Centre for Integrated Research in Biosafety

Tel: +64 3 364 2500, Fax: +64 3 364 2590
Email: inbi@canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Biosafety Forecast Service Biosafety Assessment Tool prototype version 2: Review of client feedback

Executive summary

In August 2006 the Centre for Integrated Research in Biosafety conducted its third set of workshops to gather feedback on the development of the Biosafety Assessment Tool (BAT) – an electronic, interactive information database for the evaluation of risks of genetically modified/engineered organisms (GMOs/GEOs). 53 participants were invited to use the second prototype of the BAT during a series of three application case study workshops at the 'Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms' international biosafety course in Tromsø, Norway.

Two surveys were distributed to participants during the workshops. The first was designed to gather information on the background of participants and their experience reading and evaluating GMO applications and risk assessments. A clear need was expressed in survey results for publicly available reviews of biosafety literature, reaffirming the original objective of the project.

The second survey invited comments on the content, organization and style of the BAT, the readability and depth of its text and suggested topic additions. Overall, the tool was received with enthusiasm. Respondents found the BAT very useful for evaluating the case study documents and appreciated the approach of the then available Gates: 1, with text arranged under the headings of an application; and 2, a general information database. The BAT allowed participants to quickly access relevant information about the case study and provided initial suggestions for risk identification.

The BAT was clearly a useful resource during the workshops, with 100% positive responses, 89% strongly positive. Respondents were positive about the technical level of the text; however, more detail would be appreciated for those involved in biosafety regulation, in conjunction with straightforward topic summaries aimed at those with little experience in related fields. Content requests for the next version of the BAT were wide-ranging, but centred on health and environmental assessment and socio-economic evaluation topics. Other additions for consideration include maps showing the locations of GMO development, cultivation and approvals.

95% (42) of respondents stated that they would be very interested in using the BAT for various purposes. The strongest sentiment expressed by respondents was the desire to see more content produced, and the BAT publicly released, as soon as possible. The positive reception for the second prototype provides a clear impetus for the sustained development of the tool, taking the specific topic requests of workshop participants into account.

Contents

Report prepared by Billie Moore
October 6, 2006

Introduction

The “Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms” international biosafety course was hosted by the Norwegian Institute of Gene Ecology (GenØk) in Tromsø, Norway, from 31 July to 11 August 2006. With 53 participants involved in biosafety capacity building and regulation in 50 countries, it provided an ideal group of potential users to give feedback on the second prototype of the Biosafety Assessment Tool (BAT), prototype version 2 (Pv2.0), developed by the Centre for Integrated Research in Biosafety (INBI) under the Biosafety Forecast Service project.

The Biosafety Forecast Service

The Biosafety Forecast Service is a research-based risk identification and analysis project, established under the principles of the Cartagena Protocol on Biosafety. The Service is part of the UNEP-GenØk Biosafety Capacity Building Package, funded by the Norwegian Agency for Development Cooperation. It assists scientific risk assessment and holistic decision-making by countries meeting their obligations under the Protocol, identifying areas of scientific uncertainty in applications for the release of genetically modified organisms (GMOs) as food, feed, medicine, or into the environment.

The Biosafety Assessment Tool (BAT)

The identification of relevant risk issues in GMO applications requires the close analysis of technical supporting documentation, along with the navigation of large sets of often contested literature. The BAT, an electronic, interactive risk assessment guide and information database, is being developed by the Biosafety Forecast Service to support this process.

The BAT is the means by which clients can access information and templates for customizing their own specific risk assessments or assessment evaluations. The BAT is a stand alone application through which clients interface with all information available so far under the Biosafety Forecast Service. This information includes deep subject reviews, case studies based on existing GMOs, completed risk assessments, and emerging issues of risk or social, cultural or economic impact.

The BAT will aid the evaluation of GMO applications by presenting relevant literature for both scientific risk assessment and the analysis of potential socio-economic and legal impacts in an easy-to-follow form. The aim is to assist policy and regulatory officials in government, NGOs, citizens and researchers in constructing comprehensive and context-specific assessments of GMO applications, including the identification of issues or uncertainties that ought to be addressed by either regulatory authorities or the applicant.

Review of client feedback

To ensure that the BAT is developed in line with the needs of potential user groups, INBI periodically conducts feedback sessions. Individuals involved in biosafety regulation and research from developing countries use prototypes of the BAT in application case study workshops and are invited to give their feedback on the content and its delivery.

In 2005, INBI conducted workshops using the first BAT prototype at its own biosafety course in Honiara, Solomon Islands, and at the international biosafety course in Tromsø, Norway.

BAT workshops. Left: the 2005 Regional Biosafety Course in Honiara, Solomon Islands. Right: the 2006 international biosafety course in Tromsø, Norway

This report compiles feedback from a third series of workshops, again at the international biosafety course in Tromsø, Norway, using the second BAT prototype. Three workshops were presented on the molecular, health and environmental assessment of an application for the approval of genetically modified high-lysine corn. A preliminary survey on participant roles and experience in risk assessment was distributed to gather information on the background and interests of the feedback group, followed by a second survey which solicited views on the content and use of the BAT.

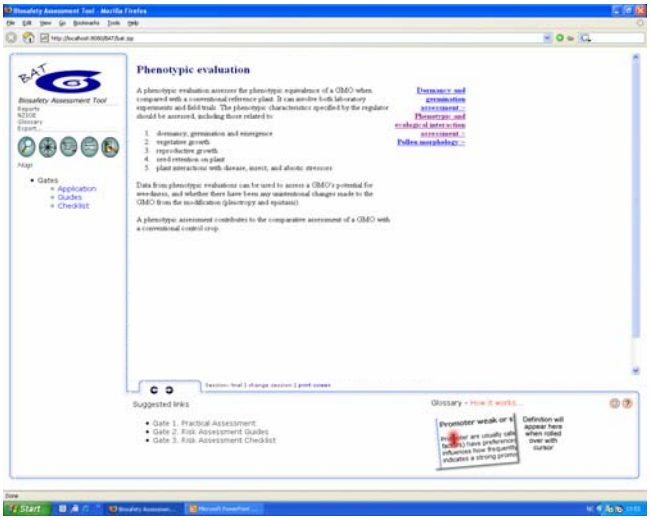
Prototype 2

Prototype 2 (Pv2.0) marks a significant advance in the development of the BAT, in terms of both content and presentation.

Content

The content and organisation of the BAT was planned after a review of existing biosafety resources (during 2004-5). This identified a need for freely-available, non-commercial information on both the scientific and social issues related to biosafety – written in an easy-to-read style, but with the support of peer-reviewed articles and sound references.

To this end, the BAT is constructed around three 'gates' or information portals. Using these gates, it is hoped that users with both specific risk assessment and general research tasks will quickly and easily find content of interest to them.



A user conducting an environmental risk assessment of a GMO may refer to information in Gate 1 on the structure and interpretation of a phenotypic evaluation.

Gate 2, in contrast, will present more general topics related to GMOs and the environment, including potential impacts on biodiversity and non-target organisms.

GATE 1

Gate 1 is organised around the common headings of an application for the approval or deregulation of a GMO, such as molecular characterisation and phenotypic evaluation. It considers the purpose of each application section, the information that should be provided, and how the quality of supporting studies may be evaluated. Within Gate 1 users might focus

on one specific component of an application or risk assessment, or work through an application from beginning to end.

With its focus on the content of applications, Gate 1 emphasises established models of risk assessment and GMO evaluation as expressed in international and regional regulatory standards.

Pv2.0 included preliminary content for most application sections in Gate 1.

GATE 2

Gate 2 is a more conventional information database, built around topic categories or 'guides'. The interlinked sets of content in Gate 2 capture a wider range of issues related to GMOs and risk assessment and can explore them more deeply. This approach should assist decision-makers in the consideration of environmental, social, political and economic contexts as well as the scientific assessment of GMO applications. Figure 1 shows an example of how topics can be organised and interlinked within the Gate 2 information database.

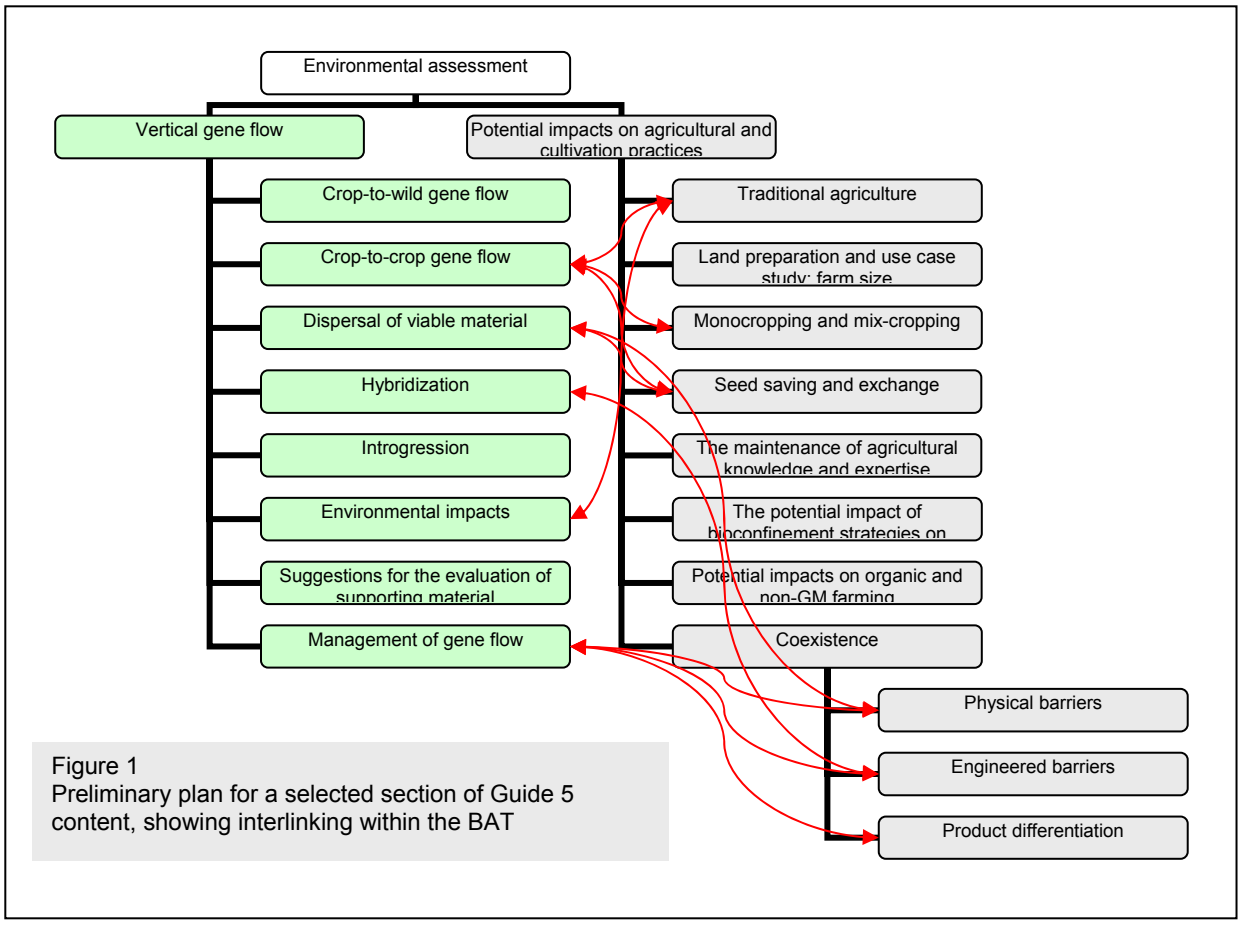


Figure 1
Preliminary plan for a selected section of Guide 5 content, showing interlinking within the BAT

The guides within Gate 2 have the following provisional labels:

1. GMO: The basics
2. GMO from DNA to insert
3. GMO from insert to trait
4. GMO and human safety
5. GMO and environment
6. GMO management and monitoring
7. GMO regulatory and legal issues

Pv1.0 included content from guides two and five. Pv2.0 includes representative content from guides one, two, three, four, five and seven.

GATE 3

Gate 3 provides a risk assessment and evaluation checklist for quick reference, drawing on the information in Gates 1 and 2 and customised for different GMO cases and contexts. Pv2.0 did not include content for Gate 3.

Presentation

The BAT will be an interactive, electronic resource. Pv1.0 was developed as a modified Microsoft Office Powerpoint presentation in order to test the general approach of the tool. The organisation of the prototype within the Powerpoint program meant that some essential components planned for the tool, such as enhanced navigation, could not be tested.

Pv2.0 introduced a customised advanced platform, with a new interface in the style of a web browser. In Pv2.0, the functionalities planned for the manipulation and presentation of content in the BAT have been largely realised. This allowed the BAT to be trialled in the 2006 workshops in a form more representative of the intended final product.

The opening page of Pv2.0 invites users to log in and create a session within the BAT. Sessions can be saved for later use or review, allowing users to keep track of their work on individual cases.

The interface includes a menu bar with the following options:

SEARCH

A limited search function was available in Pv2.0, with common queries generating suggested links within both Gates 1 and 2.

MAP

An expandable and collapsible map shows where the user is located within their selected gate or guide. Title links can be selected for quick navigation from topic to topic.

QUOTE
By clicking on indicators within text, key quotations (e.g. from international regulations) can be selected and saved. The quote icon allows users to review the quotes they have collected during their session.

NOTE
This icon opens a text box in which users can write notes on the content they are reading. Notes can also be tied to quotations that have been extracted using the quote icon.

EXPORT
Quotes and notes compiled during a session can be exported to Microsoft Word using the export function, allowing users to easily edit and print details of their sessions.

GLOSSARY
Pv2.0 included a list of technical terms for reference as users reviewed the BAT content.

This tailor-made interface, while unsuitable at this stage for public release, allows users to easily access and navigate BAT content and provides a sound template for future web development.

The course sessions

In contributing to the international biosafety course, INBI hoped to present valuable risk assessment workshops using the BAT as a resource. Box 1 shows the timetable of the BAT workshop sessions within the course.

Box 1: INBI contribution to course programme

DAY 1 - Monday July 31st

13.45–14.30
Introduction to BAT (Biosafety Assessment Tool), Biosafety Forecast Service

DAY 3 - Wednesday August 2nd

11.00-12.00
- Seminar on conducting risk assessment, including survey

DAY 4 - Thursday August 3rd

13.15-14.15
- Introduction to the BAT – substantial equivalence case study

DAY 7 - Sunday August 6th

12.45–16.15
Case study LY038 - molecular assessment

DAY 8 - Monday August 7th

09.00-12.30
Case study LY038 - health assessment

DAY 11 - Thursday August 10th

9.00-12.30
Case study LY038 – environmental assessment

13.15-14.15
BAT feedback and discussion

INBI contributed approximately 14.5 hours to the biosafety course schedule. Introductions to risk assessment and the BAT were presented in three preliminary sessions before the main workshops. The risk assessment seminar included a survey to establish participants' professional roles and experience with risk assessment and GMO applications, allowing the workshops to be tailored to their needs and expectations.

The workshops involved a GMO application case study on high-lysine corn LY038. Participants were given copies of the LY038 application documents for both Australia/New Zealand (food safety) and United States (environmental release) authorities. Each workshop focused on one major section of the LY038 case: molecular, health and environmental assessment. The BAT was provided as a resource for participants to use as they analysed the official documentation. Several presentations were made during each workshop, with participants working on guidance sheets and questioning presenters.

Participants using the BAT at the 2006 international biosafety course in Tromsø

The 2005 Pv1.0 evaluation sessions were conducted in groups, with one or two computers per group. As computer-based services are essentially individual tools, INBI concluded that it would be preferable to arrange one computer per person in future sessions to allow participants to work with the BAT independently. While we attempted to arrange this for the 2006 Pv2.0 sessions, we were only able to achieve a ratio of one computer for two participants. However, this ratio still resulted in good access to the BAT for participants, and efficient workshops.

Survey results

Surveys were prepared to mark the beginning and end of the series of BAT workshops. The first, a preliminary survey on participant roles and experience, was distributed at the start of the first seminar. Following the final workshop, a one hour slot was set aside for participants to complete a feedback survey and raise any further questions about the case study or the BAT.

This report reviews the feedback obtained from both surveys, followed by recommendations for the BAT work programme in light of the results.

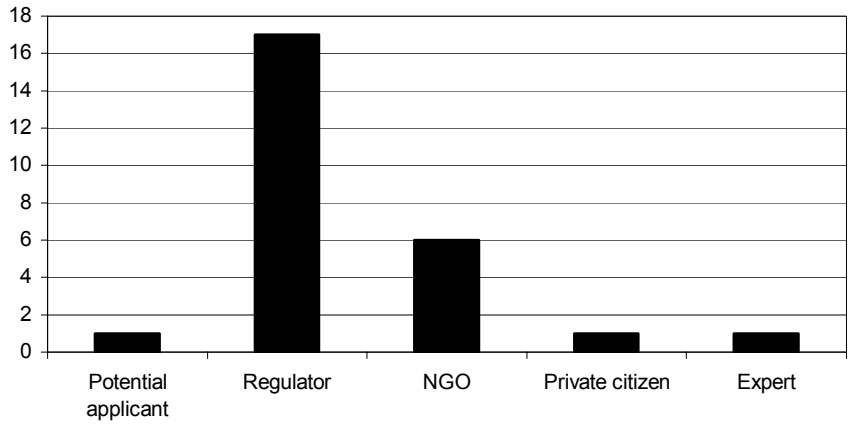
Preliminary survey on participant roles and experience

The first survey was designed to collect information on the background of participants and their experience reading and reviewing both GMO applications and risk assessments. This information was gathered initially to ensure that the subsequent workshops were at the correct level and had content of interest to participants. It can also be used, however, as a small review of a pool of potential BAT users, their experience and research needs.

Twenty-six complete surveys were returned.

1. **What role are you most likely to take in the risk assessment of genetically modified organisms?**

I am part of a group that would apply to a regulator for the approval of a GMO	1
I am a regulator/decision-maker/government official	17
I am a member of a non-governmental organisation or interest group	6
I would contribute as an individual citizen	1
I am an expert that may be consulted by a regulator or interest group for my opinion on an application	1 (6 as a dual tick)



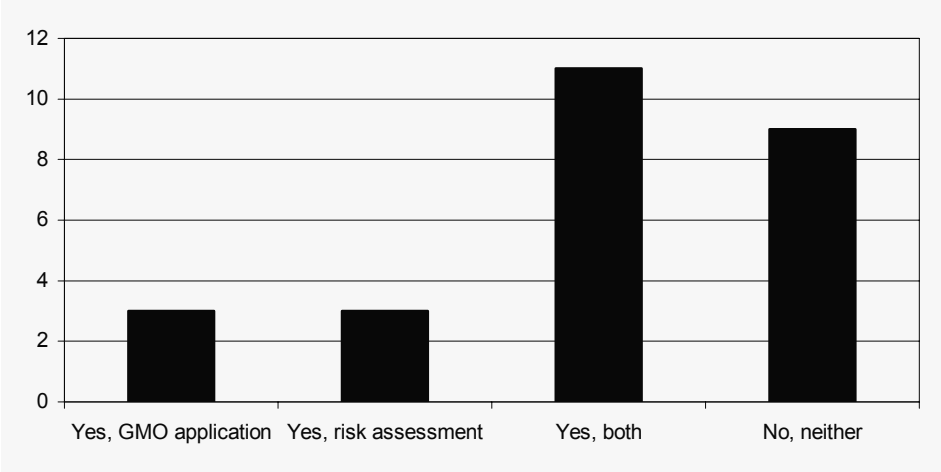
This question was essential to determine where participants were placed in the GMO regulatory process. In their professional or private roles they may conduct initial risk assessments of GMO applications, or comment on those assessments as a submitter or consultant. Both a regulator and submitter are in a position to evaluate and critique material from an applicant, but a submitter may also be interested in assessing regulatory reports. Information on effective ways for a submitter to do this may also help regulators to construct more robust reports and anticipate queries from the public and stakeholders.

The dominance of regulators in the participant group (65%) reflects the priority of the international biosafety course coordinators. This indicated that the focus of most participants in the workshops, and in their use of the BAT, would be for the analysis of application documents and the initial risk assessment of the GMO, rather than the evaluation of a regulator's assessment (as might be conducted by an NGO member or private citizen). The content of the BAT addresses both stages of assessment. By setting out what should be included in an application and to what standard, using the guidance of international and regional instruments (Gate 1), regulators can easily check the completeness and quality of an application on their desk. In turn, private citizens may use the same information in an oversight role within a regulator's public consultation process.

The 'expert consultant' option allowed participants to state the area of expertise on which they would expect to give advice, to highlight any topics of specific professional interest to participants. While one respondent solely identified as an expert, six others selected this and other categories. Fields specified included molecular biology and plant science, seed biology, socio-economic and agronomic impacts, environmental assessment, international law and biodiversity conservation.

2. Have you ever looked at a GMO application or regulator's risk assessment before?

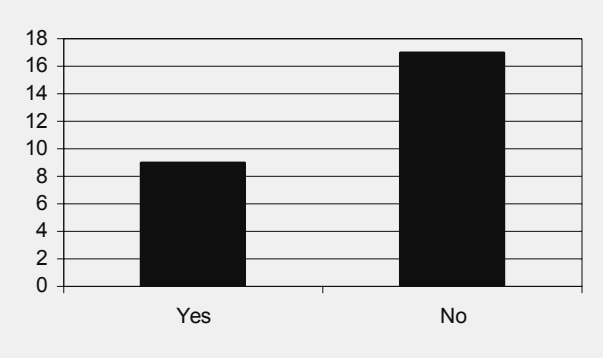
Yes, I've looked at a GMO application	3
Yes, I've looked at a risk assessment of a GMO application	3
Yes, I've looked at both	11
No, I haven't seen either of these	9



The majority of participants had seen either a GMO application or a regulator's risk assessment, or both, in the past. For a significant number, however, these workshops marked their first exposure to this kind of documentation. It was, therefore, important that the workshops included sufficient explanation of the components of the documents and time to review them. This also highlights the value of including background information on this documentation in the BAT for those with little experience reading or analysing it.

3. **Have you ever been involved in conducting a risk assessment of a GMO application?**

Yes	9
No	17

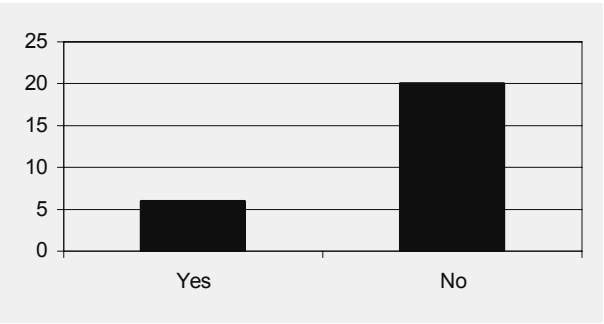


The majority had never been involved in GMO risk assessment, indicating that some of the approaches used in the workshops would be new to participants. This reinforced the decision to include a preliminary lecture suggesting strategies for how to begin an evaluation of an application or related regulatory material.

Positive respondents who included comments on the nature of their involvement were regulators who routinely conducted risk assessments. Two specifically looked at environmental risk assessment.

4. **Have you ever been involved in creating a submission in reply to a GMO application or regulator's risk assessment?**

Yes	6
No	20

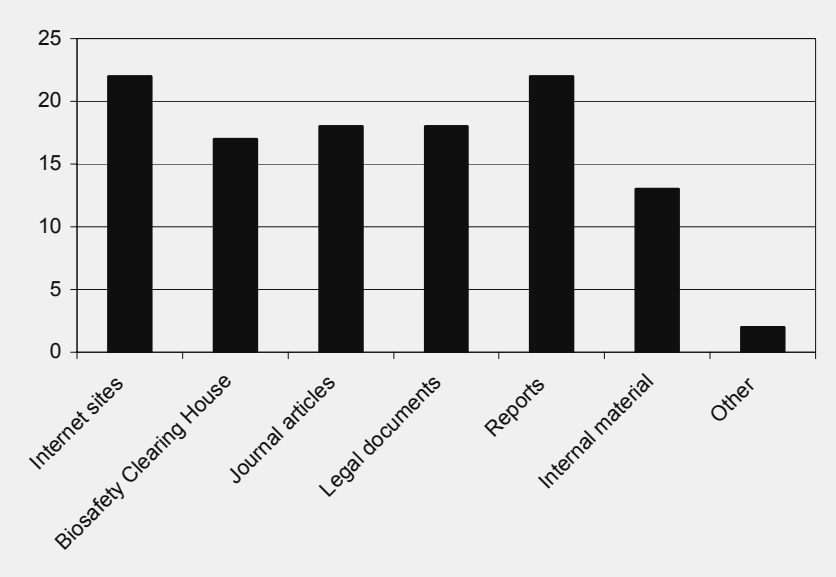


A minority of participants had contributed to submissions on GMO applications or regulatory assessments, suggesting again that features of the workshop would be new to most participants. However, identifying this small group meant that INBI could look into the difficulties and constraints they may have faced when reviewing application or regulatory material in the past, and explore whether or not they felt the BAT could assist them in the future.

Past submitters commented on a variety of elements of their involvement. They had contributed both scientific and social content in submissions, often as part of a group or coalition, and in the form of letters to regulators, both giving information and requesting further information from the applicant.

5. **What sources do you use for information on genetically modified organisms, biotechnology and biosafety?**

Internet sites	22
Biosafety Clearing House	17
Journal articles	18
Legal documents	18
Reports from countries and organisations	22
Material internal to my organisation/institution	13
Other	2



This question is useful not only to indicate the types of information participants were familiar with as they approached the case study, but also to identify the types of references and links that might be expected and desired in BAT content. All categories were well supported. The lower response rate for internal material suggests that many participants are not able to rely on set guidelines from their organisations, and must therefore actively engage in research, making the BAT a potentially attractive tool.

22 respondents used internet sites for information on GMOs, biotechnology and biosafety, and were invited to note the sites they most commonly visit. Results were wide-ranging, but

sites mentioned multiple times are recorded below. Third World Network's (TWN) Biosafety Information Centre was the most popular internet source, followed by the Convention on Biological Diversity website. Note that responses are likely to have been affected by the separation of the Biosafety Clearing House into a separate category, selected by 17 respondents, and may reflect the fact that applications for the course are advertised by TWN (so most participants would already have known about the TWN site).

Third World Network Biosafety Information Centre http://www.biosafety-info.net/	7
Convention on Biological Diversity http://www.biodiv.org/	4
European Union websites (including EU Commission, EFSA, GMO Compass)	3
Food and Agriculture Organisation http://www.fao.org/	3
International Service for the Acquisition of Agri-biotech Applications http://www.isaaa.org/	3
GM Watch http://www.gmwatch.org/	2
Institute of Science in Society http://www.i-sis.org.uk/	2
United States Department of Agriculture http://www.usda.gov/	2
Organisation for Economic Co-operation and Development http://www.oecd.org/	2
AgBioWorld http://www.agbioworld.org/	2
Industry websites (not specified)	2
Other national government websites	4

The aim of the Biosafety Forecast Service and BAT project should be to provide a resource distinct from these commonly visited websites, to avoid duplicating existing information. Many of these websites are homepages for international institutions and instruments. As the BAT may in the future include information on all related biosafety legislation, it might act as a hub, directing users to these websites for more information on specific legal issues.

6. **Is there any kind of information on genetically modified organisms, biotechnology or biosafety that has been difficult for you to find? If so, please state the topic/area.**

Determining existing gaps in information helps to guide the development path of BAT content. This question allowed participant needs to be surveyed before the workshops, to be followed up afterwards when participants were more familiar with the project. Box 2 lists specific topics identified by participants in the preliminary survey.

Most respondents specified that they found it difficult to find information on health and environmental assessment of GMOs. This reaffirms the focus on these topics in the development of content for Pv2.0, and suggests that resources should continue to be committed here.

Respondents noted that they could not find information on the experimental design of laboratory experiments and field trials relevant to risk assessment. They would like to be able to easily access lists of certified detection laboratories, and other organisations related to biosafety, available for consultation.

Respondents also identified legal information that they feel is not being adequately covered by existing resources, or is difficult to access in the form they desired. Specific topics cited refer predominantly to existing international regulatory requirements and the development of suitable regulatory guidelines.

Box 2. **Topics related to genetically modified organisms, biotechnology or biosafety cited by participants as difficult to research**

Molecular assessment
- Sequences of inserted genes/vectors

Health assessment
- Information on certified laboratories for toxicology and allergenicity analysis
- Long-term feeding studies

Environmental assessment
- Evaluating ecological interactions
- Laboratory methods for risk assessment, including field-sampling procedures
- Potential effects on soil microfauna
- Information on sowing area, harvest time and plot size in field trials
- Information for different environmental contexts and agricultural models
- Potential biodiversity impacts

Legal issues
- General information on legal provisions and processes
- Details on regulatory systems in different regions
- Requirements of supporting documentation for GMO applications, including guidelines for importers and regulators
- Processes for GMO import dispute resolution
- Liability

Socio-economic evaluation
- Potential socio-economic impacts of risk management
- Cost-benefit analysis

Respondents specified not only the content that they found difficult to find, but also the form of information that they needed. There is a clear need for publicly available, non-commercial material that can be used for education or consultation purposes - particularly free, peer-reviewed research on potential health and environmental impacts.

It appears that systematic literature reviews, topic-by-topic, are hard to come across. Instead, it is necessary to piece together information from different sources, which often conflict or are difficult to obtain. It was also raised that users require not only reviews of established and emerging biosafety literature, but also reviews of areas of omitted research, for an accurate

representation of the status of the field and what can be said with confidence in risk assessment.

The object of the BAT is to carry out this review step for the scrutiny of users. This review must be transparent, specifying all assumptions and information sources; noted in responses, and also in workshops, was a need for these lists of references to guide participants' research.

Feedback report

The primary aim of the preliminary survey was to evaluate the needs of the participants during the workshops. A feedback survey was distributed after the workshops to gather views on the approach, content and future development of the BAT.

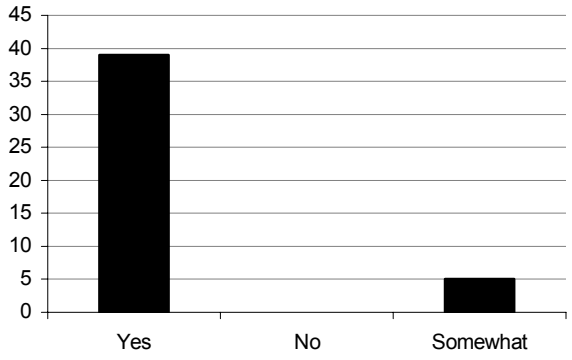
This survey covered the usefulness of the BAT during the workshops; the Gates; and the clarity and technical level of the content. Participants were also asked if they would be interested in using the BAT, and to indicate any topics that they would like to see covered in the tool.

Participants could indicate their preferences briefly or provide longer comments. Quotations reproduced here have been selected as representative of the views expressed within the group.

44 feedback surveys were returned. In the graphs that follow, the number of persons (rather than proportion) is indicated on the y axis.

1. Did you find the BAT a useful resource during the LY038 case study workshops?

Yes	39
No	-
Somewhat	5



The BAT was clearly a useful resource during the workshops, with 100% positive responses, 89% strongly positive.

"It was very comprehensive, very easy to find the information we wanted, gave an insight to the questions necessary to raise when assessing an application."

"…helped to direct me to specific areas in the application. Assisted in analyzing information that I would have overlooked."

"…it works as a map to facilitate handling all that big amount of information applications provide so that we can save lots of time and go straight to the key issues related to the biosafety of the GMO."

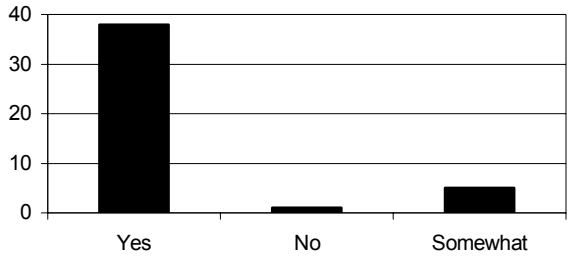
Confronted with the lists of topics in the LY038 application, the BAT helped participants to find useful and relevant information quickly and easily. Comments indicated that the BAT may be particularly useful as a starting point for risk assessment, suggesting key questions and paths for analysis. Many respondents said that the BAT provided an effective framework for constructing a risk assessment or submission. The BAT was particularly helpful to use alongside the application to define terminology.

Two respondents who found it 'somewhat' useful stated that they needed more time than was available during the workshops to review the tool fully. One felt that a "more comprehensive and interactive model" was required. Similarly, one respondent felt that more content was needed. One noted that while they found it useful, there was some confusion at the beginning of the workshops about its use alongside the case study. They felt that more careful planning and execution of the first lectures within the workshop was required in order to make the most of the short time available in the sessions.

One participant raised concerns that the content of the BAT was biased towards GMO producers. Identifying any elements of bias within BAT content remains a key task as it is reviewed and expanded.

2. Did you find the approach of Gate 1 (Application Model) useful?

Yes	38
No	1
Somewhat	5



Gate 1 organises material based on the common construction of an application or risk assessment, including topics such as toxicology, allergenicity and compositional evaluation. 98% of respondents found this approach useful; 86% without qualification.

"It gives you what you are looking for – how you want to deal with your issue, things to question before you accept GMO products. And also user friendly."

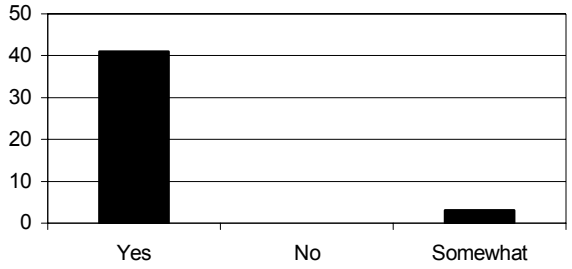
Respondents remarked that Gate 1 gave them insight into how to critically evaluate an application or risk assessment. It provided an efficient way to review what must be taken into account while reading documents. It was noted that this guidance is particularly useful for countries that do not have a comprehensive regulatory system in place. One respondent noted that the Gate 1 approach is not so important for users working under European Union regulations (as they can work from the annex to Directive 2001/18/EU).

Some respondents found Gate 1 useful, but preferred Gate 2. The respondent that did not find Gate 1 useful stated that they did not have enough time to review it.

One specific point for further clarification is the relationship between Gates 1 and 2. One respondent found it difficult to understand the interaction between the two.

3. Did you find the approach of Gate 2 (Guides) useful?

Yes	41
No	-
Somewhat	3



Gate 2 organises information based on general topics related to GMOs and risk assessment. This portal was also very well received by respondents.

"This was very well organized. Easy to understand where to go for information on the various topics."

"The guides were easy to follow and understand."

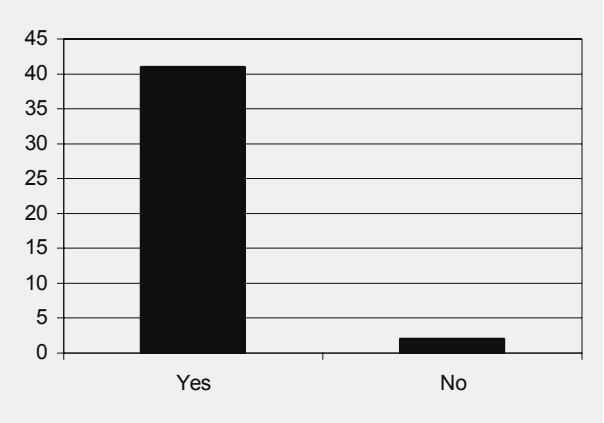
"Very well-prepared and gives good guidance to assess an application."

Exclusively positive feedback on Gate 2 was returned, with only 7% of respondents saying that it was "somewhat" useful. They noted that this strategy was a good way to display information for different evaluation areas, simplifying the risk assessment and decision-making processes. It was easy to navigate and understand.

Some respondents stressed the need for further development of this part of the tool. Topics needed to be expanded, with more references and precise information.

4. Did you find the text easy to read?

Yes	41
No	2
(one missed question)	



One of the goals of Pv2.0 was to test the ease of use and readability of content, particularly for those for whom English is a second language. By using clear text and constructing topics in a logical, ordered manner, it was hoped that the BAT could convey technical and often dense sets of academic literature to users who may have little experience in relevant fields or time available to study them.

This exercise was successful, with 93% of respondents giving positive feedback on the readability of the text. Summaries of issues in simple, straightforward language, and links between topics, were cited as particularly effective features.

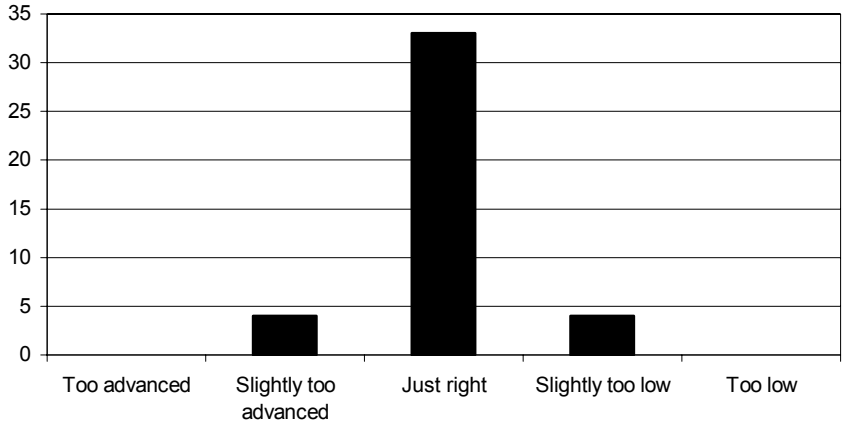
> *"The text was arranged and presented in a way that made it easy to understand."*
>
> *"Very well written. Short paragraphs, good with several headings."*
>
> *"Very easy to understand and applicable to people with different fields of expertise."*
>
> *"I think it is very easy to read even to those [without] special knowledge. It is good to show administrative personnel when you want to explain something."*

It is hoped that the BAT will be useful to people regardless of professional background or experience. Responses in this vein were split: multiple comments stressed that readability will depend on a user's language level and professional background. Others noted that knowledge of specific fields would not be necessary to understand the material. INBI's goal with the BAT is to overcome such constraints as far as possible. Technical content should continue to be tested for comprehension by readers from different backgrounds to ensure the correct writing style is being used.

Those that did not find the text easy to read stressed that English is not the language they use in their work, or that some text was slightly too complicated for their non-science background. Other responses noted that more terms should be included in the glossary, text could be made more concise, and more links would be useful. An expanded glossary may be exploited as a support for understanding technical sections of content.

5. What did you think of the level of the content?

Too advanced	-
Slightly too advanced	4
Just right	33
Slightly too low	4
Too low	-
(three missed question)	



While the previous question focused on the readability of the text, this question centres on its depth and specificity. As more content is developed, it is important to know what researchers should aim for on a general-technical continuum.

For example, it may be desirable to cover multiple points on this continuum for users of different levels of experience. It is vital to identify the level of detail required for content to be of practical use to those working within biosafety regulatory systems. While some topic summaries may be too simplistic for those working professionally in the biosafety field, they may be useful for public consultation and community engagement activities.

75% of respondents indicated that the level of the content was 'just right', with small numbers choosing 'slightly too advanced' and 'slightly too low' options. A common theme in responses to this question was that content was clear and easy to understand. The emphasis on regional and local context in the content was noted as especially useful.

> *"It is easy to understand the content with little knowledge on GMO issues, it gives a good introduction as well as giving detailed information and good references."*

More detailed and precise information was desired by several respondents.

> *"Level of the content was almost OK but needs to go [into] details in some parts"*

One form in which more detailed information may be provided is in the use of as many up-to-date scientific references as possible. This was cited by respondents as vital for the credibility and practical use of the BAT. Links to original sources should be included where possible.

Reflecting the response to the previous question, it was noted that the suitability of the content will depend on the background and experience of the user. It was suggested that

some scientific material may be too simple for scientists, but too advanced for others. One commenter noted that the content was too advanced for newcomers to the field, but suitable for those with some experience. Other comments demonstrate how individuals will vary in this regard. For example, one respondent stated that *"…actually, I'm a social scientist and it was very easy to follow up the contents"*.

One response suggested that the content could perhaps be made more technical, but as it stands it is suitable for public use. This is in line with the potential use of the BAT as a tool for public engagement with biosafety regulation and consultation. More detailed content must supplement this, however, to remain useful for biosafety practitioners.

The conflicting nature of some comments may be the result of different participants focusing on different parts of the BAT. At this stage in development, content is not uniform in style or organisation. Improvements may be needed here before the next set of workshops in order to obtain clear feedback on this issue.

Two respondents chose to withhold their opinion until seeing the finalised content.

6. **Would you be interested in using the BAT? If so, for what purpose? (e.g. to assess applications as a regulator or in another capacity; as a teaching resource; as a general knowledge tool)**

This question solicited a very enthusiastic response. 95% (42) of respondents stated that they would be very interested in using the BAT for various purposes.

> *"Absolutely yes. As a regulator and person who does not know many technical details it is an excellent tool to guide him/her through the risk assessment, but it could also be used as a teaching resource."*
>
> *"[Without the BAT] one would have to do a lot of research and may not necessarily get equal relevant information."*
>
> *"YES: for research purposes – as a guide on how best to evaluate effects and impacts particularly on the environment"*

Each respondent chose multiple purposes for which they felt the BAT would be most suited, based primarily on those suggested in the survey question:

Assessment of applications	23
General knowledge tool	15
Teaching resource	11
Reviewing the work of regulators (e.g. cross-checking assessments, submission writing)	4
Training/conducting workshops with colleagues on biosafety issues	3
Development of law and policy; setting up biosafety regulations	2
Specifically the evaluation of potential environmental impacts	2
Enhancing public consultation on biosafety issues	1

Respondents agreed that the BAT had good potential for regulatory use, particularly in explaining the technical language used in the critical analysis of applications. The BAT would

also be useful as an efficient reference database. The ability to conduct holistic decision-making, using the BAT as a guide and scoping tool, was also cited.

Of the two respondents who answered negatively, one stated that they would be interested at some point in the future, and the other once the tool is further developed and improved.

7. **Are there any specific topics or components that you would like to be included in the BAT? What topics are you most interested in? We would appreciate general and specific recommendations.**

The enthusiastic response to this question provides an excellent resource for the targeted development of BAT content. Firstly, many participants stressed the need for more information to be included in the BAT. Those sections already indicated as 'under construction' must be completed, along with the inclusion of more glossary terms. Where possible, links to source papers should be provided from BAT text. One respondent also asked for links to the Biosafety Clearing House to be included where possible.

TOPIC REQUESTS

Specific topic requests were wide-ranging – Box 3 lists common areas of interest. Responses indicated that precise guidelines for socio-economic and cost-benefit analysis are not readily available. There is a need for this part of the decision-making process to be presented and explained with as much care and depth as is more commonly given to science-based risk assessment. Multiple respondents again called for case studies on biosafety regulation in different countries.

In terms of molecular assessment, more information on laboratory protocols was requested. One respondent asked for a photo gallery of experiments and equipment related to the creation and evaluation of GMOs.

Respondents appreciated the holistic approach to the presentation of environmental material in the BAT, with the integration of content on farming practices and socio-economic impacts. Two respondents stressed the need to balance BAT content focused on GMO decision-making with information on potential alternatives to GMOs for various agronomic purposes.

OTHER SUGGESTIONS

Respondents also suggested several databases that could supplement the rest of the BAT content. Four asked for a linked map showing the results of risk assessments in different countries, i.e. where various GMOs had been approved. Two asked for a similar map showing the locations of GMO development and cultivation.

One respondent suggested the addition of an application example with side notes *"to help users learn how to identify the language and the way the information is presented"*. This would be an effective way to introduce users to the style and organisation of an application. Applications submitted to regulators in developing countries would be particularly useful as case studies.

Box 3. **BAT topic requests**

Molecular assessment
- Step-by-step information on laboratory protocols relevant to risk assessment, including photo galleries
- More information on post-translational modification
- Polymerase chain reaction (PCR)
- Gene stacking

Health assessment
- Expanded health sections in general requested, tied to international regulations

Environmental assessment
- Evaluating soil characteristics
- Crop production systems

Socio-economic evaluation
- Guidelines for considering potential socio-economic impacts in decision-making
- Cost-benefit analysis
- Discussion of political issues
- Ethical considerations
- Expanded sections on traditional knowledge, indigenous rights and access and benefit-sharing
- Practical information on facilitating public participation in the risk assessment process

Legal aspects
- Case studies on different frameworks of biosafety regulation
- Generic models for biosafety legislation

Recommendations

The responses received in the feedback survey reaffirm the existing development path of the BAT. Participants responded well to the content, its style and organisation. The approach of the Gates - integrating a practical guide to risk assessment using established regulatory standards with an information database - has been confirmed as an effective way to present content.

A particularly promising result of the workshops is the affirmation that the BAT can be of interest and value to a range of people, due to the broad scope of the content. Responses suggest that the BAT can assist users in framing an initial evaluation, quickly accessing specific information on topics of interest, and facilitating public engagement in regulatory systems in general.

Survey results confirm a number of aspects of BAT development already identified by INBI, including the importance of up-to-date, detailed referencing; case studies from developing countries; the application of content to international and regional regulatory standards; and the need for careful balance when discussing controversial issues. They also provide particularly valuable guidance on content development, style and additional resources that might be included in the BAT.

CONTENT DEVELOPMENT

The most frequent desire specified by respondents was to see the BAT freely available as soon as possible. Most respondents highlighted the need for BAT content to be completed. Existing content was very well-received, resulting in enthusiasm for seeing a more developed product. Extra resources should be put into content development to achieve research milestones more quickly.

Responses reaffirmed the focus on health and environmental assessment content in Pv2.0. As well as expanding and finalising existing sections, new topics suggested by participants (from both the preliminary and feedback surveys) should be considered. Those with most support included more detailed explanations of legal standards, guidance for the evaluation of socio-economic considerations, and reviews of laboratory testing procedures. Some of these topics are beyond the current expertise of INBI and will require input from other partners.

STYLE AND FORM

While views on content readability were encouraging, it may be necessary to continue trialling technical text for easy comprehension. The glossary is a key tool for users tackling new topics in the BAT, and should be expanded.

While respondents appreciated clear and simple summaries of issues, as much detail as possible should be included in BAT content for the practical use of those involved in regulatory processes. The importance of journal referencing was emphasised in both surveys. Content should continuously direct users to external resources for corroboration and further reading.

Many respondents also stressed case studies as a preferred form of content presentation. More should be included, drawn from a variety of regions and conditions.

EXPLORATION OF ADDITIONAL RESOURCES

Respondents expressed interest not only in the development of conventional risk assessment subjects, but also other practical tools such as maps of existing GMO development, approvals and pending applications. Presently, this area is beyond the scope of the BAT and resources of the BFS. These kinds of resources, however, will be straightforward to compile from regulatory agency data. Before this is pursued, however, a review should be conducted of similar resources already available to avoid duplication.

The fact that a significant number of participants in a targeted biosafety course had little experience with applications and risk assessment documentation reinforces the need to include clear introductory material in the BAT. The design of Gate 1 should assist those unfamiliar with applications, and could be supplemented by the application case study with side notes suggested by one respondent.

Future feedback sessions

The BAT workshops for Pv2.0 were planned after a review of the 2005 sessions, resulting in a significant improvement in their organisation and the resulting depth of the feedback. Providing more computers in 2006 allowed participants to engage with the BAT nearly 'one-on-one' in an arrangement more representative of how the Tool will be used when publicly released. By presenting three workshops on different parts of an application or risk assessment, specific sections of the BAT could be focused on and discussed by participants, rather than having various groups browsing different sections at one time.

Feedback from these surveys offers more lessons for the organisation of future sessions. Participants stated that the application was very good to review, and helped them to understand the information presented in the course as a whole. Guidance from the presenters was useful, and presentations were well-structured. However, at first it was difficult for some to figure out where to look in the case study application. A better-organised, more guided approach in the first session would have been helpful for the efficient running of the whole series of workshops. A clear presentation of the purpose and use of the BAT at the start is vital to set the scene for the workshops that follow.

For a clearer analysis of content readability and complexity, care should be taken that BAT text is consistent in depth and writing style; otherwise, more detailed surveys may be required to pinpoint the sections that require closer attention.

Appendix I: Preliminary survey on participant roles and experience

Questionnaire

In our development of the Biosafety Assessment Tool, we strive to meet the needs and desires of different users from around the world. We would appreciate any information you can give us about your interest in biosafety and the resources you would like to use.

Title (e.g. Mr., Ms., Dr.) _____

Name _____

Occupation _____

Employer _____

1. What role are you most likely to take in the risk assessment of genetically modified organisms? (tick any that apply)

□ I am part of a group that would apply to a regulator for the approval of a GMO

□ I am a regulator/decision-maker/government official

□ I am a member of a non-governmental organisation or interest group

□ I would contribute as an individual citizen

□ I am an expert that may be consulted by a regulator or interest group for my opinion on an application. What is your area of expertise? _____

2. Have you ever looked at a GMO application or regulator's risk assessment before?

□ Yes, I've looked at a GMO application

□ Yes, I've looked at a risk assessment of a GMO application

□ Yes, I've looked at both

□ No, I haven't seen either of these

3. Have you ever been involved in conducting a risk assessment of a GMO application?

□ Yes

□ No

If you answered yes, what was your role?

_____

_____

_____

_____

4. Have you ever been involved in creating a submission in reply to a GMO application or regulator's risk assessment?

□ Yes

□ No

If you answered yes, please briefly note what you did (e.g. were you a member of a group? Did you write a letter? Did you comment on scientific/social issues?).

_____

_____

_____

_____

4. What sources do you use for information on genetically modified organisms, biotechnology and biosafety? (tick any that apply)

□ Internet sites
Please list a few that you use most often.

_____

_____

_____

_____

□ Biosafety Clearing House

□ Journal articles

□ Legal documents

□ Reports from countries and organizations

□ Material internal to my organisation/institution

□ Other (please state) _____

6. Is there any kind of information on genetically modified organisms, biotechnology or biosafety that has been difficult for you to find? If so, please state the topic/area.

_____

_____

_____

_____

Thank you for taking part in this survey.

Appendix II: Feedback survey

Biosafety Assessment Tool feedback survey

We would very much appreciate any feedback you can give us on the BAT, to assist us in further development in 2007.

Did you find the BAT a useful resource during the LY038 case study workshops?

- □ Yes
- □ No
- □ Somewhat

Comment:

Did you find the approach of Gate 1 (Application Model) useful?

- □ Yes
- □ No
- □ Somewhat

Comment:

Did you find the approach of Gate 2 (Guides) useful?

- □ Yes
- □ No
- □ Somewhat

Comment:

Did you find the text easy to read?

- □ Yes
- □ No

Comment:

What did you think of the level of the content?

- □ Too advanced
- □ Slightly too advanced
- □ Just right
- □ Slightly too low
- □ Too low

Comment: (e.g. was a particular topic difficult to understand?)

Would you be interested in using the BAT? If so, for what purpose? (e.g. to assess applications as a regulator or in another capacity; as a teaching resource; as a general knowledge tool)

Are there any specific topics or components that you would like to be included in the BAT? What topics are you most interested in? We would appreciate general and specific recommendations.

Do you have any other comments you would like to make about the BAT?

(can be continued on reverse side of page…)

Thank you very much!