LOGO VSNU LOGO NFU LOGO KNAW

ANIMAL EXPERIMENTS OPENNESS CODE

Lange Houtstraat 2 * PO Box 13739 * 2501 ES The Hague * The Netherlands * T +31 (0)70 302 14 00 * F +31 (0)70 302 1495
post@vsnu.nl * www.vsnu.nl * Chamber of Commerce for The Hague 480226 * ING account number 1596415

Introduction

The Royal Netherlands Academy of Arts and Sciences (KNAW), the Association of Universities in the Netherlands (VSNU), and the Netherlands Federation of University Medical Centres (NFU) have drawn up this code in an effort to foster mandatory openness and dialogue concerning animal testing by means of self-regulation. In doing so, they are articulating the widely held belief that openness in scientific research involving animals is both desirable and necessary.

The authors of the code assume that animal experimentation in fundamental and applied research is unavoidable at the present time, and that the greatest possible care must be exercised when taking and executing decisions concerning such experimentation.

Public debate on the importance of animal testing and animal welfare is no longer the exclusive domain of government (rules, laws, supervision, enforcement) and the institutions and enterprises that conduct research, but of all stakeholders and interested parties in civil society.

Animal testing in context

For institutions that conduct medical, biomedical and biological research, animal testing is usually an unavoidable component of research projects exploring new knowledge of the causes of diseases and their prevention or cure, safety, nature and the environment, and fundamental knowledge of biological processes and mechanisms. It is vital that information on animal testing is viewed within the context of the aims and importance of such research, how the animals are used, and their welfare.

The ethical dilemma

Animal experiments constitute an ethical dilemma. On the one hand, there is the importance of scientific research in promoting better human and animal health and wellbeing and a healthy and natural environment, and in acquiring fundamental knowledge. On the other hand, there is the question of whether animals should in fact be used for such purposes. Because mankind controls the lives of animals, it has the opportunity and the responsibility to ensure that both sides of the question are given due consideration in a way that takes the interests and the welfare of laboratory animals into account as much as possible and at all times. As soon as a decision is taken to conduct in vivo research, the obligation to provide for the relevant animals' welfare arises.

Responsibility

The code assumes that the permit-holder bears responsibility throughout the chain for the decision-making concerning animal experiments and how they are in fact carried out. Part of that responsibility is to ensure the desired level of openness by making the organisational, staff and financial arrangements necessary to do so.

Public accountability and dialogue

Taking a responsible attitude toward laboratory animals and animal testing means being prepared to enter into dialogue with the public about this issue. Institutions that adhere to this code undertake to practise openness and public accountability. By accounting for their actions with respect to laboratory animals and animal testing, these institutions have an opportunity to:

- make stakeholders and interested parties partners in the various dilemmas;
- help develop a mandatory system of openness;
- take responsibility at organisational level.

The premise of openness and accountability must be firmly rooted in the institution's policy. Examples include guided tours (actual or virtual), conversations with stakeholders, lectures, participation in public debates, surveys, publications in in-house magazines, websites, explicitly drawing attention to animal testing (and the ethical issues involved) in theses and dissertations,

and press releases. Stakeholders may be organisations representing patients or consumers or concerned with healthcare, product and food safety, or animal welfare. Where necessary, the dialogue will lead to changes in the supply of information and/or policy.

If such policy is to have its intended impact (more understanding and an open dialogue), then the information will have to be presented in a way that responds the public's concerns:

- What are the aims of the research involving the animal experiments?
- What public and scientific interests are served by this research?
- Why has it been decided to conduct animal experiments, and what does this mean for the animals involved?
- Would it be possible to achieve the same aims without experimenting on animals? What is the institution doing to Replace, Reduce and Refine animal experiments?

One way of satisfying the need for information is for institutions to draw up an "annual report on the use of laboratory animals". A report of this kind makes it possible to report at research project or programme level on the following:

- the strategic research policy, the role of animal testing in the research, and the scientific and ethical reasons for the decisions taken;
- relevant and persuasive results;
- the policy on replacing, reducing and refining animal experiments (the 3Rs) and how that policy is implemented;
- activities related to education, public information and training;
- activities related to openness and dialogue.

Openness and safety

The signatories of the code are convinced that mandatory openness will help improve the public climate associated with animal testing. But openness also has its risks. A permit-holder will have to strike the right balance between openness on the one hand and the safety of the institution's researchers and other employees on the other. Intellectual property must be protected. Where necessary, data will be anonymised.

Openness and government

Although the code is intended for permit-holders, government also bears a major responsibility with respect to openness. Government should communicate more, and more effectively, about its role. It is, after all, government that makes many animal experiments mandatory, sets the rules for animal testing, finances and carries out much of in vivo research, and supervises that research. Government should make it possible for research institutions to adopt the approach to animal experiments set out in this code, and it should lend active support to that approach.

Explanatory note accompanying the Animal Experiments Openness Code

Foreword

The Royal Netherlands Academy of Arts and Sciences (KNAW), the Association of Universities in the Netherlands (VSNU), and the Netherlands Federation of University Medical Centres (NFU) have drawn up this code[1] in an effort to foster mandatory openness and dialogue concerning

[1] The boards of these organisations set up a working party for this purpose in the summer of 2007. The working party consisted of : Prof. L.M. Bouter (working party chairperson, VU), Prof. H.A.P. Pols (Erasmus MC), Prof. T.W. Mulder (Academy), Prof. M. Ritskes-Hoitinga (UMC Radboud), Dr J.G. Wolters (VU), H. Houtkooper (secretary LUMC) and Dr F.A.J. van Steijn (working party secretary, VSNU administrative secretary).

animal testing by means of self-regulation. These organisations represent approximately 25% of Dutch holders of animal experiment permits. Because they cooperate closely on scientific research, the three organisations were able to respond quickly to the public's demand for openness in animal testing. They invite all permit-holders in the Netherlands to join their initiative.

Society today would be unimaginable without science and technology. Every aspect of our daily lives is influenced by science, without our always being aware of it. Virtually every act we engage in takes place in a man-made environment, and, in many cases, involves the use of technology. Science is and will remain vital to the search for solutions to the many problems facing us. A very small proportion of scientific research makes use of animal experiments. That research has become a topic of growing public debate in recent years, and that is a good thing, because there are significant ethical considerations involved in animal testing. There are those who *object* to animal experiments on principle, but no one who *advocates* such experiments on principle. Those involved in animal testing are faced with an ethical dilemma. On the one hand, the purpose of scientific research is to promote better human and animal health and wellbeing and to care for the environment. Animal testing plays a meaningful role in this endeavour. On the other hand, there is the fact that animals are used in scientific research. Because mankind controls the lives of animals, it has a responsibility to ensure that in any decisions taken, the welfare of laboratory animals is taken into account as much as possible and at all times. The position of all those involved in animal testing is one of qualified acceptance and a wish to Replace, Reduce and Refine animal testing methods (the 3Rs).

This text concerns laboratory animals in medical and biological research and provides background information and an explanation of the Animal Experiments Openness Code.

1. Need for information on animal experiments

The public has a need for information on animal experiments and the associated ethical considerations. Although there is no hard data to demonstrate that need, in a public opinion survey conducted in 2004 by Intomart and commissioned by the Dutch Humane Society [*Dierenbescherming*] 82% of the respondents stated that they needed more information, and in greater detail.[2]

Further evidence of a genuine need for information is the fact that the website of the Foundation for Information on Animal Testing [*Stichting Informatie Dierproeven*] has had more than 140,000 hits since 15 May 2005 and receives daily requests for more information. Enterprises and institutions that conduct animal experiments receive many requests for information. The active membership of the Dutch Society for Replacement of Animal Testing [*Proefdiervrij*] and the emergence of the Party for the Animals [*Partij voor de Dieren*], a Dutch political party that aims to improve the position of animals in society, illustrate the salience of the subject.

Until 2005, organisations that objected to animal experiments on principle had what amounted to a monopoly in the "information market".[3] Little if any public information was available on why animal testing was necessary and the benefits of animal experiments for society. Nor was there much information on *how* animal experiments took place or the ethical considerations involved.

The uninitiated public is mainly interested in:

- *why* animal experiments are necessary to meet the research aims;
- the ethical considerations involved;

The working party was assisted by a group of experts who – in addition to working party members Ritskes, Wolters and Van Steijn – consisted of Dr J.M. Fentener van Vlissingen (Erasmus MC), Dr J.B. Prins (LUMC), R. Buré (WUR) and Dr C.W. Pool (Academy). The working party forwarded its recommendations to the three boards on 19 March 2008.

[2] This does not include information of interest to animal rights activists with a view to substantiating their objections.

[3] *Openheid overtuigt* [Openness persuades], 26 January 2004; survey concerning information about animal experiments in preparation for the establishment of the Foundation for Information on Animal Testing.

- the relevance of animal experiments to mankind;
- the availability of alternative methods;
- the suffering of the laboratory animals;
- what happens to them after the experiments are concluded.

The research institutions that subscribe to this code are working to achieve greater openness about the animal experiments that they conduct. Their intention is that every animal experiment in the Netherlands should be preceded by careful consideration of the ethical and other issues involved, that such experiments should be performed by skilled experts, that consistent efforts should be made to Replace, Reduce and Refine animal testing methods (the 3Rs), and that animal testing should be subject to close internal and external supervision.

1.1. Openness or disclosure

The evaluation of the Dutch Animal Testing Act [*Wet op de Dierproeven*][4] pushes for greater disclosure in the area of animal testing. Although the Government disregarded the evaluation's conclusions, the topic of "openness" or "disclosure" is no less relevant today. The difference between the two concepts must be clarified.

a. *Disclosure*: there is a statutory obligation to ensure that every member of the public has access to information on animal testing, regardless of whether he or she has invoked the Government Information (Public Access) Act [*Wet openbaarheid van bestuur*, WOB]. As a rule, that information should be complete – although there are exceptions – and the documents concerned must be the originals. The way in which the information must be provided and the time limits for provision are stipulated. This information is usually only comprehensible to experts.

b. *Openness:* a willingness on the part of those possessing information on animal experiments to engage in dialogue with the public on this issue; the dialogue is therefore entered into on a voluntary basis; the information does not need to be complete but may be condensed and need not include the original documents; it may therefore be presented in a manner that is comprehensible to a broad sector of society.

2. Public support and dialogue

The survey conducted by Intomart indicates that public support for research involving animal experiments is limited, although there are subtle distinctions depending on the purpose of the research and the type of laboratory animal used.

A slight majority of the Dutch population supports research intended to test medicines and vaccines. The same survey also reveals that the public considers animal welfare organisations as their most important and reliable source of information about animal testing. Government and industry (in particular the pharmaceutical industry) are not regarded as credible sources. Until recently, public debate in the Netherlands on the subject of animal experiments was sharply polarised and legalistic in nature; at the same time, however, the Dutch Humane Society and the Queen Sophia Society for the Protection of Animals [*Sophia-Vereeniging*] managed to engage in fertile discussion with institutions. There was and sometimes still is a lack of trust on both sides.

Until recently, animal welfare organisations focused primarily on disclosure, but this proved to be an arduous task that produced little in the way of relevant information. It was also an approach that provoked suspicion and resentment among researchers and institutions. Even when disclosure was in fact incorporated into animal experiment regulations, as in the Biotechnology

[4] *Een noodzakelijk kwaad* [A necessary evil], 2005.

and Animals Decree [*Besluit Biotechnologie bij Dieren*],[5] it failed to elicit broad public involvement in the debate; instead, discussion between the small, unvarying group who attended the hearings and the committee quickly reached deadlock.

The situation appears to have altered after the publication of *Een Proefdiervrije Wereld? Maatschappelijk verantwoord ondernemen en proefdieren'*[6] by the Society for Replacement of Animal Testing [*Proefdiervrij*] and the symposiums organised by the Dutch Association for Laboratory Animal Science [*Nederlandse Vereniging voor Proefdierkunde*, NVP] on corporate social responsibility and animal testing. The two organisations embraced openness about animal testing as their greatest common denominator and compromise between the field of animal testing and animal welfare organisations in an effort to answer the public's questions about animal experiments.

In the bottom-up procedure to prepare the amendment of the Animal Testing Act, all the parties involved were willing to negotiate a set of shared views and succeeded in doing so. It therefore appears that there is a basis for a productive, wide-ranging dialogue, although it by no means includes more radical organisations such as Respect for Animals [*Respect voor Dieren*] and the Coalition Against Animal Testing [*Anti Dierproeven Coalitie*].[7]

3. Openness and accountability

Enterprises and institutions must take into account the effect of their activities on people (internal and external) and their surroundings. They must account publicly for their decisions and efforts in this respect. In the business world, this is referred to as Corporate Social Responsibility (CSR). It encompasses all of an enterprise's core processes, such as purchasing, production, personnel policy and marketing. The issues involved include prevention of child labour, fair pay for producers, safe production processes, energy efficiency, equal treatment of employees and responsible marketing. Among the key factors of CSR are supply chain responsibility, transparency/openness and a willingness to engage in dialogue with external parties. The same principles can also be applied to research institutions. Here, the key factors include complying with legislation and regulations, promoting animal welfare (for example by adhering to the 3Rs), educating and training researchers and biotechnicians, purchasing policy and internal supervision.

3.1. Supply chain responsibility

The concept of supply chain responsibility is a useful one when considering the ethical issues involved in activities that may be harmful to those unable to defend themselves (i.e. animals). In the case of animal experiments, an ethical assessment should take place early on in the chain, when funding is awarded to scientific institutions or research projects. The European Union has already explicitly acknowledged its responsibility in this regard by subjecting research programmes to an ethical evaluation when awarding funding. The Dutch government and other funding bodies, for example charities, should follow this example. After all, by making funding available for research that involves animal testing, the funding body accepts responsibility for what happens elsewhere in the chain.

In addition to the ethical assessment by the Animal Ethics Committees (*Dierexperimentencommissies*, DECs) of the way specific animal experiments are conducted, an ethical assessment should take place at the earliest possible planning stage. In addition,

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[5] *Tweede evaluatie Besluit Biotechnologie bij dieren* [Second evaluation of the Biotechnology and Animals Decree], Ministry of Agriculture, Nature and Food Quality, 2005.

[6] M.C. Breems and N. van Geelen, *Een Proefdiervrije Wereld? Maatschappelijk verantwoord ondernemen en proefdieren* [A world without laboratory animals? Corporate social responsibility and laboratory animals], published by the Society and Enterprise Foundation [*Stichting Maatschappij en Onderneming*], commissioned by the Society for the Replacement of Animal Testing, The Hague, November 2006.

[7] AIVD report *Dierenrechtenactivisme in Nederland*, *spingplank naar Europa* [Animal rights activism in the Netherlands - Springboard to Europe], 2007.

government makes some animal experiments mandatory. This also means that it must accept a share of the responsibility meriting ethical justification.

All things being equal, this type of shared responsibility also extends to the shareholders and management of an enterprise that allocates research budgets. In a parallel case, the Access to Medicine Index makes clear that the responsibilities borne by shareholders and management are genuine, not hypothetical. Published for the first time in early 2008, the Index ranks the world's 20 largest pharmaceutical companies with respect to their efforts to enhance access to medicines in the developing world. The benchmark compares their R&D policy, patent and pricing policy and marketing. By signing an Investors Statement, investors have undertaken to review and take into account the analysis generated from the Index as appropriate in the environmental, social and governance analysis they conduct on the pharmaceutical companies they invest in To return to the subject of animal experiments, investors could also use their influence to prevent research from being outsourced to countries in which there is little or no legislation protecting laboratory animals.

A funding recipient – for example a research institute or corporate R&D director – is the second link in the chain and in turn bears responsibility for what happens farther up in the chain, where many different interests go to influence the scientific choices made over the course of various research programmes and projects. The consideration given to these interests is an implicit one, however. An explicit assessment, for example by a DEC, only comes into view at the end of the chain, i.e. for the specific experiment. The assessment does not take any of the prior choices and decisions into account. If the public is to understand and accept animal experiments, it is important to inform it of the ethical and other considerations and decisions – including those taken at higher aggregate levels – that have ultimately led to research involving animal experiments.

3.2. Transparency/openness

Openness concerning the ethical assessment of individual experiments (the advice of the DEC) only meets the demand for transparency to a limited extent. The public's main question is, naturally, why animal experiments are used to meet specific medical or biological aims regarded as important. The Minister of Health, Welfare and Sport believes it is the permit-holder's responsibility to provide the necessary information In order to do this in a manner comprehensible to broad segments of the public, such information should be provided at the aggregate level of the research project and research programme. In other words: it should be provided by those who can explain the aims of the research and the questions it poses.

Besides information on the research itself and the role of animal experiments therein, institutions and enterprises should also make their general animal testing policy clear. This includes the shelters in which they keep their laboratory animals, the way they train their researchers, biotechnicians and DEC members, and how they source laboratory animals. They should look specifically at the 3Rs; researchers need support and assistance in applying this strategy, which requires those trained in animal experimentation to have very specific forms of scientific knowledge and experience. The permit-holder must align its policy accordingly.

The requirement of openness also extends to the individual researchers. They can account for their actions in many different ways: by publishing their results, in their theses, in presentations, or in media interviews.

The DECs now publish their annual reports, and the Ministry of Health, Welfare and Sport consults with the Netherlands Association of Animal Ethics Committees [*Nederlandse Vereniging van Dierexperimentencommissies*, NVDEC] on the precise contents of these reports. The DECs may only report on their own actions and performance in their annual reports; this basically comes down to reporting a number of key figures and the details of their working methods and

assessment criteria. The Minister wishes the DECs to provide a number of example cases explaining their decision-making processes, and the DECs have agreed to do so. Inevitably, they will have to provide basic information on the scientific aspects of the relevant animal experiment covered in these example cases.

The permit-holders account for their actions to the Dutch Food and Consumer Product Safety Authority [*Voedsel en Warenautoriteit*]. They have a statutory obligation to register all animal experiments and laboratory animals on an annual basis, including a duty to provide detailed information on how and why animal experiments are conducted for inclusion in the Food and Consumer Product Safety Authority's annual report. The permit-holder makes an important contribution to openness in animal experiments in this way, specifically by revealing long-term trends in animal research and by disclosing any failures to comply with legislation and regulations.

By being open about the aims of their biomedical research and the resources that they use, permit-holders in fact present the interested information-seeker with an ethical dilemma in which they have clearly already taken their decision. They are showing that they have nothing to hide and are proud of what they do. By presenting arguments for and against in measured doses, permit-holders can demonstrate that they are well aware of the issues involved and understand any doubts raised by external parties.

3.3. Dialogue with external stakeholders

A willingness to enter into dialogue with external stakeholders is vital for institutions that accept responsibility for their actions. One absolute condition for fruitful dialogue is mutual respect for one another's positions, opinions and interests. By definition, this implies that people or organisations that avail themselves of unlawful means, such as intimidation or property damage, have excluded themselves from this dialogue.

It is important to note that the group of external stakeholders extends far beyond animal welfare and animal rights organisations. That group includes investors, funding bodies, organisations of patients, consumer organisations, charities, organisations of scientists and medical researchers, and professional associations such as the Dutch Association for Laboratory Animal Science and the Netherlands Society for Animal Technology (NESAT) [*Biotechnische Vereniging*].

A dialogue can take many different forms, for example discussions with stakeholders, participation in public debates, requests for responses, and surveys. Ideally, the dialogue will lead to policy being amended or information being modified in a way that satisfies the needs of stakeholders.

4. Permit-holders responsibility

Section 3 explained why it is up to permit-holders to take final responsibility for openness in animal testing at their institution. This final responsibility cannot be delegated to individual researchers or the Animal Ethics Committee.

5. Limits to openness

The following factors are frequently cited as obstacles to full disclosure in the public debate on animal testing:

1. the safety of individuals who work with laboratory animals may be put at risk;
2. premature disclosure of information may be a negative impact on the competitive advantage of the information's owner;
3. disclosure that may lead to legal proceedings slows the speed of innovation and has a negative impact on the Netherlands' competitiveness.

5.1. Safety

The key question is this context is whether openness will put the persons or institutions involved at greater risk. To begin with, it should be noted that the number of activists who actually avail themselves of unlawful means is very small. The relevant groups (Respect for Animals and the Coalition Against Animal Testing) know precisely where in vivo research is carried out. It is also relatively easy for them to use public sources (the Internet, Chamber of Commerce, the institutions' own websites, publications in journals) to find out who bears executive responsibility and what research programmes are under way, sometimes right down to the names of the programme managers or research coordinators.

The second observation is that activists tend to work in a structured manner and to pursue strategic objectives, often for many years and with steely consistency. Examples include their campaign to close down the Huntingdon Life Sciences laboratory and to prevent the building of new laboratories in the ScienceLink Park in Venray. Targets are never chosen simply at random.

Regardless of the above observations, there is an urgent need to ensure the safety of individuals who work with laboratory animals as much as possible. Animal experiments are carried out in the interests of human and animal health, a view upheld by a democratic majority that has made such experiments a legal requirement. Those who conduct animal experiments therefore deserve protection on the basis of this democratic principle. The task of protecting them is primarily the responsibility of the institutions or enterprises where the research is being conducted, which must see to it that the facilities and the data stored there are well protected. They can also draw on the knowledge and experience of institutions that have come under previous attack. The safety precautions include screening future staff (including interns), securing the facilities physically and providing for the necessary data security (including addresses and telephone numbers). The General Intelligence and Security Service [*Algemene Inlichtingen en Veiligheidsdienst*, AIVD] and the police force bear secondary – but no less important – responsibility.

Reports from Sweden and Denmark – where there is more openness on this subject than in the Netherlands – do not suggest that researchers or institutions are at greater risk; on the contrary. Reports from the United Kingdom have shown that a policy of non-disclosure is simply counterproductive; as a result, UK institutions and enterprises have deliberately pursued a policy of greater openness concerning their animal experiments in recent years.

It would be advisable to analyse the lessons learned in these countries and consider whether the methods used there can also be applied in the Netherlands, taking into account the particulars of its society (including the degree to which it is organised and its laws and regulations), its social and political climate and its geographical location.

A lack of openness may also involve extra risks. People tend to reason that "those who are not open probably have something to hide". Activists are quick to make use of this argument.

The law pertaining to animal experimentation and the related supervision are extremely strict; the procedures are meticulous, both in the Netherlands and most other European countries. It is important to publicise this sufficiently, as it is information that is often unknown to a majority of the public.

5.2. Competition

One absolute prerequisite for openness is that enterprises and institutions must be able to protect competition-sensitive information. It is a principle that has already been laid down in the Government Information (Public Access) Act [*Wet openbaarheid van bestuur*]. Permit-holders that cannot be held to account under this Act will naturally refuse to publish information that harms their business interests. It should also be noted that competition-sensitive information on animal experiments is often very scientific and highly detailed in nature. Such information is generally of

no interest whatsoever to the public at large. The public debate on animal experiments would therefore not be served by releasing such information (prematurely). After all, the debate concerns how we treat animals, not genes or receptors.

5.3. Litigation and bureaucracy

The lessons learned after the introduction of the Biotechnology and Animals Decree show that openness can be used/misused to throw up serious legal and bureaucratic barriers to scientific research. The fact that the engineering of genetically modified animals has, for the most part, disappeared from the Netherlands – it is much quicker to import them – is the unintentional but nevertheless serious side effect of a public procedure. As soon as there are more barriers to in vivo research in the Netherlands than in other countries, there is a risk that researchers will take their research abroad, potentially to countries where the relevant legislation is less sophisticated than in the Netherlands and where the rules guaranteeing laboratory animal welfare are less comprehensive. This is undesirable.

Because openness is voluntary and not based on imperative law, there is less risk of litigation. Whereas the media can tackle permit-holders who offer "feeble arguments" for their actions, a lawyer has scarcely any recourse. Other forms of voluntary openness (annual social reports, annual environmental reports) lead to few if any legal proceedings, whereas more mandatory rules for notification and reporting by listed enterprises have led to a steady stream of proceedings before the Netherlands Authority for the Financial Markets [*Autoriteit Financiële Markten*, AFM] and the Enterprise Section of the Amsterdam Court of Appeal [*Ondernemingskamer*].

To prevent bureaucratisation, it is important for permit-holders to have enough freedom to choose the form in which they account for their laboratory animal policy. A limited degree of harmonisation is good for benchmarking purposes, but a straight-jacket would be undesirable.

6. The code

Permit-holders that intend applying this code undertake to introduce measures starting in 2008 that will allow them to publish an annual document (starting in 2009) on the role of animal experimentation in the scientific research carried out in their institution or enterprise. This *Annual Report on the Use of Laboratory Animals* must be both relevant and comprehensible to laypersons.

The institutions also undertake to cooperate on developing a format for this annual report that makes benchmarking between enterprises and institutions possible and improves the functionality of the publications themselves.

Finally, they undertake to practise greater openness beyond publishing the annual report, as described in the code. Examples include guided tours (actual or virtual), conversations with stakeholders, lectures, participation in public debates, surveys, publications in in-house magazines, websites, explicitly drawing attention to animal testing (and the ethical issues involved) in theses and dissertations, and press releases.