Biosafety Briefings
December 2002

TWN
Third World Network
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Use and Abuse of the Precautionary Principle

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There has been a lot written and said about the precautionary principle, much of which is misleading. Some have stated that if the principle were applied it would put an end to technological advance. Others argue that it fails to take science properly into account, though in fact it relies more heavily on scientific evidence than other approaches to the problem. Still others claim to be applying the principle when clearly they are not[1].

The precautionary principle is very simple. If we are embarking on something new, we should think very carefully about whether it is safe or not, and we should not go ahead until we are convinced it is. It's also not a new idea; it has appeared in national legislation in many countries (including the United States), and in international agreements such as the 1992 Rio Declaration and the Cartegena Biosafety Protocol in Montreal in 2000.

Those who reject the precautionary principle are pushing forward with untested, inadequately researched technologies and insisting that it be up to the rest of us to prove that they are dangerous before they can be stopped. At the same time, they also refuse to accept liability. So if the technologies do turn out to be hazardous, as in many cases they already have, someone else will have to pay the costs of putting things right.

The precautionary principle is about the burden of proof, a concept accepted in law for many years. It is also the same reasoning that is used in most statistical testing. In fact, as a lot of work in biology depends on statistics, neglect or misuse of the precautionary principle often arises out of a misunderstanding and abuse of statistics.

The precautionary principle does not provide us with an algorithm for decision making. We still have to seek the best scientific evidence we can obtain and we still have to make judgments about what is in the best interest of our environment and ourselves. Indeed, one of the advantages of the principle is that it forces us to face these issues; we cannot ignore them in the hope that everything will turn out for the best whatever we do. The basic point, however, is that it places the burden of proof firmly on the advocates of new technology.

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The Burden of Proof

The precautionary principle states that if there are reasonable scientific grounds for believing that a new process or product may not be safe, it should not be introduced until we have convincing evidence that the risks are small and are outweighed by the benefits. It can also be applied to existing technologies when new evidence appears suggesting that they are more dangerous than we had thought, as in the cases of cigarettes, CFCs, lead in petrol, greenhouse gasses and now genetically modified organisms (GMOs)[2]. In such cases it requires that we carry out research to gain a better assessment of the risk and, in the meantime, that we should not expand our use of the technology but rather our dependence on it. If the dangers are considered serious enough, the principle may require us to withdraw the products or impose a ban or moratorium on further use.

The principle does not, as some critics claim, require industry to provide absolute proof that something new is safe. That would be an impossible demand and would indeed stop technology dead in its tracks, but it is not what is being demanded. The precautionary principle does not deal with absolute certainty. On the contrary, it is specifically intended for circumstances in which there is no absolute certainty. It simply puts the burden of proof where it belongs, with the innovator. The requirement is to demonstrate, not absolutely but beyond reasonable doubt that what is being proposed is safe.

A similar principle applies in the criminal law, and for much the same reason. In the courtroom, the prosecution and the defence are not on equal terms. The defendant is not required to prove his innocence and the jury is not asked to decide merely whether they think it is more likely than not that he committed the crime. The prosecution must establish, not absolutely but beyond reasonable doubt, that the defendant is guilty.

There is a good reason for this inequality, and it has to do with the uncertainty of the situation and the consequences of taking a wrong decision. The defendant may be guilty or not and he may be found guilty or not. If he is guilty and convicted, then justice has been done, as it has if he is innocent and found not guilty. But suppose the jury reaches the wrong verdict, what then? That depends on which of the two possible errors was made. If the defendant actually committed the crime but is found not guilty, then a crime goes unpunished. The other possibility is that the defendant is wrongly convicted of a crime, in which case his whole life may be ruined. Neither of these outcomes is satisfactory, but society has decided that the second is so much worse than the first that we should do as much as we reasonably can to avoid it. It is better, so the saying goes that a hundred guilty men should go free than that one innocent man should be convicted. In any situation in which there is uncertainty, mistakes will occur. Our aim must be to minimise the damage that results when they do.

Just as society does not require a defendant to prove his innocence, so it should not require objectors to prove that a technology is harmful. It is up to those who want to introduce something new to prove, not with certainty but beyond reasonable doubt, that it is safe. Society balances the trial in favour of the defendant because we believe that convicting an innocent person is far worse than failing to convict someone who is actually guilty. In the same way, we should balance the decision on risks and hazards in favour of safety, especially in those cases where the damage, should it occur, is serious and irredeemable.

The objectors must bring forward evidence that stands up to scrutiny, but they do not have to prove there are serious dangers. The burden of proof is on the innovators.

The Misuse of Statistics

You have an antique coin that you want to use for deciding who will go first in a game, but you are worried that it might be biased in favour of heads. You toss it three times, and it comes down heads every time. Naturally, this does nothing to reassure you. Then along comes someone who claims to know about statistics. He carries out a short calculation and informs you that as the “p-value” is 0.125, you have nothing to worry about. The coin is not biased.

Now this must strike you as nonsense. Surely if a coin comes down heads three times in a row, that can’t prove it is unbiased? No, of course it can’t. But this sort of reasoning is being used to prove that GM technology is safe.

The fallacy, and it is a fallacy, comes about through either a misunderstanding of statistics or a total neglect of the precautionary principle — or, more likely, both. In brief, people are claiming to have proven that something is safe when what they have actually done is to fail to prove that it is unsafe. It’s the mathematical way of claiming that absence of evidence is the same as evidence of absence.

To see how this comes about, we have to appreciate the difference between biological and other kinds of scientific evidence. Most experiments in physics and chemistry are relatively clear cut. If we want to know what will happen if we mix copper and sulphuric acid, we really only have to try it once. We may repeat the experiment to make sure it worked properly, but we expect to get the same result, even to the amount of hydrogen that is produced from a given amount of copper and acid.

Organisms, however, vary considerably and don’t behave in closely predictable ways. If we spread fertiliser on a field, not every plant will increase its growth by the same amount, and if we cross two lines of maize, not all the resulting seeds will be the same. We often have to use some sort of statistical argument to tell us whether what we have observed represents a real effect or is merely due to chance.

The details of the argument will vary depending on exactly what it is we want to establish, but the standard ones follow a similar pattern.

Suppose that plant breeders have come up with a new variety of maize and we want to know if it gives a better yield than the old one. We plant one field with each of them, and we find that the new variety does actually produce more maize.

That’s encouraging, but it doesn’t prove anything. After all, even if we had planted both fields with the old strain, we wouldn’t have expected to get exactly the same yield in both. The apparent improvement might be just a chance fluctuation.

To help us decide whether the observed effect is real, we carry out the following calculation. We suppose that the new strain is actually no better than the old one. This is called the “null hypothesis” because we assume that nothing has changed. We then estimate as best we can the probability that the new strain would perform as well as it did simply on account of chance. We call this probability the p-value.

Obviously, the smaller the p-value the more likely it is that the new strain really is better, though we can never be absolutely certain. What counts as a small enough value of p is arbitrary, but over the years statisticians have adopted the convention that if p is less than 5% we should reject the null hypothesis, i.e. we may infer that the new strain is better. Another way of saying this is that the increase in yields is ‘significant’.

Why have statisticians fastened on such a small value? Wouldn’t it be reasonable to say that if there is less than an even chance (i.e. p=0.5) of such a large increase then we should infer that the new strain is better? No, and the reason why not is simple. It's a question of the burden of proof. Remember that statistics is about taking decisions in the face of uncertainty. It is a serious business advising a company to change the variety of seed it produces or a farmer to switch from one he has grown for years. There could be a lot to lose if we are wrong. We want to be sure beyond reasonable doubt that we are right, and that's usually taken to mean a p-value of 0.05 or less.

Suppose we obtain a p-value of greater than 0.05. What then? We have failed to prove that the new strain is better. We have not, however, proved that it is no better, any more than by finding a defendant not guilty we have proved that he is innocent.

In the example of the antique coin, the null hypothesis was that the coin was fair. If that were the case, then the probability of a head on any one throw would be 0.5 so the probability of three heads in a row would be $(0.5)^3=0.125$. This is greater than 0.05, so we cannot reject the null hypothesis. Thus we cannot claim that our experiment has shown the coin to be biased.

Up to that point, the reasoning was correct. Where it went wrong was in the claim that the experiment has shown the coin to be fair. It did no such thing.

Yet that is precisely the sort of argument that we see in scientific papers defending genetic engineering. A recent report "Absence of toxicity of Bacillus thuringiensis pollen to black swallowtails under field conditions"[3] claims by its title to have shown that there is no harmful effect. In the discussion however, the authors state only that there were "no significant weight differences among larvae as a function of distance from the corn field or pollen level." In other words, they have only failed to demonstrate that there is a harmful effect. They have not proven that there is none.

A second paper[4] claims to show that transgenes in wheat are stably inherited. The evidence for this is that the "transmission ratios were shown to be Mendelian in 8 out of 12 lines." In the accompanying table, however, six of the p-values are less than 0.5 and one is 0.1. That is not sufficient to prove that the genes are unstable and so inherited in a non-Mendelian way. But it does not prove they are, which is what was claimed.

The way to decide if the antique coin is biased is to toss it more times and see what happens. In the case of the safety and stability of GM crops, more and better experiments should be carried out.

The Anti-Precautionary Principle

The precautionary principle is so obviously common sense that we might expect it to be universally adopted. That would still leave room for debate about how big the risks and benefits are likely to be, especially when those who stand to gain if things go right and those who stand to lose if they do not. It is significant that corporations are implacably opposed to proposals that they should be liable for any damage caused by the products of GM technology. They are demanding a one-way bet: they pocket any gains and someone else pays for any losses. It also gives us an idea of how confident they are about the safety of the technology.

What is harder to understand is why our regulators are still so reluctant to adopt the precautionary principle. They tend to rely instead on what we might call the anti-precautionary principle: When a new technology is proposed, it must be approved unless it can be shown conclusively to be dangerous. The burden of proof is not on the innovator; it is on the rest of us.

The most enthusiastic supporter of the anti-precautionary principle is the World Trade

Organisation (WTO); the international body whose task it is to promote free trade. A country that wants to restrict or prohibit imports on grounds of safety has to provide definite proof of hazard, or else be accused of erecting artificial trade barriers. A recent example is the WTO's judgement that the European Union's ban on US growth hormone injected beef is illegal.

By applying the anti-precautionary principle in the past, we have allowed corporations to damage our health and our environment through hormone disrupters, carcinogens and mutagens. The costs in human suffering and environmental degradation and in resources to attempt to put these right have been very high indeed.

Conclusion

There is nothing difficult or arcane about the precautionary principle. It is the same reasoning that is used every day in the courts and in statistics. More than that, it is just common sense. If we have genuine doubts about whether something is safe, then we should not use it until we are convinced it is. And how convinced we have to be depends on how much we really need it.

As far as GM crops are concerned, the situation is clear. The world is not short of food. Where people are going hungry it is because of poverty. Hardly anyone beleived that there will be a real shortage within 25 years, and a recent FAO report predicts that improvements in conventional agricultureand reductions in the rate of increase of the world's population will mean we will continue to be able to feed ourselves indefinitely.

On the other side, there is both direct and indirect evidence that gene biotechnologt may not be safe for health and the environment. The benefits of GM agriculture remain hypothetical.

References

1 See, for example, S. Holm and J. Harris (*Nature*, 400 (1999) 398). Compare C.V. Howard & P.T. Saunders (*Nature*, 401 (1999) 207) and C. Rafffensburger *et al*. (*Nature*, 401 (1999) 207-208).

2 We are now told that in the case of tobacco and lead, many in the industry knew about the hazards long before the public did. It is not always wise to accept broad and unsupported assurances about safety from those who have a very strong interest in continuing the technology.

3 A.R. Wraight *et al* (2000), Proceedings of the National Academy of Sciences (early edition). Quite apart from the use of statistics, it generally requires considerable skill to design and carry out an experiment to provide a convincing demonstration that an effect does not occur. It is all too easy to fail to find something even when it is there.

4 M.E. Cannell *et al*. *Theoretical and applied Genetics 99* (1999) 772-784.

Source: ISIS News 6, September 2000.

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The Precautionary Principle and Scientific Evidence

The precautionary principle is not an algorithm for making decisions. It does not make decisions for us, but it is a principle on which to base decisions. It is a principle for assigning the burden of proof, in much the same way that the defendant in a criminal court is assumed innocent until proven guilty 'beyond reasonable doubt'[1].

This important rule reflects society's view that convicting the innocent is far worse than acquitting the guilty. It has a profound effect on the outcome of many trials, but it still leaves the jury with a lot to do. They still have to weigh up the evidence, and they have to decide for themselves what constitutes 'reasonable doubt'.

In the same way, the precautionary principle requires us to assign the burden of proof to those who want to introduce a new technology, particularly in cases where there is little or no established need or benefit and where the hazards are serious and irreversible. It is up to the perpetrators to prove that the technology is safe 'beyond reasonable doubt'. We cannot expect the precautionary principle by itself to tell us what to do about GM crops or any other new technology. Like a jury, we have to weigh up the evidence, and like a jury we have to come to a decision.

So, what is the evidence on GM crops? There is practically no evidence that they are safe, of the kind that could stand up in a court of law. A survey published last June showed that there is less than a handful of papers on the subject of safety assessment published in peer-reviewed scientific journals[2]. The vast majority consists of unpublished reports submitted to regulatory bodies for product approval, and these, far from supporting claims of safety, actually provides evidence to the contrary[3].

The published papers from the industry are no better. For example, Monsanto's study on Roundup Ready soya was seriously flawed. Two papers[4,5] showed, among other things, significant increases in milk fat in cows and lower weight gains in male rats fed GM soya. There was also a 26.7% increase in a major allergen and growth inhibitor, antitrypsin in the GM soya. Monsanto had failed to submit even more damning data indicating that another allergen, a soya lectin, was increased by 100% in retoasted soya beans[6].

On the other hand, there is already plenty of evidence of actual and suspected hazards from findings reported in the scientific literature.

We summarise some of the findings giving direct evidence of hazards, omitting those giving indirect evidence of hazards. These have been reviewed extensively[7,8] and only new references are cited below.

1. GM genes such as those coding for Bt toxins are harmful to beneficial and endangered insect species. Several of the toxins are also known to be actual or potential allergens for human beings[9] and to be harmful for mice[10].
2. New, unexpected toxins and allergens have arisen from the inherently random, uncontrollable nature of the process whereby GMOs are made.
3. GM constructs in GM plants have spread to related species by cross pollination, and weeds and superweeds resistant to multiple herbicides have appeared.

4. GM constructs containing antibiotic resistance genes have spread to bacteria in the soil and in the gut of bees. These bacteria constitute a reservoir of antibiotic resistance genes, which may be passed on to pathogenic bacteria, making infections very difficult to treat.
5. DNA is found not to be readily broken down by most commercial processing or in the gut of mammals[11].
6. The gut of livestock and human beings contain bacteria that can take up foreign DNA containing antibiotic resistance genes.
7. Viral and plasmid DNA resist complete digestion in the gut of mice and transfer to blood, liver, spleen and kidney cells. In pregnant mice, the DNA passed through the placenta to end up in the cells of the fetus and newborn.
8. Many forms of cancer in humans and animals are associated with random insertion of invasive genetic elements into the cell's genome. Cancer risks are a major concern in human 'gene therapy'.
9. New viruses have been created in many GM plants with viral genes in the GM construct.
10. GM constructs and vectors used in 'gene therapy' generate live viruses in cells used to package them by recombining with dormant viruses in the cells' genome.
11. A deadly virus that killed all its victims has been created accidentally through genetic engineering in the laboratory[12].
12. GM lines are notoriously unstable, do not breed true, and do not perform consistently in the field. Evidence is emerging on yield drag, increased use of herbicides, susceptibility to disease, and other failures.

Given the weight of evidence, it seems obvious to us that no GM crops should be planted in open fields, unless and until we can be convinced, by counter-evidence, that the risks are minimal.

But by being cautious, are we, running equal risks in the other direction, of losing potential benefits, or the ability to deal with needs that may appear in 50 years time? Not at all.

The biotech companies and their supporters say we need GM crops to increase yield to feed a growing world population. Norman Borlaug, father of the green revolution and prominent supporter of agricultural biotechnology, claims GM crops are needed to feed a projected 10 billion. Again, let us look at the evidence. There is no scientific report documenting that yield has been increased in GMOs compared to non-GMOs; quite the contrary is the case, as mentioned earlier, yield drags are frequently reported.

What about population increases? According to the United Nations Population Division, world population growth had been slowing down since the 1960s. The estimate in 1998 was that total world population will peak at 7.7 billion in 2040, then go into long term decline to 3.6 billion by 2150, less than two-third of today's number. Similarly, a FAO report published in July 2000[13] concludes that existing technologies, not counting GMOs, will produce enough and more than enough food to meet population growth. The real problem is one of distribution, as generally acknowledged. People are starving in the midst of plenty.

What about the possibility that at some time in the future we may have to make changes in the crops we grow and that genetic engineering may be needed? Or that with more research, gene biotechnologists will be able to produce new varieties that are indeed better and safer than the present ones? Even allowing for those possibilities does not mean we have to rush ahead with the present inadequately researched and tested technology. Nor does it mean we have to accept unsubstantiated promises that GM crops will provide the answer.

Looking at all the evidence and taking seriously the precautionary principle thus lead to the following conclusion. We should continue doing basic research in molecular genetics, including research relevant to the safety of GM constructs as well as making GM plants; for example, on how to modify existing genes precisely and safely, rather than to transfer in GM constructs haphazardly. But all that should be done in the laboratory and in the greenhouse under carefully contained conditions.

There should also be major efforts devoted to developing better varieties of crops by conventional breeding and research on organic, low-input farming methods. Agroecological farming methods which use crops and knowledge adapted to local conditions have increased yields by two to three-fold since the 1980s. They provide social, environmental and health benefits in Latin America, Africa and Asia. There are good reasons to encourage farmers to grow and sell local crops that are adapted to local conditions, and not to pressure them into growing national or international varieties for export. Export industrial agriculture is responsible for a great proportion of the fossil fuel consumption that contributes to climate change. Furthermore, there is incalculable health bonus to be gained in phasing out agrochemicals that are known to be linked to cancers and many other illnesses.

In that way, we can be confident about feeding the world and we will still stand to gain from whatever benefits GM technology may bring. The only losers will be the biotech industry, because they cannot afford to wait. The rest of us can.

References

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1 "Use and Abuse of the Precautionary Principle" by Peter Saunders, ISIS News#6 www.i-sis.org

2 Domingo JL. "Health risks of GM foods: Many opinions but few data". *Science* 2000: 288: 1748-9.

3 See transcript of Dr. Arpad Pusztai's statement on Chardon LL hearing, London, October 24, 2000 www.maff.gov.uk

4 Hammond *et al*, 1996, *Journal of Nutrition* 126, 717-26.

5 Padgette *et al*, 1996, *Journal of Nutrition* 126, 702-16.

6 "Buried data in Monsanto's study on Roundup Ready soybeans" by Barbara Keeler dooles@netins.net(Ericka)

7 Dr. Mae-Wan Ho's statement to public hearing on Chardon LL, October 26, 2000 www.maff.gov.uk, also www.i-sis.org

8 See "World Scientists' Open Letter" and other papers, www.i-sis.org

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