

Assessing ethics and animal welfare in animal biotechnology for farm production

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Summary

This paper addresses the ethical issues involved in animal biotechnology. Considerable advances in this field have been made with transgenic fish, which may be the first real test case for regulatory bodies. Intrinsic concerns about animal biotechnology are often voiced in public debate, and the paper presents and critically discusses these issues. Even though these concerns may be hard to reconcile with standards of rational argument, they might still have practical consequences for ethical policy making. Animal welfare and environmental issues are discussed as the most salient extrinsic concerns about animal biotechnology. The most serious obstacle to a good risk assessment of animal biotechnology is the extent of scientific uncertainty. Ethical assessments need to address these uncertainties upfront, and the precautionary principle provides a good criterion for responsible policies. At the end of the paper, a practical method for the ethical assessment of animal biotechnology, the so-called ethical matrix, is briefly presented and discussed.

Keywords

Animal biotechnology – Animal ethics – Animal welfare – Ethical matrix – Precautionary principle – Risk assessment.

Introduction

Ethical issues have become more salient in many walks of life and are often the matter of wide-reaching policy decisions. In regard to the use of animals for farm production, ethics and animal welfare are very much on the political agenda and in the mind of the general public. This is especially true for modern industrial food production. There is a sense in which one may claim that more traditional forms of husbandry have always been anchored in one or another implicit professional code of ethics (32). Whatever the historical truth of such a claim may be, it is certainly the case that modern forms of industrial rearing of animals rest on a much less secure ethical basis. This underlines the need to assess ethical issues more explicitly.

This paper will address the assessment of ethics and animal welfare issues in the case of animal biotechnology for farm production. The paper will deal with farm production of

both agricultural and aquacultural animals. The term 'animal biotechnology' is used to cover all those genetic modifications of the living organism that are brought about by recombinant deoxyribonucleic acid (DNA) techniques (gene technology or genetic engineering) and that may include gene transfer or cell technology (cell fusion). The term 'animal' will consistently be used in the sense of 'non-human animal', and the paper will not consider the genetic modification of micro-organisms. The author will leave open the question to what extent the use of modern recombinant DNA-vaccines (that is, the transferral of DNA or ribonucleic acid to a target organism without genetically modified organisms [GMOs] as intermediaries – a modification of gene-therapy for animals) should classify an organism as a genetically modified (GM) animal (14).

The question of animal biotechnology arises in different settings, all posing different ethical challenges. For

instance, it is widely recognised that one needs to differentiate between GM animals for biomedical production (e.g. for human insulin or use of xenographs), for animal models in research, for pleasure or aesthetic purposes (such as aquarium fish), and for ordinary food production. The intended use of the organism and the value attached to that use are important for an ethical assessment. This paper will concentrate only on animal biotechnology for food production.

The aim of the paper is to delineate some topics that can be assumed to be important for ethical assessment. The author will also comment on some welfare issues. The final section provides a framework, a 'tool', for the ethical assessment of individual cases.

Current developments

Current scientific development is still some distance away from genetically engineered ordinary farm animals like pigs, cows, sheep or chickens that would come close to the marketing stage. This is in part certainly due to the relatively low success rate:

'The success rates of the techniques are low: for farm animals, overall, only about 10% of embryos on which genetic modification is attempted survive to birth and only about 10% of the offspring will be transgenic. So the overall rate of transgenic animal per injected embryo is 1% (compared to 3% in mice)' (2).

However, some future applications to increase growth rates or to improve disease resistance are conceivable. While several agricultural species have successfully been cloned, no major effort seems currently underway to bring cloning or transgenic mammals to the marketing stage. One may assume that this is only partly due to the scientific and technological difficulties that still lie ahead. More importantly, there appears to be considerable consumer resistance in industrialised countries towards such a development (2, 17). However, it seems safe to assume that the use of genomics will become important for breeding programmes for agricultural animals. Several efforts are under way to chart animal genomes for this purpose.

More progress has been made with GM fish for aquaculture production (12). The reasons for this are probably twofold: first, fish eggs are being fertilised externally, thus eliminating many complicated techniques required for mammals and increasing the success rate of DNA incorporation; second, aquaculture is currently the fastest-growing food-producing sector in the world, and thus provides incentives for further developments. Many of the ethical issues arising with respect to GM animals can be discussed in relation to GM fish, since such fish will most

probably be the first GM animal product that the average consumer will see on the market. Furthermore, GM fish production raises all the ethical issues that relate to other farm animals, such as animal welfare, but also raises concerns that are less apparent in other animals, such as environmental issues related to biodiversity.

Development of transgenic fish has reached the stage where several species are ready to be marketed in different countries. This is thought to be the case for GM tilapia in Cuba, GM salmon in the United States of America (USA) and Canada, and GM carp in the People's Republic of China. However, Cuba appears reluctant to go ahead with production at present, and in the USA the approval process at the Food and Drug Administration (FDA) has been unexpectedly delayed. European countries state that no developments are under way that would be likely to introduce GM fish to the market in the near future. Basic research in these countries may help pave the way for new breakthroughs, if the hurdle of consumer acceptance can be overcome. Thus GM fish will probably first be introduced in markets of the South and the People's Republic of China, and perhaps also the USA. What the effects of such a development will be for the global nature of aquaculture exports, and for the more restrictive policies of the European Union (EU) countries, can at present only be guessed.

Ethics: intrinsic arguments against animal biotechnology

Ethical concerns about the genetic engineering of animals may conveniently be divided into two basic types. The genetic engineering of a living organism may for a variety of reasons be thought of as being morally problematic in itself; for example, such engineering may be perceived as wrong or morally dubious due to the mode of production or to the source of genetic material. In such cases the author will use the term 'intrinsic concerns'. But genetic engineering may also be thought of as morally problematic because of its consequences. In that case, the term 'extrinsic concerns' will be used in this paper. When discussing the ethical issues of GM animals it is important to keep these two categories apart. For instance, considerations of risk are often central to extrinsic concerns, but have no force whatsoever where objections to a procedure are based on fundamentally intrinsic concerns.

Comstock (9) argues that all the variants of intrinsic arguments against (animal) biotechnology could be summarised in the following claim: 'it is unnatural to genetically engineer plants, animals and foods'. Such an argument could be spelled out in more detail in various ways. This paper will consider three of the most salient ones.

We should not be 'playing God'

Some people hold that it is ethically questionable to transfer genes from one species to another. This attitude is sometimes grounded in a religious belief that humankind should not violate boundaries set by God, and so this line of reasoning is usually referred to as the 'playing-God argument' (8, 20). Any 're-designing' of nature through the insertion of new genes is morally unacceptable according to this view. The argument does not occur in the Bible (in fact one may cite statements that contradict it), but is based on an interpretation of God's will. If one accepted the playing-God argument, this would entail an unconditional rejection of the genetic modification of fish and other farm animals.

The basic assumptions of the argument are the following: God has drawn up invisible boundaries between the realm of God and the realm of humans. Those that transcend this boundary are guilty of hubris (excessive pride). Obviously any such argument depends on specific religious assumptions about the relationships of God, humans and animals, and the argument is generally proposed by adherents of some forms of Christianity. The problem here is to know where the ethical boundary lies. The only 'safe' assumption would be not to interfere with the course of nature at all, but this would arguably exclude all systematic breeding efforts through the whole sphere of agriculture, particularly all selective breeding of animals. If, however, society wants to allow for breeding, then people must presumably regard some changes in the genetic make-up of species as ethically acceptable. In this regard the results of selective breeding and the results of recombinant DNA-techniques are on a par. The techniques differ in only two main respects:

- the first is the way offspring are conceived
- the second is the fact that, in the case of recombinant DNA techniques, the source of the inserted genetic information is not necessarily taken from the same species.

Are these differences ethically relevant for the playing-God argument? If the first difference were ethically relevant, then a prohibition would equally rule out artificial insemination or test-tube offspring. Most people, including deeply religious people, apparently accept both these techniques, and arguments based on this line of reasoning could not apply solely to transgenic animals.

The second difference is somewhat more complicated. However, an argument based on this point would have to clarify what the ethically relevant difference is between genetic information obtained from a distant species and genetic information that occurs through natural mutation. In each case, there is simply a certain sequence of adenin, thymin, cytosin and guanin in the DNA molecule. When expressed in an individual, mutant genetic information is

an important tool for selective breeding. In principle, the results of mutation could be just the same as the results of recombinant DNA techniques, given sufficient time. After all, according to evolutionary theory all species have developed from a common core. If we assume that there is an ethically relevant difference between a piece of genetic information obtained from a species other than the target species (and inserted by genetic engineering), and the same piece of genetic information but this time obtained from a mutant individual of the same species (and brought to expression by breeding), then that difference would have to relate to how this piece of genetic information came to be part of the genetic make-up of the target species. Since we are not at this point considering the way offspring are conceived or the role of technology in it (this was the first point), the only conceivable difference left is the history of this piece of genetic information. In the second case we have to wait until evolution creates this genetic information, while in the first case we shortcut evolution. Thus, in an ethical argument based on the second point mentioned above, the dimension of time must become a morally relevant feature for ethical considerations. In other words: all other things being equal, a long time span as in natural evolution would be acceptable, but a short time span as in genetic modification would be unacceptable. While time may indeed play a crucial role in regard to the risks (from the extrinsic viewpoint) involved in genetic modification (e.g. concerning the 'disrupting' effects of the spread of a genetic modification to the environment), it is difficult to conceive of time as an intrinsic ethical consideration. Therefore the author does not believe this difference could be viewed as ethically relevant without either making a number of questionable ad hoc assumptions, or rejecting the most basic assumptions of evolutionary theory.

This paper has already noted that the playing-God argument is typically associated with some proponents of Christianity, and that even within the Christian tradition there is considerable debate as to whether such an argument can indeed be based on religious belief. It is worth noting that no such worries have apparently been expressed by adherents of other world religions such as Hinduism, Buddhism, Judaism or Islam. The general impression is that concern with animal biotechnology on the part of these religious communities will largely relate to more specific aspects (extrinsic viewpoints), such as the utilisation of genes from certain animals (e.g. pigs or cows) rather than the technology as such. Developing countries may also face food needs that make them adopt a more pragmatic approach to animal biotechnology. Thus it is doubtful that religious arguments of the type mentioned here will have an important impact on the development of international standards.

In sum, the author does not believe that the playing-God argument can be backed by weighty rational reasoning.

The argument would imply that, for instance, breeding programmes in agriculture or the introduction of new plant species in a given ecosystem are morally unacceptable. Yet the domestication of animals and their 'design' for human production purposes is celebrated as an important cultural achievement. The proponents of this argument should be equally critical of traditional agricultural practices. It seems incoherent to restrict such an objection to gene technology. The author therefore suspects that the argument is based on ad hoc reasoning.

It is interesting to note that proponents of such a view will run into profound difficulties when asked to evaluate, for instance, the transgenic Atlantic salmon now targeted for marketing. This product does not contain a 'foreign' gene; rather it contains copies of its own genetic material. Other, similar developments are apparently also based on DNA from homologous species. If there is any initial intuitive force to the playing-God argument, much of it will be lost in these cases.

Alternatively, proponents of the playing-God argument could reject the demand for rational justification, relying instead on personal feelings. This would form the basis for argument, and the proponents would presumably add that they somehow intuitively 'feel' that the dividing line should be drawn precisely at the point where transgenic animals become possible. As a consequence, the argument is restricted to explaining people's personal preferences, without attempting to convince others. Empirically speaking, this may be precisely what explains the scepticism towards gene technology that is common among some (but not all) groups of people in European societies (5, 22). If the argument is framed in this way, the proponents retreat from rational social debate with groups that hold different opinions. This does not, however, imply that these sceptics should be disregarded in an attempt to build a social consensus. Their viewpoint should still command respect from those who disagree. Thus, the ethically correct way to deal with those sceptics would be to provide for informed consumer choice and participatory decision making: in other words, to stress procedural ethics rather than substantive ethics.

Genetic modifications of animals break down natural species boundaries

Intrinsic ethical concerns of a similar kind may also be raised without relying on an explicit religious foundation. Respondents in surveys about biotechnology (e.g. in the Eurobarometer surveys conducted on behalf of the European Commission) (2, 17) often express concern that genetic engineering is unnatural. The argument then is that the genetic modification of animals breaks some natural order among species that is in a finely tuned state of equilibrium. Nature and all that is natural is then assumed

to be valuable and good per se; tampering with nature, as do all forms of genetic engineering where species boundaries are crossed, appears as a hubristic interference with the natural order, and is thus conceived as intrinsically wrong.

Any such argument faces two difficulties that need to be examined. First, what is meant by being natural or unnatural, and second what is good about being natural and, conversely, bad about being unnatural?

It seems quite clear that a large part of our food production represents some form of unnatural element in nature. All domestic species and most agricultural crops are the results of selective breeding. Most of the 'nature' surrounding our cities has been shaped by human intervention and is, therefore, far from being natural. Thus a notion of nature in a general sense seems at least problematic when used in this argument.

More specifically, it may be argued that it is the genetic boundaries that exist between species that constitute what is 'naturally' given and that need to be respected. The insertion of unrelated genes may change the entire direction of evolution and represent human goals rather than a natural development. Against this view is the argument that species are never static: their genetic make-up changes over time. It can also be claimed that species are not genetically isolated. Certain viruses, for example, carry genetic material from one species to another. Also the notion of species may not be so firmly established from a biological point of view as many seem to assume; there are alternative conceptions of what a species is. In sum, the reference to nature and the natural is not such a firm foundation as the argument seems to presuppose. It merely points to the essential social construction of the term 'nature'.

Even if we were to accept some notion of natural, we need to ask why everything natural should be seen as good and everything unnatural as wrong. After all, conceptions of nature vary widely, from nature as benign and beautiful to nature as threatening, chaotic and pitiless. Charles Darwin for one viewed the works of nature as 'clumsy, wasteful, blundering, low and horribly cruel'. Nature carries with it a number of characteristics, and not of all them need be unequivocally good.

Furthermore, philosophers since David Hume have recognised what is normally called the 'naturalistic fallacy'. It states that one cannot infer an 'ought' from an 'is'; in other words, you cannot deduce a normative statement out of purely descriptive premises. Therefore, a given notion of nature does not carry with it any normative force without further normative assumptions of some kind. It remains unclear what such assumptions could be. It thus seems reasonable to conclude that arguments about the

unnaturalness of crossing species borders in genetic manipulation do not appear to have much ethical weight. They rest on unclear and imprecise language.

Animal biotechnology implies the commodification of all life forms

The main intuitive argument here would rest on the reductionist nature of genetic engineering. This reductionism implies that living organisms are treated the same way as all other parts of nature that become the object of techno-scientific intervention: in other words, life-forms are seen as nothing other than complicated machines (9). The complaint is then that such an approach implies a disrespect for life. Life is of a higher value than can be measured in economic terms alone.

The problem with this kind of reasoning is parallel to the arguments mentioned before. Generally speaking, if this argument were true and taken as a general and unconditional principle for the moral acceptability of interventions in nature, then a lot of other activities would fall prey to it – activities that are normally regarded as morally acceptable. Food production with animals that are not GM implies a commodification of life and in some sense reduces the organism to an economic value, as does all trading in living organisms. The fact that the assumed moral principle leads to what many would regard as counterintuitive consequences – namely, that these practices are morally wrong – would then be taken as evidence that the principle fails, at least if taken to its logical conclusion. Therefore, even if the assumption that genetic engineering entails a commodification of life forms is true, this in itself would not be sufficient to reject animal biotechnology in general.

Is there a way to counter this objection and preserve the reductionist line of argument? Some people would hold that what really matters here is not so much the fact that humans do indeed sometimes treat living organisms as commodities, but the degree to which they do so. This would be a version of the slippery slope argument. While some degree of treating living organisms as mere commodities is seen as consistent with our human nature (that is, as moral beings), the radical extension of such behaviour would be seen as seriously dehumanising. It may be assumed that such developments could deprive us of a basic respect for life that is essential to our moral nature. Therefore, a limit should be set on how far we may treat nature as a mere commodity on a market. But again, similar considerations to those discussed in regard to the playing-God argument apply here. It is far from clear why selective breeding would be viewed as still within acceptable bounds, while genetic engineering would violate these boundaries. To what extent can the techniques through which changes are induced be seen as more morally decisive than, say, the properties with

which the organism is endowed through such techniques? May it not be the case that factors such as animal welfare considerations, rather than the techniques used to modify animals, are really the decisive criteria of what may be dehumanising?

It seems there is no really convincing intrinsic argument against animal biotechnology. Obviously the proposed intrinsic arguments point towards important ethical considerations, but in the end they fail to establish a convincing case. Yet there are two important provisos here. First, the strong initial intuitive appeal of some of these arguments should count as sufficient reason not to disregard them out of hand, but to re-evaluate their relevance in every qualitatively new case. Perhaps an unrestricted and extensive use of animal biotechnology at some point does indeed cross borders that are unprecedented and causes us to forget the basic respect for life that is essential to our moral nature. Second, the mere fact that some of these intrinsic arguments are apparently strongly felt by many people – that these arguments represent what people sometimes call their ‘gut-feelings’ – should count as sufficient reason not to force upon them products that they find morally unacceptable. Even if we are unable to detect sufficient rationality in these reasons to accept them for ourselves, we should out of respect for other humans – who apparently operate with a different sense of rationality – ensure that we do not deny them the opportunity to make moral choices in the light of their beliefs. This would mean two things: there should be alternatives to food from animal biotechnology on the market, and there should be clear labelling of products from animal biotechnology.

The other ethical aspect to be considered in this paper covers the extrinsic arguments against animal biotechnology: arguments about the consequences rather than the nature of our technology. One such line of argument relates to animal welfare, another to environmental considerations.

Extrinsic arguments against animal biotechnology

Animal welfare

There are different ‘schools’ in regard to animal welfare, some more restrictive than others. Some take as their only reference point the feelings of the animal, so that the ability to feel pain becomes the crucial factor (11). Others look at animal health and physiological functions (7) as crucial criteria for defining animal welfare. Others again (such as those propagating eco-farming) regard the conditions of the animals’ natural living environment as the foundation

of animal welfare, so that the ability to follow natural instincts in a biologically preferred environment becomes crucial. These differences among competing conceptions are only partly based on science. To a considerable extent the differences are due to different philosophical outlooks, and may not be reconcilable. This is not altogether surprising, since views of animal welfare obviously depend on a variety of implicit value assumptions.

In Europe, the 1965 United Kingdom report on animal welfare that became known as the Brambell report was highly influential. The Brambell report (6) included the well known 'five freedoms':

- a) freedom from hunger and thirst – by ready access to fresh water and a diet to maintain full health and vigour
- b) freedom from discomfort – by providing an appropriate environment including shelter and a comfortable resting area
- c) freedom from pain, injury or disease – by prevention or rapid diagnosis and treatment
- d) freedom to express normal behaviour – by providing sufficient space, proper facilities and company of the animal's own kind
- e) freedom from fear and distress – by ensuring conditions and treatment that avoid mental suffering.

While it would certainly be wrong to claim that these freedoms have actually been translated into national law, one might still hold that they set a soft-law standard that is often referred to and that some countries have aimed to include in their national regulations for farm animals. Like all such general principles, these freedoms are imprecise and leave room for different interpretations. Much effort has therefore been devoted to specifying what phrases such as 'sufficient space' might mean for specific species in animal production, e.g. battery hens. It is not too far fetched to say that these animal freedoms function in much the same way as the Charter of Human Rights does for humans. They define a *prima facie* ethical standard that informs our judgements of particular cases. Indeed, there are striking parallels between the five freedoms of the Brambell report and the celebrated hierarchy of needs of the psychologist Abraham Maslow (24), who defined a five-level scale of basic human needs. The five freedoms seem loosely to match this thinking.

In regard to animal biotechnology, the challenge is certainly not less than the challenge of assessing animal welfare in general. The crucial question seems to be whether the genetic manipulation of the animal affects properties relevant to animal welfare. Many would consider that if there were negative effects on animal welfare the probability of a positive regulatory decision on

the production and marketing of GM animals would be severely reduced. For instance, the Norwegian Animal Protection Act, § 5 states:

'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' (3; author's translation).

Even though such legislation may not be the rule in all countries, pressure from the public and non-governmental organisations will probably create a situation in which the need to justify animal biotechnology in particular cases and in regard to animal welfare will in effect have similar results, regardless whether such provisions are encoded in law or not.

Exceptions to such a strict regime can be envisaged for the production of laboratory animals for use in medical research and for the production of animals as bioreactors for pharmaceutical products. In these cases an overriding human interest is often presumed that may in certain cases, where no alternatives exist, legitimise a significantly reduced level of animal welfare. Yet for farm animals, whether in agri- or in aquacultural production, it is hard to see that animal biotechnology can get away with standards of animal welfare that are lower than those applicable to ordinary animal husbandry. In the final instance, this will be decided by continued societal pressure, in particular from consumers, and a critical attitude towards biotechnology in general.

Animal welfare in regard to transgenic animals

It is difficult to say anything specific about the welfare of transgenic animals in general. In principle it may be better or worse than the welfare of the original animals. Obviously, a lot will depend on the kind of modification that has been made: in other words, which genes have been modified. Thus research will be needed to document the effects of such modifications. Even though the principal responsibility for documenting welfare effects may rest with the company that seeks to market the product, the availability of independent research scrutinising the effects is likely to be crucial. This will be a consequence of the lack of trust that the public now expresses towards industrial research.

However a range of experience is already available in regard to transgenic fish. It has been claimed that

unexpected phenotypical disadvantageous changes are the rule rather than the exception in the genetic modification of fish (33). More specifically, deformities of the head and other parts of the body have been documented for transgenic salmon (*Oncorhynchus kisutch*) (10). The documented deformities obviously have serious welfare implications for the fish. In addition, morphological changes and changed allometry have been documented for the same fish, leading to reduced swimming abilities (13, 23, 29). It also seems that transgenic salmon show deviant behaviour in the sense that there is an increased level of activity in regard to feed-intake and swimming (1, 10). Thus one can claim that the literature documents changes in morphology, physiology and behaviour in transgenic salmon.

On the basis of these findings one may claim that the welfare aspects of biotechnology in animal production require a close case-by-case and step-by-step evaluation in order to avoid negative impacts of the technology. There are still many 'unknowns' in our use of genetic biotechnology, and without more research on these issues there is good reason to opt for a precautionary practice that would give the animal the benefit of the doubt. Indeed, a precautionary approach to the welfare issue in animal biotechnology would seem to be justified if not implied by humanity's assumed ethical responsibility for the stewardship of production animals.

Environmental effects of animal biotechnology

Some animal biotechnology may have negative effects on the environment and biodiversity. As a general rule, it is probable that the larger the animal and the better the containment, the lower the risk of unintended environmental effects. This relates to the ease with which processes can be controlled. Since the ecological interactions of species may be quite complex and not always easily or quickly detectable, such a rule cannot be applied in all cases.

Leaving aside other environmental effects of feeding and containing the animals in appropriate surroundings (effects that may not be specific to animal genetic biotechnology), the main concern today is the spread of genetic material to wild relatives. Disturbances in our ecosystem raise ethical concerns, especially when some of the affected species and populations may already be at risk of extinction. Again, the main studies of these effects have been undertaken in regard to transgenic fish. One way to approach the possible gene flow from one population to another is to assess the net fitness of a specific type of fish (30). Muir and Howard (26, 27) list six traits that determine the net fitness of any animal, including transgenic fish:

- juvenile viability: chances of surviving to sexual maturity

- adult viability: chances of surviving to procreate
- fecundity: number of eggs produced by a female
- fertility: percentage of eggs successfully fertilised by male sperm
- mating success: success at securing mates
- age at sexual maturity.

Rather than regarding these as independent or associated factors, scientists now develop mathematical models to combine these parameters of the organisms' net fitness in order to assess the genetic consequences of escapes of a transgenic organism into the environment. Three possible scenarios or hypotheses can be discerned (30).

The purge scenario

When the net fitness of a transgenic organism is lower than that of its wild relatives, natural selection will work to purge any transgenes that the wild relatives may inherit (21). Some transgenic fish may indeed fall under this scenario, depending on the kind of modification that has been done. It is claimed, though, that this scenario need not be without any long-term effects. In small populations even temporary declines in net fitness are said to potentially threaten the survival of the population.

The spread scenario

A 2003 report by the Pew Initiative on Food and Biotechnology stated that when 'the net fitness of a transgenic fish is equal to or higher than the net fitness of a wild mate, gene flow is likely to occur and the genes of the transgenic fish will spread through the wild population' (30).

Some transgenic fish, such as growth-enhanced Coho salmon, reach sexual maturity earlier than their wild counterparts, and this has a significant effect on net fitness. In this scenario the invasion of transgenic fish has a lasting genetic effect on the wild counterparts.

The Trojan gene scenario

In this model it is suggested that enhanced mating success coupled to reduced adult viability would result in a rapid decline of the wild population. The transgenes would quickly introduce their genetic material into the wild population, while the lower viability would reduce population sizes. Thus, interbreeding of transgenic organisms with wild relatives would cause a rapid decline in total population.

Again there are a number of significant uncertainties relating to the effects on the environment and biodiversity. Obviously, no general or definite answer is possible at this

stage of our knowledge. One may point out that factors such as the introduction of sterile transgenic species could change the potential environmental threats significantly. Even in these cases, however, instability and uncertainty are factors to be taken seriously in our assessments. While transgenic fish may pose an environmental threat of serious proportions due to the lack of control of escapes, the principal points apply to all animal biotechnology. The experiences of exotic species can serve as a rough model for some of the potential threats.

It should be pointed out, though, that some of the risks mentioned in this paper are equally posed by organisms obtained from traditional selective breeding. It would thus be wrong to restrict these considerations one-sidedly to genetic biotechnology. From an extrinsic point of view, it is the consequences that matter, not the technology that brings them about. Therefore, one consequence of ethical clarification on these issues would be to argue for a stricter regime of control and licensing for all new breeds that are brought to production and market.

There is now a widespread agreement that the environment deserves our moral consideration. Several different positions have been propagated in environmental ethics, ranging from more moderate anthropocentric positions (34), to biocentric, ecocentric and deep-ecology positions (31). The discussion of these issues is currently characterised by a very basic and probably unavoidable pluralism. Yet, in spite of this there is recognition that some moral concern and value have to be assigned to environmental factors, regardless of how the arguments are presented, and how far people are willing to go with them. Even with a minimalist anthropocentric account one cannot morally defend many of the harmful environmental impacts that human technologies cause, given that the natural resources turn out to be scarcer than was previously supposed. The ethical assessment of animal biotechnology needs to take account of this, and include these considerations explicitly. Current practices seem to indicate that society falls short on any ethical measure that can be applied to environmental concerns. The inclusion of these concerns in ethical assessments thus appears as a moral imperative.

Assessments

Any kind of risk assessment of an innovation entails an implicit value stance. This follows directly from what kind of harm one is willing to test for (and thus what kind of harm is disregarded) and implies that the methods employed necessarily display some kind of value bias. Shrader-Frechette (35) argues convincingly that choices among various approaches, e.g. to identify carcinogenic or toxicologic risks, are beset with implicit value judgements. The same holds true for estimates of dose-response

relationships. Risk assessment is thus never totally value free or objective. By extension this will also be true for risk management and risk communication.

How to assess the risks of a genetic modification in an animal is a matter of some scientific controversy (15). It should be clearly understood, though, that the public ethical concern about GM animals cannot be fully satisfied by a merely scientific assessment of the involved risks. Many so-called consensus conferences (28) with lay panels have clearly shown, for instance, that people expect a reasonable level of safety for GM animals as a *sine qua non*, but that other considerations may be even more salient. Aspects that are frequently viewed as crucial for ethical acceptance include questions about what kind of need is satisfied by the genetic modification, who is to benefit most from it and who carries the risks, or whether the modification will contribute to long-term sustainable development. There seems to be a growing recognition that such assessments need to explicitly accompany the mere assessments of risks.

It should also be noted that benefits and risks, needs and values, cannot simply be weighed against each other in a manner that is implied by traditional risk-cost-benefit analyses. Many studies (35) show the ethical shortcomings of such an approach. Considerations of justice, for instance, typically are weighted too weakly if treated this way. Whereas risk-cost-benefit analysis treats justice as an aggregate of singularities, common viewpoints hold that justice has decisive qualitative features, for example when vulnerable groups like children or minorities are involved. These features imply that a mere sum of singular cases does not capture justice considerations adequately.

The same can be said in regard to ethical considerations of the need to respect dignity. Dignity, much like human autonomy, functions as a deontological principle that cannot fully be subjected to tradeoffs. In regard to the animal world it would be a weaker principle than the principle of human dignity found in the Human Rights Declaration, for instance, but would essentially demand a similar basic respect for living beings. Typically, philosophers would specify the principle as a form of gradualism, where 'higher' life forms demand more respect than 'lower' organisms. In deciding what is higher or lower, people typically choose a property that is considered morally relevant: evolutionary proximity (which brings primates closer to us than other animals), for example, or capacity to suffer (which will vary with the nervous system of the species), or sentience and/or 'intelligent' social behaviour (which would bring species such as whales and dolphins close to us as well). While there is still considerable discussion about how such a principle of dignity could be spelled out in detail, there seems to be some emerging agreement that pure anthropocentric considerations should be extended by some form of

biocentric ethical considerations as well. In this sense, animals become 'morally considerable' (18) and some form of dignity should be extended to them.

Risk assessments of GMOs are in many ways different from risk assessments of, for example, chemicals. We need to be pro-active, and thus cannot count on a large number of data collected over many years. The risks have to be assessed before actions are taken. This is why we normally proceed step-by-step and case-by-case. However, more important in a moral sense is the fact that what decision makers know may be insignificant in relation to what they do not know. In other words, the uncertainties involved may carry more moral weight than the knowledge that is available. That is why it is of the utmost importance to improve the ways of making the involved certainties visible for the decision maker. There are as yet no generally accepted ways to make uncertainties in scientific assessments visible. One of the earliest schemes to do so was presented by Funtowicz and Ravetz (16), and termed the Numeral, Unit, Spread, Assessment, Pedigree (NUSAP) scheme. However, since then several other approaches have been suggested. Currently the best and most elaborate approach is by Walker *et al.* (37). It depicts scientific uncertainty as consisting of essentially three dimensions (location, nature and level) that together make up an uncertainty matrix. Making the uncertainties of genetic modifications visible to the decision maker is a crucial condition for the ethical regulation and handling of GM animals. This includes taking due account of scientific controversy and of minority opinions or alternative expertise. Public decision making related to technological change needs ways to account for inherent scientific uncertainties (19). Unless the uncertainties are addressed in an explicit way, the most salient ethical worries of the public and the decision makers cannot be answered.

Addressing the uncertainties upfront is also a precondition for the application of the precautionary principle. This principle, though currently the subject of heated discussions between the USA and the EU, is widely interpreted as an ethically responsible way to deal with an uncertain future where great dangers may be lurking. In an ethical sense, it is natural to compare the principle with the legal (and moral) concept of culpable ignorance (36). The precautionary principle is essentially designed to manage scientific uncertainties in such a way that one errs rather on the side of nature than on the side of expected benefits.

What is important in our present context is that the assessment of the introduction of GM animals/fish for food production will always be faced with considerable scientific uncertainties, and that the good management of these uncertainties is the factor that seems decisively to be at the heart of ethical concerns for large sections of the public. There are considerable uncertainties about animal health and welfare that need to be taken into account. There is

significant uncertainty related to the environmental, and in particular biodiversity, effects (such as ecosystem imbalance, genetic depletion of wild stocks or transfer of diseases). The uncertainties surrounding the indirect possible effects of genetic modification, rather than the modification itself, may be the factors that are experienced as morally troubling. These worries are morally legitimate since environmental damage in general may be hard to repair, and may even be practically irreversible.

A practical framework for the ethical assessment of genetically modified animals

The above points represent a summary and rough overview of the most salient ethical issues surrounding the use of animal biotechnology. One of the main messages is that more specific assessments need to be made on a case-by-case and step-by-step basis. The question therefore arises of how an ethical assessment of a given animal biotechnology can be made in practice. The remainder of the paper presents one (but not necessarily the only) practically useful way to perform this task.

One method of ethical evaluation originates in principle-based ethics. It starts not with ethical theory, but with a selection of principles that can find a broad degree of support from different ethical theories or cultural beliefs. The principles are selected in such a way that they can be seen as roughly representative of families of values, thus capturing the relevant plurality of ethical concerns that are brought to the fore. The origin of this method is Beauchamps and Childress' approach in medical ethics (4). Inspired by medical ethics, Mepham (at the University of Nottingham) was the first to transfer Beauchamps and Childress' principles from medical ethics to a practical approach for addressing broader policy-related problems, modifying them slightly (25). Mepham produced what was termed an 'ethical matrix'.

The challenge with this approach consists in moving from the general level of the principles down to the level of practical questions. The first stage of the method is thus the setting up of a two-dimensional ethical matrix where chosen ethical principles are specified in regard to the interests of the stakeholders (the relevant stakeholders must be identified beforehand). One way to capture the relevant ethical principles would be to mirror the four-principle approach known from medical bioethics: do no harm, do good, respect dignity and be fair (do justice). The principle of respect for dignity seems more appropriate than the alternative principle of autonomy when dealing with animal stakeholders or the environment. The next

step is to determine how the technology at stake, in our case the genetic modification of animals, will affect the values described in the ethical matrix. This state of affairs can be structured in a consequence matrix, which will consist of the same cells as the ethical matrix. The consequence matrix gives a brief description of the assumed or possible consequences of a decision upon every affected value specified in the ethical matrix. With the ethical matrix and consequence matrix filled in, it is possible to see whether the different consequences amount to a violation of certain specified norms (expressed as a minus, for example), or whether they seem to be in accordance with the values (which may be expressed as a plus). These relations of consequences to specified norms are noted in an evaluation matrix. The evaluation matrix is thus a matrix that provides an overall picture of the ethical status of the issue at stake. No correct ethical answer can automatically be deduced from the evaluation matrix since weighting will be essential; the best ethical solution is essentially a moral judgment based on the totality of considerations expressed in the matrix.

Assume the aim is to assess the ethical aspects of a certain genetic modification of a fish species for food production in a region. Following the ethical matrix approach, the first task would be to identify the relevant stakeholders, e.g. small-scale producers and consumers. Another requirement would be to identify potentially affected organisms and their components of the environment, for example fish and biota. A proper set of ethical principles needs then to be established: justice/fairness, dignity/autonomy, the obligation to do no harm and the goal of doing good, for example. Once a common understanding of these principles is ensured, it is important that the principles are specified for each interest perspective. The result is an ethical matrix that represents the starting point of the ethical assessment (see Table I). It is clear that some of the cells in this table (marked *) relate directly to the scientific descriptions in the safety and benefit assessments of GM animals. Thus there is an

overlap between the ethical assessment and risk assessment and management. Scientific data will provide information on how the technology relates to the qualities described in the various cells of the matrix. This is termed the 'consequence matrix'. One can now mark whether specific consequences of the new technology promote, inhibit or remain neutral to each of the specifications in the cells. At the same time, the significant uncertainties in the matrix must be marked. In the end, recommendations can be made that are informed by the totality of ethical considerations and conflicts. Table I depicts a tentative basic matrix. The next step would be to evaluate how the consequences of a specific product would affect the considerations expressed in the different cells.

This method has been applied and analysed in various ways by different research groups (see 'Overview tools to facilitate the ethical decision-making by governmental regulators' at www.ethicalbiotatools.wur.nl/docs/Overview_Tools.doc). Once the need for a tool or framework to assist ethical evaluation in decision making is acknowledged, it seems logical to work with a practical framework of the kind presented here. The absence of such formalised ethical decision frameworks invites accusations that the ethical evaluation is either ad hoc or biased, hinders transparency of the involved process, and makes international comparison and mutual learning difficult. The ethical matrix is a tool that can facilitate quality assurance in practical ethics.

Conclusion

When ethical assessments need to be made in a practical setting, an explicit framework or tool to assist this task should be employed in order to allow for greater transparency and quality control. This paper has attempted to show that explicit ethical and welfare assessments of animal biotechnology are necessary and, in spite of their

Table I
Simplified ethical matrix for the hypothetical case of genetically modified fish

Ethical matrix for genetically modified fish	Avoid doing any harm	Try to do some good	Dignity/autonomy	Justice/fairness
Small producers	Dependencies on nature and corporations	Adequate income and work security	Freedom to adopt or not to adopt	Fair treatment in trade
Consumers	Safe food*	Nutritional quality*	Respect for consumer choice (labelling)	General affordability of food product
Treated fish	Proper animal welfare*	Improved disease resistance*	Behavioural freedom	Respect for natural capacities (telos)
Biota	Pollution and strain on natural resources*	Increasing sustainability*	Maintenance of biodiversity	No additional strain on regional natural resources

* items that relate directly to the scientific descriptions in the safety and benefit assessments of genetically modified animals

value dimensions, are far from being relegated to the realm of the merely subjective and idiosyncratic. Science and ethics can work together to make such assessments practical and transparent. It is hoped that this can pave the way for ethics and animal welfare aspects to become concrete and permanent features of our regulatory systems and to be integrated in routine quality assessments of animal biotechnology for farm production.

(Parts of this article have previously been published online as working paper topic 6, in connection with expert hearings on Biotechnology and Food Safety, arranged jointly by the Food and Agriculture Organization and the World Health Organization; see: http://www.fao.org/es/esn/food/risk_biotech_animal_en.stm.)



Évaluation de l'éthique et bien-être animal dans le cadre de la biotechnologie animale appliquée à la production en exploitation

M. Kaiser

Résumé

Le présent article traite des questions éthiques engendrées par la biotechnologie animale. Les poissons transgéniques pourraient représenter pour les organes de réglementation la première situation dont la résolution aura véritablement valeur de test. Les préoccupations inhérentes à la biotechnologie animale sont souvent exprimées dans les débats publics. L'article présente ces craintes et les soumet à un examen critique. Même si ces inquiétudes peuvent être difficiles à concilier avec les principes d'une argumentation rationnelle, elles pourraient encore avoir des conséquences pratiques sur l'élaboration des politiques liées à l'éthique. L'auteur analyse les problèmes de bien-être animal et d'impact sur l'environnement, en tant qu'ils constituent les principales problématiques extrinsèques suscitées par la biotechnologie animale. Le principal obstacle à une bonne évaluation du risque lié à la biotechnologie animale est représenté par le degré d'incertitude scientifique. Les évaluations d'ordre éthique doivent d'abord prendre en compte ces incertitudes et le principe de précaution est un bon critère pour l'élaboration de politiques responsables. Une méthode pratique d'évaluation d'ordre éthique de la biotechnologie animale, appelée grille éthique, est brièvement présentée et examinée à la fin de l'article.

Mots-clés

Appréciation du risque – Bien-être animal – Biotechnologie animale – Éthique animale – Grille éthique – Principe de précaution.



Valoración de las cuestiones éticas y de bienestar animal que plantea la biotecnología aplicada a la ganadería industrial

M. Kaiser

Resumen

El autor trata las cuestiones de orden ético que plantea la biotecnología aplicada a los animales. Para las instancias normativas, el caso de los peces transgénicos podría constituir una primera experiencia en condiciones reales y sentar por ello un precedente. Por otra parte, en la opinión pública se manifiesta a menudo cierta inquietud por las posibles consecuencias de todo ese conjunto de técnicas. El autor describe y examina desde distintos puntos de vista dichas preocupaciones, que, aunque a veces no correspondan a lo que cabría esperar de un debate racional, en la práctica pueden influir en la elaboración de políticas sobre los aspectos éticos de la cuestión. El autor se detiene en los dos temas que más preocupación extrínseca suscitan: el bienestar de los animales y el medio ambiente. A la hora de realizar una buena determinación de los riesgos asociados a la biotecnología aplicada a la zootecnia, el principal obstáculo reside en el alto grado de incertidumbre científica que acompaña al tema. Para proceder a una evaluación desde el punto de vista ético es indispensable afrontar esos interrogantes, y en este sentido el "principio de precaución" ofrece un buen punto de partida para elaborar políticas responsables. Al final del artículo el autor describe y examina someramente la denominada matriz ética, que es un método práctico para evaluar la dimensión ética de la biotecnología aplicada a los animales.

Palabras clave

Bienestar animal – Biotecnología aplicada a los animales – Determinación del riesgo – Ética animal – Matriz ética – Principio de precaución.



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