

On the new European Directive on vivisection: a dangerous and cruel pseudoscience enforced against the will of the European citizens

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The following account is meant as a partial remedy to a concerted attempt at stealing vital information from the European citizens. It will be revised periodically, in order to report new developments or add relevant information. Please use it and distribute it freely. Comments are welcome (info@hansruesch.net).

What is happening at the European Parliament concerning animal experimentation

A proposal by the European Commission for revising the European Directive 86/609/EEC concerning «the protection of animals used for scientific purposes» is under examination at the European Parliament since its publication on the web in November 2008 (Proposal 2008). This is a topic European citizens know very little about, as the mainstream media are silencing the issue to the best of their ability.

So far there have been two votes, one on March 31 and the other on May 5, 2009.

The Members of the European Parliament (MEPs) voted on March 31 *rejecting*: 1) compulsory ethical review on animal experiments, 2) prohibition of using nonhuman primates for “basic research” (i.e. research without likely application to medicine), 3) inclusion in the “protected” animal list of more invertebrate species and of all animal foetuses in the last three months of their development, 4) prohibition to use animals caught in the wild populations.

On May 5 the MEPs voted again, in favour of *still less restrictions* to the use of nonhuman primates and to re-using animals in successive experiments.

The institutional procedure is by no means at the end. «The series of consultations, votes, amendments, and discussions that follows is intricate and may take anywhere from 1 to 3 years to be completed» (Coelho 2009). All interested people should do their best to get informed and to make pressures on their MEPs, just as the Che-Me-Vi (Chemical, Medical, Vivisectionist) Kombinat, to use Hans Ruesch’s formula (Ruesch 1992, 2006), has spared no efforts in its lobbying.

However, it is fair to say that those who think that emphasis on the rights of laboratory animals is the winning strategy to abate *vivisection* (i.e. invasive experimentation on live animals) have been proven wrong once again; in fact, it is now more evident than ever that to use this strategy means playing into the hands of the vivisectionist lobby. The decisions taken so far reveal not only that animals cannot hope for any mercy from the Che-Me-Vi, but also, as we shall see, the deep disrespect of our “representatives” at Strasbourg concerning the opinion of the citizens they are supposed, and lavishly paid, to represent.

Why the European Commission (EC) is making new regulations on animal welfare – and why everybody should care

But first let us ask why the EC should be right now working out new regulations for «the protection of animals used for scientific purposes». Not even the most naive people might imagine that this proposal arises from concern for the well-being of laboratory animals – you have only to consider what is happening all over Europe as regards the rights of (human) workers and migrants.

The answer to the question is contained in a label: REACH – the European directive on “Registration, Evaluation, Authorisation and Restriction of Chemicals” which has been published in 2003 and become a law in 2007. The reason for this directive is that, contrary to what the average citizen believes, *most of the chemicals which are on the market have never been proven safe* – indeed, these chemicals have *never been tested, not even by improper means*: in particular they have not been tested on animals. The last part is good news from the point of view defended in this paper. But... have we not been told for decades that animal tests were our dam against a sea of adverse effects produced by chemicals? Have we not been told again and again that we had to choose between a dog and our children?

Yes, we *have* been told so. But it was a lie... and in more ways than one! The basic mistake was to suggest that animal tests are reliable, which they are not (more on this below). However, there was a second point, which by now has been well documented: the industry has always done its best (or its worst) to *avoid making safety tests*, of any kind, and has gone for the animal tests only when forced by accumulating evidence of damage on humans and public outcry. The grim balance is that *for 86% of all marketed chemicals there are no data adequate to a safety assessment*.¹

You may conclude that humans have been treated as guinea-pigs. But it would be incorrect: *we have been treated far worse*. In fact, in the laboratories guinea pigs are usually examined for ill effects after they have been administered some chemical, because this is the reason they are there in the first place. On the other hand, *there has never been a post-marketing surveillance for chemicals administered to humans, with the only partial exception of drugs*. I say that drugs are an exception because there are indeed regulations on reporting adverse effects of drugs after they have been put on the market; however I call it “partial”, because these regulations work on a voluntary basis, and it has been estimated that today under the best conditions «reporting rates of serious reactions rarely surpass 5 or 10% of the total».² *Five or ten percent of the total!* If this seems an appallingly low figure (and yes, it is), I must add that in Italy the Health Minister stated in 2001 that 85% of the reported adverse drug reactions had «not yet been examined»!³

By the way, this provides also an explanation for the huge 86% figure reported above: if chemicals had been subjected to post-marketing surveillance, we would have, by now, a host of perfectly

¹ Hartung 2009.

² Meyboom & Edwards 2004.

³ Ruesch 2006, p. 278.

relevant archived data concerning their toxicity *on humans*. But this essential precautionary measure has never been enacted, lest the human lesser-than-a-guinea-pig started growing suspicious of the purported safety of all the “goods” that he or she was supposed to unremittently buy and unthinkingly use.

After several, alas, successful attempts at reducing the number of substances subjected to testing, the industry has landed on a relatively small number: only 5,500 out of 30,000 chemicals included in the REACH regulations (at the beginning the latter figure was over 100,000). However the cost of this testing with the traditional animal tests is still very high: it has been estimated to be 8.8 billion euros (that is, 1.6 million euros for each chemical, each test requiring 3,200 animals).⁴ For this reason the industry is not completely unwilling to switch to other, less costly tests, although it surely will fight all attempts at declaring unsafe chemicals which have been proven profitable, and this attitude will make life very hard for any new testing method, particularly if it is a *good* method. In this fight vivisection has always been proven invaluable.

Why animal tests will always be an hindrance in the path to a scientific toxicology

In fact it is easy to understand why animal testing, though expensive, is also so convenient: you can use it to prove anything. In fact it has been used for decades to contradict *human* evidence concerning toxicity and/or carcinogenicity of tobacco smoke, benzene, ionizing radiation, lead, arsenic, fluoride...⁵

Take as one present-day example, among many possible choices, trichloroethylene, an industrial solvent. Of 29 «independent risk assessments»,

[...] 6 studies deemed it non-carcinogenic; 10 found it to be carcinogenic in animals but unlikely to be carcinogenic in humans; 9 found it a plausible carcinogen in humans but with negative epidemiological findings; and 4 found it a plausible carcinogen in humans, with positive epidemiology. [Hartung 2009, p. 211]

It is clear that animal tests, which can always be “interpreted” as “confirming” any claim, no matter what has been their outcome, are even in this case serving the cause of underplaying the results obtained on human cell lines and epidemiology.

Or take Bisphenol A, which is one of the most used industrial chemicals (3 million tons are produced yearly worldwide!), as an important ingredient of the plastics of which many containers for food, particularly infant food (like feeding bottles), are made. The evidence of toxicity of this substance (which is easily released when these plastics are in contact with hot water or food, for instance) is very strong, if one refers to data obtained by non-animal methods, as the association Antidote Europe has done. Here is their report (BA 2009, where all references can be found), which is worth quoting at length also for its pedagogical value:

There is an abundance of scientific literature describing the effects of BPA in animal “models” but Antidote does not consider these studies to be relevant to human health, since no species can reliably substitute another when evaluating chemical toxicity.

There are three relevant approaches: the study of human biological material; epidemiological (human population) studies; molecular studies, where the structure of test substances is compared with those of known biological activity in humans.

⁴ Hartung 2009, p. 209, 212.

⁵ Mamone-Capria 2009.

As an early screening test, the science of toxicogenomics is ideally suited to the task at hand. Results can be obtained quickly, cost-effectively and are relevant to the species in question – humans.

Several such studies are already in the public domain. One such study – commissioned by Antidote Europe - shows that BPA and its metabolites (breakdown products) significantly interfere with the ability of the cell to guard against oxidative stress, uncontrolled cell growth (cancer), excessive hormonal stimulation and incorrect protein folding. This type of cell damage increases the likelihood of so-called “conformational” diseases, including Parkinson's disease, Alzheimer's, and adult onset (type 2) diabetes. Other effects on the body include hormonal imbalances during sexual development and a decrease in male fertility. The data from our study has been duly logged in an international database.

Additional studies with toxicogenomics and human cells, have shown that the oestrogenic effect of BPA is at least as powerful as the naturally occurring hormone, 17beta-estradiol, but that BPA and other estrogen-mimicking chemicals tend to amplify normal gene function associated with this hormone. Even tiny concentrations – which may have undetectable activity – are therefore sufficient to produce significant hormonal effects (leading to breast or prostate cancer) as well as genital malformations¹. These effects have been confirmed in human population studies.

Not only that, but from structural point of view Bisphenol A is similar to DES, one of the most insidious carcinogens ever man-made, causing transplacental cancer, a discovery that Hans Ruesch was one of the first reporters to disseminate in the 1970s (cf. Ruesch 2003, pp. 380ff):

It is an established fact that chemicals resembling each other structurally will have similar biological properties (QSAR concept). The compound diethyl stilbestrol (DES) also has two phenol rings, joined by two carbon atoms (instead of just one in the case of BPA). For a period of 30 years, DES was prescribed to pregnant women in France, as an aid to prevent abortion (but for which it was ineffective). A total of 200,000 women were exposed to this drug. It would take science 30 years to discover that this drug was teratogenic, producing serious birth defects (chiefly cervical cancer) in the daughters – and even the grand daughters – of these women.

It is worth stressing that even in the case of DES, repeated animal studies had not given the slightest suspicion that it could cause cancer.

Since BPA and DES closely resemble each other structurally, it is very likely that they will have similar biological properties. The catastrophic effects of DES are documented in medical history for all to see. **There is now the grim possibility that we will face a BPA "time bomb" sometime in the future.** Unlike DES, it will be a much greater challenge to remove BPA from our environment. Equally disturbing is the fact that not only pregnant women will be affected, but the entire population, especially young children. This represents an existentialist threat to the survival of the human species, where fertility in both sexes will be affected, in addition to causing an increase in diseases such as cancer, neurodegenerative conditions, diabetes, and many others.

Now, how has the Che-Me-Vi Kombinat acted in front of this wide-ranging scientific evidence on the hazards that Bisphenol A poses to humans? Why, they have made experiments... on rats, concluding that Bisphenol A poses only a «mild» or «insignificant» risk to humans:

Based on studies conducted in rats, the European Food Safety Authority (EFSA) published 23 July 2008 what it considers to be a “Tolerable Daily Intake” (TDI) of the chemical, at 0.05mg per kilogram of bodyweight.

Despite acknowledging significant differences between humans and rodents, EFSA apparently chose to ignore data on BPA obtained in human cells, which Antidote Europe presented to it in May, to bring the TDI figure more into line with data relevant to humans.

In support of its recommendations, EFSA stressed the fact that “*people metabolize and excrete BPA far more quickly than rodents*”, and concluded that “*the exposure of the human foetus to BPA would be negligible because the mother rapidly metabolises and eliminates BPA from her body*”. This

suggests that rapid metabolism of a chemical provides protection against adverse effects. However, many prescription drugs are also metabolized quickly in the body and eliminated in a matter of a few hours, **yet are able to exert powerful pharmacological effects on the body.** [BA 2008]

So European authorities are using a pseudoscientific methodology (vivisection) to exonerate, in the face of very convincing scientific evidence (which has been sufficient to Canada to ban BPA in 2008), a chemical which is highly profitable to industry.

These examples should also be useful in dissolving once and for all a spurious controversy about REACH sometimes debated between environmentalist groups and animal-rights groups, the first ones extolling REACH's importance, the latter ones criticizing it because of the 17.6 million animals that would be "used" (i.e. tortured) to comply with REACH's requirement *in case animal testing were systematically adopted*. The way-out from this impasse is simple: 1) *REACH with animal testing is a fraud, harming both animals and humans*, while 2) *REACH with really scientific methods is a very good thing* – indeed it is a shame that so much time had to pass before its emanation and implementation.

The double strategy of the governments to stifle opposition to vivisection

I think it is by now clear why the EC is working at new regulations: the aim is to grant animal testing a future to comply with the industry's "needs" (in the sense explained above), and at the same time to satisfy naive European animal lovers, who, unfortunately, are a sizable proportion of all who care for the well-being of animals.

As to disappointed AVs, who have been forced to endorse direct action in order to see some real change in the way animals are treated, it is a few years that a real war has been waged against them by governments in U.S. and Europe to protect trans-national corporations. This is another piece of censored news, indeed Project Censored included it in its "Top 25 Censored Stories for 2008" (PC 2008). The incredible fact is that in U.S. animal activists are called "terrorists" (even if no person has ever been injured by them!) and treated by law as such. Here are some details of this frightening development:

The term "terrorism" has been dangerously expanded to *include acts that interfere, or promote interference, with the operations of animal enterprises*. The Animal Enterprise Terrorism Act (AETA), signed into law on November 27, 2006, broadens punishment present under the Animal Enterprises Protection Act (AEPA) of 1992. One hundred and sixty groups, including the National Lawyers' Guild, the Natural Resources Defense Council, the League of Humane Voters, Physicians' Committee for Responsible Medicine, and the New York City Bar Association, oppose this Act on grounds that its terminology is dangerously vague and poses a major conflict to the US Constitution.

The broad definition of an "animal enterprise," for example, may encompass most US businesses: "any enterprise that uses or sells animals or animal products." The phrase "loss of any real or personal property," is elastic enough to include loss of projected profit. Concerns deepen as protections against "interference" extend to any "person or entity having a connection to, relationship with, or transactions with an animal enterprise." [...]

Author Will Potter argues that the harsher amendments that AETA brings to its predecessor, AEPA, are hardly necessary, as AEPA was successfully used to disproportionately prosecute the SHAC 7—six animal rights activists organized to expose the illegal and inhumane operations of Huntingdon Life Sciences—for "animal enterprise terrorism." Budgerigar of Earth First! recounts that three of the defendants were charged under AEPA in September of 2006 with interstate stalking and conspiracy to commit interstate stalking for organizing demonstrations and running a website that published names and addresses of those involved in

the vivisection industry. The group was collectively sentenced to twenty-two years in prison. “The supreme irony of this case,” notes Budgerigar, “rests in the fact that these activists were convicted of conspiracy to damage the profits of an animal enterprise, but not of actually damaging it. Even so, the ever-so-honorable judge ordered the defendants to pay a total of \$1,000,001 in restitution fees.”

Yet Congress deemed that AEPA was not a serious enough tool for going after animal rights “extremists.” [...] Budgerigar concludes, “The message could not be more clear: run an effective activist campaign, and you will be vilified, criminalized, and imprisoned.”

Equating animal activists with terrorists may seem too much even for an Administration like the one led by Bush jr, but in fact nothing is too bad to be impossible – if misinformed and credulous citizens let their government act against their own will.

What is Scientific Antivivisectionism

It is no coincidence that in the media and also in official documents the whole discussion on vivisection is being constantly framed in spurious terms, that is, in terms of «protection of animals». This assumes what must be proven, i.e. that the very enterprise of making experiments on animals is scientifically worthy.

Unfortunately, even groups which should know better contribute to the confusion. For example, it certainly does not help that the Dr Hadwen Trust for Humane Research, «the UK’s leading non-animal medical research charity», misleadingly commented on the second European Parliament voting as follows: «Today’s vote has been a partial victory for humane science offering a glimmer of hope for animals in laboratories but it doesn’t go far enough». ⁶ Some hope! You have only to read the exulting commentary by the vivisectionist journal *Nature* (NE 2009) to realize that a bad defeat is something different from a partial victory.

The present article is offered as a contribution to the public assessment of Proposal 2008 from the viewpoint of *scientific antivivisectionism*, according to which animal experimentation for the purpose of *medical and healthcare* advance and management *has no scientific merit* and as such *should be abandoned – completely apart from any ethical considerations concerning the respect which is due to nonhuman animals*, although, obviously, there is no denying that these considerations are also relevant in their own rights.

People perform experiments on animals for a variety of reasons, including the sheer curiosity of seeing what happens when they do this and this to such and such animals. While sheer curiosity may appear at first sight as an unobjectionable purpose from a purely scientific, as opposed to an ethical, point of view, in fact the issue is not so simple. As has been documented several times, the basic requirement for scientific experimentation in any research field, namely *reproducibility*, is often lacking in animal experimentation. In other words, there is no guarantee that the results found in a given experiment on a certain animal species are applicable *even to that very species!* ⁷

⁶ Hadwen Trust 2009.

⁷ See in general Giles 2006, and in particular Schnabel 2008, among many others («“People will do an experiment once with ten animals and get a result, and if it’s the right result it gets published in a high-profile journal”, says [Karen] Duff [of Columbia University, «who developed a popular Alzheimer’s mouse model»] [...] “And there’s no requirement that you show the effect again with a different set of mice, or in a larger group of mice, or in a different model” [...] Mike Sanser, a neuroscientist [...] notes that spontaneous genetic changes often affect the disease-causing mutant gene directly. [...] “You might create a mouse in your lab and distribute it to ten different people”, he says, “so there’s ten different colonies all over the world, and they’re all diverging from each other, genetically. So when I’m publishing my paper I’m talking about this

Moreover, as we shall see, a large majority of European citizens (68,0%) are strongly against the “curiosity” justification for experimenting invasively on animals.

This is also officially, if clumsily, recognized by the EC. The EC Protocol on Protection and Welfare of Animals annexed to the 1997 Treaty of Amsterdam «recognizes animals as sentient beings», and «requires the Community, and the Member States, to pay full regard to animal welfare» (TA 1997). Clearly, sheer curiosity separated from a rational expectation of useful applications fails to meet this requirement, and it certainly does not strengthen its case to qualify it as “scientific” in the noncommittal sense that *some scientists do have that expectation*. To throw a cat in boiling water does not deserve a different appraisal whether one does it out of a psychopathic condition or out of “scientific curiosity”. Indeed, *it is hard to distinguish this sort of “scientific curiosity” from a psychopathic condition* – and, alas, there is plenty of hard evidence for the substantial incidence of this variety of mental illness among laboratory workers (at any hierarchic level). In fact the prophet of vivisection, Claude Bernard, described as follows the attitude of the *ordinary* vivisector in 1867:

The physiologist is not a man of the world, he is a scientist, a man caught and absorbed by a scientific idea that he pursues; he no longer hears the cries of the animals, no longer sees the flowing blood, he sees only his idea; organisms which hide from him problems that he wants to discover. He doesn't feel that he is in a horrible carnage; under the influence of a scientific idea, he pursues with delight a nervous filament inside stinking and livid flesh rthat for any other person would be an object of disgust and horror [...]⁸

Whether or not this description fits the criteria of paranoid schizophrenia, as has been surmised and seems likely, there is no doubt that the “physiologist” as described here is a psychiatric profile. Is it reasonable to entrust the care of our health to *these* people?

Scientific antivivisectionism (AV) is the outcome of more than 150 years of reflections by several categories of authors (scientists, medical doctors, historians, methodologists, philosophers) on the scientific merit of experimenting on live animals to safeguard human health and life. It has been stated in detail in several works, most famously in *Slaughter of the Innocent* by Hans Ruesch (Ruesch 2003) and *Vivisection or science?* by Pietro Croce (Croce 1999). The verdict is a sharply negative one: no species can be taken as a suitable mirror for another species whenever the workings of chemical and physical agents, and in particular drugs and medical treatments, are investigated. To rely on supposed analogies at this level is in fact like playing Russian roulette with human health.

This has been tragically brought home by thousands of flawed and dangerous drugs being recognized as such only in the post-marketing surveillance, from Thalidomide to Vioxx (and beyond).⁹ Notice that «according to the US Food and Drug Administration, for every 100 pharmaceuticals that successfully pass animal safety testing, 92 fail in human trials».¹⁰ Today it should seem unnecessary to emphasize this point, since even pharmaceutical industry's CEOs agree

mouse, and you think you have the same mouse in your hands. But do you really?». Cf. also Fallon 2008, who leaves it as an open question: «Why are there differences between data generated by different groups *on apparently the same mouse model or strain?*»)

⁸ Cit. from Ruesch 2003, pp. 297-8.

⁹ On Thalidomide, see the short update Matthews 2008b; of the same author see also Matthews 2008°, and the reply by a well-known spokesman for the Che-Me-Vi Kombinat, revealing the intellectual and moral inanity of his position: «Animal research is morally and scientifically defensible whether it has contributed to some, many or virtually all medical advances of the last century» (Festing 2008).

¹⁰ Matthews 2008b.

that the future of their business lies in tailor-made drugs, i.e. drugs designed to fit the individual genetic make-up of the (human) patients. It is utterly absurd to hold that a dog or a mouse may “model” a human illness accurately while at the same time conceding that human individual responses to drugs can vary so tremendously as to make the engineering of individualized drugs a profitable undertaking! And yet today’s vivisectionists wallow in this huge contradiction – without sometimes even noticing it, especially at the lower steps of the hierarchic ladder,.

Why the chemical and pharmaceutical industry is for vivisection

The fact that the chemical and pharmaceutical industry can accept and is willing to go on indefinitely with animal experimentation cannot be used as a rational ground for accepting it at the regulatory level.

This is because industry is mainly concerned with being allowed by law to patent and sell profitable products. If the system which bestows this approval is unreliable as regards human health protection, well, this fact is poignantly important (indeed scaring) for a citizen, but not necessarily, and certainly not to the same extent, for the industry itself. In fact, as has been shown thousands of times, the industry can easily get away, in economical terms, even in the worst scenario by paying out-of-court settlements to victims of adverse drug reactions, or to their families. This is quite a deal, since the industry has reaped huge profits, as a rule, in the first two or three years of the marketing of what eventually turns up as a tragically unsafe drug. It is also documented that in some cases the pharmaceutical industry, in promoting new drugs among doctors, offers them to pay (apart from other gifts or bribes!) all legal expenses in case they should be sued by damaged patients.¹¹

The following principle cannot be emphasized too loudly: *citizens will not accept that a decision as important to their lives as that which concerns the approval system of drugs, chemicals and new technologies should hinge on its economical viability as judged by a power system which profits from them regardless, to a very large extent, of their actual safety.*

In particular, *citizen’s health must be guaranteed by sound scientific testing, not by an obsolete and unreliable confidence trick.* Any other decision is a decision against the peoples of Europe, and the fact that it disguises itself as a law *protecting animals* cannot be considered an extenuating circumstance for those guilty of taking it.

There was a time when some influential animal rights groups presented their opposition to vivisection as based on “purely ethical” reasons, and when they even criticized those advancing scientific arguments against vivisection. Happily, this time is no more. Indeed, the divide between scientific AVs and animal right groups had no grounds to exist at any time, since, as it happens, there is no conflict between human health protection and concern for animal rights as far as animal experimentation for medical purposes is concerned. In a useful report published in August 2008 the British association “Animal Aid”, a self-defined animal rights group, has explicitly embraced the scientific AV approach, by making the following unequivocal statement:

[...] objections on the grounds of animal suffering are unlikely ever to win the day for so long as the public believes what those with a stake in animal testing repeatedly tell them: experiments on animals yield data that can reveal whether a new drug is safe and beneficial for human patients to take. [AA 2008]

Thus, given that even animal rights groups are by now aware that the fight against vivisection must rely mainly on scientific arguments, and that in fact there is by now a vast amount of scientific

¹¹ A notorious example is that of Rezulin (Willman 2002).

evidence which utterly discredits vivisection, it is shocking that, as we shall see, the EC may think it can evade entirely the scientific issue, except for some groundless claims.

Two recent official statements on the unreliability of animal tests

Just to make the reader sure that scientific AV is not just an opinion among many, but *the only scientifically sound and politically sane position on the issue*, I will quote from two important official documents.

From the (official) outline of a report by the National Academy of Sciences (NAS 2007):

Using the results of animal tests to predict human health effects involves a number of assumptions and extrapolations that remain controversial. Test animals are often exposed to higher doses than would be expected for typical human exposures, requiring assumptions about effects at lower doses or exposures. Test animals are typically observed for overt signs of adverse health effects, which provide little information about biological changes leading to such health effects. Often controversial uncertainty factors must be applied to account for differences between test animals and humans. Finally, use of animals in testing is expensive and time consuming, and it sometimes raises ethical issues.

There could not be a clearer statement of the fact that vivisectionist testing is, in purely scientific terms, an unwarranted leap into the dark. It is true that in the same report one reads:

For the foreseeable future, some targeted testing in animals will need to continue, as it is not currently possible to sufficiently understand how chemicals are broken down in the body using tests in cells alone.

This is typical committee's smokescreen, aiming at not causing displeasure to any sector of the scientific community, no matter how inconsistent the committee has to get in the process. In fact, while it is not completely outrageous to state that «it is not currently possible to sufficiently understand how chemicals are broken down in the body using tests in cells alone» (although it is hard to defend such a portentous general assessment on a very fast developing field, which is, by the way, very poorly characterized by labelling it “cells alone”), this *does not imply that testing chemicals on animals enables us to do what testing “in cells” cannot*. In fact there is plenty of evidence that the controversy surrounding «assumptions and extrapolations» from animals to humans firmly stands in the way of any clear conclusions from animal experiments to human physiology and pathology.

Another, still more recent statement has been made by a well-known specialist, Thomas Hartung, in a long survey devoted to the “Toxicology for the twenty-first century” and published in the 9 July 2009 issue of *Nature* – one of the most “authoritative” journals internationally. Notice that *Nature* has hardly ever missed an opportunity to *defend* vivisection, also rejecting letters from readers wishing to express a different opinion, and shamelessly publishing rabid and incoherent letters from vivisectionists. Four years ago Hartung, who was at the time Director of ECVAM (European Centre for the Validation of Alternative Methods), was interviewed by the same magazine, which reported:

The toxicity tests that have been used for decades are “simply bad science”, he [Hartung] explains. “We now have an opportunity to start with a clean slate and develop evidence-based tests that have true predictive value”. [Abbott 2005, p. 144]

Now he expands on this basic judgment as follows:

The crucial question therefore is how useful are the current models, which are mostly animal models, and how incorrect are they? [...]

It is clear that the use of animals has limitations: *we are not 70 kg rats; we take up substances differently; we metabolize them differently; we live longer (allowing certain diseases to develop and prompting evolutionary adaptations to protect against them); and we are exposed to a multitude of environmental factors.*

This is what AVs have been saying all along for more than 150 years. Also, Hartung makes it clear that, notwithstanding all the time the animal tests have been used, there have been few attempts to estimate their value. In simpler words, *they have never been validated*, and what data we have, are *against* the continuation of these tests. I shall quote several passages, because I wish everyone to understand that the standard AV claims should by now be *considered and treated as scientific currency*, not as any minority view:

However, few studies have systematically measured the accuracy of animal models. In one example, results from animal models were compared with information from poison centres: comparing the dose of a chemical that is lethal to 50% (LD₅₀) of rats tested and the lethal concentration of the same chemical in the blood of humans showed a rather poor correlation (coefficient of correlation of 0.56; unpublished observations from an international validation study).

Just a pause to consider why there should be such scarcity of data, and why Hartung should refer to an *unpublished* study: clearly animal experimenters (and the industry supporting their “researches”) have not exactly been leaning over backwards to inform the citizens – or even their own colleagues, for that matter – about how unreliable vivisection is. Again, this is not guessing: it is certainty. This is how an unsigned editorial article on *Nature* described the situation in 2005, with reference to an «action plan» put forward by ECVAM (I interspersed under square bracket some comments of mine, signed MMC):

Perhaps the most difficult point in the action plan concerns its call for the release of more information on the performance of animal tests: *how robust, reproducible and relevant are they? The data so far give grounds for concern. Yet industry has been resistant to this.*

If the gold standard of animal tests against which new tests are to be compared turns out to be made of tin, [and by now there is no doubt that it *is* made of tin (MMC)] the political fallout would be considerable [if only citizens knew about it (MMC)]. Public trust in the ability of regulatory authorities and industry to address safety issues would be damaged [It is high time it should be! (MMC)] But in the interest of a thorough, economically viable and scientifically valid product-safety testing regime, information about the methods used in the past needs to be shared, and fairly investigated. [NE 2005]

But let us go back to Hartung’ article:

Similarly, in another study, 40% of the chemicals that irritated the skin of rabbits were found not to be irritants in the skin “patch tests” in humans.

Given the overall lack of data, this problem can be considered in more general terms by looking at how one species models for another. *In several animal species, similar experiments with the same agents have been carried out, and there is no reason to assume that, for example, mice, rats and rabbits predict each other’s response to a lesser extent than they predict that of humans.* Typical results from such studies show agreement between animal species for 53-60% of chemicals.

Similar results have also been obtained for pharmaceuticals (as opposed to chemicals) that have been tested in humans. In one study, 43% of toxic effects in humans were correctly predicted by tests in

rodents, and 63% by tests when non-rodent animals were also included. *It is clear therefore that many adverse effects are not uncovered by such traditional tests.* This is also evident in data from the pharmaceutical industry, showing that 20% of the failure of drug candidates occurs as a result of toxicity only after the drugs have been administered to humans in clinical trials. And it is estimated that 6.7% of hospitalized patients experience unexpected adverse reactions to drugs (1 in 10 of which are fatal) , showing the limitations of anticipating toxic effects from preclinical animal studies.

Personally I have strong doubts about the reliability of such figures as 43% and 63%, which are probably much higher than the true figures.¹² However, even taking them as correct, it is clear that no sane person would accept to be exposed to a substance which has been licensed as safe and in fact has a 57% or even a 37% likelihood of being harmful... and yet the CHE-ME-VI Kombinat has succeeded in having citizens do just that, and also in getting away with it. One last quotation from Hartung's article, just to emphasize that those still mentioning medical progress as a reason to go on using animals are entirely off track:

With human proteins or antibodies (collectively known as biologicals) making up about half of the new drugs entering the market, classical toxicology is largely useless, because these proteins mostly have species-specific actions and animals raise antibodies to them, limiting of animal testing. [...] The inadequacy of current methods is also evident for new products such as genetically modified food and animal feed, functional food (food with intended health effects), and nanoparticles [...]

I think that this suffices to make it clear that vivisection is essentially no more a scientific issue (in case one thinks that it was one in the past),¹³ as the available scientific evidence overwhelmingly condemns it: it is just a dangerous, cruel, and de-humanizing practice that has thrived and is thriving on industrial deviousness and academic careerism. But if vivisection is no more a scientific issue, it is certainly *an urgent political issue*. We shall see in the following at least two reasons why EC has really no choice as to which course to follow.

What European citizens want and how opinion polls should be made in a democracy

The first reason is that *European citizens do not want vivisection to continue*. From June 16 to August 18 2006 an European consultation has taken place concerning vivisection, to which 42,655 people responded, «the third largest number of responses to a Commission internet consultation ever», according to the EC web site (Consultation 2006). This shows that these percentages have to be taken very seriously, which is admitted also by the EC, notwithstanding an attempt at “damage reduction”:

The results of the citizens' consultation are based on the responses of citizens who are interested in the subject and took the initiative to fill in the questionnaire. Therefore, the results are not comparable to those obtained from surveys, such as Eurobarometer. *However, the large participation gives a strong indication of the public interest in this area. A large majority of respondents supports measures at EU level to increase the welfare of animals.*

In other terms, the results of this consultation might not be very representative if it is assumed that a considerable amount of European citizens have no interest in the issue... Notice also that the outline provided in Consultation 2006, or in Proposal 2008, stresses the issue of the «welfare of animals». But the questions concerning animal welfare were not the most important ones which were asked in the questionnaire. Here is *the crucial question*:

¹² See Perel *et al* 2007 and my commentary Mamone Capria 2007; see also Knight 2008, MRC 2006, Taylor 2006.

¹³ Ruesch 2003 gives the basic evidence for doubting that vivisection was ever a scientifically viable option for the progress of medicine.

22. For each of the following purposes, do you consider that the use of animals is acceptable?

The possible answers were: *Yes, certainly*; *Yes, probably*; *No, probably not* (=NPN); *No, certainly not* (=NCN); *I don't know*. We shall aggregate as "NO" the groups choosing either NPN or NCN.

a) To improve basic understanding of the functioning of a living organism

Those who responded NO were 68.0% (NPN: 18.7%; NCN: 49.3%; I don't know: 2.3%).

b) To study and understand abnormalities in humans, animals and in the environment

Those who responded NO were: 62.3% (NPN: 18.7%; NCN 43.6%; I don't know: 2.7%).

c) To develop treatment for disease and medicines, and test their safety prior to placing on the market

This item had the lowest percentage of disagreement of all, as was to be expected, and yet those who responded NO were still a clear majority: 56.5% (NPN: 15.0%; NCN: 41.5%; I don't know: 1.7%).

d) To develop and test chemicals for industrial, household and agricultural use for their safety for human, animal and the environment

Those who responded NO were 78.1% (NPN: 16.3%; NCN: 61.8%; I don't know: 1.5%).

e) For education and training purposes e.g. in secondary schools, universities and veterinary/medical schools

Those who responded NO were 74.1% (NPN: 16.0%; NCN: 58.1%; I don't know: 1.6%).

f) To develop applications in other areas such as information technology including leisure products and equipment

Those who responded NO were 92.6% (NPN: 9.7%; NCN: 82.9%; I don't know: 1.3%).

From these results, it appears that most «interested» European citizens think *animal experimentation is unacceptable even when it has strictly medical purposes*. What the questionnaire or, for that matter, the website of the European Commission concealed, is that *the issue of the protection of laboratory animals has been denounced since decades to be a fake issue as far as animal experimentation is concerned*. You cannot do a serious opinion poll when you contrive to deliberately ignore that a sizeable part of your statistical population considers your questions as ill-posed.

Moreover, a survey aiming at strengthening the control of citizens on political decisions, rather than the control of the power system on the citizens, should be preceded by an adequate information campaign. The fact that there are professionals who claim that by making experiments on mice or monkeys they are trying to discover the best treatments for serious human illnesses should be presented *together with another fact*, namely, that there are no less qualified professionals who claim that making such extrapolations from mice to humans is, *methodologically speaking, an absurd guesswork and, as a matter of historical record, a tragic failure*. Only once this information has been properly and accurately conveyed, it may be plausible to explore the moral sensitivities of the interviewees by asking them what they feel about confining mice into cages and causing them

several *other* sorts of suffering – indeed, as far as the “animal rights” issue is concerned, citizens should be informed in the first place that being in a laboratory cage is in itself a cruelty for rats and mice, let alone for nonhuman primates.

Why the new Directive is basically misconceived

Now I shall examine some passages from the text of the new Directive, in order to show how it is falling short of a rational treatment of the issue at hand. All quotations in the following are taken from the draft (Proposal 2008), unless otherwise specified.

Let us start by examining the «Explanatory Memorandum» of the available draft. The EC expresses its concern for the fact that the uneven implementation of the current Directive 86/609/EEC is in contrast with the «objectives of the internal market». The stated aims are

ensuring a level playing field, throughout the EU, for industry and the research community, at the same time strengthening the protection of animals still used in scientific procedures in line with the EC Treaty's Protocol on Animal Welfare.

The EC identifies its ideological reference in «the principles of the Three Rs – Replacement, Reduction and Refinement of animals in experiments». In a footnote it says that the Three Rs is «a commonly accepted principle among scientists, academia and industry internationally when using animals in scientific procedures». Now the Three Rs is compatible with a total phase-out of animal experimentation, but in fact this is just one of the Rs (Replacement), which seems to be there only in order for the other two not to feel alone. As the EC later explains (p. 11):

The basis of the specific measures is anchored in the globally acknowledged principles of the Three Rs (Replacement, Reduction and Refinement). 'Replacement' means the attempt to replace procedures involving live animals by alternatives which do not use live animals; 'reduction' means the attempt to reduce the number of animals used in procedures to the minimum necessary without compromising the quality of scientific results; 'refinement' means the employment of methods to ensure that any possible pain and suffering by the animals are reduced to the minimum, as well as to improve the care, treatment and living conditions of the animals to enhance their well-being, taking into consideration the life-time experience of the animals.

In fact the basic presupposition is that

with current scientific knowledge, a complete phase-out of animal experimentation is not yet achievable [4]. Therefore, it is imperative to ensure that those animals that are still used for legitimate reasons receive the highest protection and welfare consistent with the aims of the experiment.

So, as usual, animal protection is predicated on the false assumption of the impossibility, in the present state of science, of avoiding animal experimentation. What is the reason, then, the EC has for changing the existing directive? It is rooted in concerns over «distortion of the internal [European] market» arising from the present regulations:

The scientific grounds on which Directive 86/609/EEC was founded dates back over 20 years. A number of provisions are out of date and the Directive therefore does not cater for modern techniques in the field of animal experimentation, nor does it incorporate the latest advancements in the field of animal welfare. Furthermore, the wording of the Directive follows that of an international Convention; the style of some provisions is thus more political than regulatory. A significant number of provisions are open to interpretation and provide guidance rather than harmonisation.

Contrary to the objectives of the Directive, the afore-mentioned factors have resulted in a distortion of the internal market, with significant differences in the level of regulation between Member States. Moreover, the current provisions contain ambiguities and inconsistencies, leading to transposition and compliance problems.

After having mentioned the estimate of around 12 millions animals being «used on a yearly basis in scientific procedures in EU-27» the EC writes:

There is an increasing awareness of and concern for animal welfare in the public arena. The participation in recent opinion polls and public consultations gives a strong indication of the public interest in this area – two of the three largest public consultations ever launched by the European Commission amongst any of its various policy activities addressed the subject of animal welfare[5]. The existing measures do not sufficiently mirror these expectations and fail to provide a sufficient level of transparency in this highly controversial field.

So the EC states that they are concerned with animal welfare, although there is a suggestion of awareness that much more is at stake: it is where it mentions that this is an «highly controversial field». Now there is no controversy about the fact that there are few less enjoyable places for an animal to stay in than a laboratory desk or cage. The only controversy may be only on *what is the point of their being there in the first place.*

Other Community policies and legislative measures, such as REACH,[6] may have as a temporary negative effect an increased use of animals in regulatory testing, despite the provisions already taken to avoid unnecessary tests. In light of this and the provisions of the Cosmetics Directive,[7] the necessity to reduce our dependency on animal experimentation is compelling. The ultimate goal should be to replace the use of animal experiments all together. In addition to animal welfare benefits, alternative methods also have the potential to provide robust information through quality-controlled, state-of-the-art tests which could be faster and less cost-intensive than classical animal-based tests.

This is about the only part of the Memorandum that can be partly agreed upon. “Partly”, because when the EC says that the non-animal «alternative methods» (an expression which should be avoided insofar as it wrongly suggests that the current methods are themselves an acceptable alternative, which they are not) should be preferred, they only emphasize that they «could be faster and less cost-intensive than classical animal-based tests». This is true, but what is grievously missing is a reminder that the «classical animal-based tests» *have never been validated.* I do not think that a law «on the protection of animals used for scientific purposes» can neglect the basic point: is it enough that the use of animals is *purportedly* scientific or is it necessary that it should be *truly* scientific?

Directive 86/609/EEC has encouraged the development of alternatives to animal testing. For example, in 1991 the Commission created the European Centre for Validation of Alternative Testing Methods (ECVAM)[8] within the Commission’s Joint Research Centre. To move forward to the next level, the proposal has a specific emphasis on complementing this structure by introducing a number of measures to promote alternative approaches, though recognising that *the identification and setting of regulatory testing needs is done and should be done through the use of other pieces of legislation.* The measures to promote alternative approaches range from a general requirement to use alternative methods as soon as they become available, to further concrete measures to promote their development, validation and acceptance, also at international level. Generally the proposal requires that the principles of the Three Rs are fully taken into account when developing Community measures to protect the health and safety of human beings, animals and the environment.

The italicized statement must be questioned. A law aiming at the protection of animals used «for scientific purposes» cannot avoid tackling the basic issue of what is to count as a «scientific

purpose». It is in fact ridiculous that the EC takes pain in clarifying (Article 3) what is meant by: «procedure», «project», «establishment», «breeding establishment», «supplying establishment», and «user establishment», while failing to make it clear what is meant by «scientific purpose»! Should this expression be construed in sociological terms, i.e. as *anything* which is presented by professionals in the biomedical field?

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

- (1). 'procedure' means any use of an animal for experimental or other scientific purposes, with known or unknown outcome, which may cause the animal pain, suffering distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition or in the creation of a new genetically modified animal line;
- (2). 'project' means a programme of work having a defined scientific objective and involving one or more procedures;
- (3). 'establishment' means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;
- (4). 'breeding establishment' means any establishment where animals are bred with a view to their use in procedures or for the use of their tissue or organs for scientific purposes;
- (5). 'supplying establishment' means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures or for the use of their tissue or organs for scientific purposes;
- (6). 'user establishment' means any establishment where animals are used in procedures.

No explanation is given, here or elsewhere, of the use of “scientific” in the proposal. Unfortunately, on a substantive level, the EC presents as follows its opinion in what must be considered as the crucial passage in the Memorandum:

The use of animals in scientific procedures today, however, still remains essential for ensuring a level of safety for human beings, animals and the environment and for the advancement of knowledge which will lead to improvements in human and animal health and welfare [9],[10]. There are strong arguments for differentiating the use of animals with respect to the species, in particular in relation to their genetic proximity to human beings. Although the proximity of non-human primates makes some of these species the only suitable ones for certain types of testing, this differentiation is supported by science and should be respected.

This passage is remarkable. The EC endorses the controversial view that «only» some species of non-human primates might be considered as acceptable «for certain types of testing», and yet at the same time proclaims that the use of other species in these very cases «should be respected» since it is «supported by science». What does the EC mean here by «supported by science»? Again, what the EC is unwilling to do is to state as a matter of principle that no testing on animals (or on whatever else, for that matter) «should be respected» *unless it has been validated*. There is no other meaning for the phrase «supported by science» that can be allowed in this context. Of course this is a painful point for vivisectionists, since the little dirty secret they are trying to conceal and that bears repetition here, is that *vivisection has never been validated*.

Vivisection for medical purposes contradicts the precautionary principle

Sometimes AVs are asked to provide definitive evidence of the misleading character of vivisection, as a necessary condition for their plea for outlawing vivisection, or putting a moratorium on it, to be taken seriously. We have seen that this challenge can be fully met, but it is important to realize that *it is not one that the EC can rightfully endorse*.

In fact the basic legal reference for Europe in the context of animal experimentation is provided by the *precautionary principle* (PP), whose scope is to ensure that appropriate steps are taken to protect citizens *even when there is no certainty of danger, but only a sufficiently argued ground for fear*: the aim of the PP, in fact, is to give direction on «how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully» (EC 2001). Here is the crucial passage:

The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction. Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised.

Now, with animal experimentation we have a case which fits at least this description – I say “at least” because there has never been a serious poll in the scientific community which would enable us to say with some degree of certainty that only a «minority fraction of the scientific community» considers vivisection a hazard for human health. Of course, those whose academic or economic prosperity depends on making experiments on animals have no qualms in voicing fanatical and groundless claims concerning the purported virtues of vivisection (Caminiti 2009 is a recent example), but the opinions of such people, soaked as they are in deep conflict of interest, should be appropriately weighed, if not immediately rejected out of hand.

The conclusions that can be drawn from the above can be outlined as follows:

- 1) the EC and the European governments should not regulate as “scientific” a practice whose scientific status is at best controversial;
- 2) there is a sizeable and respected portion of the scientific community which believes that official endorsement of animal experimentation for medical applications is a permanent hazard for public health and the environment;
- 3) the EC and the European governments owe it to the European citizens to take point 2) very seriously, as the precautionary principle implies that what is considered a dangerous and unnecessary practice by a qualified minority should be replaced by other, less dangerous procedures.¹⁴

The EC wrote in 2001:

On 13 April 1999 the Council adopted a resolution urging the Commission inter alia "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle". This Communication is part of the Commission's response.

¹⁴ Cf.: «In some cases a total ban may not be a proportional response to a potential risk. In other cases, it may be the sole possible response to a potential risk. Risk reduction measures should include less restrictive alternatives which make it possible to achieve an equivalent level of protection, such as appropriate treatment, reduction of exposure, tightening of controls, adoption of provisional limits, recommendations for populations at risk, etc. One should also consider replacing the products or procedures concerned by safer products or procedures.» (EC 2001).

The dimension of the precautionary principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well-being of future generations.

A decision to take measures without waiting until all the necessary scientific knowledge is available is clearly a precaution-based approach.

It seems clear that, as far as animal experimentation is concerned, it is by now high time to pass from words to acts.

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posted: August 28, 2009