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Animal biotechnology: A study of opinions among stakeholder groups in the academic, pharmaceutical and agrifood sectors

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Abstract The commercialisation of animal biotechnology for use in human medical applications and as food will require the availability of accurate market information. As witnessed in the case of genetically modified plants, a failure to assess market receptivity accurately can have significant ramifications for the biotechnology industry. This paper describes the findings of a survey of attitudes among a scientifically literate audience (predominantly the university and biopharmaceutical sectors) regarding animal biotechnology and associated parameters. As shown in previous studies, the use of transgenic technology for medical applications was found to carry a higher acceptance rating than its use in agriculture. Additionally, the phraseology and terminology used in questions were found to have a measurable effect on influencing respondent replies. The results of the survey are interpreted in the context of transgenic animal technologies currently in development.

Keywords: transgenic animals, stakeholder opinions, xenotransplantation, animal pharming

Introduction

The exploitation of animals for human gain is a controversial topic that can provoke strong emotional reactions among the public. It is an accepted social norm in all civilised societies, usually embodied in legislation, that unnecessary suffering of animals is ethically wrong and wholly unacceptable. In the European Union (EU) and North America especially such views continue to evolve in accordance with an increasingly reflective and introspective social dialogue, now taking place in an affluent society.

Despite this new social ethic, it is still true to say that the majority of the populace does not equate human and animal rights. The minority views of those who hold that animals should be afforded equal treatment with humans are perhaps the easiest to characterise and define, and the non-compromising stance of the vegan philosophy (well articulated by Regan[1]) is a good example in this regard. More difficult to discern are the detailed, case-specific views of the majority of the populace who passively support the rearing, slaughter and

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consumption of animals – often in highly processed form – as a component of human nutrition.

Undoubtedly, at the heart of this discussion is the need to achieve a balance between animal welfare and animal rights (discussed by Albright[2]). Recent history shows that the public's attitude to different animal species is influenced by a continually changing, complex and overlapping variety of factors. For example, our current knowledge of the evolutionary relatedness of some animals to humans (such as the great apes), and a perception of considerable intelligence in many species (dogs, dolphins), has led to a re-evaluation of the way in which we interact with animals; indeed, serious questions are now being asked in some quarters about the future of such familiar institutions as zoos. In today's information-driven society, the perceived need to exploit an animal (say in terms of food, clothing or sport) will also be modified on an individual-specific basis by a complex set of values and precepts. These may be expected to include upbringing and social background, gender, age, religion, tradition, national identity, social conformity and education. The primacy of any one of these factors is difficult to gauge.

As evidenced by the current fox-hunting debate in the UK, the legality (and therefore public tolerance) of human activities with respect to animals is not necessarily synonymous with the majority public opinion; the same may be said about such practices as hare-coursing and the use of fur in fashion. Increasingly, ordinary members of the public are beginning to exert pressure for changes in this area. For example, within the USA, public concern on issues of animal welfare and wildlife management has resulted in a form of 'management by referendum' in a number of instances:[3] it is therefore likely that the treatment of animals will increasingly become a part of the European political agenda.

Within Europe, a perceived social inertia in halting fox-hunting and animal testing has prompted direct action against proponents of such activities by certain individuals and groups who feel disenfranchised, and also disillusioned with the pace of political change.

The use of animals in research

Undoubtedly, the area of animal experimentation has received the brunt of negative public attention in recent times, perhaps epitomised by the campaign against the contract research services company, Huntingdon Life Sciences, in the UK. Continued protests, combined with threats, intimidation and criminal acts by extremists, significantly damaged the company, and resulted in withdrawal of support by British investment institutions that feared activist retribution and collateral damage from the perceived adverse publicity (recently reviewed by Smith[4]).

Animal testing is used in such fields as medicines development, fundamental biomedical research and safety assessment of products used in industry, agriculture and the household.[5] About 44 per cent of EU animal usage is in commercial R&D and quality control for products used in human health and the veterinary medicine sector; this is followed by fundamental biological research (25 per cent) and toxicological studies (9 per cent).[6] In 1996, about 11.5 million animals were used for research purposes in the EU, with rodents and rabbits accounting for about 81 per cent of the warm-blooded animals. This was followed by cold-blooded animals (12.9 per cent) and birds (4.3 per cent). Animals such as horses, donkeys, pigs, goats and sheep represented about 0.3 per cent of the total.[6]

A similar breakdown is evident in the UK, where the main type of animals used are specially bred rodents (82 per cent);[5] dogs, cats, horses and non-human primates account for less than 1 per cent. The use of chimpanzees, orangutans and gorillas is now banned in the UK, and the only EU member state conducting research on great apes and chimpanzees is the Biomedical Primate Research Centre in the Netherlands.[7] In the UK, the total number of animals used in scientific research was 2.65 million in 2000, an increase of 2.9 per cent compared with 1999;[5] additionally, the use

of genetically modified (GM) animals increased by 14 per cent.

Animal experimentation for scientific purposes is covered by EU Directive 86/609/EEC, which also stipulates that the European Commission and member states must encourage the development of equivalent alternative *in vitro* test systems. An earlier Directive (76/768/EEC) includes a provision to ban the marketing of cosmetic products containing ingredients tested on animals since 1st January, 1998.

The use of animals in modern biotechnology

While genetically modified (GM) plant technology has been controversial in Europe, transgenic animal biotechnology poses additional challenges, broaching metaphysical and philosophical dimensions for many commentators.

European awareness and understanding of genetic modification and modern biotechnology has been largely formed by publicity surrounding GM foods, which featured plant innovation, and also Dolly, the first cloned sheep (the latter an example of 'biological' rather than genetic engineering). However, other reference points for the formation of public opinion on animal biotechnology, in both agriculture and medicine, do exist. These are uniformly negative. A patent covering the development of a GM mouse predisposed to developing cancer, to be used as a disease model (the 'Harvard oncomouse'), has formed the basis of a long-running court battle in Europe. In agriculture, the use of recombinant bovine somatotrophin (rBST) to boost milk yield in cattle was rejected by the EU on grounds of animal welfare and human safety.

Attempts to date to develop transgenic livestock for human consumption have failed, encountering either inefficient transgene expression or unacceptable side-effects;[8] the US Department of Agriculture (USDA) Beltsville pig experiments perhaps represents the most unfortunate example of the latter.[9] While a notable exception to this relates to transgenic fish technology, the possible threat to wild populations of salmon from GM fish that possess accelerated growth rates has also been highlighted.[10]

Many market commentators now accept that a problem with first generation GM innovation, such as herbicide-tolerant crops or rBST, was that the immediate benefits were not visible to the consumer.[11] However, in the field of human medicine, two aspects of transgenic animal technology would seem to eschew this problem: direct benefits to the consumer/patient are provided by the use of animals in biopharmaceutical production and production of 'humanised' organs for use in human transplant medicine (xenotransplantation).

Biopharmaceutical production: The use of animals as bioreactors

Using recombinant DNA (rDNA) technology to make human medicines, best exemplified by the production of human insulin in the bacterium *Escherichia coli*, is well accepted by the public.[12,13] Early rDNA biopharmaceuticals, such as insulin and human growth hormone, represented good targets for bacterial production systems, as they are relatively simple proteins. However, the widespread prevalence of complex post-translation modifications on many of the body's proteins, such as glycosylation, has necessitated the use of mammalian cell culture-based production systems for biopharmaceuticals that require such processes for proper *in vivo* functioning.

However, there are potentially significant economic advantages in using transgenic animals to produce such biopharmaceuticals, with the cost reduced to hundreds of dollars (rabbits) or tens of dollars (cows).[14] Goats offer particular advantages, possessing a short generation time relative to cattle and much lower incidence of prion infection.[15]

However, countering such advantages, the cost of making the animals is high (US$100,000–200,000 to make a cloned transgenic cow[15]), while there is currently a

high rate of pre-, peri- and post-natal deaths and developmental defects among the animals produced by cloning, and more reliable ways of targeting the transgenes to regions of the genome active in mammary tissue are needed. Brom[16] has pointed out potential ethical questions relating to production of human medicines in transgenic cattle.

Companies pursuing transgenic 'pharming' include PPL Therapeutics (Roslin, Scotland: alpha-1-anti-trypsin, Factor IX and fibrinogen from sheep), Genzyme Transgenics (Massachusetts, USA: antithrombin III, human serum albumin (cows) and a range of monoclonal antibodies (goats) and Pharming (Leiden, the Netherlands: alpha-glucosidase, lactoferrin and fibrinogen). In addition, some 20 other products produced in transgenic goats, sheep or cattle are at earlier stages of development.[17]

Xenotransplantation

An estimated 63,000 patients are currently awaiting an organ donation in the USA.[18] The shortage of donor organs has prompted medical science to consider inter-species (xenogeneic) transplants, producing 'humanised' animal organs that will not be rejected by the human immune system. Xenotransplantation is under active investigation for replacement of such organs as heart, kidney and lungs. Research to date has largely focused on pig organs, because their profile in many ways is similar to that of human organs.

The potential problems with xenotransplantation include hyperacute/delayed rejection and cell-based immune rejection, while there is also a danger of novel infections being transmitted to humans.[19] In 2000, PPL Therapeutics announced the first pigs to be cloned from adult cells, and followed this in December 2001 by the creation of 'knock-out' pigs, in which the gene at a single allele for alpha-1-3-galactose transferase is inactivated. This gene is responsible for the sugar group in pig cells that is recognised by the human immune system as foreign, thus causing transplant rejection. This significantly advances the challenge of producing modified pigs whose organs and cells can be transplanted into humans. It is predicted that by the year 2010, the market for xenotransplant technology will be worth US$6bn per annum.[20]

Predicting market dynamics for animal biotechnology products

Market forecasting, conducted with the aim of predicting the uptake and projected market penetration of biotechnology products, is inherently difficult due to the typically long product development cycles, allied with an intensely competitive business and regulatory landscape. However, industry experience to date with GM plants has added a further dimension of complexity, and proven conclusively that unpredictable socio-political factors may also come into play during market launch and development. In certain territories, such as the EU, this has had a profound negative impact on basic 'freedom-to-operate' type issues. Consolidation among some major agrochemical players has followed, while the appeal of the entrepreneurial plant bioscience sector to the investment community has declined significantly.

Therefore, for certain classes of biotechnological innovation, a successful grant of patent and the commitment of significant financial resources to marketing by a company, are no longer an assurance of conventional product uptake dynamics. This uncertainty has been further exacerbated by the adoption of the 'precautionary principle' within Europe, a supplementary hurdle to already stringent safety regulations that is potentially open to non-objective political interference.

Surveys to date of consumer opinion have shown that the application of recombinant DNA technologies to animals are perceived negatively.[21–28] However, early work has also shown that southern Europeans and the Irish are more positive to genetic modification of animals than their northern European counterparts,[29] and risk perceptions appear higher in northern European countries.[30]

Consequently, it is a matter of importance to continue to generate information on current and anticipated future market acceptance of such technologies; the data will have profoundly important implications for biotechnology companies, investment analysts and government agencies.

Objective of study

In considering the well-documented public views on animal welfare issues, the adverse publicity surrounding GM plants and the difficulty for non-specialists in trying to comprehend such technologies as xenotransplantation, there are strong grounds for expecting complex market dynamics in the commercialisation of animal biotechnology.

As part of a larger programme aimed at analysing future market conditions for biobusiness, the current study was performed to yield a preliminary insight into present views on transgenic animal technology. As it was felt that the technology and terminology surrounding this area are still largely unknown to the general public, the survey targeted an audience that was likely to have some knowledge of the potential of transgenic technologies. The acknowledged element of bias in such a sample frame was offset against the prospect of achieving a more informed insight into views about the technology. In addition to scientists in relevant faculties within universities, and also the pharmaceutical and biotechnology sectors, government regulators and agribusiness personnel were also surveyed. A secondary aim of the study was to identify underlying sociological factors that may impact on perceptions regarding transgenic technologies, especially pre-existing views on animal testing and blood sports.

Materials and methods

A series of multiple choice and dichotomous questions were devised in written questionnaire format to test responses to areas relating to animal experimentation, transgenic animal technology and associated issues.[31]

The survey schedule was divided into two stages. Firstly, questionnaires were completed by delegates attending the annual BioResearch Ireland conference (February 2000). This is an annual closed meeting where life sciences personnel from five geographically separate, university-based research centres come together to review corporate activities. A respondent rate of 47 per cent was recorded (90 questionnaires distributed).

Subsequent to this, between the period March to May 2000, a postal survey was conducted (with geographical spread restricted to Ireland and the UK). The sample frame was generated using a proprietary in-house contacts database, which was originally developed for the purposes of technology transfer. The target audience was primarily selected on the basis of involvement in the area of life sciences, biotechnology or agriculture, taking into account the actual or potential relevance of transgenic technology to their sphere of activities. An additional key criterion was that respondents should preferably be decision-makers, holding key functions in R&D, regulation, management or administration. Based on these parameters, the survey sample was classified into the following broad categories (number of questionnaires dispatched/respondent rate): Irish university academic sector (14/57 per cent); pharmaceutical-biotechnology industry (129/16 per cent); agri-food sector (12/58 per cent) and Irish government/regulatory agencies (30/40 per cent).

All survey data were pooled to yield an overall respondent rate of 32 per cent (total poll of 89 respondents).

Results and discussion

Respondent age profile was evenly spread across a wide range (Figure 1a), while a male-to-female ratio of nearly 2:1 confirmed established statistics regarding the prevalence of men in decision-making roles in the science field. Women are

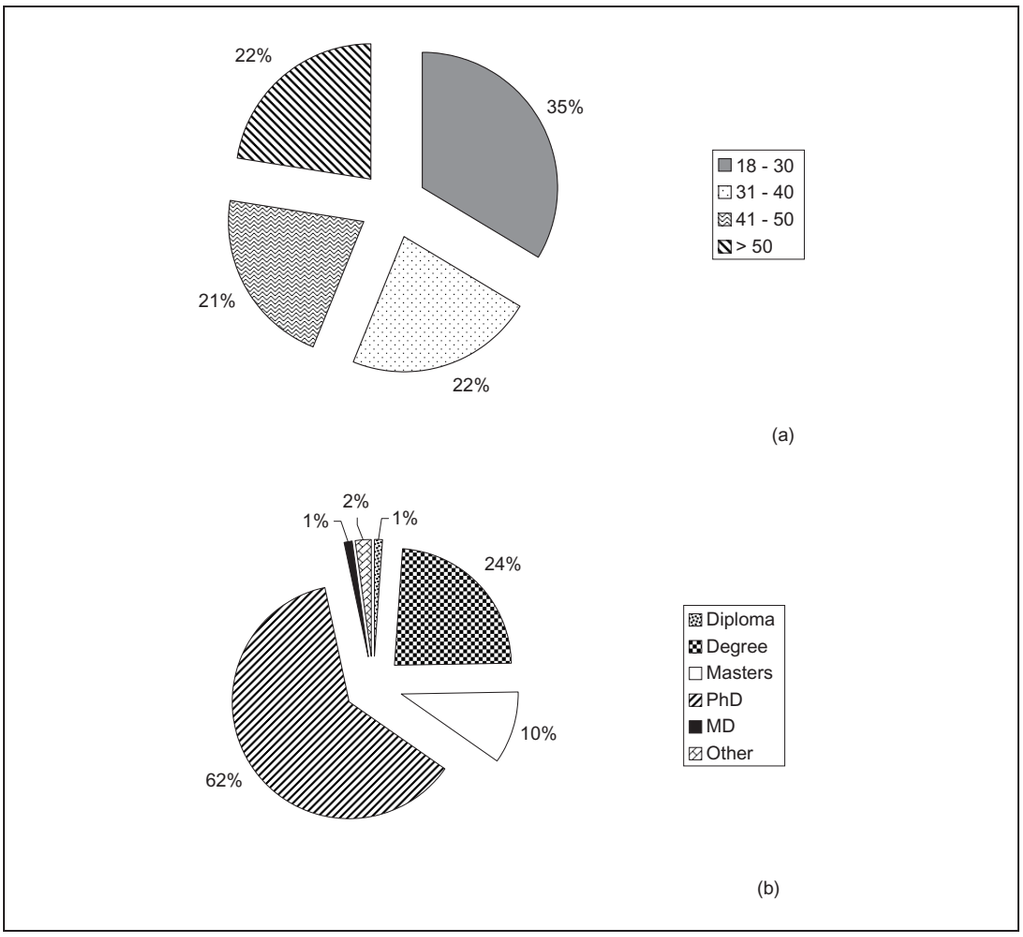

Fig. 1 Respondent profiles: (a) age range (years); (b) highest educational qualification achieved

conventionally considered to be more caring and sensitive than their male counterparts. Recent EU-funded work suggests that women are indeed more concerned about animal welfare,[32] while they also tend to be more sceptical of GM technologies.[33,34] Conversely, a number of studies have shown that well-educated males are more favourably disposed to biotechnology.[22,35]

Respondents were found to be educated to a high level in life sciences, with 63 per cent of the poll holding the degree of PhD or MD (Figure 1b), thereby increasing the likelihood of prior exposure to the topic of the survey; only three respondents did not hold a formal life science qualification. When asked to rate their current knowledge of genetically engineered (transgenic) animals, the majority indicated a 'very good' (11 per cent), 'good' (33 per cent) or 'average' (28 per cent) understanding ('fair', 19 per cent, and 'poor', 9 per cent).

Respondent profile was further dissected to explore personal background and values/beliefs. Only 3 per cent of the poll indicated that they were vegetarians, while 38 per cent considered themselves to be religious (14 per cent abstained); denomination was not explored. Although 50 per cent professed to have had an urban upbringing, 84 per cent of the poll also indicated current or previous pet ownership, implying a good degree of prior personal contact with animals. Indeed, over 70 per cent of those canvassed

classified themselves as an 'animal lover', with the majority supporting animal welfare issues (64 per cent) (Figure 2). About half the poll acknowledged their support of animal rights organisations (49 per cent; 16 per cent abstained, not shown), but the same does not extend to animal liberationists (3 per cent support; 9 per cent abstained). Therefore, while an obvious affection for animals was apparent in respondent answers, a conventional anthropocentric philosophy also prevailed. This was confirmed by the finding that a resounding 92 per cent of respondents indicated their support of animal experiments 'for certain uses'. More difficult to reconcile with an apparent proactive stance on animal welfare was the finding that although only a small percentage (12 per cent) of the poll were actively in favour of blood sports, numbers were evenly divided on whether such pursuits should be banned (45 per cent agree, 48 per cent disagree, 7 per cent abstained). While not a *volte face* as such, this result implies that some respondents are capable of reconciling being an 'animal lover' with the passive support of 'recreational cruelty' to animals.

When asked to agree or disagree with a contrasting set of statements pertaining to genetic engineering of animals, the resulting respondent profile indicates overall support, and also points to a perceived need for the technology (Figure 3). Critically, such support is application-dependent, and 55 per cent of the poll did not view transgenesis as 'an extension of the natural breeding process'. More information on the area was also desired (58 per cent of poll).

Unsurprisingly, approval or disapproval of transgenic animal technology is also strongly influenced by the terminology and phraseology used in questions, and under certain circumstances, this may even take precedence over the perceived benefits of the application. Therefore, while 99 per cent of respondents approved of this technology to 'help medical research', approval drops

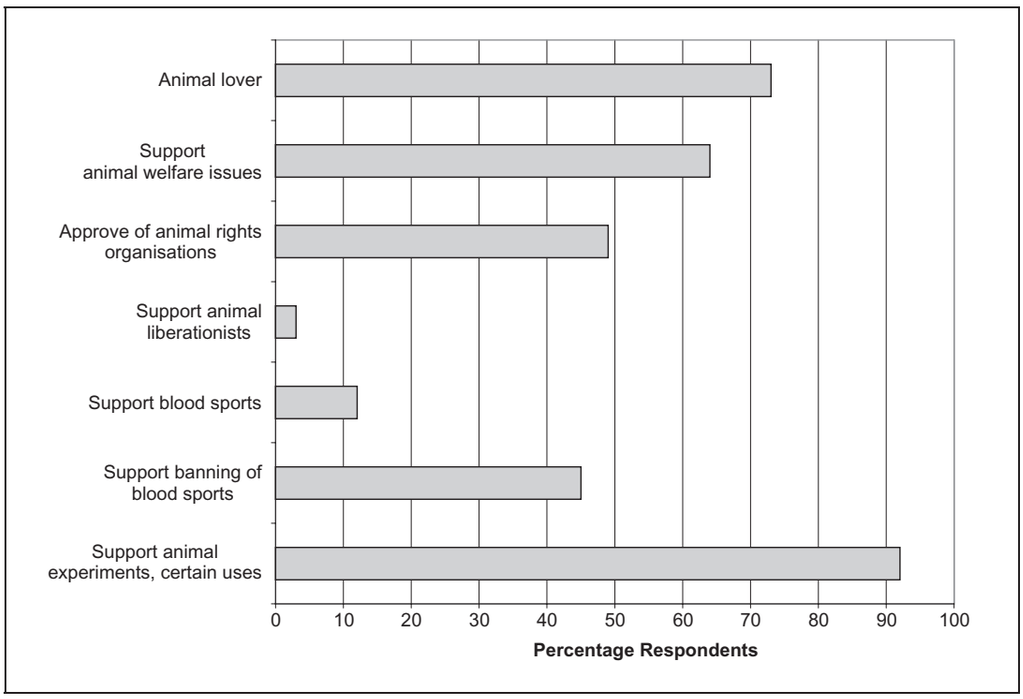

Fig. 2 Respondent beliefs and values. Respondents were asked to indicate agreement to a series of statements about themselves

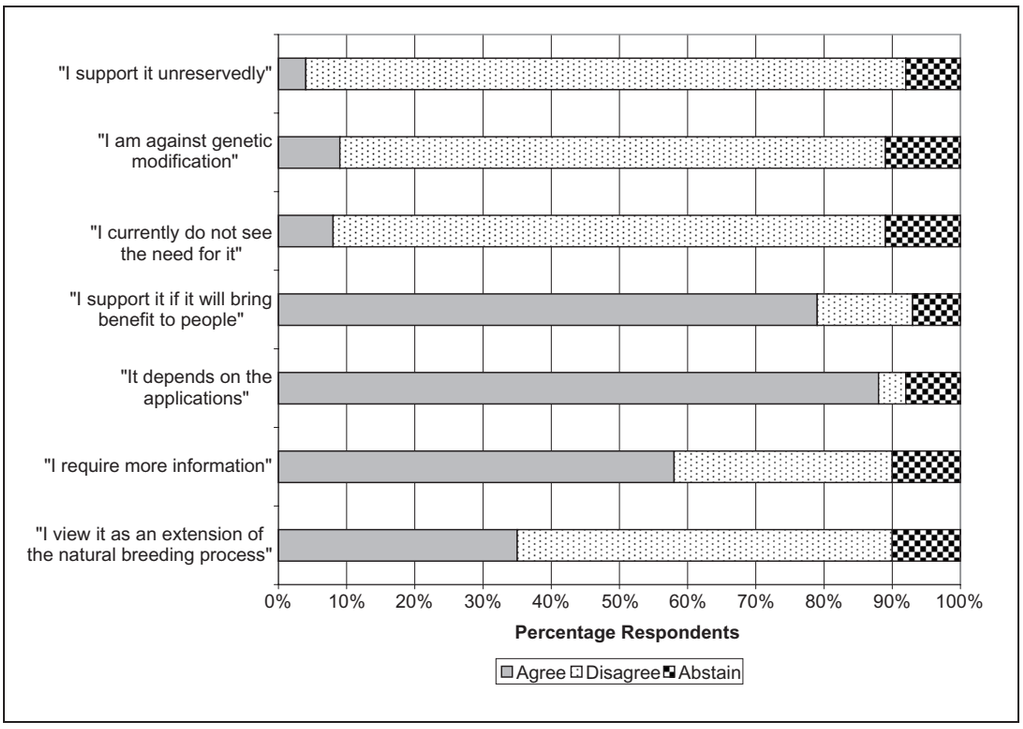

Fig. 3 Respondents were asked to indicate how they felt about the genetic engineering of animals, by answering 'agree' or 'disagree' to each of the statements indicated

to 64 per cent for 'decreasing medical production costs' (Figure 4); approval is lowest (35 per cent) when couched in terms of agricultural need, such as 'reducing the need for subsidies in agriculture'.

Regarding the use of transgenic animals in medical research, an approval rating in excess of 50 per cent was encountered for a diverse range of applications, with slight preferences being shown to those where the benefits translate directly to patients (producing medicines in milk or 'humanised' animal organs), as opposed to traditional animal experimentation uses (Figure 5).

When further questioned about possible reservations regarding genetic modification of animals, concerns about animal welfare were accompanied by interestingly non-scientific fears on the grounds of 'unknown risks' and 'interfering with nature' (Figure 6).

Excluding the agri-food and government/regulatory groupings (21 per cent of poll), the experience profile of remaining respondents was investigated regarding their hands-on exposure to genetic technologies. A relatively small number had previously conducted research on GM plants (4 per cent) or transgenic animals (10 per cent), relative to recombinant DNA technology using microbial cells (57 per cent) (Figure 7). However, a substantial number (19–23 per cent) had previously used animals to make polyclonal/monoclonal antibodies, and had also worked on animals as disease models.

When provided with specific examples of animal experimentation, purposes such as medical research carry a much higher approval rating (97 per cent) than uses such as testing the toxicity of dietary aids (40 per cent) or cosmetics (10 per cent) (Figure 8). When respondents are provided with a scenario whereby animal testing will be used as part of medicine development for a serious human disease, mice and rats gain the greatest acceptance (94 per cent

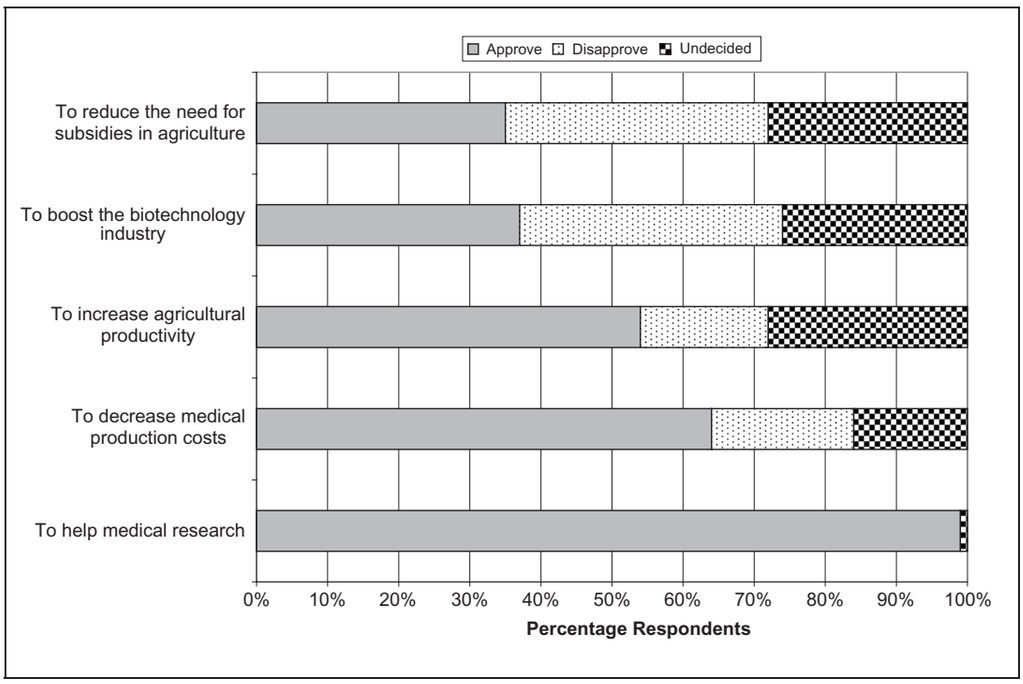

Fig. 4 Respondents were asked how they felt about a range of possible benefits relating to the genetic engineering of animals for medical research by answering 'approve', 'disapprove' or 'undecided' to each of the statements shown

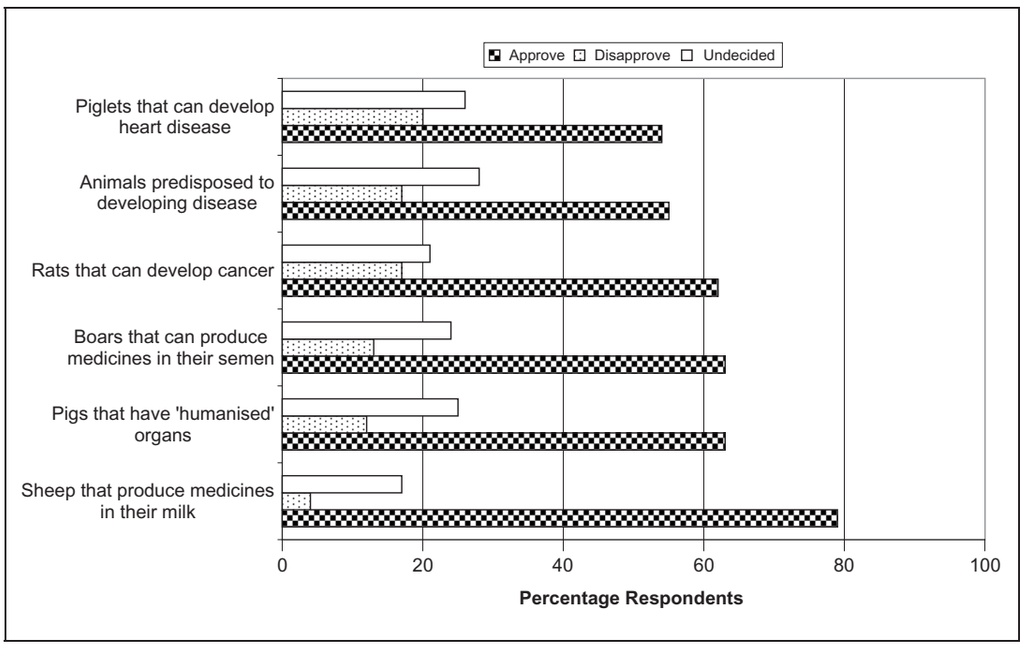

Fig. 5 Respondents were asked to indicate how they felt about the possible benefits of genetic engineering of animals by answering 'approve', 'disapprove' or 'undecided' to each of the statements shown

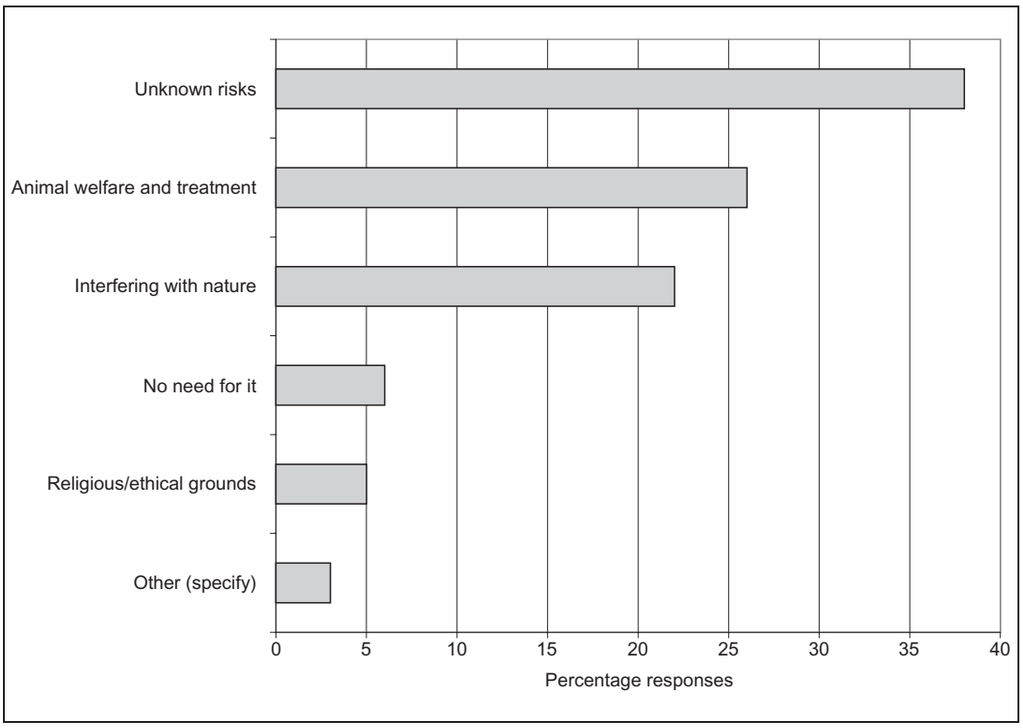

Fig. 6 Respondents were asked to state on what grounds, if any, they would have reservations about genetic modification of animals (with multiple answers permitted). The scores for each statement were expressed as a percentage of the total number of responses ($n = 161$)

approval rating), while dogs (65 per cent) and cats (71 per cent) have the least approval, followed by sheep (74 per cent) and chimpanzees (76 per cent) (Figure 9). The ready association of rats and mice with animal experimentation in the minds of the general populace has been previously documented.[36] In the present work, the precedence of domestic species over primates can presumably be explained on familiarity grounds, but arguably it might have been expected that this particular audience would show more sensitivity towards the chimpanzee, as it is generally agreed that such animals demonstrate markedly higher levels of intelligence and socialisation.

Conclusion

From the experience with 'first generation' GM crops in Europe, it is clear that conventional market analysis conducted with the considerable resources of the agrochemical majors was insufficient to predict the negative public reaction. However, while it is undeniable that biotechnology represents a special case for marketeers, critics have tended to ignore the fact that spectacular product failures have occurred in market areas that are considerably more transparent and amenable to clear-cut analysis. Business is based on measured risk and proprietary market insight/position, and much time and effort are currently being expended by the biotechnology sector to reconcile the new regulatory climate in Europe with so-called second generation GM plant products. Simultaneously, the economic imperative to create a more open market structure within Europe is also being fuelled by the planned accession of former Eastern bloc states to the EU. Thus, the European market climate for forthcoming biotechnology products will be noticeably

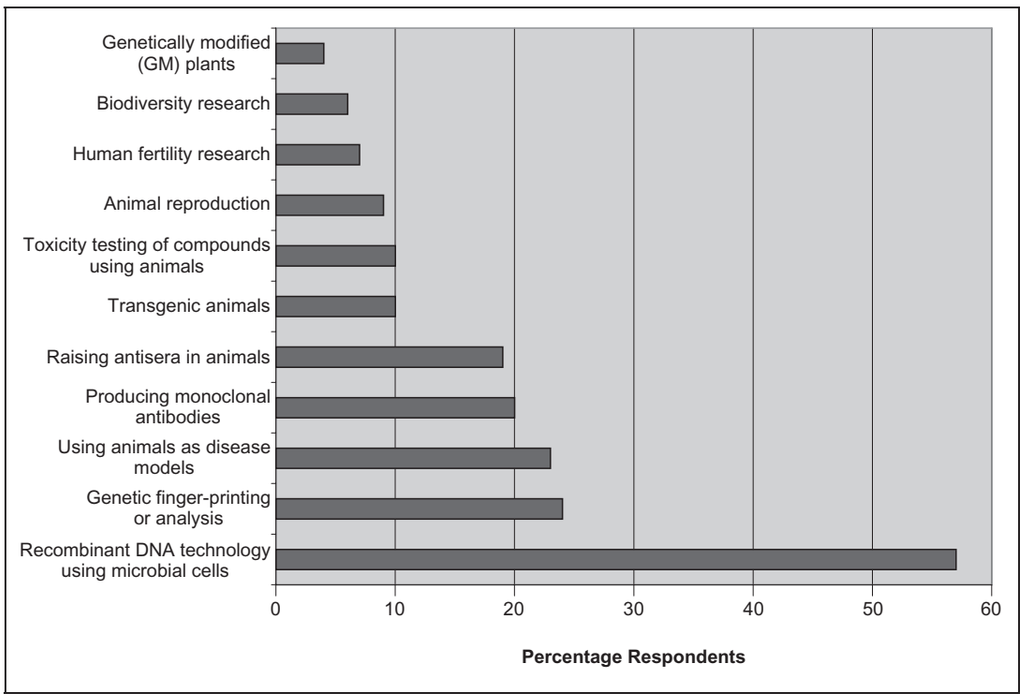

Fig. 7 Research experience profile of respondents. Agri-food and Irish government/regulatory excluded ($n = 70$ respondents). Respondents were asked to indicate any previous involvement with the research areas shown

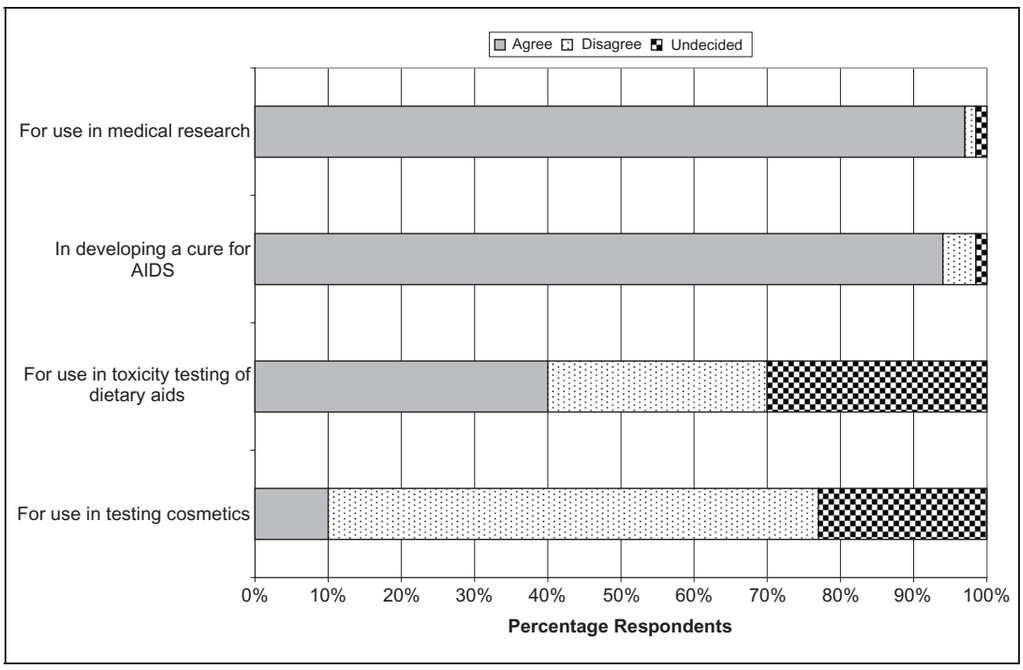

Fig. 8 Respondents were asked to indicate how they felt about animal experimentation by answering 'agree', 'disagree' or 'undecided' to each of the applications shown. Agri-food and Irish government/regulatory excluded ($n = 70$ respondents)

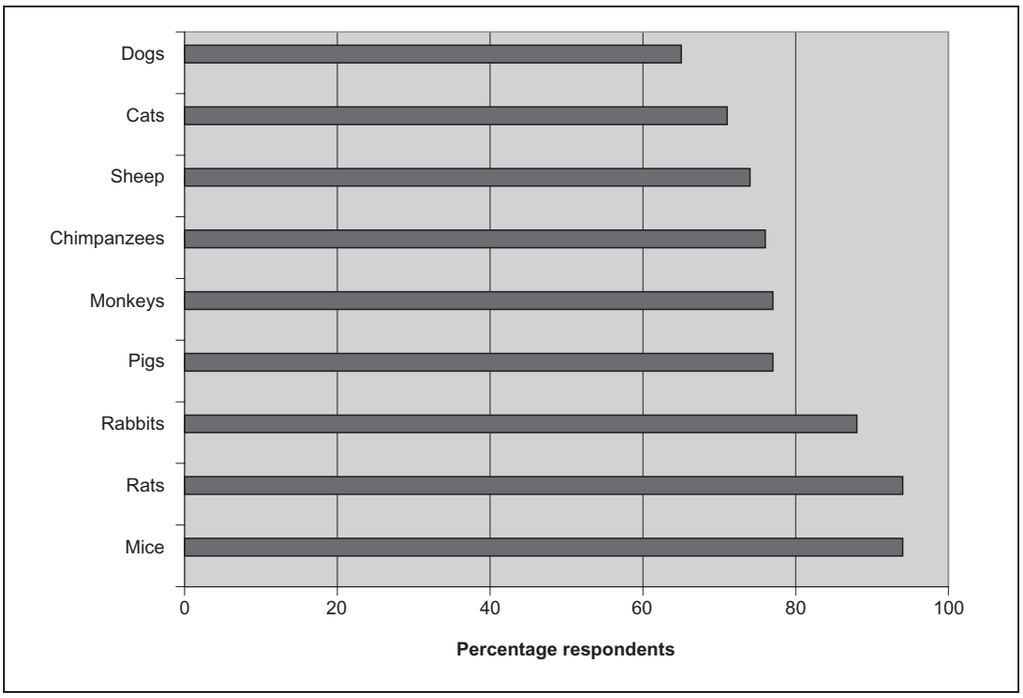

Fig. 9 Comparison of approval ratings for experimentation on different animal species. Agri-food sector excluded ($n = 82$ respondents). Respondents were provided with the scenario of whether they would approve of the use of an animal to test a new medicine intended to treat a serious human condition, 'such as AIDS or cancer'

different from that facing the industry in the early 1990s.

In the present study, the small sample size and the deliberate targeting of a highly educated and conservative audience dictate that the results of this work cannot easily be extrapolated to the views of the general public. Additionally, there are reservations about the appropriateness of interpreting these findings in a transnational context. Certainly, this is an audience which by any yardstick might be expected to be receptive to the concept of transgenic animals. Conversely, using the same logic, the expression of negative attitudes to any aspect of this technology from such an audience carries increased weight. Indeed, similar to many studies of this nature, it is easier to identify aspects that are currently 'taboo' than those that are unequivocally supported. Therefore, the finding that the use of transgenic animals in agriculture is much less supported than their use in medicine is significant, and confirms the findings of other surveys on this question.

The negative influence of biotechnology terminology on consumer attitudes has been previously reported.[37] However, the present study has shown that even with a scientifically educated audience, question phraseology and the indicated end-use may strongly influence the outcome of questions directed at the conventionally more favoured medical technology. Additionally, as seen with responses on whether blood sports should be banned, within this survey population there existed a cohort, which while not condoning certain practices, would passively support them through unwillingness to effect change.

Technological progress and opportunity do not wait for favourable market conditions to develop. There is currently a natural hierarchy of transgenic animal technologies progressing through the commercial development process.

Xenotransplantation, which for some people reportedly holds an almost visceral fear, is still some years away, and luckily will probably benefit from the integration of animal bioreactor technology in the intervening time period. Additionally, recent endorsement of xenotransplant technology by the Vatican[38] will undoubtedly ease its passage. The key question now relates to the development of transgenic animals for human food, and more detailed studies of public views on this area need to be conducted.

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