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PERSPECTIVE

Can science justify regulatory decisions about the cultivation of transgenic crops?

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Abstract Results of scientific studies are sometimes claimed to provide scientific justification for regulatory decisions about the cultivation of certain transgenic crops. A decision may be scientifically justified if objective analysis shows that the decision is more likely than alternatives to lead to the achievement of specific policy objectives. If policy objectives are not defined operationally, as is often the case, scientific justification for decisions is not possible. The search for scientific justification for decisions leads to concentration on reducing scientific uncertainty about the behaviour of transgenic crops instead of reducing uncertainty about the objectives of policies that regulate their use. Focusing on reducing scientific uncertainty at the expense of clarifying policy objectives may have detrimental effects on scientists, science and society.

Keywords Risk assessment–policy gap · Scientism · Uncertainty · Decision-making

Introduction

Germany and France recently banned the cultivation of transgenic MON810 maize. The bans were implemented because scientific studies, conducted after MON810 maize was approved for cultivation in the European Union, were judged by government committees to provide significant new evidence that the probability of environmental harm from cultivation of MON810 maize was greater than originally thought (Sinha 2009; Davison 2010). The conclusion that the studies indicated higher environmental risk has been criticised (e.g., Rauschen 2010), and has led to a debate about whether the bans were "scientifically justified" (Ricroch et al. 2010; Hilbeck et al. 2012). This article discusses in what sense regulatory decisions may be scientifically justified, and examines some consequences of seeking scientific justification; it does not consider the merits of decisions to permit or prohibit the cultivation of particular transgenic crops.

Decisions to allow or forbid the cultivation of transgenic crops are matters for environmental or other policies (Sanvido et al. 2012b). A crucial distinction regarding questions of scientific justification of regulatory decisions is between policy as ends and policy as means; or, put another way, the difference between policies as ideas about what we want, and policies as ideas about how to get what we want. What we want are called policy objectives, and the means to get what we want are called policy instruments, or simply policies.

Policy objectives are statements of values—the state we think the world *ought* to be in—and are often judgements about trade-offs or allocations of limited resources. An example of an environmental policy

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objective might be to achieve specific water-quality standards in rivers, and these standards might be set to reconcile the competing requirements of, say, industry and recreation, and perhaps ethical obligations to conserve wildlife. Policy instruments, on the other hand, are statements about empirical knowledge—the state we think the world *is* in—and are deductions from theories and data. Policy instruments are actions taken that will realise policy objectives if the deductions from empirical knowledge are correct. Environmental policy objectives regarding river quality might be sought by prohibition of particular activities from certain areas and fines for releasing specific chemicals above permitted thresholds. Such policy instruments might be derived from theories of the environmental transport of chemicals, theories about the ecological effects of those chemicals, and economic models of behaviour in response to penalties.

In considering whether a decision is scientifically justified, it is important to be clear whether science is claimed to support a policy instrument or a policy objective. A policy decision might be said to be scientifically justified if scientific knowledge is used to design a course of action most likely to achieve or bring closer agreed policy objectives: from relevant scientific theory and data, it is deduced that of the available policy instruments, policy instrument A is the most likely to achieve policy objective X. Scientific justification does not imply there can be no disagreement that the decision is correct, because there may be disputes about the accuracy of the theories, the quality of the data and the validity of the deductions from those theories and data. A different interpretation of accuracy, quality and validity might lead to the conclusion that policy instrument B is the best way to achieve policy objective X. The point is that scientific justification for selection of A or B is based on objective reasoning about the likelihood of achieving X, not on a preference for A or B for reasons unrelated to the achievement of X, such as achieving a different policy objective Y.

It follows that for regulatory decisions to be scientifically justified, policy objectives must be defined such that the probabilities of achieving the objectives following different decisions can be compared objectively. Policy objectives should therefore be unambiguous and, at least in theory, measureable; that is, they must be operational. A decision taken to achieve a policy objective of improving the environment could not be justified scientifically without a definition of improvement in terms that allow objective comparison of the selected policy instrument with alternatives. The definition of improvement need not be precise: more of something or less of something than exists now may be sufficient, provided there is a clear definition of that "something"—the abundance of particular species of fish in rivers, for example.

When a decision concerns the definition of a policy objective, or reconciliation of many objectives should it prove impossible to devise policy instruments that deliver all of them, it is less clear that the decision can be scientifically justified. Suppose we predict that a ban on the cultivation of a transgenic crop will lead to increased abundance of a certain species relative to continued cultivation. The knowledge behind that prediction implies nothing about which policy instrument—prohibition or continued cultivation—should be preferred. Our preference will depend on how we value the species concerned: if it is a pest, we may favour reduced over increased abundance, and prefer that cultivation continues; if it is a beautiful butterfly, we may favour increased over reduced abundance, and prefer a ban, all other things being equal. These decisions may appear obvious, but they are not scientifically justified in the sense that science justifies our preference for fewer pests or more butterflies. The decisions are only scientifically justified in that having expressed preferences—fewer pests and more butterflies—the decisions are more likely than alternatives to deliver them.

If a ban were predicted to increase the abundance of pests and butterflies compared with continued cultivation, we would have to make a judgement on the relative merits of our policy objectives. Scientific analysis might predict that a ban gives a 90 % probability of a two- to ten-fold increase in the abundance of pests and a 60 % probability of a 5–10 % increase in the abundance of butterflies. Does the 60 % chance of a small increase in butterflies outweigh the 90 % chance of a large increase in pests? Science cannot tell us: we may value the butterflies so highly that we are prepared to tolerate the high probability of a serious outbreak of pests, or having slightly fewer butterflies may be judged a trivial disadvantage compared with the costs of a pest outbreak. Further scientific studies might increase the accuracy and precision of the predictions, explore further the implications of increases in pest or butterfly abundance, or investigate risk management options to mitigate unwanted side-effects of a decision. Nevertheless, even if we had perfect knowledge of what will happen to the pests and butterflies after a ban or under continued cultivation, we would still be faced with a decision based on values. Science cannot "justify" our decision no matter how confident we are in its predictions.

To recap, a regulatory decision to ban the cultivation of a transgenic crop could be justified scientifically if deductions from relevant theory and data lead to a conclusion that the ban is more likely than not to achieve stated policy objectives, whatever they may be. However, it is not clear that arguments over scientific justification are really about the likelihood of regulatory decisions achieving policy objectives. That is because the policy objectives underlying the regulations are not defined operationally (Sanvido et al. 2012b). Furthermore, decision-making criteria regarding policy instruments that increase the probability of fulfilling some policy objectives and decrease the probability of fulfilling others are not clear. If policy objectives are undefined and not prioritised, it is not possible to deduce from theory and data which policy instrument (e.g., permission or prohibition of cultivation) is more likely to achieve the desired result, and on the definition above, scientific justification of the decision is impossible.

The problem of absent or unclear policy objectives for risk assessment has been called the "risk assessment–policy gap" (Evans et al. 2006). Attempts to bridge the gap in regulatory decision-making about transgenic crops concentrate on reducing scientific uncertainty—increasing the accuracy and precision of predictions about how the crop will behave when cultivated—instead of reducing policy uncertainty—clarifying what we want to achieve or avoid when the crop is cultivated. Concentration on scientific uncertainty leads scientists to make unspoken assumptions about policy objectives and to claim scientific justification for regulatory decisions. These assumptions are illustrated below.[1]

[1] This article concentrates on the gap between risk assessment and operational definitions of environmental harm because risk is usually the focus of regulatory decision-making. Similar arguments would apply to gaps between opportunity assessments and operational definitions of benefits.

Unspoken assumptions about policy objectives: an example of non-target organism effects data

Arguments about the scientific justification of regulatory decisions regarding the cultivation of a transgenic crop often centre on the detection of adverse effects in laboratory studies in which test organisms were exposed to material of the transgenic crop, or to purified protein acting as a surrogate for the intended new proteins produced in the crop (e.g., Ricroch et al. 2010; Hilbeck et al. 2012). Suppose a laboratory experiment exposed some groups of a non-pest species to material from a transgenic crop and other groups to comparable material of a genetically similar non-transgenic crop. Further suppose that in the groups exposed to the transgenic material, average survival, growth and reproduction were lower than in the groups exposed to the control material (an "adverse effect" of the transgenic material on the organism in the study). Finally, suppose that cultivation of the transgenic crop was banned because the study results were taken to indicate environmental harm. Was the decision *scientifically* justified?

The decision would have been scientifically justified if objective reasoning had concluded that a ban was the best option for preventing environmental harm, and if prevention of environmental harm was the overriding policy objective. If there were no operational definitions of environmental harm, or if there were competing policy objectives, the decision could not have been scientifically justified. Nevertheless, with certain assumptions about science, but particularly with unstated assumptions about policy objectives, scientific justification might have been claimed:

1. *Scientific assumption: the adverse effect detected in the laboratory is not an artefact.* The reliability of laboratory ecotoxicology studies that have revealed adverse effects of proteins or transgenic crop tissue has been questioned. Critics have pointed out that adverse effects might have been artefacts of poor study design or analysis (e.g., Shelton et al. 2009). Equally, failure to find adverse effects in laboratory studies has been suggested to result from poor study design or interpretation (e.g., Lövei et al. 2009; Hilbeck et al. 2012), although field data suggest that laboratory studies are conservative regarding the

detection of effects (Duan et al. 2010). No study is without flaws; nevertheless, there are design criteria that improve the reliability and interpretability of ecotoxicology studies (Romeis et al. 2011), and deviation from these criteria could lead to incorrect conclusions that the protein or transgenic crop has an adverse effect, or to undue confidence that it has no adverse effect.

2. *Scientific assumption: the adverse effect in the laboratory indicates similar effects in the field*. Reduced survival, growth or reproduction in the laboratory study indicates that under the conditions of the study, a hazard of the crop or protein (e.g., lower nutritional quality of the crop or toxicity of the protein) results in an adverse effect on the test organism. Adverse effects in laboratory studies do not provide certainty that adverse effects, such as reduced population size, will result when similar organisms are exposed to the same stressor in the field, because ecological and environmental processes may result in exposure to the crop or protein in the field below amounts that have adverse effects, or may compensate at the population level for adverse effects on individuals (Chapman et al. 1998; Raybould et al. 2011). Such effects are examples of the well-known general problem of laboratory experiments over-estimating the ecological importance of single factors (e.g., Peters 1991).
3. *Scientific assumption: adverse effects in the field are ecologically relevant*. Predictions from the laboratory study may indicate with high probability that particular species exposed to a transgenic crop in the field will have lower growth, survival or reproduction than those organisms exposed to a genetically similar non-transgenic crop. Furthermore, it may be predicted that, all other things being equal, these effects will result in smaller populations of those species if the transgenic crop were cultivated instead of the genotype or variety of non-transgenic crop used as a control. Nevertheless, the difference between the predicted population sizes associated with the transgenic crop and the non-transgenic control should be placed in context. If, for example, the difference in predicted population sizes was smaller than the variation in population sizes among varieties of the crop that are already grown, the ecological relevance of the adverse effect of the transgenic crop would be questionable.
4. *Policy assumption: ecologically relevant effects in the field constitute environmental harm*. The results of the laboratory study may indicate with high confidence that cultivation of the transgenic crop will have an ecologically relevant effect: it will reduce the abundances of certain species significantly below those associated with current cultivation practice. This indicates a high risk from cultivating the transgenic crop only if reduced abundance of at least one of the species is regarded as environmentally harmful. Smaller populations of all of the species may be seen as environmentally insignificant, or even beneficial, and maintenance of their abundance may not be an objective of environmental policy.
5. *Policy assumption: harmful environmental effects are unacceptable*. The results of the laboratory study may indicate high ecological risk from cultivating the transgenic crop: there is high probability of an adverse effect on one or more valued species. Cultivation of the crop may still be approved if the opportunities (probability and value of benefits) outweigh the risks (probability and seriousness of harms). Approval would depend on whether decision-making were utilitarian—the chosen option has the highest expected net benefit—or ethical—there is an absolute limit on the tolerable amount of risk (Sanvido et al. 2012a). If the risks outweigh the opportunities, or if the risk exceeds an acceptable amount regardless of the opportunities, then cultivation would probably be banned, or other risk management short of a ban could be applied to reduce the risks to an acceptable level.

The above discussion shows that a decision to ban cultivation of a transgenic crop solely because of the detection in the laboratory of adverse effects of exposure to the crop, or a component of the crop, depends on a series of assumptions about the scientific implications of those results and on assumptions about policy objectives. One could be explicit about the scientific assumptions and say that under uncertain knowledge, one will be precautionary and assume that the adverse effect detected in the laboratory indicates that an ecologically relevant effect is certain to occur should the crop be cultivated. To make sense of a ban, however, one also needs to assume that the ecological effect is harmful and unacceptable. One could reduce scientific uncertainty by developing and testing theories about the relationship between ecotoxicological effects in the laboratory and ecological effects in the field (e.g., Forbes and Calow 2002), and the tested theories may show that we were justified in assuming that ecologically relevant effects were indicated by the initial laboratory data. Nevertheless, that those ecologically relevant effects are harmful and unacceptable it is still an assumption.

Attempts to justify decisions scientifically may be based on a belief that an increase in scientific certainty leads directly to selection of policy objectives: greater confidence that observed adverse effects in the laboratory are real and accurately predict ecologically relevant effects in the field somehow demonstrates that the ecological effect is harmful and unacceptable. However, even if the scientific theories underlying assumptions 1, 2 and 3 above were rigorously tested and corroborated, the new scientific knowledge would not imply anything about the value we should place on the ecological change. It is a mistake to think that increased knowledge of the likelihood of an ecological change can replace judgment about the value of the change: if assumptions 1, 2 and 3 are correct that does not imply that assumptions 4 and 5 must also be correct.

Detrimental consequences of scientism in regulatory decision-making

Attempts to bridge the risk assessment–policy gap using only science are examples of scientism: "the notion that science gives us certain knowledge and might even be able one day to give us settled answers to all our legitimate questions" (Magee 1985). Scientism in regulatory decision-making about transgenic crops may be defined as an overemphasis on the reduction of scientific uncertainty about the effects of the crops at the expense of defining policy objectives on which decision-making criteria depend. Such overemphasis on scientific uncertainty creates problems for scientists, science and society generally.

Risks from scientism to scientists may arise if decisions and policies are seen to be made by scientists instead of politicians. Scientists may be blamed for unpopular decisions, which in turn may harm their ability to advise decision-makers because scientists should be "impartial arbiters of data" (Favaro 2012). If a decision is controversial because of disagreements about policy objectives, emphasis on scientific disagreements may blur the distinction between scientists as impartial interpreters of the likely results of policy instruments, and scientists as advocates for preferred policy objectives. Scientists wishing to advocate policies for or against the use of transgenic crops should state that their advocacy is based on a preference for certain policy objectives, and that they think particular policy instruments are the best means to achieve those preferred objectives. It is not correct to imply that science justifies their preference; that would be indulging in what Lackey (2007) calls normative science: "science that is developed, presented, or interpreted based on an assumed, usually unstated, preference for a particular policy or class of policy choices'.

A risk of scientism to science is the wasting of scarce research funds. If regulatory decision-making is problematic because of unclear policy objectives, scientific research to reduce uncertainty about the behaviour of transgenic crops is unlikely to help (Raybould and Poppy 2012). Research may help to clarify by how much the abundance of certain species will increase or decrease following cultivation of a particular transgenic crop, but if we are unsure of the value to place on those changes in abundance, the research may have little significance for decision-making. Research is increasingly asked to justify itself by relevance to applied problems (Lane and Bertuzzi 2011), and the temptation to claim relevance of studies to regulatory decision-making is likely to increase. There is a danger that scientism in regulatory decision-making will allow any study of any effect of a transgenic crop to be claimed relevant and worth funding even though it does not test hypotheses of interest to basic research or that help evaluate the probability of achieving policy objectives (Raybould 2010). Diverting funds from potentially excellent basic research to trivial applied research will hinder the development of science. The opportunity costs will be particularly high if Braben (2004) is correct that the greatest risk to humanity comes from "debilitating attrition…of human ingenuity" caused by "rising tides of bureaucracy and control" of curiosity-driven research.

Societal risks from scientism in regulation of transgenic crops arise because concentration on scientific uncertainty may prevent proper discussion of the risks and opportunities posed by the cultivation of transgenic crops. The hopes and worries of people about the cultivation of transgenic crops may be lost in arguments about the scientific worth of particular studies. It is better to have an open debate about what should be the objectives of agricultural, environmental, social and economic policies, than to have that debate by proxy over the interpretation of the results of, say, an ecotoxicology study.

Moreover, if science is regarded as the sole arbiter of whether transgenic crops should be cultivated, there may be a backlash against the technology because development of new products is seen as an end in itself, not an attempt to solve pressing environmental, social, economic or political problems (Diedrich et al. 2011; van den Hove et al. 2012). Opportunities to solve such problems may thereby be lost because all uses of agricultural technology are rejected regardless of what they may achieve (Raybould and Poppy 2012).

Finally, there will always be uncertainty about the exact agronomic performance of transgenic crops and precisely how they will be used by farmers; however, uncertainty is not the same as risk, because the unforeseen results may be neutral or beneficial. Failure to differentiate between scientific uncertainty and risk will paralyse decision-making if it gives the impression that we must acquire perfect knowledge to make the "right decision" that eliminates risk. Nevertheless, as Miller (1994) points out, "the aim of the rational agent is not really to make the right decision (there may be no such thing); it is to make his decision right". The corollary of Miller's point is that we should make a decision once we have sufficient knowledge to conclude, on the balance of probabilities, which option gives the highest net benefit, or which options do and do not exceed absolute limits on the tolerable amount of risk. In the case of permitting cultivation, the decision could be made right by risk management, monitoring and incentives to use the crop to achieve policy objectives; in the case of a ban, the decision could be revisited if new knowledge shows that the opportunities are higher or the risks lower than originally thought.

It is important that methods for reviewing and refining decisions are regarded as ways to expedite the initial decision, not as uncertainties that further complicate that decision; for example, monitoring is a means to allow a decision under uncertainty, but it will only improve decision-making if there is agreement about what should be monitored to evaluate whether policy objectives are being met. If the development of a monitoring plan is merely another means to try to discover policy objectives through scientific analysis, a requirement for monitoring will hinder decision-making, not advance it.

Regulatory paralysis because of scientism may increase risk by unduly delaying or preventing the development of potentially beneficial products (Cross 1996). Such considerations are particularly important for public sector institutions producing products for developing countries because they may be unable to afford high costs of regulation (Entine 2006; Qaim 2009; Raybould and Quemada 2010). To avoid such problems, the likely achievement of policy objectives, not scientific justification through minimisation of scientific uncertainty, should be the basis of regulatory decision-making.

Scientism is not just found in regulation of transgenic crops

Scientism is not unique to regulatory decision-making about transgenic crops, and scientists who work closely with governments have alluded to its dangers in policy-making generally. Kassen (2011) quotes a senior Canadian civil servant: "scientists… think too highly of their own view of the world and fail to appreciate the complex, multifarious nature of decision making. Our mistake is to think that science will be given a privileged voice on an issue." Lawton (2007) wrote similarly in his Presidential Address to the British Ecological Society: "My ultimate aim is simple: to make sure that when ecologists do enter the political arena they do so with their eyes open, expecting to be in it for the long haul in a process that is messy, complex and iterative, with many other legitimate players and some less legitimate vying for the attention of government".

While recognising that science is not the only factor in political decision-making, Kassen, Lawton and others advocate the necessity for scientists to become involved; for example, Kassen says that "poor scientific decisions in politics do not necessarily result from a lack of understanding. They are, rather, a failure of scientists to communicate their message effectively in what is ultimately a political, not a scientific, arena." If we are to avoid scientism, what should be the message from scientists to policy-makers?

The answer may lie in a comment by Kassen (2011) when he suggests that science does not get a fair hearing in policy debates: "most politicians are not economists, yet in the battle for decision-makers' attention, economists have a history of winning". This implies that the job of natural scientists when acting as expert advisors in policy debates is ensuring that politicians better recognise that decisions have environmental consequences as well as economic consequences. Nevertheless, scientists should be careful not to argue that because estimates of environmental consequences are based on scientific knowledge that makes them the most important consequences, or that somehow scientific predictions can replace values in setting policy objectives. It is not only a mistake to think that science *will* be given a privileged voice in policy debates, but also a mistake to think that science *ought* to be given a privileged voice: as Lawton (2007) says, "policy has to be formulated to take into account many other legitimate issues and constraints, not least the cost of various options".

Lawton's comment summarises well the problems of attempts to scientifically justify regulatory decisions about transgenic crops. First, it is not legitimate for science to determine policy objectives; science can predict the consequences of policy instruments, but it cannot place a value on the objectives of those instruments (Lubchenco 1998). Ultimately, regulation of transgenic crops is an instrument to deliver objectives of agricultural, environmental, economic and social policies. If those objectives are obscure, scientific research cannot reveal them.

Secondly, there are constraints. We must acknowledge potential opportunity costs owing to diversion of resources from basic research and the development of potentially beneficial products to ever more detailed characterisation of the structure and behaviour of transgenic crops, particularly when it is not obvious how finer characterisation will help decision-making. More fundamentally, there are constraints on knowledge. All solutions to problems have unexpected consequences, some beneficial, some harmful; in effect, solutions to problems are hypotheses that may be refuted as circumstances change and the consequences of the solutions become clear (Popper 1968). Unexpected consequences are not unique to technological solutions, nor will inaction necessarily have fewer unexpected consequences than action. Scientific justification of regulatory decisions is, therefore, impossible, not only because science cannot ascribe values, but also because the act of seeking scientific justification through reducing scientific uncertainty creates other uncertainties that are legitimate considerations for decision-makers.

Conclusion

Scientific knowledge may be used to evaluate various means (policy instruments) to achieve certain economic, social, political or environmental ends (policy objectives); however, it is probably best to avoid the term scientific justification for this activity. Scientific justification implies that regulatory decisions follow directly from scientific studies without reference to operational policy objectives. Recent examples include adverse effects in laboratory studies of non-target organisms exposed to transgenic crop tissue being claimed as scientific justification for a ban on cultivation of that transgenic crop, regardless of whether the effect is likely to be seen in the field, but more importantly, regardless of whether the effect in the field is considered beneficial, harmful or neutral, and if harmful, whether the likelihood and seriousness of the harm (the risk) outweighs the likelihood and value of the benefit that may accrue (the opportunity). Scientific justification leads to a focus on scientific uncertainty, when often uncertainty about policy objectives is more important. Without clear policy objectives, additional scientific studies merely provide a larger collection of data from which proponents and opponents of particular decisions can select facts to scientifically justify their political views (Gray 2004; Sarowitz 2004). That is not to say that political opinions should be banished from discussions about the use of transgenic crops, only that they should not hide behind science. Political disagreements should be openly debated, so that policy objectives can be agreed properly, and science can fulfil its legitimate role of designing policy instruments, including regulatory decisions, to achieve those objectives.

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