. All GM products must be labelled, including meat. How such requirement is implemented, however, is not clear (IFPRI, 2007) In 1997, Greenpeace filed an unsuccessful court action against the importation of GM food and seeds.	in Dec. 1998. In Aug. 1999, in a lawsuit filed by IDEC, IBAMA (Ministry of Environment) and the Worker's Parly (PT), a federal judge decision bans GM cultivation until environmental impact assessment is addressed. In 2003, PT-government, acknowledging illegal GM cultures were developing in the South since 2000, adopts a moderate position: authorizes the marketing of products sown from 2002-2003 crop (Provisional Measure 113), while introducing labelling and segregation requirements. Authorization re-enacted in 2004, though planting stay illegal. Oct 2003: State of Parana bans import, sale and planting of GMOs. Finally, in March 2005, following intense debate in all political and social arenas, the Biosafety Law gives full federal power s to CNTBio, with no external independent environmental assessments. Applications need 2/3 approval votes from the Commision.	set up.
China	Strong political support for biotechnology in general and GM crops in particular. On GM food, however, Government adopts protectionist decisions on traditional food. No major opposition has been expressed, apart from declarations by foreign associations such as Greenpeace.	Since June 200 1 Biosafety Law, all GM food is submitted to safety assessment procedures. Such regulations have been interpreted in terms of International Relations: China's policy on GM food has become less supportive, partly in order for its exportations not to be banned by European and other countries, and partly in order to maintain a protectionist national food policy (Rousu&Huffman, 2001). The 2002 administration's refusal against US-imported food with soybeans - except in cooking oil - can be interpreted from the same point of view. 2001 regulations set up a	June 2001, Biosafety Law applies to research, field trials, production, food processing, management, as well as import and export. As in most countries, the administration establishes 4 risk categories and assesses risk on a case-by-case basis. Open-field release needs Government approval. It is difficult, however, to oversee that GM are planted with the appropriate seeds and technical specifications:: land is vast, farmers are many, their pieces of land are small, and their average education and willingness to comply with administrative rules is not as high as in developed countries.	No legal requirements for coexistence. One might consider requirements would be as difficult to apply as other requirement on voluntary release of GM organisms into the environment and for the same reasons.

		mandatory labelling policy with O% tolerance. This has only been partially implemented (Ifpri, 2007)		
India	India was the first country in Asia to set up a biosafety regulation system. Following nation-wide controversy, Bt Cotton eventually raised a deep interest from farmers unions associated with industry. In Dec. 2002, was created the Indian Farmers and Industry Alliance. In 2005 was created the National Biotech Development Strategy (Ministry of Science and Technology), following 2004 Advice from the Ministry of Agriculture Taskforce promoting GMOs in agriculture, and highlighting food and health safety issues, protection of the environment, and trade and economic well-being. Government expressed protectionist concerns for national food such as Basmati rice, soybean and Darjeeling tea. Such concerns were voiced in 2004 by Task Force on application of biotechnology, which rejected any research in such plants.	Import, production, and selling of GM organisms need approval, on a case-by-case basis, from the Genetic Engineering Approval Committee (GEAC, Ministry of Environment and Forest) As the leading agency on ethics, health and research, the Indian Council on Medical Research (ICMR) issued Guidelines for GM food and made recommendations to the Government in 2004 promoting a specific safety committee within the Central Committee for Food Standards. No labelling for imported and domestic GM food is required. This became a concern when India's restriction on imports was removed in 2002. In 2005, ICMR proposed a mandatory labelling policy, as an amendment to the Prevention of Food Adulteration Act: any food product, incl. meat, derived from GM organisms would be labelled, whether or not containing GM ingredients; regulation would first target importation. Labelling discussions continued in 2006. However, this would need competent laboratories, able to analyze products and certify the proportion of GM ingredients. Although India enjoys well-trained biotech researchers, it has few biosafety researchers (Ifpri, 2006)	No specific legislation, but guidelines and commission advising government on applications. Statutory committees are mostly composed of scientists and experts from the DBT and Ministry of Environment and Forests. Recurrent calls for a single regulatory authority have been expressed, including from the Task Force on Applications of Biotechnology in Agriculture in 2004 and the Minitry of Science and Technology in 2006. **Contained use**: The Institutional Biosafety Committee (IBSC) receives notifications and applications. The Review Committee on Genetic Manipulations (RCGM) issues authorizations. The Recombinant DNA Advisory Committee (RDAC) assesses compliance with the DBT Indian Recombinant DNA Safety Guidelines and Regulations. Inspections are conducted by the Review Committee on Genetic Manipulation (RCGM) **Open-field:** The Environmental Protection Act 1986 regulates large scale production and field testing of "hazardous substances", including GM crops since Dec. 1989 regulation. DBT guidelines have been issued in 1990, 1994 and 1998.	No legislative coexistence provisions, but government shows concerns for unauthorized or ill-sown crops, which caused debate in 1997 and 2003. Farmers are required to inform the government about the location of intended crops. Such information is not available to the general public. In 2003, following GEAC's discovery of unauthorized cotton seeds in Gujarat State, government appoints the 'Task Force on Application of Biotechnology in Agriculture. 2004 Task Force Report suggests a single body, the National Biotechnology Regulatory Authority (NBRA) should develop, monitor, evaluate, promote biotechnology and GM products. Critics consider this would lead the authority to be judge and party. Unauthorized sowing raises concerns on the possibility to implement biosafety regulations in India, and on the meaninglessness of forbidding GM crops through national regulation when farmers use them. More generally, it highlights issues on developing countries' ability to handle such sensitive technologies.
Japan	Public opinion is positive on GM research, much more than on GM food safety issues.	The Food Sanitation Law applies to the regulation of genetically engineered (GE) food.	Since the National Cartagena Law, which followed the implementation of the Convention on Biological Diversity,	No national laws against the crossing of GM crops with non-GM crops.

	The traditional brewery industry might explain that an important part of the public accepts that food can derive from technical manipulation. In 2006 Hokkaido State organized the first Consensus Conference as a part of "risk communication" strategy and inspired by Denmark. Lay panel, divided on risks and benefits of commercial GM cultivation, called for reinforcement of long-term toxicity testing and GM food labelling regulations. Considered no commercial cultivation should be allowed without the citizens' consent. Very active consumer and associations (No!Gmo Campaign, AntiGM Rice Farmers Network) opposing to GM cultivation since 1996. Protectionist views on traditional food have been a main driver in this, as in the 2002 and 2003 victorious campaigns against Monsanto GM rice in Aichi and Iwate Prefectures. Japanese associations have participated to an international mobilization in 2004 with Korean consumers, as the two countries are major American-exportation markets. This campaign against the use of GM wheat in Canada and the US was followed by a halt in such culture. Some farmers support GM crops and consider they would save labour.	Importation and marketing needs prior governmental approval. Since April 2001, "GE" labels are mandatory when GE ingredients are, in weight measures, among the three main ingredients and represent more than 5%. of a food product. Many consumers campaigns have called for European model of 0,9% threshold. In Aug. 2004 public controversy was intense, as the National Consumers Affair Center found that 60% tofu products labelled "non-use of GM soybeans" present GM rates of 5% of lower. Labels are not mandatory when products are processed from GE organisms, but do not contain any - such as in soy sauce or cooking oil.	GM crops cannot be produced without notification/authorization from government. Release requires approval from national government, with advice from the Biodiversity Impact Assessment Commission. Local State Laws also apply, where they exist. In Hokkaido, field trial and commercial cultivation need Governor's approval. The Japanese Biosafety Clearing House (J-BCH) provides internet based information on approved living modified organisms, including precise risk assessment and excluding specific location.	In Hokkaido, following the discovery of GM maize seed contamination in Hokkaido (Japan Agricultural Newspaper 2005/10/19), a Preventive Measure Ordinance against Crossing by GM Crop cultivation has been issued, to be reviewed in 2009. Buffer zone distances have been established from scientific assessment of pollen migration. Hokkaido Governor has been keen on implementing prudent law. In 2006, when the Hokkaido Research Center re-examined proper distances between GM and conventional crops, it reported that maize species-crossing had occurred at 600m distance.

Country Profiles - Welfare of cloned and transgenic animals

	Social context	Regulation of animal welfare in research settings	Specific opinions and regulations on cloned and transgenic animals
EU	June-August 2006, important participation of the public (more than 42500 answers) in the public consultation concerning the revision of Directive 86/609/EEC. 93% respondents "believe that more needs to be done to improve the level of welfare of animals", and 80% consider EU public funding for alternative methods is not sufficient. Animal welfare NGOs, under the EuroGroup umbrella organization, are influential on EU policy decisions regarding animal welfare. Not all EU members express the same concern for animal welfare as a public policy issue. For many, regulation and debate mostly come from within EU institutions.	Protection of animals and their welfare in research starts in 1986, with the European Convention (ETS No.123, March 1986, came into force in Dec. 2005) and Council Directive **86/609/EEC on the protection of animals used for experimental and other scientific purposes. They integrate minimum standards for housing and care, training of personnel, and encourage alternative methods (Articles 7[2]-7[4] and 23[1] of the Directive).** **Following this Directive, the European Commission set up the European Center for Validation of Alternate Methods (ECVAM) in 1991.** **Revision of the Directive has been planned since 2001, and opinions expressed on explicitly including principles of Reduction, Refinement and Replacement (3R doctrine), ethical review processes and compulsory authorizations - and the necessity not to shackle biotechnology development. The Technical working group issued a Final Report in 2003, and the Animal Health and Welfare Panel (AHAW) of the European Food Safety Authority (EFSA) has answered its scientific questions about humane methods of euthanasia and the sentience and capacity to feel pain of invertebrates and prenatal forms of animals in 2005.** **In 1997, a Protocol on the "protection and respect for animals as sentient beings" was included as an annex to the Treaty of Amsterdam. Derogations are accepted for religious rites, cultural traditions and regional heritage.**	May 1996 and May 1997: Opinions by the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB)on the ethical aspects of gene modification and of cloning techniques. Genetic modification and cloning of animals are likely to contribute to human well-being and welfare. However, it "is acceptable only when the aims are ethically justified and when it is carried out under ethical conditions", provided risks to health and environment are addressed and all is done to reduce, replace or refine experiments (3R doctrine). April 1997 ECVAM Workshop. By contrast to a modest decrease in the number of animals used in research, the number of transgenic animals used has dramatically increased. Transgenic animals "could promote greater animal use, a greater variety of applications and an increased likelihood of animal suffering." Many welfare issues are specific to transgenic research procedures. Unexpected detrimental effects might appear. Different uses of transgenic animals (disease models, for instance) raise specific concerns. The workshop highlights transparency and the necessity for all stakeholders to play a role in decision-making. Cost-benefit approach is deemed insufficient, as it limits the consideration of cultural values and human responsibility. Legal approval of research should depend on animal health and welfare assessments. Transgenic animals is addressed within general GMO legislation, while cloned animals are not. Standard interpretation is that the latter are not covered by Directive .2001/18. Cloning farm animals for research depends on national regulation. Specific legislation has only been issued in Denmark. Jan 2007, EU members agree not to differentiate cloned animal food products (meat & milk) from other animal products. Consumers' rights to informed choices are recognized by Regulation (EC) No.178//2002, but this does not address food derived from cloned animals.
France	Animal welfare NGOs have little influence on political decisions, research or public opinion. By contrast, orphan disease advocacy groups such as the AFM (muscular dystrophy association) support and fund research using transgenic animals. Animal welfare is addressed, but is not a priority, as scientific improvement is the main target. March 2005 - Feb. 2006: INRA	July 1976 Law on domestic animals: first legal recognition that some animals are sentient beings. Oct 1987, Governmental Decree (Ministry of Agriculture) implementing the 86/609/EEC Directive. Identifies licit animal experiments, suffering and pain management, and requires facilities to obtain licences and scientists to issue notifications or authorizations to the Minister of Agriculture. The Decree also creates a National Commission for animal experimentation (CNEA),whose advice must be obtained by the Ministry of Research and Agriculture on	No specific legislation on transgenic or cloned animals. The current regulation procedures are deemed sufficient. Transgenic animals fall into regulations concerning GM organisms: contained uses are addressed by the Commission on Genetic Engineering (CGG) and release would be addressed by the CGB, as with other GMOs. These commissions, however, do not consider animal welfare, but address issues of safety for human health and the environment. Trust in the researchers' willingness to respect animal welfare is high within administration.

	(national scientific agronomy institution) public conferences on animal ethics, including transgenic and cloned animals	eventual modification of legislative and procedural regulation and general aspects of research. May 2001, the modification of the 1987 Decree addresses release into the environment and is more stringent on non analgesic experiments. Authorizations from the Department prefect are reduced, from 10 years in 1987 to 5 years now. Applications must not only provide qualification evidence, but explain why such animals and why so many are necessary, and show that no alternative method is applicable. The Commission meets on a 2-year basis, instead of once a year. Though it is not mandatory to submit research to local or regional ethics committee, many laboratories ask advice from these on animal welfare issues. However, as no public authority has been created to check scientific research complies with 3R doctrine, this is left for researchers to decide. Research institutions ethical committees may provide researchers with advice Since March 2005 Decree, the national ethical committee of ethical thought on animal experimentation (CNREA) provides researchers with a general guideline chart and CNEA with precise opinions.	Sept 2005, AFSSA Report: Risks and Benefits related to Livestock Cloning Applications. Cattle bred from cloned animals can be treated in the same way as their equivalents. More in-depth evaluations are however necessary. The report refers to the "moral obligation" EU members have to animals since the 1997 Treaty of Amsterdam. The experts consider cloning techniques in themselves pose "genuine welfare problems".
Germany	Animal welfare is a very controversial political issue. Animal rights supporters oppose to many animal researchers. Until 2002, the latter group argued on the right to research development and education and was usually victorious in court trials. Political elites are divided. The Green Party has opposed to some animal research. The Animal Welfare Federation (DTSchB), an umbrella organization for animal welfare, advocates the replacement of many transgenic research by *in vitro* research on GM cells, including human cells (Sauer *et al.*, 2006). Biotech and pharmaceutical industry, including Bayer, is eager to communicate on its respect for animal welfare.	Animal Protection Federal Act (1934, amended 1972, 1986, 1993 and 1998) is differently applied in the 16 States - thus creating disparities between research institutions. Regional authorities licence research on animal vertebrate, and are advised by regional commissions composed of at least 1/3 welfare supporters. As these are only advisory commissions, some members have eventually resigned and publicly claimed their opposition to pieces of authorized research. 1993 revision of the Act led to a massive mediatic lobbying from scientists, refusing to wait as long as three months to obtain approval for research. An advisory Animal Welfare Officer is required in each institution to express advice on studies involving vertebrates. 2002: After a 10-year debate, Parliament includes animal welfare recognition in the national constitution. This had been rejected in 2000 by Parliament, when supporters of the amendment were in the majority but did not obtain the necessary 2/3 votes.	According to the Animal Welfare Act, as amended in 1998, breeding vertebrates or changing them through genetic engineering is explicitly prohibited if it causes their living, or that of their offspring, to be painful or distressing, or if behavioural abnormalities in the offspring are expected to entail increased aggressiveness. This prohibition, however, does not apply to vertebrates which are necessary for scientific purposes. The German Federal Government actively promotes the development of non-animal genetic methods, such as research on cell cultures. Animal welfare associations consider, though, that more funding should be devoted to alternative methods, and that both animal and human cells could be used. Associations consider that certain procedures should not be accepted in themselves, no matter the eventual benefits they could entail. Theses groups have called for more transparency in the ethical evaluation process, and for a public debate on whether society would be willing to dispense with pieces of knowlege to be gained through animal suffering. Such associations have expressed the view that biomedical research can do without transgenic or cloned animals. No specific regulation on cloned animals

Italy	The Italian public is much more concerned with the welfare of farm animals than with that of animals used in research. Animal welfare NGOs have little influence on political decisions, research or public opinion. Animal cloning has triggered controversy - an incidental effect of a general ban on cloning. Separating human and animal cloning issues was more than an administrative decision, as it implied a change in mentalities.	In 1992, a Legislative Decree implements EU Directive **86/609/EEC. Researchers must "communicate" their project or apply for "authorization" from the Ministry of Health, depending on the species involved and its intended use.** **In case of an application for authorization, the Ministry follows the advice of the Service for Biotechnology and Animal Welfare at the Superior Institutes of Health (ISS). Within the Service, one veterinarian is responsible for ensuring that animal welfare is properly addressed. Applications for authorization contain details on how and why animals will be used and questions on alternative methods.**	Following Feb. 1992 Law, the Italian National Committee for Biosafety and Biotechnology (CNBB) is created, to implement both EU Directives on contained uses ('90/211/EEC) and deliberate release (90/220/EEC). It provides advice on transgenic and cloned animals where needed, on safety grounds. Animal welfare of genetically engineered animals is addressed by researchers, who may seek advice from institutional review boards. Cloning: - In March 1997, Government issued an "ordinance" to ban "any experiment targeted directly or indirectly to human and animal cloning." It was however not illegal to clone transgenic animals, or to clone individuals from endangered species when the goal was preservation and not experimentation. - In 1999, however, following legal trial against the successful cloning of a bull ("Galileo"), a High Court Judge eventually ruled, on appeal, that such a ban was illegal. Government eventually maintained the ban for human cloning only.
UK	Consultation of campaign groups is frequent in public policy decisions regarding animal use. The 1986 Act was adopted after extensive consultation and pressure of several groups such as the British Veterinary Association (BVA), the Committee for Reform of Animal Experimentation (CRAE) and the Fund for the Replacement of Animals in Medical Experiments (FRAME). Scientific societies willing to defend the 3Rs policy, and opposed opposed to extreme animal rights activism, have united in the Bioscience Federation, aiming at identifying proper ethical procedures. The Universities Federation for Animal Welfare (UFAW) is also involved with research professionals.	In 1965 the Brambell Reportwas highly influential on regulation. Highlighted the 5 five animal freedoms: from hunger and thirst; from discomfort; from pain, injury and disease; to express normal behaviour; from fear and distress. This has become a UK soft-law standard (Kaiser, 2005). The Animals (Scientific Procedures) Act 1986 implements Directive 86/609/EEC and regulates the breeding, supply and use of vertebrate animals in research. The 3R doctrine plays a regulatory role. Personal licence is given to researchers provided they have attended training courses on animal welfare; facility certificate implies evidence that proper care and housing will be ensured; and project licence applications must explain the likely benefits, potential ill-effects on animals, what and how animals will be used, and why so many. Since Apr. 1999, it is mandatory to submit animal research to internal Ethical Review Processes. The A(SP) Inspectorate advises the Secretary of State about whether and on what terms applications should be granted. The A(SP) I also inspects facilities. The 1986 Act also establishes the Animal Procedures Committee (APC) to advise the Home Secretary, Department of Health and Social Security on animal welfare issues concerned with the Act. The APC includes members of campaign associations such as FRAME or the Boyd Group.	In the elaboration of the 1986 Act, reflections were expressed on genetically engineered animals, and considered the general framework could become more specific if needed. Indeed, since the 1992 Home Office Supplementary Guidance to applicants for project research to generate and/or maintain genetically modified animals, both the elaboration of GM animals and the welfare of their offspring is considered regulated under the Act. No specific regulation on cloned animals, though. While the general use of animals for research purposes is declining, the use of genetically engineered animals has been reported to dramatically increase since the 1990s. Between 1990 and 1997, a 525% increase had been observed in the UK, according to a 1996 Report for the State Office (HMSO) providing Statistics of Scientific Procedures on Living Animals . Different reports from well-trusted societies and advisory commissions have expressed concern for such increase and for specific animal welfare concerns relating to genetically engineered animals: - the 2006 Report from the Royal Society for the Prevention of Cruelty to Animals, expressed "worries" at the genetic modification and cloning of animals; - a 2005 Report was issued by the Nuffield Council on Bioethics Working Party on animal research and ethics. The Report identified five morally relevant features qualifying animals, as well as humans, as moral subjects: sentience, higher cognition capacity, the capacity to flourish, sociability, possession of a life. No consensus within the Working Party as to which should be considered most important, nor as to which attitude is best, between consequentialist and deontological ones. UK regulations and public attitudes are presented as "hybrid". Consensus of the Working Party, however, on the necessity to take into account animal welfare and ascertain validity, usefulness and relevance of using animals and respect for the 3Rs with animal biotechnology. - in 2002, a report was issued by the Agriculture and Environment Biotechnology Commission (AEBC) on Animals and Biotechnology highlighted the need for an advisory body on the use of genetic biotechnology in farm animals; - the 2001 report from the APC (Animal Procedures Committee) Working Group on Biotechnology and Openness called for an AEBC assessment of current regulation, as AEBC had been established in 1999 to advise government on biotechnology issues impacting on agriculture and the environment.

			- in 2000, the Royal Society Report on The Use of Genetically Modified Animals highlited specific prospects and issues. - the 1998 Report from the Farm Animal Welfare Council (FAWC) on cloning animals called for a National Standing Committee on these animals. - in 1995, the Banner Committee (Ministry of Agriculture Fisheries and Food) Report on the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals, 1995) highlighted the need for an ethical body to address forthcoming ethical questions. The Medical Research Council has instituted a MRC Centre for Best Practice in Animal Research Working Group on Welfare Assessment in Genetically Modified Animals.
Denmark	1992 Consensus Conference (Danish Board of Technology and Danish Research Council) on technology animals. Lay panel's main recommendations: - Research results and animal assessments should be transparent to the public. - Interest groups and lay people should be more represented - It would be "irresponsible" to create animals difficult to control, such as fish or insects. - The 3R doctrine should be respected. All the more so as animal welfare is greatly affected by the use of gene technology. - It is ethically acceptable to produce these animals to develop new methods for curing diseases. - It is unethical to do so to improve existing methods of agricultural production, as well as to for cosmetic testing or designing new pets.	Animal Testing Act and Animal Welfare Act apply. The Danish Ethical Council for Animals monitors developments regarding animal care and welfare. Denmark, Finland, Norway and Sweden have issued rather similar legislation on animal protection and welfare legislation since the 1970s.	The Gene Technology Act addresses animals involving genetic modification, but not cloned animals. June 2005: first EU member state to issue direct legislation on all kinds of animal cloning, including nuclear transfer and embryo splitting. Authorizes cloning and genetic modification of vertebrate animals, on a case-by-case basis, when the goal is the general benefit for society, for at least one of the following purposes: basic research, applied research to improve health and or the environment, education or training. The Animal Research Inspectorate receives applications and provides licence authorizations, irrespective of whether the activity can be categorized as "animal testing" under the Animal Testing Act. Farm animal cloning is not authorized. Animals bred from cloned animals are subject to the same requirements. The law does not address imports. However, Government has taken first steps to restrict clone importation of animals and their products in Nov. 2006 Cloning had been a major issue since the 2004-2006 Danish Centre for Bioethics and Risk Assessment (CeBRA) Project "Cloning in Public" (EU 6th Framework Program). In Jan 02, Statement by the Danish Council on Ethics announced it would not oppose 2 veterinary professors' proposal to lift the ban on animal cloning experiments to result in the birth of fully developed individuals: there could be a legitimate research interest in completed animal cloning trials that may be able to make a contribution to creating new drugs. DCE considered that the international opposition to human cloning in recent years makes meaningless the ref to the argument that such research could open the way for animal cloning. Since the Feb. 97 cloning of Dolly, the issue was on the Danish Council of Ethics (DCE) agenda (May 97 Working Paper). Committee was divided: some considered Dolly evidenced an unerring step along the road to human cloning (An Report 2002) and should be banned. Others supported all research, while advocating constraints should mostly apply to technologies, not research. DCE also called for improved openness in research. DCE statement led the May 1997 legally binding Parliamentary motion: animal cloning should be restricted to research settings, and not result in fully developed animals. Th e motion called for regulation by the Government. In Feb.01, the Ethical Council for Animal's issued its position on animal cloning is issued,

			in a joint statement with CDE position on human cloning.
USA	Researchers and animal welfare organizations are most often in constant opposition and keep static positions. The American Anti-Vivisection Society expresses virulent positions on animal welfare issues in research settings. Some joint efforts, however, can be observed. The Hastings Center and Animal Welfare Institute, for instance, work with professionals to improve animal well-being in research. The Humane Society is the largest animal protection organization in the USA.	Animal Welfare Act (1966, amended in 1970, 1976 and 1990 sets standards to minimize pain or distress and requires researchers to consider alternatives. The Health Research Extension Act of 1985 "Animals in Research" address the utilization and care of vertebrates in testing, research, and training. Inspection of facilities is conducted by the Animal and Plant Health Inspection Services (APHIS) All research involving animal use must be reviewed by animal ethics committees. Researchers, though, enjoy a rather high liberty in their use of animals.	No specific law concerns the welfare of transgenic or cloned animals in research. General welfare provisions apply, as with other animals. Other provisions deal with GM safety assessments, aimed at evaluating risk level and necessary containment measures. Such evaluations have been inspired by the NIH guidelines which followed the 1974 ban proposed by the Berg Commission and 1975 Asilomar Conference. Clones should not submitted to these assessments, as they are considered substantially equivalent, as it were, to their origin, despite eventual development abnormalities. Most discussion has focused on food from GM animals, and the evaluation of these food products. In 2001, commissioned by the FDA, a National Academy of Science Committee Report on food derived from cloned animals presented such as a "low-level of safety concern", but Report insists more information should be sought for. The 2003 Follow-up Report conclude they pose no increased risk. Following an Apr. 2005 scientific statement published in the review *Nature*, a Dec 2006 FDA Draft Guidance on the safety of food & feed from animal clones considered that clones are "similar to identical twins but born at different times" and meat and milk from clones of adult cattle, pigs and goats, and their offspring is safe. Sheep clones would need further information. Biotech research associations such as the Biotechnology Industry Organization (BIO) supported such view. Following FDA's 2006 decision, Japan quickly asked the US regulators to prevent beef from cloned cows to being mixed in shipped meat.
Canada	The general public and media show most interest on the eventuality that food from GM animals could be authorized, much more than on the welfare of animals in research. Public authorities such as the Canadian Council on Animal Welfare of CFIA Biotechnology Unit, however, actively monitor these issues, including on biotechnology-derived animals. Canadian researchers have expressed positive attitudes towards the Animal Care Committees (ACC), which avoid a too centralized regulation of animal welfare issues. Canada was the first country to issue	All research on animals imply approval by Animal Care Committees (ACC), who consider whether welfare provisions are respected. Alberta, Ontario, Saskatchewan, Quebec have specific regulations dealing with animal experimentation. Since 1968, the Canadian Council of Animal Care provides guidelines on animal care and welfare. Different biosafety regulations apply, with animals in research which could be pathogenic: <u>Environmental risk</u>: Environment Canada is responsible for environmental safety assessments, in accordance with the New Substances Notification Regulations and the Canadian Environmental Protection Act 1999. <u>Human health</u>: Health Canada, assessments on the	No specific law on transgenic or cloned animals. Under the 1999 Canadian Environmental Protection Act, transgenic animals are considered "new" and their manufacturing, importing and selling require notification in line with the New Substances Notifications Regulations under the Act. Such biosafety imperatives apply also to cloned animals, although their has been debates as to whether they were indeed "new". General animal welfare provisions should also be respected. The CFIA Biotechnology Unit is responsible for ensuring regulations on animal health and welfare are respected regarding "biotechnology-derived" animals, including clones. No biotechnology-derived animal has yet been approved for release in the environment or for food. Cloned animals for food are considered as "novel food", according to Health Canada's Interim policy, and thus need pre-market assessment. As long as data is considered unsufficient, a moratorium is agreed. In 1997, a Canadian Council on Animal Care Report on transgenic animals, animal

	refinement measures on limiting suffering when the animal reaches the end of its life (endpoint measures).	safety for people working with animals. Animal health: since the Health of Animals Act 1999 and the Feeds Act Regulations, the CFIA(Canadian Food Inspection Authority) is responsible for ensuring animal health. The CFIA is committed to operate with transparency (Moreau & Jordan, 2005): consultations with stakeholders, public protocols and procedures, public final risk assessments.	welfare and ethics expressed concerns concerning specific animal welfare issues and a net increase in the number of animals used in research.
China	Animal welfare issues in research are in the beginning of gaining public consideration. Many researchers, however, have expressed these concerns might create economic difficulties and delays for research institutions. China is supporting significant farm animal cloning activities.	Since 2004, the Regulation on the Management of Experimental Animals includes a paragraph on animal welfare.	No published laws or guidelines specifically on cloned or transgenic animals.
India	Respect for animal welfare is rooted in religious beliefs. Pharmaceutic research on animals is developed and depend on the Department of Biotechnology and the National Institute of Immunology.	According to the Prevention of Cruelty to Animals Act (1960, amended 1982), and Environment Protection Act 1986, an Animal Welfare Board is constituted, with a Committee for the Control and Supervision of Experiments Animals (CPCSEA), in charge of legal and ethical aspects or animal research. General Guidelines on caring for animals in research have been issued (1992, amended in 2000) in accordance with the International Committee for Laboratory Animal Science (ICLAS) Guidelines.	No specific law or guidelines for cloned and transgenic animals. In 2000, an Indian Council of Medical Research Report promotes transgenic animal research as long as it would pursue a higher scientific goal. Regrets were expressed about the lack of information to the public, which made animal biotechnology researchers unfairly unpopular.
Japan	A public feeling of sympathy towards animals is shared by an important part of the population. Significant implication from government in farm animal cloning activities. In Jan. 2006, Japan authorities were close to approving milk and meat from clones (CeBRA, 2006) Pressure groups, involving former opponents to GM food from plants and animal welfare activists, express opposition to GM animals and food from GM animals	Legislation and standards have considered animal welfare. The Law Concerning the Protection and Control of Animals (1973, revised in 1999), express a "feeling of love" for animals among the people and rules that minimum pain must be inflicted to the animals within the research purposes. A Animal Protection Council provides advice to the Prime Minister on these matters. In 1980, the Ministry of the Environment issued Standards relating to the care and management of experimental animals. Most institutions have independently established animal care committees, but legislation does not require the registration or inspection of animal facilities to promote the 3 Rs (Matsuda, 2004).	No specific law or guidelines.

Country Profiles - Stem Cell Research

	Social Context	Deriving stem cells from supernumerary embryos, before their 14th day, provided consent from donors is obtained and research might bring medical progress.	Conducting research on imported ES cells.	Reproductive cloning	Deriving stem cells from embryonic nuclear transfer technology
France	Most influential disease associations include the AFM, which supports ES cell research through the creation and co-funding of the I-Stem laboratory in 2006 in association with the INSERM national research institute. Since 1998, researchers have pushed for more flexibility in public regulation. Progress have been made. Not all scientists, however, would support nuclear transfer. Catholic groups exist. Seem more influential on public opinion than on political decisions.	Authorized by derogation. Public regulation has evolved since the 1994 Bioethics Law ban. The new 2004 Bioethics Law ban is mostly formal, as exceptional five-year derogatory case-by-case authorizations are delivered by the Biomedical Agency. The formal ban is intended for all past, present and future ES cell lines. After 1994, the National Academy of Medicine rapidly called for use of left over embryos. More influential on public opinion and media, the National Ethics Advisory Committee (CCNE) Advice (March 1997): embryos with no parental project should be used for research instead of being lawfully destroyed after 5 years' conservation. A view supported by the National Commission on Human Rights and the Council of State report (Nov 1999), and legislative proposals following revision of 1994 Bioethics Law. June 1999, National Ethics Committee on xenotransplantation: more research is needed against infectious risk, but this is less the cause of public reluctance than is the mental difficulty to accept the transgression of species frontier.	Derogation.	Forbidden by Law.	Forbidden by Law. However, France did not sign UN ban on all forms of human cloning, as its position might evolve with scientific progress. Feb. 2001 positive Advice from CCNE on "therapeutic cloning" from a small majority (14 pro / 12 against), but President Chirac opposed to it, on ethical grounds (risk of future reproductive cloning and of oocyte illegal selling).
Germany	A very sensitive issue. Churches and researchers (incl. Friedrich Ebert Foundation, April 05) both have expressed disappointment, following June 2002 law No. 40, yet for opposite reasons. Scientists also regret a not more progressive public opinion. Political parties are internally divided, for religious and ethical reasons.	In Dec 2001, a majority of the National Ethics Council favoured importation, among which 9 out of 15 approved of deriving SC lines from supernumerary embryos in Germany. Forbidden by 2002 Stem Cell Act. As in Italy, research may be conducted on embryos derived from VIP. The Robert Koch Intitute (RKI) provides authorization and keeps a register on the stem cell lines used and research approved. Its	Authorized since 2002. Public regulation has evolved: while forbidden under Dec 1990 Federal Embryo Protection Law, it becomes legal in 2002, with strict commonly adopted criteria and	Forbidden. Nov 2002, National Ethics Council unanimous, "prompted by media reports of the forthcoming birth of a baby", "regardless of whether such cloning is a serious scientific project and irrespective of its technical feasability". Calls for a worldwide ban, together with French National Ethics	Forbidden by law. Voted in favour of the UN ban. Sept 2004, National Ethics Council (Nationaler Ethikrat) Consensus Position: moratorium on human cloning for research purposes. Before publication of the Opinion, the media reported a majority of the Council would

		Central Ethics Committee for Stem Cell Research provides guidance. July 2003, German Research Foundation (DFG) decides not to fund ES cell banks, as it would be ambiguous.	assessment commissions. ES cell lines must have been developed before January 2002. Approval depends on RKI, and research must be registered.	Committee; discussions with US National Bioethics Advisory Commission.	favour authorization with strict regulations. Following intense controversy, the report dispensed with publishing results of the vote.
Italy	A Transversal Party issue. The 2004 Law was adopted through a secret vote, after much debate and influence from Vatican. Opposition to such decision is visible within the public and members of Parliament from different parties. Opponents proposed, through a June 05 referendum, that the law be amended. Consultation failed, however, because of a low number of voters.	Forbidden (Feb.2004 Law). Isolating ES cell lines from voluntary Interruptions of pregnancies is possible, as the ethical issues have been addressed, and as long as criteria from the May 1978 Law on VIP are respected. 27 Oct 2000, Italian National Bioethics Committee Opinion on the "therapeutic use of stem cells". A majority of the members considers research on supernumerary embryos as legitimate.	Not forbidden.	Forbidden	Forbidden. Voted in favour of the UN ban. The National Bioethics Commission Opinion on the Therapeutic Use of Stem Cells did not reach a consensus on this matter in 2000.
UK	Public opinion is generally favourable to ES cell research. Authorizations to conduct nuclear transfer research did not lead to massive public opposition. Policy decisions follow public debates and appear quite accessible and transparent to the public. Some, religious or not, protest groups. Disease associations and charities (incl. Genetic Interest Group) publicly support any research on the embryo aimed at medical progress.	Authorized. The 1990 Human Fertilization Act regulates the creation, use and keeping of embryos derived from IVF. The HFE Authority created in 1991 is responsible for assessing applications for embryo research. Feb 2001, Third Report from the U.K. Xenotransplantation Interim Regulatory Authority (UKXIRA): xenotransplantation has not lived to its early promise, and danger of infection from animal viruse might never be resolved. Stem cell research would yield greater benefits. Animal welfare associations and societies, including the RSPCA, have produced negatives comments on xenotransplantation, on both safety and ethical grounds.	Authorized	Forbidden (Human Reproductive Cloning Act, 2001)	Authorized through 2001 Parliamentary amendment of the 1990 HFE Act. This decision lead to intense mediatic legal and judicial controversy on the definition of the embryo, from Pro-Life Alliance claims that the 1990 HFE Act only regulates "fertilized" embryo and not embryo produced by nuclear replacement. The Appeal Court eventually recognized the competence of the HFE Authority on these matters. The Nuffield Council of Bioethics 1999 Roundtable drew a very positive conclusion therapeutic cloning. The UK Voted against March 2005 UN ban on all forms of human cloning.
Denmark	The Danish Council of Ethics enjoys is quite well listened to, both within the general public and political decision arenas.	Embryo research is explicitly authorized since 2003 Act amending the 1997 Act on Medically Assisted Reproduction, following Danish Council of Ethics 2001 Report on cloning (published as joint statement with Ethical Council for Animal's	Authorized.	Forbidden since 2003 Act, following Danish Council of Ethics 2001 Report on cloning, considering it is a "violation of human dignity" which would	Explicitely forbidden since 2003. Voted against the UN ban on human cloning.

	3 June 1996, Danish Council of Ethics (DCE) public meeting on Ethical Limits to the Use of Biotechnology on Animals In 1996-1997, the DCE Working party on transplantation considered xenotransplantation, and wondered if any ethically relevant differences could be found between animals to be used, or between organs to be implanted.	position on animal cloning). For its Feb. 2001 Report, the Danish Council of Ethics was divided on ES cell research: 5 members opposed to it, arguing human life arises when fertilization has taken place, making the embryo a person, while 11 approved research on supernumerary embryos, arguing one should balance protection for embryo life against consideration for seriously ill patients who could benefit from it. Xenotransplantation: Danish Council of Ethics Jan 2001 Statement: once a breakthrough abroad, Danish Law will not prevent such use. It is therefore necessary to address the ethics and safety issue. Insistance is on the safety issues, however.		reflect "disrespect for the status of embryo" and go against any individual's "right to an open future" Since the Feb. 97 cloning of Dolly, animal & human cloning was on the CDE agenda. May 97, Working Paper on cloning: there is no need to argue against the self-evident: producing a human being that replicates an already existing person is unacceptable.	Feb. 01 DCE Report opposed to the creation of embryos for research purposes as it could generate a "demise of values". Among the DCE members, 2 were in favor of it, however, 5 were opposed to it arguing the respect for the embryo as a person is absolute and cannot be balanced against other considerations, and 9 consider there no pressing need for the moment and recommend to use only supernumerary embryos until research progresses.
Finland	Stem cell research is well accepted by the general public. The Juvenile Diabetes Research Foundation (JDRF) support for Stem cell research includes effective partnership with the Academy of Finland. Lutherian faith plays a role on public frame of mind and institutions, as in other Nordic countries. Since the world has fallen, far from God, reality does not mirror theological truth or reflect normative meaning. Science, ethics and politics, are independent from religion.	Authorized since 1999 Medical Research Act. The Academy of Finland and the National Technology Agency fund stem cell research. Finland does not conduct xenotransplantation or xenotransplantation project. Neither has issues guidelines or regulations on the matter.	Authorized.	Banned since the 1999 Medical Research Act.	Not forbidden: the cells produced by nuclear transfer are not considered an "embryo" by the 1999 Act. As research continues, the Finnish Ethics Committees called for clarification in a 2005 report. Voted against the UN ban
Norway	A very debated issued, with drastically diverging views concerning its political regulation, in great part for religious reasons. Public institutions manifest care for transparency. Nov. 2001 Consensus Conference organized by the Board of Technology and Biotechnology Advisory Board on Stem Cells and Therapeutic Cloning: Lay panel unanimous on legalizing research on supernumerary embryos,	Forbidden by Dec. 2003 (in force in 2004) Law on the use of Biotechnology in human medicine, without real evolution since August 1994 Law. In Feb. 2007, Government reflects on evolving towards authorization, however. Feb. 2000 Working Party Opinion on ES cell research (Ministry of Social Affairs and Health): four members out of six considered such research might be ethically acceptable. The National Committee of Medical Research Ethics and the Norwegian Medical Association adhered to such view. Ministers for Health, however, adopted the view	Forbidden by law	Forbidden by law. In Sept 2004, the Board of Technology issued a Pamphlet on Stem Cells and Cloning, distributed at schools.	Forbidden by law. Members from the 2000 Working Groups expressed unanimous opposition to such research. Voted against the UN ban, as it did not express true international consensus.

	while banning the fertilization of human eggs and "therapeutic cloning". Results were widely covered by national media.	of the minority of the working group. One member of the Board of Technology participates to the Working Group commissioned by Nordforsk to consider ELSI of stem cell research. Members include members from the Nordic Committee on Bioethics and external experts. Report is to be issued in Fall 2007.			
Sweden	ES cell research is well accepted within the public. Disease charities (Swedish Diabetic Foundation, Juvenile Diabetes Association,...) support and co-fund stem cell research, including ethics, with the Swedish Research Council.	Authorized. - 2001 Guidelines from a working party from the Swedish Research Council (SRC) medical branch. Consider that the situation is not different to that addressed by the 1991 Act on the Use of Fertilized Ova, authorizing embryo research: local medical ethics research committees (RECs) must assess research on scientific and ethical grounds. The SRC insisted on consent forms and called in 2002 for public regulation. - April 2005 Law amending the 1991 Act allows research on fertilized eggs for purposes other than IVF, provided an ethical review is conducted..	Authorized.	Forbidden since 2003 Law	Authorized since April 2005 Law, provided it has undergone an ethical review. The 2001 Working Party had opposed to it, as the risk of intrumentalization of human life was too high and as this could be a slippery slope towards reproductive cloning. The National Council of Medical Ethics agreed in large parts with such view. The SRC, by contrast, was influential in Government's decision to make such research lawful. Voted against the UN ban
USA	A very controversial issue. Though some Protestant associations agree to stem cell research, Christian opposition is influential on public opinion and political institutions. Disease associations (American Parkinson's Association, American Juvenile Diabetes Association,...) campaign for federal funding of research.	No federal law, but no federal funding for such research in the USA, according to NIH guidelines of August 2000, as destroying embryos for research purposes is deemed unacceptable. Some States, such as New Jersey and Connecticut, following California's decision in 2002, have passed legislation to support such research. Others, such as Michigan or South Dakota have outlawed it. Many debates, including in the political arena, concern this controversial issue. Most Democrats approve stem cell research and federal Bills aiming to allow research from supernumerary embryos, while most Republicans oppose to it. Political evolution: while 1999 Clinton administration considered it ethical and legal to fund ES cell research, the Bush administration opposes to it since 2001, even through vetoing Congress decisions.	No federal law. Although NIH guidelines oppose to funding ES cell research, President Bush in Jan 2001 agrees to federally fund research on lines imported before 2001.	No federal law, but many State Laws prohibit it and the general public opposes to it, despite the "Reproductive Cloning Network" and "Human Cloning Foundation" campaigns. No federal funding.	No federal law, but no federal funding. The USA voted the UN ban on human cloning. State legislation is a patchwork, as some States, such as California, authorize and fund it, while others, such as Arkansas, prohibit it.

		2001, US Governmental guidelines on xenotransplantation research, to reduce risk of exposure to serious animal disease. The health of participants should be monitored throughout their lives (the same recommendation has been expressed by the American Medical Association), even if the transplanted tissue or organ is removed. 50-year storage is needed. AMA insists children and incompetent adults should not participate.			
Canada	Public policy has been very supportive of stem cell research. Assisted Human Reproductive Legislation had been announced since 1996. Christian and Catholic pro-Life groups, linked with similar US groups had been actively campaigning. They have also been calling for more funding on adult stem cell research, a moratorium or ban on ES cell research. Including Declarations.	Authorized. March 2004 Act on Assisted Human Reproduction applies to the derivation of stem cells from human embryos, but not to those previously derived. 2007 Guidelines apply to both. The Assisted Human Reproduction Agency issues licences for derivation on new lines of stem cells. 2000, Ad-Hoc Working Group (Canadian Institutes of Health Research) on stem cell research to assist CIHR in policy-making. Jan 2002 Report was unanimously accepted, led to an update of the Tri-Council Policy Statement (TCPS) and formed the basis of stem cell research guidelines for CIHR-funding, updated in 2005 and 2007. All research must be approved by the Stem Cell Oversight Committee (SCOC, integrated in the CIHR), in addition to review by local Research Ethics Boards (REB) xenotransplantation: 2001 Canadian Public Health Association reports against clinical trials, as critical safety issues remain.	Authorized. Research must be approved by SCOC.	Prohibited by Law.	Prohibited by 2004 Act. Guidelines and TCPS have followed ad-hod Working Group recommendation that such research be ineligible for funding. Vote against UN ban on human cloning.
Brazil	Controversy stems from religious beliefs. Religious groups, incl. Brazil's National Council of Catholic Bishops, opposed the 2005 Biosafety Law, in a country where 74% of the population is Catholic and abortion is allowed in very exceptional, still controversed, cases. Political elites are divided. Congress voted the Law by a important majority, however. Against the Attorney General's claim that Law	Legal since March 2005 Biosafety Law voted by a large majority in Congress, after 10-year battle. An ethics committee must assess research projects.	Permitted by Law.	Forbidden (art.6)	"human cloning"is forbidden (art.6), including "therapeutic cloning". However, Brazil did not vote UN ban, as the text inspired too much division.

	violates the constitutional right to life, Supreme court conducted public hearings.				
China	No expression of public opposition to National support to stem-cells. Researchers and health professionals agree to it, and some have been influential, since 2002, in the Ministries' decisions to issue national guidelines.	Permitted and supported through public funding. The Jan.2004 "Guidelines for Research on Human Embryonic Stem Cells" (Ministry of Science and Technology / Ministry of Health) regulate the matter. No general regulation compliance control system. Obtaining a licence is not necessary. However, research projects applying for MoST funding are assessed and controlled.	Permitted	Prohibited (Guidelines, Art. 4). Already banned in 1998 governmental declaration.	Authorized (Guidelines, Art. 5). Voted against March 2005 UN ban on all forms of human cloning.
India	No religious or political opposition to ES cell research. Hindu religion does not consider it immoral to conduct experimentation on embryos, and does not consider technology is "unnatural" Within society, the therapeutic goal of such research is what matters, much more than the status of the embryo. Abortion Law allows pregnancy termination up to 20 weeks of gestation. Since 1995 Disability Law, debates on the acceptability of disability have occurred in the media.	Authorized by 2006 National Guidelines for Stem Cell Research and Therapy (National Bioethics Committee Task Force: Indian Council for Medical research + Department of Biotechnology), inspired by the 2000 ICMR Consultative Guidelines on stem cell research. National Bioethics Committee prepared the consent form for embryo donors. Following the 2006 Guidelines, new research is submitted to notification and registration with two new types of multidisciplinary ethics committees: the multi-agency NAC-SCRT (National Apex Committee) and, within each research institution, an expert IC-SCRT (Institutional Committee for Stem Cell Research and Therapy). The creation of a human zygote by IVF is not prohibited, but, as a "restricted area of research", it would need approval from the NAC-SCRT, through IC-SCRT.	Permitted (guidelines). Authorization must be obtained from IC-SCRT.	Prohibited (guidelines)	Permitted (guidelines). As a "restricted area of research", it needs prior approval from NAC-SCRT. ICMR 2000 Guidelines promoted a moratorium. Voted against March 2005 UN ban on all forms of human cloning.
Japan	Public awareness of medical biotechnology is quite high. The public is more concerned than the scientists by ethical issues relating to manipulating and selecting life. Public policy decisions are not influenced by campaign groups. Medical professional and researchers have an effective influence on the regulations adopted. Public trust in public authorities and scientists is not very high.	Permitted by 2001 Law on Cloning Techniques and other similar Techniques, following report from Japan Council for Science and Technology(JCST). JCST is in charge of authorization and control.	Authorized.	Prohibited by 2001 Law, following 2000 JCST Report.	Permitted. Evolution: The 2001 Law did not forbid it, but Government had then called for a moratorium. In 2004, following JCST positive report, it is authorized and funded, for basic research or regenerative medicine prospects. Japan voted against March 2005 UN ban on all forms of human cloning.

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