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Contexts for regulation: GMOs in Zimbabwe

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Summary

This paper looks at the regulation of biotechnology in Zimbabwe. It argues that key uncertainties in biosafety debates are context specific; this means that locally-developed, flexible regulatory systems are more appropriate than the standardised, internationally harmonised, solely science-based forms of risk-assessment often advocated for developing countries. The paper begins with a brief examination of the development of regulatory institutions in Zimbabwe. It then looks at biosafety regulation in practice through two case studies, field testing of GM maize and cotton, and safety assessment of GM food aid imports. A final section moves to consider the limitations of the existing regulatory process and identifies challenges that exist for effective regulation in a small, agriculture-dependant country such as Zimbabwe.

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Preface

Biotechnology Policy Series

This IDS Working Paper series emerges from a series of three interlinked projects. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy-making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to "democratise" biotechnology?

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1 Introduction

This paper explores the contexts for the regulation of new agricultural biotechnologies in Zimbabwe. It argues that many of the key uncertainties about GMOs are context dependent, and that there is a need for a locally developed, flexible regulatory system which recognises inevitable uncertainties and encourages broad forms of engagement with regulatory decision-making. This argument runs counter to those who claim that a universalistic, solely science-based approach is required, allowing a harmonisation of regulation in this area (cf. Scoones 2002; Newell 2002).

The paper examines the emerging experience of the Zimbabwean biosafety regulatory system, focusing on two issues: the release of Bt (*Bacillus thuringiensis*) maize and cotton crops and the importation of GM maize as food aid. Both questions have tested the regulatory system in different ways. Both cotton and maize are important in Zimbabwe and are grown in both the small-scale and large-scale farming sectors. In the last few years there have been a number of proposals both by multinationals alone and in partnership with local seed houses for the incorporation of the Bt gene in both locally developed lines and others, creating insect resistant crops. From 2001, Bt maize underwent testing in field trials for one season, as part of the regulatory requirements. Although these were not repeated in 2002, there are plans for more trials in the coming season. From 2002, the major food crisis in the country has required the importation of maize. Much of the available maize on the international market, and virtually all that offered by the US government as food aid to the World Food Programme, was GM maize. This again presented a dilemma for the regulatory system, with the decision to import being granted with the proviso that all maize was milled before distribution.

Both these decisions – to allow field trials on Bt maize and cotton and to import GM maize as food aid – involved a range of debates among different actors. This paper examines the nature of these debates: who was involved at what stages, and, in particular, how science was deployed in regulatory decision-making. The paper highlights both the strengths and limitations of the current regulatory system, and points to a set of issues that have been raised by these two policy decisions which go beyond the relatively restricted framing of biosafety policy based on "sound science", the basis of the current regulatory provision. The paper highlights how the deployment of a narrow regulatory science – focused on particular notions of risk and its management – limits debate on a range of other contextual issues, pertinent to wider concerns about the future of agriculture in Zimbabwe. Therefore the need for a broader framing of the biosafety and biotechnology debate is pointed to. Some pointers as to how this might be done are referred to in the conclusion.

The first section of the paper sets the scene by looking briefly at the regulatory environment in Zimbabwe and the formal structures and procedures for regulating the testing, release and importation of GM crops and products. The paper then looks at the first case – decisions around the testing of Bt maize and cotton. This highlights the areas of scientific uncertainty confronted by the regulatory process, and shows how these are dealt with in practice, particularly through the design of field trials. The next section looks at questions raised about the regulation of GM food aid imports. The paper then moves to an

examination of the almost inevitable limitations of the existing regulatory process, and examines some of the challenges raised, especially by the context within which regulatory decisions in a small, agriculture-dependent country like Zimbabwe must be made. The implications for the future of regulation in the Zimbabwe context – and by extension other similar countries – are then briefly reviewed.

2 Structures and procedures: the formal regulatory process

In 1998 the Biosafety Board was established with the passing of an amendment to the 1986 Research Act [Chapter 10: 22]. A Statutory Instrument 20/2000 Research (Biosafety) Regulations was passed giving statutory authority to the Biosafety Board and the biosafety procedures and guidelines first issued in 1998.[1] The Board operates under the Zimbabwe Research Council within the President's Office. It has a small secretariat, overseen by a registrar. The regulations have been a long time in coming, and involved much debate and discussion. As one of the architects of the current regulatory system explained:

> We started in 1991 on biosafety regulations. Its taken ten years and lots of discussions. So many people have been involved. But each time we had a meeting the representatives changed. And then they complained that they were not consulted.

The process of developing the biosafety regulations started with consultations initiated by the Zimbabwe Biotechnology Forum together with the NGO ENDA-Zimbabwe, and with Dutch government support. A range of meetings, along with a series of consultancies and field studies (Woodend and Muza 1993; Woodend 1995; Bary and Drijver 1995), were held and a core group was identified, largely scientists with an existing expertise in biotechnology (Mnyulwa 2002; Mohamed-Katerere 2001; ISNAR-IBS 1999; Persley and McIntire 2001; Falconi 1999). In addition to the range of consultations, model guidelines and regulations were looked at from elsewhere in the world (including India, Australia and the US), as well as international approaches (notably the UNEP model guidelines). With the involvement of key members of the nascent Biosafety Board involved in the Like-Minded Group during the negotiation of the Biosafety Protocol, ideas on broadening the scope of the regulations to include issues of socio-economic importance, for instance, was derived from debates promoted during the international negotiation processes (Mugabe 2001).

More recently Board members have taken part in different forms of training and regulatory capacity building through the UNEP-GEF National Biosafety Framework capacity building programme on risk assessment and public participation, the Africa-Bio NGO programme based in South Africa, and the Southern Africa Regional Biosafety programme (SARB) funded by USAID and managed by the

[1] See: Procedures for assessment of planned trial release or general release of genetically modified organisms (last revised, 20 August 1998) and Biosafety Guidelines (last revised, 20 August 1998).

Agricultural Research Council of South Africa with support from Michigan State University.[2] In different ways, and with different emphases, each of these "capacity building" programmes have encouraged a framework of risk assessment and biosafety regulation which coincides with the requirements of the Cartagena protocol. The emphasis has been on science-based risk assessment and associated style of regulatory procedure now common throughout the world.

The Biosafety Board has 12 members, each present as "experts" in their own right and not formally representing any organisation or interest grouping. The Board is now the focal point for biosafety issues, although, as the Protocol relates most directly to the Convention on Biodiversity, the Ministry of Environment also is an important link. The location of the Board was, prior to its establishment, the subject of much debate. Various ministries – Environment, Health, Agriculture and so on – were potential hosts. The President's Office compromise was however seen to be a suitable, and politically astute, compromise. The Board is chaired by a scientist working in the tobacco industry, and the current deputy is a scientist from the Biochemistry Department at the University of Zimbabwe. The original Board (to May 2002) was composed almost exclusively of scientists, with the dominant group being molecular biologists and biotechnologists from universities and research institutes. This group included many of those who were involved in the initiation of policy development in the early 1990s, and all were known to each other through close networks and professional interactions. The composition of the Board changed during 2002, with the retirement of around half of the members. The new members include some new specialisations, including environmental issues (with someone from the Ministry of Environment), toxicology (a scientist from the National University of Science and Technology) and a lawyer. The new composition, although with a broader range of specialist expertise, still maintains the dominance of scientists with biotechnology backgrounds.

External criticism of the Board composition has heightened, with some arguing that this group is unlikely to make impartial decisions, and, without NGO or consumer group staff as members, many issues may not get discussed. The response to this is that the Board only deliberates on scientific matters, and requires qualified people to do this. As senior members of the Board and its secretariat argue, the Board is open to any representations from different interest groups and indeed has been active, often in alliance with NGOs, in encouraging wider debate and discussion of the issues.[3] The Board has a difficult task. Its mandate includes both the "promotion" of biotechnology in the country and its regulation. Some, not surprisingly, wonder whether this might result in a conflict of interest. And, further, some question

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2 See: www.africabio.com/about.shtml for an overview of AfricaBio and www.africabio.com/conference for a report on the Biotechnology in Africa conference, 26–27 September, 2001 organised by AfricaBio, ABSF, ISAAA and GBDI. For information on ABSP, see www.iia.msu.edu/absp and www.arc.agric.za/institutes/roodeplaat/main/intro.htm. Also: USAID (2001). USAID launches biotechnology initiatives with Africa. Programs foster improved regulation, research, development. USAID press release, 12 January. www.usaid.org

3 In recent years, for example, Biosafety Board members and officials have participated in a number of BTZ (Biotechnology Trust of Zimbabwe) workshops (see BAZ 2001a,b; BTZ 2001; 2002a,b; Rufu 2002), activities organised by ITDG (see ITDG 2000) and a workshop convened by the Institute of Development Studies, University of Zimbabwe (November 2002).

whether the Board has the appropriate composition to encourage a fair and open deliberation of regulatory issues in the public interest.

The approach to risk assessment laid out in the procedures and guidelines is familiar to most biosafety regulatory systems around the world. A long checklist of questions is made available around which all applications must be structured. Decisions are to be made, it is argued, on the balance of evidence and the presentation of scientific facts. The Board chair notes: 'Our aim is to reduce the risk within parameters which are scientifically acceptable'. A particular style of scientific enquiry is required, moving from lab tests to contained greenhouse experiments to field trials of varying scales. This is expected, in turn, to result in a set of data that the Board (and any experts it calls upon) must deliberate upon. As we shall see below, the way the regulatory science is framed necessarily excludes certain questions and so blackboxes particular uncertainties.

Nevertheless, in the process of developing the checklists for risk assessments many people's views were sought. As those involved commented: 'The checklists got longer and longer in the process'. As one industry applicant commented 'It is a formidable questionnaire. I got yellow bellied and chickened out [before submitting]'. Early applications were often rejected by the Board because of lack of details. A Board member noted 'There is a problem with the arrogance of companies. One took three years to give a full application. They are being sloppy, and think we are not serious'. Another industry applicant recalled: 'With the application system we were originally too casual. They wanted so many details. They even wanted the grid reference!' For those that persist, applications are assessed on a case by case basis. As one Board member explained:

> We have a case by case approach. The checklist must be answered. But for the assessors there is no systematic way of looking at the information. You go through a huge list and make a summary. In the end it is your judgement. And that's affected by your predisposition.

Despite the "science-based assessment", of course, judgements must enter the decision process. And, with these, as this informant termed it, predispositions. Given the current composition of the Board such predispositions are fairly apparent. Someone else commented on the difficulties of pursuing a really thorough assessment:

> It is just too costly to do the whole process of testing. People are not prepared to test properly. Recently things have become more lenient. So things will inevitably slip through. In the US they may spend more than US$40 m dollars evaluating one event. Here the whole budget is unlikely to be over one million, at the very most.

Another member of the Board distinguished between regulation on paper and regulation in practice: 'If the regulations are properly implemented, they are tight enough. But there can be thieves anywhere'. As many commentators pointed out, the issue of capacity to implement is key: 'There are five or six people in the country with the expertise. Anyone who has a training in biotech is already on the Board. Workshops

are necessary to train others – even the new MSc graduates from the UZ [University of Zimbabwe] course'.

A team of thirty trained inspectors, invited from different organisations, including the private sector, carries out checks on the crop trial process at several different stages in the growing season, and oversees the final disposal of the trial crop. Such inspectors have also been deployed to oversee the containment and milling of imported GM maize. However, realistically, the chances of thorough inspection and full oversight is very limited. As a Board member commented: 'Inevitably you have to cultivate an element of trust. You just cannot monitor everything'. Another member observed 'Site inspection is the most we can do. What of gene flow? What of toxicology tests? We just can't look at everything. Nor can we afford it'.

Despite these limitations there is reasonably widespread view that "The Biosafety Board is effective. It has rejected many applications and destroyed illegal trials". An industry applicant commented: 'There was a stage where they wouldn't say yes or no. There was an impasse. But now the systems are in place. We know the score. We are being encouraged to apply by the Board'. Someone else noted that (in contrast to other places in Africa): 'Monsanto have learnt that in Zimbabwe we can say no!' Arguing for a well-established biosafety framework, the registrar noted:

> If you don't have frameworks, confusion is there. People can knock at any door, and then a decision is taken . . . We have our own systems in place. Our own laws, regulations. We are our own sovereign state . . . In Zimbabwe, decisions are made by competent authorities – the technocratic wing of government.

Yet there are clearly limitations. As we shall see, particularly in the case of GM food imports, external pressures on the form of idealised technocratic decision-making talked about by the registrar, certainly can impinge. Similarly, there are inevitable potential loopholes. Despite the now celebrated destruction of an illegal Bt cotton trial by the government in 1996, there is nevertheless some evidence that some illegal trials have also taken place alongside formal trials in the last year. While the company may have admitted its "mistake" to the Board, and been duly fined, there is of course no possibility of knowing what is going on everywhere. As one former Board member observed wryly: 'We are one big field trial aren't we? Inspectors? What can they do?'

Another complaint about the regulatory process, particularly from the industry side, is the seeming inefficiency of the process. An industry representative said it was impossible to get a written response from the Board despite numerous informal exchanges. Procedures are, to some degree, open-ended, and, despite the detail of the application forms, there is a lot of leeway for the Board to decide how to implement, and few rights for applicants in terms of being able to expect particular types of response at particular moments. The same informant commented in relation to his delayed application that his sense was that the Board was 'stalling to see what the policy is'. The wider political context for regulation is clearly important, and, as we discuss below, this became particularly pertinent over the decisions surrounding GM food imports during 2002.

However, the overall level consultation and sequential development of the regulatory framework over more than a decade has been seen by many as a good process. One NGO commentator observed: 'Zimbabwe has been cautious. Others call us slow. But we bought time. The trials if done openly will help build trust'. A Board member observed 'Unlike Kenya people are sceptical here. It requires a different approach'. A frequent critique of the regulatory approach voiced particularly by NGO observers, but also others, is that 'formal provisions for stakeholder participation are missing from our guidelines. They will have to be changed'. What such participation should entail, and who the "stakeholders" should be is an open question, and one to which we return later. First, though, we will discuss the centrepiece of the regulatory process surrounding GM crop releases – the field trials.

3 Crop trials: dealing with uncertainty

In 2001 permission was granted by the Board for small-scale field trials of three transgenic crops (Bt cotton, and two Bt maizes, one yellow, one white). The proposed trials were: Bt cotton using a Monsanto Bt construct in an American cotton variety (from DeKalb), yellow Bt maize (C3330), a solely Monsanto product, a white maize (SC407), a Seed Co line with the Monsanto Bt Mon810 Cry1ab construct. In the end only the maize trials took place at two sites – at Monsanto's research station at Mt Hampden and on Seed Co's station in Kadoma. The Mt Hampden trial was, however, destroyed during the season and all the maize was stolen. The cotton trials were abandoned before planting, as the applicant – Monsanto (with DeKalb) – apparently changed its mind on the desirability of pursuing a trial programme in Zimbabwe. There was therefore only one trial that went ahead therefore, and none in the 2002–03, as, according to the Board, the companies did not submit acceptable applications in time.

These trials are a key part of a set of procedures and guidelines established for risk assessment, with "contained" field trials at a small scale being a core requirement before any commercial release is approved. In parallel to the biosafety approval process, any new release would also have to be scrutinised by the Variety Release Committee under the provisions of the Seed Act. Thus a minimum of three years of trial data is required before any release, assuming that the two approval processes occur in tandem.

The system is apparently straightforward, requiring specified data and relying on a formal assessment according to a list of scientific criteria. But, as we demonstrate below, things are never quite so simple. While framed as a simple scientific exercise, using a checklist of apparently neutral, objective indicators, an examination of the process in practice shows how uncertainties are legion. Any assessment must be based both on accepting the limitations of available information and, with this, a range of uncertainties. This, in turn, requires a judgement by the assessors on the Board, which goes well beyond simply objective, scientific metrics to a range of context-specific social, economic, and even political factors.

The focus on field trials, however, concentrates attention on a particular form of scientific experimentation. From these trials data is collected, according to a certain format, which is aimed at providing the basis for a decision on commercialisation. But how are these experiments designed? What is left in, and what is left out? What questions are by-passed, and what unknowns are left unaddressed?

Should the regulatory system actually set so much store in such trials? In practice, the (official) Zimbabwean Bt maize field trials to date, as we have already mentioned, are essentially assessments limited to plot-based assessment of agronomic performance over two to three seasons at two sites. Both of these are in higher potential areas, on company-owned research stations and are carried out under highly controlled conditions; clearly not representative of the conditions under which commercialised crops would be actually planted if approved. But does this matter? Everyone agrees, it seems, that the science by any standard is limited. But the regulators argue that this is all that is realistically possible. There is no capacity for independent assessment, nor for multi-sited trials in different conditions, they say. And, anyway, they argue, this is the standard approach suggested by international approaches to regulation of biosafety. Further, they point out, the list of assessment criteria is extensive, and goes beyond what is required in many other countries, particularly in the developing world. Socio-economic considerations, for instance, are part of the picture, as are standard agronomic performance criteria. But, nevertheless, all commentators concede, there are limitations, and a range of uncertainties most certainly do exist.

First, there are questions about how different transgenic events perform in different environments. The assumption for insect resistant Bt products is that a high dose is expressed throughout the plant, and that this is maintained throughout the season, consistently reducing pest attack by sucking pests/borers, notably bollworms for cotton and stalk borers for maize.[4] But there are a number of interacting variables here which need investigation. Different events may perform differently depending on the wider genetic environment of the background line. Expression dynamics of Bt may depend on crop physiology, for example, with Bt levels and concentrations spread in different ways over time through different parts of the plant. The environmental context is also of obvious and critical importance. Yet, as already noted, the trials to date have not been carried out in low potential, high nutrient and moisture stress environments where most smallholder farming is carried out. As one scientist noted: 'The trials were conducted for the yield levels of Bt. But this doesn't tell you anything about the small farmer setting'. In relation to Bt maize, as many pointed out, 'Stem borer is more of a rich farmers' problem . . . Under nitrogen stress stem borer attack reduces . . . Well-fertilised crops have high protein levels and attract stalk borers. Of course there will be high infestations'. This is further enhanced by the late planting of the trials in order, in part, to increase pest pressure and so "demonstrate performance".

In addition to the plant-environment interaction, more uncertainties are introduced when one considers the nature of the pest complex associated with maize or cotton. This differs not only spatially, but also over time. For example, the existing system of integrated pest management for cotton has been evolved to adaptively respond to this changing, dynamic situation.[5] The uniform Bt product may not

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4 See, for example, discussions in Gould (1998); Peck *et al.* (1999); Liu *et al.* (1999); Bharathan (2000); Dinham (2001); Tabashnik *et al.* (2000); Mayer (2002); Benbrook (2001a,b), among others.

5 In Zimbabwe there has been a long tradition of integrated pest management. The Commercial Cotton Growers' Association manual lays out the approach (see CFU-Zimbabwe – www.mweb.co.zw/cfu/commodities/cotton.htm). This has been the basis for training at the Cotton Training Centre (see Mariga 1994; Vaughan-Evans 1990). In addition, through FAO support, training in farmer field schools has occurred in partnership with the agricultural extension agency (PAN 2001).

perform so well in different settings, and with different types of pest attack some claim. For example, again in cotton, the Monsanto Bt product, Bollgard, was developed for the American bollworm. But in southern Africa it is the pink bollworm that is the most prevalent. And, with different feeding behaviours, and different susceptibility to Bt doses this may have very different results. Of course the field trials are aimed to pick this difference up and test efficacy in Zimbabwean settings. Nevertheless given pest pressure changes over time and space, a few trials over short periods in particular locations are clearly insufficient to tell the whole story.

Pest resistance is not only based on the ability of the plant to express Bt toxins through genetic transformation. The broader genetic make-up of the plant is also significant. Early attempts to test Bt cotton in Zimbabwe by Monsanto, as already mentioned, were based on the use of a US non-hairy variety (from De Kalb) which is vulnerable to jassid/aphid attack. While the Bt event may confer some resistance to bollworms, the lack of leaf hairs may result in higher jassid and aphid incidence, and so a different pest complex and yield response. Cottco/Quton will now work with Syngenta using VIP technology (another insect-resistance construct), transformed using local varieties, which gets round the obvious problems associated with using US varieties. While the trials are focused essentially on the biosafety issues of Bt products, these broader issues of variety-transgenic event interactions may be as critical in assessing what is the most appropriate technology for local settings.

Issues of cross pollination and isolation distances are critical in the design of GM crop trials. Without any knowledge about the likelihood of gene flow risks, the Board has opted for traditional crop breeding protocols, and isolation distances of 400m for maize and 100m for cotton, in the design of trials. One industry scientist suggested that the distance of 400 metres for maize was simply the 360 metre isolation distance for conventional trials, with 40 m added on to make it up to 400! The mesh fencing surrounding the trials was intended (unsuccessfully in one case) to prevent theft and spread of the transgenics by other means. The placing of the trials on research stations, rather than out on farmer's fields, was, it was argued, another precautionary stance. But some sceptics remain worried about the risks of contamination, despite elaborate protocols for preventing cross-pollination, through, for example, the detassling of maize at flowering. The full destruction of the crop following harvest is another measure required, along with, somewhat bizarrely, the compulsory wearing of rubber gloves when handling the transgenic plant. Sceptics argue that, because of potential risks, trials should remain fully contained and under greenhouse conditions. One Board member argued: 'Given the concerns about GMOs, we need to tread very, very carefully with Bt. We should aim for greenhouse containment first'. Questions of liability were raised by others: 'We should start investigating the factors that are controllable. And then later move out to those which are difficult. The field situation worries me a lot. If any mistake is made, people will point fingers at us in government. It is costly and complex to sue companies. We must be careful'.

However, others suggest, given the precautions taken, risks are reduced to effectively zero. In cotton, they point out, there is less of a risk of gene flow than for maize given differences in reproductive physiology. And, for maize, given the lack of a major reservoir of indigenous varieties in the country, and the preponderance of hybrids (although this may change with the approval of open-pollinated variety

(OPV) releases of late), again, dangers of gene flow are limited, especially with the strict trial protocols. In relation to the large isolation distances, one commentator observed: 'you would have to be some kind of crazy bee to fly that far in a straight line!' However, when pressed, no-one – board members, government scientists, industry personnel – appears to know much about the actual pollination dynamics of maize or cotton in Zimbabwean field situations.[6] As one board member admitted; 'In the field there are a number of pollinating agents. We don't know the distance they cover – cross-pollinations, wind transfers. We just don't know'.

The admission of uncertainty and ignorance becomes even more pronounced when conversations move to questions of pest resistance and refugia design. Should refugia be arranged at village or field level? Would alternatives of crop mixes of Bt and non-Bt work? What is the likely genetics of resistance? Would stacking of genes make a difference and increase resistance times? How on earth would this be implemented in the smallholder sector? The answers to all these questions, from all we discussed with, was, again and again – we don't know. The regulators point out that these are not issues to be considered now. The trials are not aimed at looking at these questions, and these will only have to be addressed on commercial release. But on the basis of what information? There are no studies on-going of pest dynamics and resistance on Bt in Zimbabwe. Some work in South Africa may be pertinent, and on-going research in Kenya supported by CIMMYT may throw some light on the issue[7]. But this certainly remains, as everyone admits, a big, unpacked black box on the horizon. In the farming systems of Zimbabwe existing approaches to implementing refugia arrangements look to be nearly impossible given the patterns of diverse smallholder agriculture. In thinking about options, the only choice is to use extrapolated models of very complex, uncertain systems, with few parameters defined and many not even known about. As one regulator noted: 'All those questions about refugia are being asked. But we have no answers.'

The crop trials also make a set of assumptions about time – what matters is what is seen over the testing period, and recorded in the experimental data sheets. Key scientific questions that cannot be addressed through collection of adequate data over the two or three years of the trials are discounted as concerns that cannot be practically addressed. As a senior Zimbabwean scientist observed: 'Environmental impacts – that is where we are not sure. What can happen over time? The trials are not adequate for this. We need longer experimental times'. There is a range of possible long-term effects of GM crops recognised in the literature. We have already noted issues of gene flow, insect resistance and changing pest ecologies. These are at least part of the debate in Zimbabwe, although not being addressed through any substantive scientific enquiry. But there are other areas, such as microbial interactions, soil biology impacts and soil microfauna, where fundamental ignorance – and with this lack of debate – prevails (see Mayer 2002, for example). Such factors are not, and cannot be, part of short-term trials, and

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6 This appears to be more generally the case, with very little published information on pollination dynamics in cotton.

7 Research in South Africa is being conducted under the auspices of the Agricultural Research Council (ARC) – see www.arc.agric.za. In Kenya, the IRMA project involving CIMMYT and KARI is reputedly collecting data on such issues (CIMMYT 2002).

nor are there even speculative models on which to base best-guess solutions. In this situation, as many concede, we really don't know what we don't know.

So what will be the basis for commercial release? After all the data is compiled, the questionnaires completed and the data forms analysed, what sort of information will be available? Certainly not even tentative answers to many of the questions and uncertainties raised above. The trials will be able to say a limited set of things. Under these conditions (of soil nutrients, moisture, rainfall etc), in these years, with this level of pest attack, with this variety and combination of pests spread over the season in a certain way, the Bt crop (with event *x* in background *y*) performed (in relation to yield and pest damage levels) in this way compared to a chosen control exposed to – more or less – the same conditions. With this sort of data in front of them the Board must then make a decision. The chair of the Board, at a workshop for parliamentarians interested in the GM issue, explained the process of decision in these terms: 'When we are satisfied that things are safe within logical reason, varieties are released'.

But where does this "logical reason" emerge from? Essentially the field trials are the basis of the decision. The focus on the field trial methodology allows for the presentation of a well-established, familiar, and, importantly, visible scientific method (randomised block design, replications, anova statistics etc.), but one that can only ask, as we have seen, a restricted number of questions, leaving many unanswered. The current practice of regulation – despite, it must be said, considerable informed and reflective debate and discussion among the parties involved – is forced effectively to ignore such uncertainties, focused as it is on a limited conception of risk and a restricted set of experimental methodologies and capacities.

Field trials, then, are visible, tangible demonstrations of regulation in practice. People can visit them, the press can be shown them, inspectors can monitor them. Whatever the flaws of the underlying scientific design, their symbolic role, we would argue, is key. Although the trials are designed to test such a limited range of features, they do have other roles. With the effective removal of other more complex issues from the enquiry, the field trials – with all the trappings of their inspected and approved mesh fences, scientists wearing rubber gloves and so on – become symbolic features of the regulatory process. Field trials, as a consequence, mean different things to different actors in the policy process.

For the companies, they have GM crops in the field, an opportunity for "witnessing" events, publicity photographs and some selective data collection. For them this is a breakthrough, a foot in the door. Their task, they feel, is to use this as an opportunity to break down the reticence and scepticism of Zimbabwean officials, and seek a consensus on the basis of the results obtained. Monsanto have invested considerable effort – through field trips, videos and presentations – in promoting the experience of smallholder Bt cotton production on the Makhatini flats in KwaZulu Natal, South Africa among Zimbabwean audiences. But people have remained sceptical. 'South Africa is different to Zimbabwe', they say. People need to see Bt crops performing in their own settings, and field trials fulfil just this role. By completing the required tasks to the letter – filling the forms, developing the checklists, monitoring the trials, the companies' hope is that Bt products will be approved, and a regulatory process (defined in this limited way) established for a range of other products waiting in the pipe-line. One seed company

manager commented, despite the obvious limitations of the trial process, they continued to put in applications to 'keep the system going and keep in with the Biosafety Board, so that one day we will be able to use the technologies'.

For the Biosafety Board, the fences, inspections and checklists demonstrate some degree of control, authority and oversight of a process that they have no capacity to fully cover. It shows, on one hand, that they are willing to try things out, and see what happens (with an apparently open mind), but also show that they are following a precautionary stance and that science is doing its job to allay fears and ensure biosafety guidelines are upheld. Scientists involved are sanguine about the limitations of the process, but accept that there is little more they can do. Developing the capacity to implement the trial programme is a major headache. Training workshops for inspectors have been scheduled, but plans were put on hold due to donor boycotts of Zimbabwe. While there is some budget available to the Board, this is limited to some travel and per diem allowances for inspectors. There is a reliance on companies to do the work, collect the data and present the results. Trust is a key issue in this. That this has been previously broken by companies not following the rules means that scepticism is rife. In the end, the fences, officials concede, have no value other than to mark the presence of the trial site, and keep out thieves (although with limited effectiveness, as we have seen). With maize being detasselled on flowering there should be no possibility of cross-pollination in any case, and the whole panoply of requirements about isolation distances, fences, and even the use of rubber gloves to handle the GM crops, is more about imposing some strictures and so authority on the companies than anything else it seems. For the Board, then, the dilemmas in implementing the field trials highlight some of the basic problems of running a trial process in a country with limited resources. As a Board member pointed out: 'Testing costs are prohibitive. The molecular arms race means there are more and more possible tests. Everyone wants to do the most high level one because it is possible. But Zimbabwe does not even have the most basic equipment. What can we do?' The unrealistic expectations of internationally harmonised risk assessment processes based on up-to-the-minute scientific approaches is, it appears, not reflected in the realities in Zimbabwe.

In other countries (from Europe to India), field trials have also become symbolic sites of opposition and resistance for NGOs and civil society groups of different hues. To date this has not been a feature of the Zimbabwe debate. The only trials uprooted and burnt have been under the instructions of the government regulatory authorities, or at the hands of thieves from neighbouring communal areas. While the type of direct resistance seen in Europe or India may not be a feature of the Zimbabwean GM debate, there have been some searching questions raised about the nature of the trial process by NGOs and others. NGO activists insist that they should be involved in the trial monitoring process, and they are keen to probe and challenge the results as they emerge (raising questions of pest resistance etc.). Yet, they claim, they have not been invited. The Board's response to this comes in two parts. First, they question the "scientific" expertise of the NGO activists, and, second, they observe that NGOs don't actually want to become involved. As a Board official commented: 'What is their expertise in science? . . . Anyway, most of the NGOs want to be outside the system and then complain later. They don't want to be involved in any case'.

As is widely conceded, outcomes of any decision on GM crops are, of course, dependent on a range of factors far wider than the narrow framing of a conventional risk assessment, where crop trials have enormous importance. The "logical reason", noted by the Board chair (see above) as the basis for regulatory decisions, must inevitably encompass a broad range of issues, way beyond the results of the trials. The trials, then, while important in symbolic terms, may have less importance scientifically. As someone involved in the trials candidly observed: 'The experiments were very simple. A weak design which told us little. They were symbolic really. But we are just following the rest of the world in these trials'. Certain information can of course be gleaned from them, but decisions emerge from other sources, including the "predispositions" of the experts involved in the Board (see above). This, of course, challenges the notion of an independent, controlled, rationalist science-based assessment, but, perhaps, if we accept this is what really happens in practice, makes the real and difficult challenges of regulatory control more apparent.

As we have seen, the rituals of regulatory science in the Zimbabwean context, as elsewhere, is all about garnering evidence, developing rational assessment criteria, and basing judgements on so-called sound science, with crop trials as central. But, as many involved in the process agree, it is also about trust, transparency, deliberation, control and authority. If regulatory decisions are to be upheld, they must carry broad support. Thus the science used in regulatory decisions has a broader political-social aim. For this reason, the field trials have another symbolic role associated with the politics of regulation, which again goes way beyond their notional scientific aims. But this is not an argument for rejecting science. Of course science is important, but this is inevitably limited and limiting. Resorting to "experts" and symbolic forms of science are clearly not enough, and a wider framing of the regulatory debate and a more inclusive form of decision making is therefore, it seems, required.

Later in the paper we will return to this theme, and discuss the forms of engagement that might enhance the regulatory process, moving it from – in the case of crop trials – a rather absurd exercise of "symbolic science", where ritual and performance override substantive debate and discussion, to something more embedded, inclusive and democratic. Next, though, we turn to the debate over GM food aid imports and how this too has raised challenges for the regulatory process.

4 Importing GM food aid

In the latter part of 2001 it became clear that Zimbabwe would have to import food at some point over the coming year. By 2002 this had evolved into a serious food crisis, with a forecasted maize deficit of 237,320MT in national requirements of 1.64 million MT of maize estimated for the consumption year ending March 2003, even after allowing for significant imports. This comes on the back of low harvest production in the 2001–2002 season (estimated at under 500,000MT of maize) and low stock levels. By the end of 2002, 788,389MT of maize had been imported, 14 per cent of this from humanitarian assistance and the rest commercially. By the end of March 2003 a further 592,127MT is expected to be imported. Given the slow pace of imports, and uncertainties about government's ability to pay and

donors' willingness to support Zimbabwe, how the remaining deficits will be covered until the 2003 harvest is unclear (FEWSNET 2002; GIEWS 2002; DFID 2002). With maize as the main staple, eaten regularly by Zimbabweans three times a day, getting hold of maize was a major priority. The government sought food imports from a variety of sources both within the region and beyond. But the scale of the deficit was such that the UN World Food Programme (WFP) became increasingly involved. As the major donor to the WFP, the US (through its aid programme, USAID) provides support in terms of food grain (rather than financial contributions offered by most other donors). US maize is predominantly GM, and this raised questions about biosafety. The chair of the Board took a proactive stance in 2001, and organised a number of consultations on the issue. By the time the crisis was heating up, an emerging position existed within the Board.

But this was not just a technical decision, this was also hot politics. Initially, it appears, the WFP did not have a thought through policy on GM food imports into the southern African region, and confusion reigned.[8] One Board member complained: 'WFP behaved very arrogantly. They took no notice of the existing regulations'. The Board insisted that the whole importation question must come under the regulations, and any imports should be approved by the Board. This was expressed in strong terms to the WFP and USAID. As the controversy developed across the region, especially following the rejection of any GM imports of any sort by Zambia in 2002,[9] the pressure intensified.

This heated international and regional debate was preceded by a number of discussions within Zimbabwe. In November 2001, the Board met, together with a range of invited stakeholders, and

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[8] James Morris, the WFP Executive Director and Special Envoy of the UN Secretary General for Humanitarian Needs in Southern Africa was sent to the region to clarify the situation. He paid visits to the Robert Mugabe, the Zimbabwean President, among others (see IRINnews.org, 'GM maize accepted as crisis deepens', 6 September 2002). WFP came under intense pressure from the US government to clarify the GM food aid position, with Judith Lewis, director of WFP's regional office admitting that 'it has become a very real issue for us', and going on to comment 'it's a moral dilemma in terms of, yes, we have this food available, you make a decision not to receive it, people die'.(*Agence France Presse* (2002). WFP grapples with GMO dilemma in southern African food crisis, 24 July). In the end WFP issued a document stating its policy, together with statements from the EU and the US clarifying their positions (WFP 2002). See also: in addition, other UN agencies – including the FAO and WHO became involved. See: FAO (2002). Director General urges countries to think carefully before rejecting GM food aid. FAO Press Release, 30 August. FAO: Rome. www.fao.org/english/newsroom/news and AllAfrica.com (2002). WHO urges acceptance of GM food aid. 28 August.

[9] See press coverage, including: *Environment News Service* (2002). USA: Poor countries reject GMO food aid. June 14; *Environment News Service* (2002). Zambia: African nation accepts US GM food aid. 29 July; *Reuters* (2002). Starving Africa should accept GMO food, US says. 29 July; *Reuters* (2002). US calls food aid refusal a crime against humanity, 9 December; SciDevNet (2002). African hunger and GM maize. www.scidev.net/archives/editorial/comment28.html; *UK Independent* (2002). Row grows over GM food aid for Africa as 14 million starve. 19 October. *The Economist* (2002). Better dead than GM Fed. Economist, September 23. The Zambian government produced a report following extensive consultations in late 2002 – Government of Zambia (2002). Genetically modified food and crops. Lusaka. Local NGOs (e.g.KATC/JCTR (Kasisi Agricultural Training Centre and Jesuit Centre for Theological Reflection) (2002). What is the impact of GMOs on sustainable agriculture in Zambia. www.jctr.org.zm/gmos.htm) offered support to the anti-GM position, as did international groups (e.g. Greenpeace 2002; GRAIN 2002). Industry and US government-linked scientists offered a counter position, see: Apel *et al.* (2002). To die or not to die. This is the problem. Response to KATC/JCTR report on Zambia. October, 2002. Prakash@tusk.edu. The US also offered its own statement, see: US Department of State (2002). Zambian rejection of US food assistance. Statement by Richard Boucher, Spokesman. Press release, 30 October and USAID (2002). Confusion on biotech affecting famine, trade, official says. USAID press release, 16 December. www.usaid.org.

considered a range of different options, and finally reached a decision on what was the most appropriate strategy for GM imports, assuming they would be needed. They concluded that, on the basis of available evidence from studies in the US and 'basic understanding of gut physiology and biochemistry' the risks of consuming Bt maize were not significant. However, the dangers of introducing GM maize through planting were apparent, and so all maize coming into the country should be milled before distribution. To their credit, Board members took part in a number of public discussions around the food safety, environmental and trade impacts of GM maize imports convened by NGOs and others during 2002 as the public and media debate heightened. There was also intense press interest in the issue in mid 2002, and Board members were expected to comment on the pros and cons.[10]

The context for the regulatory decision should be borne in mind. Even in late 2001, there was a sense of urgency and a need for a firm decision. From 2002, pressure was high – from the WFP, USAID and the US State Department who issued during 2002 a series of statements arguing that southern African states should accept GM food or, in the words of Tony Hall, the US Ambassador to the UN Food and Agriculture Organisation be accused of "crimes against humanity".[11]

The decision to import, but to require milling, essentially said that the regulatory judgement was that eating GM maize was OK, but planting not, for a range of biodiversity, trade and other reasons. That this decision required some short-cuts and leaps of faith is recognised by many. But as one Board member put it:

> There is no time in a humanitarian crisis . . . We don't have the leisure to debate. We are not going to sit here in the eleventh hour and find out if Bt is safe to eat. We rely on the FDA system of the US. There is plenty of literature and FDA assessments to rely on. We assume the US data is OK. We are not in a position to test.

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10 See for example (among many): *Daily News* (2002). Firms urged to seek authority for modified food imports. 24 January; *Daily News* (2002). Governments, scientists seek alternative to GM technologies. 10 October; *Financial Gazette* (Harare) (2002). Rejection of GMO maize a smokescreen. 12 September; *Financial Gazette* (Harare). (2002). Food aid deal collapses. 28 November; *The Herald* (Harare) (2002). Region in quest for food security. 12 October; *Zimbabwe Independent* (2002). GMO products threaten seed varieties – ZFU. 7 June; *Zimbabwe Independent* (2002). SA seed distributors can't supply Zim. 22 November.

11 See: Reuters (2002). US calls food aid refusal a crime against humanity, 9 December, reporting on comments made by the US Ambassador to the FAO, Tony Hall who visited Zimbabwe in October 2002. The earlier US State Department press release was similarly strongly worded. See: US Department of State (2002). Zambian rejection of US food assistance. Statement by Richard Boucher, Spokesman. Press release, 30 October. The US administration, perhaps reflecting a broader shift towards unilateralist, interventionist, pre-emptive foreign policy, laid out a series of threats during 2002. In November, the *UK Guardian* reported 'US may intervene to save Zimbabweans' (7 November 2002), quoting a US official saying that 'we may have to be prepared to take some very intrusive, interventionist measures to ensure aid delivery to Zimbabwe'. In June, Andrew Natsios, USAID Administrator commented that 'USAID's Bureau of Democracy, Conflict and Humanitarian Assistance believes that unless the government of Zimbabwe waive its restrictions on the import of US corn, it will be difficult, if not impossible, for the US government to respond to the extensive food requirements that have been identified (ENS 2002, USA: Poor countries reject GMO food aid, 14 June). Natsios later accused green groups of endangering lives in the region, commenting 'They can play these games with Europeans, who have full stomachs, but it is revolting and despicable to see them do so when the lives of Africans are at stake . . . The Bush administration is not going to sit there and let these groups kill millions of poor people in southern Africa through their ideological campaign' (Greenpeace, 2002: 1, quoting *Washington Times* (2002), Greens accused of helping Africans starve, 30 August).

As with the field trials, the capacity to test for the food safety of imported GM maize was severely limited, either in terms of assessing which, if any, antibiotic markers were being used in which shipment or, for longer term effects, what were the consequences of eating GM maize in the volumes and at the frequency that Zimbabweans eat it. In other words, the FDA assessments on food safety – with all their limitations[12] – had to be taken as the basis for the decision. That the Board rejected the importation of whole grain maize was easier to make, given the requirements imposed by the Board (and the Variety Release Committee) for all releases (deliberate or otherwise) to pass through in country testing and field trials. This of course irked the US protagonists of GM imports. As a Board member commented: 'They [the Americans] shouted louder and louder. But we had our regulations, unlike our neighbours [the Zambians]'.

The existence of the regulations, combined with prior discussions of the Board together with different stakeholders (admittedly limited, but including key NGO and government personnel), was clearly important in providing authority for the decision nationally in the face of intense external pressure. But, in contrast to the image of science-based technocratic decision-making outlined by the Board registrar (see above), the decision on GM food imports was projected into a wider political and diplomatic realm. With intensive lobbying behind the scenes, and high profile visits to senior government officials and the President by the UN Special Envoy Morris, the niceties of technical biosafety regulations took a back seat. When President Mugabe travelled to the World Summit on Sustainable Development in Johannesburg in August 2002, events took another turn. He returned to Harare to be welcomed by the party faithful waving placards proclaiming that Zimbabwe should be GM free. The GM issue in Zimbabwe had become wrapped up in international political posturing and increasingly vitriolic rhetoric.[13] Being GM-free was seen by some as a nationalist stance against unreasonable external US pressure. GM would not be forced into Zimbabwe through the back door. Zimbabwe would not be subject to new forms of imperialism. 10000MT of maize was sent back from the borders and proclamations were made on television. At this point Board members were telephoned and asked to advise. Within a few days the position had reversed and Zimbabwe had agreed to take a WFP shipment of GM maize, provided it were milled prior to entry in the country, or immediately on entry if this were not to be possible.[14]

There are several aspects of this debate that are of interest. Firstly, in the context of a heated public debate on GM imports, the government decided to act in a precautionary fashion, and adopt a position which assured the GM free status of Zimbabwean maize seed. Similarly, the status of Zimbabwean

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12 See: Sherman, D.G., (2002), Holes in the Biosafety Net. www.cspinet.org

13 See: *Financial Gazette* (Harare) (2002). Rejection of GMO maize a smokescreen. 12 September.

14 For some of the press commentary on the moving policy position in Zimbabwe, see: *BBC News* (2002). Zimbabwe turns away US food aid, 31 May; *Washington Post* (2002). Starved for food, Zimbabwe rejects US biotech corn. 31 July; *Financial Gazette* (Harare) (2002). Rejection of GMO maize a smokescreen. 12 September; IPS, Inter-press service (2002). Die of hunger now or eat and die later. 26 August; IRIN (2002). Zimbabwe: GM maize accepted as crisis deepens. 6 September; Vidal, J. (2002). US dumping unsold GM food on Africa. *The Guardian*, 7 October; *UK Independent* (2002). Row grows over GM food aid for Africa as 14 million starve. 19 October; *Financial Gazette* (Harare). (2002). Food aid deal collapses. 28 November.

livestock exports as non-GM fed would also be protected.[15] As already mentioned, it is highly likely, according to many commentators, that GM maize has already found its way into Zimbabwe, as one board member put it: 'We are a landlocked country, our borders are porous. The whole country is a field experiment'. Given this, there is a symbolic element to the decision to block the import of maize seed, but one that sent an important signal to US GM companies and others wanting to by-pass regulations, as well as a parallel signal to export markets requiring GM-free status that Zimbabwe was keen to maintain this, for the time being at least.

The decision to mill reflected a choice that GM maize was safe to eat. This was based on particular and very limited models of food safety, alongside some informed, but necessarily speculative, arguments about gut function and digestive chemistry. The establishment of new allergenicity or toxicity experiments, with designs taking into account the particularities of Zimbabwean consumption patterns, were deemed impossible and too expensive. Nor was it deemed necessary to go back and evaluate the circumstances of the production of the knowledge in the original FDA research documents, and what they left in and out. The decision to say that GM maize was safe to eat can therefore be seen as contingent in the extreme, with a precautionary stance on food safety abandoned in favour of quick action in the face of a growing food crisis.

Regulatory decisions in this context, then, must be understood in the wider context of public debate, trust, and the politics of food aid and international relations. Perhaps if Zimbabwe had wanted a more full-on collision with the US and the WFP a different decision would have been reached. A compromise decision that did not alienate potential European GM-free markets and allowed some imports of US grain was therefore sought. Given the precarious situation of the Zimbabwean economy, in part resulting from the withdrawal of aid and loan support, and the increasingly urgent need to import food, perhaps there was no other possible decision. While the decisions made by the Biosafety Board served to communicate the impression of control and authority, and decision-making made on technical grounds, this must be qualified by the recognition that, in practice, the decision was less about food safety or biodiversity – the focus of the biosafety regulations – but more about politics, diplomacy, trade and aid.

For countries, such as Zimbabwe, dependent on overseas markets for foreign exchange earnings, and where US or European pressure on domestic policy making can be overbearing, the chances of a sound-science based technocratic approach rising above such pressures is, of course, remote. The GM food import saga, therefore, revealed the real world politics of GM regulation in the developing world. In this case the heavy-handed moralising and haranguing of the US State Department and others was there for all to see. More often, though, the politics of regulation is played out in more subtle terms, through back-room lobbying and more discreet advances and overtures to regulatory authorities. The degree to which a well-drafted, legalistic and technocratic administrative response in the form of the Biosafety Board and its

[15] But EU position see Berglund (2002). EC clarifies its position on GMOs. Press Release, Lusaka 28 August. Delegation of the European Commission: Lusaka.

regulations is sufficient to sustain autonomy and independence is a question more and more people in Zimbabwe, and elsewhere in the developing world, are asking.

Given the experience of these two cases – crop trials and food imports – what lessons do this tell us about the scope and effectiveness of a regulatory regime based on a fairly standard model of biosafety regulations? Zimbabwe is not alone, as these are being promulgated around the world by international agencies in numerous well-funded "capacity building" activities in the wake of the Cartagena protocol. What room is there for improvement, particularly in respect of engagement by the range of stakeholders involved in any decision about GM crop releases or imports? The concluding section of the paper, then, addresses these questions with a look at a number of emerging policy and regulatory dilemmas.

5 Conclusion: future challenges

There seem to us to be two important challenges for policy and regulation of biotechnology in Zimbabwe, and perhaps more broadly. First, a more thorough interrogation of the scientific basis for decisions, including, importantly, the crop trial process. Second, there is a clear need to expanding the scope of policy deliberation, and link narrow, risk-focused regulatory decision making with a broader, more strategic assessment of technology options.

5.1 Interrogating the science: unpacking the blackboxes

In our discussion of both the case of field trials and of GM food imports, a range of uncertainties impinge, inevitably, on the regulatory decision-making process. While these are widely recognised, they are often not made explicit. By relying so heavily on the process of field trials which, because of their design, time-scale, spatial location and so on, can only answer a limited series of questions, other issues are put to the side, as "beyond our capacity" or "for further research". In the same way, a judgement about the potential food safety implications of GM food imports was made based on "science from elsewhere" and an assessment based on "common sense understanding" of gut physiology, rather than any sense of complete information providing definitive closure.

As we have seen, the science-based nature of risk assessment looks a bit thin when put under closer scrutiny. Institutional contexts for risk assessments and judgements arising from them then become key. The Biosafety Board as a group of notionally independent experts – largely scientists – has been given the statutory decision making authority to come to conclusions. But, with uncertainty, sometimes ignorance, and certainly conflicting evidence and views, this must come, in the end, to judgements made in the public interest. Yet, with the trial process controlled by the applicants and the Board having limited capacity to set up independent assessment processes – for instance on food safety or pest dynamics – then much faith must be placed on the Board members themselves.

The bottom line, of course, is whether this is enough. One important move must be, in our view, to increase the transparency of the process. If, as is going always to be the case, judgements must be made on incomplete information, then being explicit about what is known and what is not, and the limitations of

existing knowledge is an important step. In conversation all those involved were prepared to discuss such issues. But whether, given the way the risk assessment process is structured, around assumptions of science-based decision-making, such doubts, concerns, uncertainties and questions are able to be made explicit and enter a wider set of deliberations is unclear. In the end, any regulatory process must be based on trust. And this applies as much to concerned publics as it does to industry applicants.

The challenge then, is to unpack the blackboxes, expose the uncertainties for what they are and open up the decision-making process to discussion of such issues, ensuring that judgements emerge from an explicit assessment of trade-offs and concerns – many of which, as we have noted, are not specifically "scientific" in nature. This, in turn, raises the second challenge we identify, that of public engagement in the process.

5.2 Expanding the scope: challenges for deliberation and policy-making

As currently framed, regulatory decisions in Zimbabwe focus on a fairly limited definition of biosafety. But asking whether Bt products are safe is, as we have seen, only one part of the equation. In the debates about Bt crops and GM food imports a number of other issues have been raised. The degree to which these come into the regulatory frame is key. Naturally, different actors have different views as to how broadly the debate should be cast.

Industry players who see a commercial opportunity in Bt products argue for a narrow form of risk assessment. They argue that the type of biotech applications being offered are a known quantity and have been widely tested in the US and other parts of the world without problems and have offered substantial benefits to farmers. The chance to increase yields and reduce pesticide applications for key crops such as cotton should not be missed through insistence on unnecessary costly, cumbersome and lengthy regulatory procedures. Missing out on biotech would in turn undermine the potentials of the seed industry in Zimbabwe and the viability of agriculture in globally competitive markets. The widespread commercialisation of Bt maize and cotton in South Africa, and the apparent enthusiasm for biotech products in Kenya, show the benefits and suggest Zimbabwe is already being left behind. In relation to food aid, the issues are different, but urgency is again key: in a country where people are starving the luxury of debating endlessly about apparently negligible risks cannot be afforded. The proponents go on to argue that safety can be convincingly demonstrated through science-based assessments – using field trials and food safety tests, and following models developed elsewhere will be sufficient to allay fears.

However, others, including ourselves, are more cautious. Maize and cotton are so central to the economy, and support numerous livelihoods. The export value of both crops may be substantially in their being GM-free, with import niche markets in Europe, and even South Africa (e.g. for maize for baby food). A broader assessment that explicitly incorporates socio-economic, trade and livelihoods criteria is required. GM crops, it is argued, are linked to a particular style of agriculture that is potentially highly damaging either for specific commodity producers or the most vulnerable farmers. If, for instance, a biotech future is dependent on licensing deals with MNCs this may mean that the costs of inputs go up and the range of technology options is narrowed in a way that is problematic for the most risk-prone

farmers who either cannot afford the costs, or ride out the difficulties if promised high returns are not realised (cf. Keeley and Scoones 2003). Similarly, livestock producers have expressed fears that GM maize feed may result in a loss of EU export markets, either now or in the future, despite assurances from EU officials in the region (see above). In relation to food safety, concerns are expressed that Zimbabwe uses maize in a fundamentally different way from other places where it is approved for human consumption: it is used largely unprocessed, and is consumed as much as three times a day by the bulk of the population. This potentially exposes virtually the whole population to a set of unknown, and potentially avoidable, risks. In addition to asking if Bt is safe, others wonder whether Bt is the priority. Is insect resistance the main problem or are other constraints more significant? Getting locked into a particular technical solution for pest management might undermine other options, sceptics argue. Also the opportunity costs of going the transgenic route may not be the most appropriate, given other available (bio)technologies.

A key question, then, is who will make decisions on these wider issues, and how will such debates be organised. These debates are live in Zimbabwe with organisations such as the Biotechnology Trust of Zimbabwe (a Dutch funded NGO) organising public debates and consultations, and others such as the Zimbabwe Farmers' Union convening debates within their membership. The media has also made biotech and particularly GM food aid a key issue, particularly in the past year or so. However, the mandate of the Biosafety Board remains narrow. In the final analysis their competence to address these other questions is doubtful, as they themselves admit. Yet, at the moment, there is no other route to address the wider set of concerns beyond the narrow technical issues of biosafety. There is no formal policy process looking at wider issues of agricultural change and strategy that articulates with biosafety regulation, beyond ongoing informal debate and lobbying by the range of actors from NGOs to industry. The Board is in a difficult position. As the obvious focal point for such interventions, it may be seen by some as more important and influential than it really is. But, as we have seen, it neither has the mandate nor the capacity to deliberate on such issues, nor, does it seem, to be willing to question the scientific basis of its decisions.

Participation and consultation are, as everywhere it seems, the buzzwords in Zimbabwe. The Board claims it consults widely, and accommodates views. Others disagree. But there are a variety of views on what an ideal process should be. An industry commentator observed: 'Debate is always good, but there is a limit. Let's plant these things and see what happens. Time for action is now'. A leading official in the Zimbabwe Farmers Union was cynical about the likelihood of effective consultation: 'They say they have consulted, but they have already decided. They give a document today to make a decision next week. There is no time to consult our membership. They just want ZFU to rubber stamp'. A Board official observed the dangers of a more inclusionary stance from his perspective:

> There is a lot of concern about the role of NGOs – they make a lot of noise. Debate needs to be measured. If you open the debate, the NGOs can become collaborators and partners rather than adversaries . . . But in the end do they have the scientific expertise?

It is this closing off of space for discussion by claims to expertise that is particularly pernicious and prevalent. The chances of reframing the debate, to extend the discussion to other realms beyond the strictly technical seems off the cards for those in charge. As one NGO person noted: 'The issue is voice not expertise. It is not the science we [NGOs] lack – we can always subcontract. We need to be able to monitor from inside. We want to be in the driving seat. If we have any reason to doubt we can get others in to give advice'. The same commentator argued for a tactical collaboration with government:

> Government has no capacity. They know it. For the coordinating group, the NGOs created it and are running it, designing the whole legislation. Government gets the credit though. It's a strategic approach by civil society. It is best to bring government on board. If you go head on, power relations are always tilted towards government. You can never win. Some things you just have to win without talking.

With the changed political mood in the country in the past few years, the openness and encouragement of government to join with NGOs and others as partners in policy dialogue and development has significantly receded. As someone commented: 'These days you have to watch out for politics'. This has bred mutual mistrust and suspicion.

Yet the government clearly recognises the need to take people with it in any decision. The furore about GM food imports and the public discussions and media debates were vibrant, open and often forceful, with divergent views being expressed. As one interviewee put it: 'Fear of the unknown is gripping the nation'. And, as we have discussed, it is these unknowns about GM food or crops that are at the centre of the policy and regulatory debate. What the GM food import controversy has certainly done has raised the tempo of the debate and increased public and media awareness of the issues. This is an important precursor to a more wide-ranging and engaged debate about science, regulation and policy. As one NGO worker put it: 'Now the debate has changed. Before people did not relate to how biotech might affect your life. But food is so central. It is now like AIDS – it is about everyone, not just scientists and doctors'.

In contrast to only a year before a Biotechnology Trust of Zimbabwe staff member observed that today, if he was walking about in town with his BTZ t-shirt on, people will stop him and quiz him: 'What is this biotech? What are you guys doing about it?' Of course such engagement needs to go beyond the well-informed urban consumer in the capital city to the range of potential users of GM technologies in the rural hinterlands of the country. But it is this sort of public awareness, questioning and debate that must lie at the centre of an effective regulatory system that encourages the unpacking of scientific statements, expands the scope of debate, and ensures a more inclusive form of deliberation on complex, controversial and important strategic issues affecting both the future of Zimbabwe's key economic sector – agriculture – and the most basic of human needs – food.

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