

Effective Policies in the Animal Genomics Era: How Best to Involve Ethics, Expertise and the Public

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Summary — Genomics will have a significant impact on animal use in life science research. Together with related developments such as animal biotechnology, it also raises ethical issues that have to be addressed by society. Societal demands for regulatory accountability and transparency make it very unlikely that these issues can be addressed solely via current Institutional Animal Care and Use Committee (IACUC) reviews. New, more open ways of public policymaking are needed to effectively deal with these issues. Policy science can offer guidelines on how to structure such new policies. In particular, the so-called *theory of policy problems* sheds light on how to approach such a new development. Taking the Dutch animal biotechnology policy as an example, and keeping this theory in mind, some of the do's and don'ts with regard to involving experts and the public in public policy will be discussed.

Key words: *committees, ethics, genomics, public participation, public policy, The Netherlands.*

Introduction

Only a few decades ago, it would have been unthinkable that established researchers in the life sciences would have accepted the authority of Animal Ethics Committee (AEC) over their research. Nowadays, it is unthinkable that established researchers would not accept the authority of an AEC, better known in the USA as an Institutional Animal Care and Use Committee (IACUC). In the life sciences, not only the research itself evolves rapidly, but also the way of thinking about what counts as ethically credible research. The general acceptance by researchers of the *ex ante* approval procedure to carry out research on vertebrate animals, in itself, shows the success of the IACUC system. IACUCs, as small committees of scientific experts supplemented with a few “non-specialists”, typically assess whether the harm done to animals can be justified in the light of the societal importance of the research project. In this utilitarian approach, assessing the harm done to animals usually takes the form of assessing whether the Three Rs have been duly considered, so that the invasion of animal welfare has been minimised. Furthermore, this review procedure typically takes place in a local, closed setting: the review normally is not open to the public and is tied to the experiments performed at a specific institute.

Developments in Science and Technology

It has become clear that recent developments in science and technology, especially in biotechnology,

raise issues that ask for a more open discussion in society, beyond the Three Rs paradigm. Public debates about animal biotechnology and biotechnology in general have shown that citizens, at least those in the Western world, have extrinsic concerns beyond animal welfare, as well as intrinsic (deontological) concerns (1). Extrinsic concerns exist with regard to long-term effects on animals and the environment (biodiversity), but also, for example, with regard to human food safety. Intrinsic concerns are often expressed in the form of objections to scientists “playing God” with no respect for the dignity and integrity of creation. In its secular variant, this is called “tampering with nature”, reducing animals to a mere commodity. With regard to animal biotechnology, these concerns are expressed as objections to the crossing of species barriers and the violation of species integrity. On another level, these objections are expressed as objections to specific new “instrumental” use of animals; as bioreactors for the production of biomedical proteins, as organ donors for xenotransplantation or as clones of beloved pets.

The Genomics Research Programme

Looking at more recent and future developments, one can see the field of genomics rapidly evolving into a whole new branch of the life sciences (2). To date, little research has been done on the specific influences animal genomics will exert on the use of animals in science. Some qualitative assessments about the impact of animal genomics can, however, be made. For example, it is clear that genomics will

boost the demand for animals in fundamental research on developmental biology and aetiology of diseases, as well as boost the use of (transgenic) animals as specific disease models (3). At the same time, however, genomics offers great opportunities for the Three Rs. Opportunities exist for *replacement* by *in vitro/in silico* experiments and by extrapolating data from “lower”, but genetically related, species. *Reduction* opportunities exist due to better understanding of the relationships between genotype and phenotype. *Refinement* can arise due to better understanding of physiological interaction: more accurate and humane endpoints and research on sub-clinical effects.

Several other “trends” more indirectly related to genomics can also have a substantial impact on the use of animals in science. More knowledge about the relationships between genotype, health and food can, for example, give a scientific boost to the trend toward healthy and personalised diets. New health claims on food, however, have to be substantiated, which will undoubtedly lead to more and stricter safety standards for these new foodstuffs. This will have significant consequences for both the way animals are reared on farms and for the way the safety of foodstuffs is tested on animals in laboratories.

Another indirect impact of genomics is that it will further the evolutionary “metaphysical” view on the place of humanity in the world: Darwin’s evolutionary theory is now being corroborated on a molecular level, leading to further knowledge of evolutionary kinship between humans and other animal species (4). This, on the one hand, may support the scientific claim for using animals as human disease models in research, but on the other hand, it may support the ethical (proportionality) claim for not using these animals, no matter the scientific benefits. In comparison to biotechnology, genomics can thus bring some additional concerns to the scene but also alter — either by enhancing or by reducing — some existing ones.

From a policy maker’s point of view, it is also relevant to note that genomics is strongly linked to biotechnology, both in research programmes and in infrastructure and commercial interests. In some ways, genomics may even become an alternative for biotechnology procedures, applying precisely targeted “genetic modification” without “transgenesis” (2). As such, genomics will also blur the differences between biotech and non-biotech research and their issues. Undoubtedly, such contextual aspects will also strongly affect the public perception of genomics. The embodiment of genomics in “big science” will, for example, link the concerns about it to genomics. Genomics thus adds to the observation already made about biotechnology: that a focus on animal welfare and the Three Rs concept alone no longer suffices (5). The dynamic modern life sciences,

with their biotechnology and genomics branches, will render a wider perspective necessary to the debate about the use of animals in science.

Developments in Society and Policymaking

In parallel to the sensational developments in science and technology, the societal context within which these developments take place also has changed dramatically. Society and its constituent structures have become increasingly democratised and globalised. This has had its impact on the conditions set on regulatory frameworks in societies. National and international governmental bodies are looking for ways to make the decision-making processes in public policy more democratic, transparent and accountable (6). With regard to scientific enterprise, governments have been and are looking for ways to democratise expertise and to establish transparent, independent and accountable scientific reference systems. Governments also look to ethics committees as a means to establish “transboundary” bodies that mediate between science, law, politics and public debate. The big question here is which conditions such ethics committees will have to meet in order to be effective in the new era of international animal biotechnology and genomics research. It is clear that local, closed forums, such as an IACUC, will not suffice — but is there a viable alternative?

An Alternative Approach from The Netherlands

The need for a broader, more open and accountable discussion was recognised early in The Netherlands. In Dutch society, the debate about animal biotechnology had already started in the late 1980s, when Dutch biotechnologists started research in which they inserted human genes into cows (7). This research caused a lot of debate in society, and in particular, also in politics. The early attention for this new technology led to governmental regulations that are quite unique in the world. These regulations are laid down in a chapter of the *Animal Health and Welfare Act 1992*, and in the *Animal Biotechnology Decree 1997* (8). The regulations state that biotechnological procedures on animals in principle are prohibited, because these procedures conflict with the “intrinsic value of the animal”. Only for substantial societal interests an exemption from this prohibition can be granted. This legal stance became known as the “no, unless” policy. The implementation of this policy was largely delegated to the national Committee on Animal Biotechnology (CAB), consisting of experts in both

ethics and biotechnology (nine members in total). The practical decision-making process was structured by following a specific review procedure in which the CAB gives case-by-case advice to the Minister of Agriculture on granting licences. Both the CAB advice and the proposed decision of the Minister are publicly available. For each individual case, citizens can request a public “hearing” and also file objections to granting a licence.

Another interesting aspect about the CAB review is that “respect for animal integrity” is an explicit assessment criterion. This criterion provided the ground to discuss and assess wider issues beyond animal welfare, such as intrinsic objections to instrumental use of animals in, for example, cloning or xenotransplantation. The criterion partially refers to a “respect for autonomy/dignity”, similar to that in human medical ethics, and partially more concretely to a respect for the nature of the animal: respect for species-specific behaviour, physical wholeness and overall fitness of the animal.

The general aims of the Dutch policy, as stated by the Government, were the following.

1. Clarification of the moral position of animals.
2. Strengthening of the moral position of animals.
3. Early assessment of morally problematic developments, thus facilitating societal debate.

The Government furthermore stated that this should lead to the drafting of general rules regarding the acceptability of animal biotechnology, based on a yet to be developed societal consensus on the acceptability of animal biotechnology.

So Did it Work?

In the Dutch approach, a national ethics committee thus was intended to function as a new instrument in “government and society co-decision-making”. In an empirical study conducted for the Dutch Office for Technology Assessment, the Rathenau Institute, we assessed whether this new approach in governmental policy realised its aims (9). For this study, we reviewed committee documents, carried out interviews with relevant actors and lay citizens, and carried out a media analysis. This provided qualitative information about the practical constraints on governmental ethical review and decision-making. The main findings were:

1. “Clarification of the moral position of animals” was largely confined to the biomedical field, since almost only for this field applications were filed (10).

2. Substantial strengthening of the moral position of animals could not be clearly identified. The CAB has not substantially changed the way Dutch researchers use and treat animals, nor does the Dutch use of animals in biotechnology research seem to differ substantially from neighbouring European Union (EU) countries. Some stakeholders however saw the review procedure itself as a procedural strengthening of the moral position of animals.
3. Within the CAB, differences of opinion existed. Furthermore, stakeholders involved in the licensing procedures dissented with the CAB and with each other on both factual and normative claims regarding the acceptability of animal biotechnology research.
4. There was no substantial public involvement or debate, nor substantial media coverage, with regard to activities of the CAB.

A Conceptual Analysis of Policy Problems

The Dutch experience demonstrated that there are several constraints on effectively realising the policy’s aims via a committee of experts. When we analysed the somewhat disappointing results with regard to achieving the policy aims, several factors causing structural constraints could be identified. Two important factors that impeded achieving the policy aims were the juridical context and the lack of clarity about key concepts. In identifying such constraints, it is important to separate structural from the more practical constraints. An obvious practical constraint is a lack of resources, such as time, money and staff. Whereas practical constraints can be solved without substantially changing the form and content of the policy as such, structural constraints are more difficult to address without such changes.

This can further be explained conceptually by way of the so-called *theory of policy problems*, developed by American and Dutch policy scientists (11, 12). This theory suggests that the overall review procedure itself, as a type of policy strategy, can only be effective if it matches how society frames the problem at hand. The theory conceptually classifies a policy problem according to the level of consensus/disagreement regarding norms and values on the one hand, and to the level of consensus/disagreement regarding the certainty of relevant facts on the other. These characteristics can be graphically depicted as two independent axes, as shown in Table 1. Thus, four types of policy problems can be identified. On both theoretical and practical grounds, these types of policy problems can be related to their own most suitable type of policy strategy, which has also been presented in Table 1.

The resulting types of policy problems and strategies are the following:¹

1. In an *unstructured problem*, there is no consensus between stakeholders, neither about facts nor values. An example of such a problem is the past and current debate about global warming. A *policy as learning* is appropriate here. This is the only policy not aimed at problem solving, but at problem structuring. In this type of policy, the focus is on gathering information about the problem, leading to a new vision on what the problem actually is.
2. In a *moderately structured problem (ends)*, there is consensus about the nature of the problem and about the general aim of a policy that should deal with the problem. There is, however, still no consensus about the best means to achieve the policy aims in practice. This type of problem is often found in environmental policy with a spatial component. Here, one can see the so-called “Not In My Back Yard” (NIMBY) effect, for example, with regard to deciding on the location of a waste incineration plant. A *policy as negotiation*, in which all relevant stakeholders participate in choosing between a limited number of alternatives, is appropriate for such a problem.
3. In a *structured problem*, there is overall consensus about both the problem and the way to solve the problem. This is the case for technical issues, such as the proper maintenance of roads. This results in a *policy as rule* (applying clear and non-contested rules).

4. In a *moderately structured problem (means)*, there is consensus about the best way and means to address the problem. There is, however, no consensus about what the problem actually is or what the aim of the policy actually should be. This is a type of problem that “logically” cannot occur, but it often arises with regard to ethical issues, such as euthanasia or abortion. The solution sought here is a *policy as accommodation*, usually resulting in procedures or very general policy recommendations, so as to pacify stakeholders.

This short article lacks the space for an in-depth overview of our conceptual analysis (see 9 for a detailed analysis), but some general points can be made here. The framework of the theory of policy problems highlights the remarkable differences between the CAB and stakeholders in framing the problem of animal biotechnology. Table 2 gives an impression of these differences. It shows that the arguments of the CAB are mainly found in the two bottom parts of the table. Due to its remit to advise the minister on licensing, the CAB predominantly focused on finding (legally sound) solutions to the problems encountered. As such, it was “forced” to treat all issues it encountered as solvable or at least “decidable”. It managed to do this in mainly two ways. On the one hand, it came to treat some issues as technical issues about which both factual and normative consensus existed, at least within a majority of the CAB (policy as rule). On the other hand, some unsolvable normative conflicts (in which factual uncertainties often also played a role) were frozen by depoliticising them with procedural decisions. These procedural decisions typically left the purport of ethical criteria

Table 1: Differentiation between types of policy problems and strategies according to the theory of policy problem

Consensus about facts	Consensus about values	
	No	Yes
No	Unstructured problem Suitable policy strategy: <i>Learning</i>	Moderately structured problem (ends) Suitable policy strategy: <i>Negotiation</i>
Yes	Moderately structured problem (means) Suitable policy strategy: <i>Accommodation</i>	Structured problem Suitable policy strategy: <i>Rules</i>

¹The theory also specifically differentiates the role science can play in the different types of policy problems. It thus also gives “rules of thumb” on how scientific expertise can effectively be implemented in public policy.

and norms open and deferred the real, substantial decision to the later place and time where the adverse event would occur. *De facto* the decision was thus deferred to IACUCs. This procedural way of handling a problem is typical for a policy as accommodation.

At the same time, however, many critical stakeholders were still focused on articulating and learning what they saw as problematic, stressing the problem rather than looking for solutions. Also, some “pro-research” stakeholders felt that there wasn’t a serious problem in the first place. The debate amongst stakeholders, therefore, mainly focused on the unstructured nature of the problem and on the lack of consensus between them. As such, the main points of debate amongst stakeholders are represented in the upper left corner of Table 2.

The discrepancy between the CAB and others in framing these problems itself has caused a persistent controversy about the Dutch policy. This is because stakeholders find that the policy, however well intended and laudable it may be, does not address their concerns (either about animals or about research). These conceptual considerations point out that some tasks cannot

efficiently be carried out at the same time by the same body, especially when the problem involves dissent about values. In particular, the tasks of problem-solving and problem articulation and clarification — in close cooperation and dialogue with society — do not combine well. As such, there was a structural constraint to bridging the discrepancy in problem framing between the CAB and the public (and thus to achieving the policy aims), because the discrepancy was, to a large extent, generated by the structure of the policy itself.

Remedying Constraints on Involving Ethics, Expertise and the Public in Decision-making on Animal Genomics

On the basis of our analysis, we have proposed several recommendations for remedying the problems encountered in practice (9). They come forth from our research on the Dutch approach, but they are based on the conceptual characteristics of the different types of policy problems, which have been comprehensively studied in different contexts. As such, the remedies put forward are relevant not

Table 2: Opinions of the CAB and stakeholders with regard to animal biotechnology research

Consensus about facts	Consensus about values	
	No	Yes
No	<p>Unstructured problem</p> <p>[chance for] serious suffering occurring should be prevented? (citizens)</p> <p>What are realistic alternatives? (CAB and citizens)</p> <p>What is the importance of the research? (CAB, citizens and professionals)</p> <p>What is the ‘weight’ of animal integrity? (CAB, citizens and professionals)</p> <p>Crossing of species barriers is a problem? (citizens and professionals)</p>	<p>Moderately structured problem (ends)</p>
Yes	<p>Moderately structured problem (means)</p> <p>[chance for] serious suffering occurring has to be monitored and when it occurs assessed by IACUC (CAB)</p> <p>Alternative has to prove itself first (CAB)</p>	<p>Structured problem</p> <p>Aim research realistic because financing by third parties (CAB)</p> <p>Violation of animal integrity not a reason to reject research (CAB)</p> <p>Crossing of species barriers not a problem if no welfare effects (CAB)</p>

only for the Dutch context, but also for the policy problem of “animal use in modern life science research” in general. Four recommendations will be briefly discussed.

One of the remedies proposed is to clearly separate problem identification from problem solving. An important aspect of structuring a policy problem is that a robust learning process of identifying and explicating problematic issues clearly precedes the process of actually dealing with these issues: in the process of problem-solving by taking case-by-case decisions. Both processes require their own, significantly different policy structure and organisation. This is especially important with regard to evaluating ethical concerns about intrinsic value and integrity. These are issues of a more general nature, less concrete than case-linked issues, such as determining the degree of animal suffering in an experiment. Already, out of pragmatism, these wider issues are not easily discussed or addressed in the context of problem solving, even when they may be broadly held. Problem identification of new, lesser-concretised concerns will easily be held hostage to the strategic, vested interests surrounding problem solving.

Another point worth noting is that these more general (intrinsic) ethical concerns will, in practice, often be evaluated against decontextualised sweeping statements of human benefits that can be achieved with such experiments. Against the backdrop of new breakthroughs in medicine imagery, less acute and concrete ethical concerns may be readily dismissed in the end, even when widely held and articulated in a learning process. It is, therefore, also important to discuss and develop alternative routes to achieve these breakthroughs, if these general concerns are to have any influence on the development and use of technology.

Collingridge’s so-called dilemma of control (13) points out the difficulty here; a technology can be easily influenced in its infancy, but at that stage, the interaction between technology and society is so poorly understood that the social consequences of the fully developed technology cannot be predicted. At the same time, when a technology is fully developed and its social consequences are known, it is then very resistant to change. It is, therefore, also important not to limit the process of problem identification and learning to a “one-off” affair. If an assessment framework is based on one quick problem identification process, there is a big chance that the framework starts defining (framing) problems according to what the assessment framework can assess (e.g. animal welfare), rather than freely and openly conceiving problems as they develop over time. Thus, it is important to revisit the process of problem identification and learning at regular intervals.

On a similar note, when in the phase of problem solving, it is important to identify and reflect upon structural constraints in policy-related discourse. One should especially be aware of possible discrepancies between problem framing in a policy context versus how society frames the problem. To involve society on these complex and somewhat (still) abstract matters, non-specialists will have to be elicited to participate. This requires that the discussion refer to personal experiences that non-specialists can relate to. For that reason, more abstract terms, such as animal integrity, probably have to be translated into concrete, appealing and experienced terms, such as freedom, independence, choice, dignity.

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