

Research Team

Prof. T. de Cock Buning PhD F. Haker MSc Prof. P. Bereano PhD J. de Boer PhD Prof J. Bunders PhD

ATHENA Institute for Research on Communication and Innovation in Health- and Life Sciences Faculty of Earth & Life Sciences De Boelelaan 1087 1081 HV Amsterdam The Netherlands

Research Team Vrije Universiteit Amsterdam

Prof. T. de Cock Buning PhDF. Haker MScProf. P. Bereano PhD (University of Washington)Drs. J. de Boer PhDProf J. Bunders PhD

Advisory Panel

Dr. J. Cohen,	IFPRI (USA)
Dr. G. Fuller,	Croplife Asia (China)
Prof. Dr. O. M. El-Tayeb	University Cairo (Egypt)
Dr. T. Young	IUCN (Germany)
Prof. Dr. K. Chong Lek	Nanyang Technological University (Sinagpur)
D. MacKenzie PhD	agbios (USA)
J.Mayr	former minister Environmental affairs (Colombia)
P. Phifer	U.S. Fish and Wildlife Service (USA)
Dra E. Bravo	Red por una América Latina Libre de Transgénicos
	(Equador)

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Introduction

The Cartagena Protocol for Biosafety under the Convention for Biological Diversity was adopted in January 2000 and entered into force on 11 September 2003. The Protocol goal is "contributing to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms (LMOs)".

The Global Environment Facility (GEF) council has requested a general evaluation of all activities, financed by the World Bank, that are undertaken to assist countries to develop a National Biosafety Framework based on the Cartagena Protocol and the Convention for Biological Diversity. Many of the evaluated activities are carried out by the UNEP-GEF Biosafety team. One of these activities is a set of five documents that are meant to be a guide for countries to set up a National Biosafety Framework in five phases (from phase 0 till 3). This set is referred as "UNEP-GEF Toolkits" and can be downloaded from the UNEP-GEF website (www.unep.ch/biosafety).

Two of these evaluation projects were launched in the spring of 2005. The first evaluated the UNEP-GEF program by means of in-depth interviews and country visits. The evaluation team carrying out this project consists of specialists and experts in the field of LMO Legislation and Biosafety. This first evaluation was done in 10 countries through visits and in-depth interviews. Ten other countries are being evaluated by telephone interviews.

The second evaluation, discussed in this report, complements the first project and is carried out by The Athena Institute for Research on Communication and Innovation in Health- and Life Sciences, based at the Vrije Universiteit in Amsterdam. The purpose of this evaluation is to get more insight in to how stakeholders in the various countries assess to what extent the UNEP-GEF Toolkits are or have been relevant and helpful in the process of setting up a National Biosafety Framework (NBF). The evaluation was carried out by means of questionnaires distributed via e-mail.

The aim of this evaluation is twofold. Firstly, to assess the degree to which the UNEP-GEF Toolkits, used for the development of National Biosafety Frameworks (NBFs) are consistent with the Cartagena Protocol, responsive to country needs, and of sufficient professional quality. Secondly, to get a good overview of what the general issues/difficulties are that respondents encountered during the process of setting up a National Biosafety Framework. The latter research question especially will provide a good basis to link the two evaluation projects.

Procedures

The UNEP-GEF Toolkits Evaluation is being done in a period of 3.5 months (15 May-August 2005) and is therefore limited in scope. During one month (15 May-15 June) the questionnaire was developed (See appendix A). The questionnaire was made up of different sections. First of all, the respondent is asked to give some personal details, such as, professional background and involvement with LMO legislation and Biosafety related issues. Secondly, there is a section that specifically evaluates the UNEP-GEF Toolkits. In this section the respondents are asked to evaluate the Toolkits with respect to consistency with the Cartagena Protocol, professional quality, and as an instrument to assist their country in setting up a NBF. Thirdly, due to the

fact that the use of the UNEP-GEF Toolkits cannot be analyzed completely separately from their context, two small sections were added. These sections acknowledge the UNEP/GEF Toolkits as functional instruments in a process to accomplish the general goals of the Protocol: to evaluate UNEP-GEF support, offered expertise, and the progress their country has made so far. Finally, four open questions give the respondent the opportunity to elaborate on the preceding closed questions and provide insight into which aspects need attention and why. Most questions had four graded answering options (i.e. very satisfied, satisfied, not so satisfied, not at all satisfied), and an option for 'do not know' or 'not applicable'.

The questionnaires were sent to 30 countries that have used the UNEP-GEF Toolkits in the last 4 years. These countries were chosen in order to obtain an equal distribution over regions (Eastern and Central Europe, Asia-Pacific, Africa, Latin America and Caribbean) and over development phase of the National Biosafety Framework (starting up including phase 1 until phase 3(I&II), versus a fully developed NBF). The people that received the questionnaire are often members of the National Coordinating Committee or other stakeholders that are or have been involved in the process of setting up a NBF. In order to safeguard representativeness of the evaluation, various ways were used to find additional informed respondents, who are at more arm length distances of the NCC. The National Project Coordinators provided the research team with contact details of NCC members and other important stakeholders. Also, global industries and global active NGOs assisted in finding other contacts in the selected countries. However, as discussed below, the returned questionnaires were not from very diverse sectors.

In addition to sending out the questionnaires to the selection of 30 countries, there were also questionnaires sent to respondents of global industries, global active donors, and/or global operational NGOs. These respondents received a shorter version of the questionnaire, in which only general, and not country specific, questions about the UNEP-GEF Toolkits were asked.

In total 500 Questionnaires have been sent out to contacts in 30 countries, and 40 to informants representing global industries, NGOs, and Academia.¹ The latter category of respondents is referred to as 'global players', i.e. persons who deal mainly with biotechnology safety regulation/policy at an international/global level and are not particularly affiliated with a specific country's NBF development project.

The questionnaires were sent out between 22 June 2005 and 19 July 2005, and collected during the same period. At the end of July about 100 questionnaires were returned. These were analyzed and the results were written down in a draft report that was subsequently sent to all these respondents. The research team also took the opportunity in this 'second round' to ask the respondents a couple of additional questions (see appendix B) on topics that had aroused interest in the previous round but were not yet clear. These questions focused on the issue of the Roster of Experts (the use countries made of the Roster of Experts and what advice they were given) and Timing (the timing of the introduction of the Toolkits and the timeframe for the

¹ This number of questionnaires that were sent out excludes all emails that did appeared to reach the intended person due to persistent errors or otherwise not operational email addresses.

development of the NBF). The respondents were asked to respond and fill out the additional questions by 15 August.

The 3.5 months period that was given to conduct this research in combination with the late approval (the project shifted towards the summer holydays) severely restricted the efforts to solicit a large enough and varied enough sample. The second round of questions did shed some light on issues that were not fully covered in the first round. However, few informants filled out the additional questions. Considering these realities the following conditions need to be taken into account while analyzing the data and discussing the results:

- The Evaluation focuses mainly on the 5 Toolkit documents. There are two categories of respondents at the national level: Those working professionally with the Toolkits (i.e. National Project Coordinator, and some members of the National Coordinating Committee), and the other category of respondents who are not very familiar with the Toolkits but are in general involved with the process of NBF development and biosafety/biotechnology in general. It is likely that those informants who have experience with the Toolkits through their profession are more inclined to respond.
- 2) There are two possible types of responses that can be expected, triggered by reactions of the different informants who received the questionnaire. Firstly, it could be that informants who have a negative opinion about the Toolkits see this evaluation as an opportunity to give their opinion. Because of their strong sentiments, they might be more inclined to fill out the questionnaire than informants who have a positive attitude towards the Toolkits. On the other hand, institutional self-interest might play a role. Informants who are involved in the process of NBF development may view this evaluation as a grading of their own performance or their institution's/country's performance. This might give respondents an incentive to evaluate the Toolkits and their NBF positively.
- 3) For the selection of the countries the availability of a functional internet connection was essential. However, it is still likely that many respondents have experienced difficulties getting access to the internet. Also, many of the email addresses provided were no longer in use or could not receive the questionnaire due to unknown technical reasons.
- 4) Even though the questionnaires were provided in the English, French, and Spanish languages, there may still have been informants who could not answer the questionnaire properly due to language problems. Especially the fact that the questionnaire was not translated into Russian and Arabic might have influenced the response rate from Eastern Europe, Middle Asia and North African countries.
- 5) Many of the countries that were included in the evaluation have relatively few human resources in industry and academia (to lesser extend also NGOs) in the field of biotechnology and legislation. It is therefore likely that these groups were underrepresented in the data.

Hypotheses

The aim of the UNEP-GEF Toolkits Evaluation is twofold:

- Assessment of the Toolkits:
 - Consistency with the Cartagena Protocol
 - Responsive to country needs
 - Of sufficient professional quality
- Assessment of the general issues/difficulties that respondents encounter during the process of setting up a National Biosafety Framework in their own country.

It is hypothesized that the evaluation of these different aspects will vary for different groups of stakeholders, different regions, and between countries with a different development phase of the NBF. Moreover, it is expected that the global players can have a different evaluation than the country informants.

Data Analysis

The data is analyzed by SPSS. Due to the small sample size the analysis methods that can be used are limited. Hence, the data will mostly be discussed by looking at frequencies.

During the analysis of the data the potential biases in filling out the questionnaire are controlled for. Respondents could have an overall tendency to answer positively or negatively due to cultural or political conventions. Also, often respondents have 'end aversion' while filling out the questionnaire, meaning that they avoid to score at the ends of provided scales. Furthermore, questions on satisfaction may be positively skewed due to the psychological observation that most people without an explicit opinion tend to give positive answers. These different answering patterns might blur the picture when all questionnaires are stacked and analyzed as if all informants answered the questions in the same straightforward way. Hence, in order to control for these biases a mean score was calculated for each respondent within subsets of questions. Subsequently the actual score on each individual question was subtracted from the mean score on the sub-set of related questions. By studying deviations from the mean (e.g. within an array of positive answers one sub-question is answered more negative), those elements that stand out could easily be identified and the score of deviation (i.e + 1 or -1) can be stacked over the whole sample while at the same time individual answering 'patterns' are controlled for.

In order to analyze differences in answers between stakeholders, region, and development phase of the NBF, the Kruskal-Wallis test is used.²

 $^{^2}$ Kruskal-Wallis is a non-parametric test that is used when no assumptions can be made about the distribution of the data (e.g. normality). Kruskal-Wallis makes a comparison between the distribution patterns of two or more samples to determine if the samples have come from different populations. For example, it can be tested whether the different groups of stakeholders have answered a question in a similar manner or that there are significant differences in their answers. If the null-hypothesis, being that the samples originate from the same population, is rejected (P<0.05), then the conclusion is that the data is influenced because of differences between populations (in this example: the stakeholders). This could be the case if, for example, NGO representatives answer the question more positive than the other stakeholders.

The qualitative analysis of the open questions is done by coding. The keywords/topics were counted and clustered. One respondent can have mentioned several aspects and therefore his/her text may be coded several times. Hence, coding is the indication of how many times an issue is mentioned and not of how many respondents have mentioned it.

Triangulation is applied to interpret and validate variations in the patterns of answering. It is a methodology in which three (or more) data collection methods are used on the same topic. When these different data sets point to the same direction it is regarded as a reliable conclusion. We applied triangulation by using different data sources (questionnaire, expert consultation, participative observation COB-MOB meeting Montreal), and different analytical tools (qualitative open questions, qualitative analysis of response patterns on closed questions, quantitative non parametric test on the distribution of stakeholders, regions and development phase upon sets of questions and individual (sub)questions, quantitative non-parametric tests to detect significant deviations from individual answering patrons).

Results

As of 15 August, 110 questionnaires were received. Since 540 questionnaires were sent out, this is a response rate of 20%.

Stakeholder	Frequency	Region	Frequency	Development phase NBF	Frequency
Government	56	Africa	30	Drafting	60
NGO	17	Asia-Pacific	17	Completed	42
Industry	5	Eastern and Central Europe	34		
Academia	24	Latin America and Caribbean	21		
Global players	8	Global players	8		
Total	110	Total	110		102

Table 1a: First round. *Distribution of respondents over stakeholders, region and developing phase.*

There were a couple of respondents who indicated that they represented more than one stakeholder category. In these cases the research team assigned the respondent to the stakeholder category that seemed to correspond best to the professional and background information of the respondent.

The draft results and the additional questions were sent to all respondents on the first of August (2005). Only 17 respondents who had filled out the questionnaire also filled out the additional questions, which is a response rate of 16%. The distribution of these respondents over stakeholders, region and developing phase is given in the following table.

Stakeholder	Frequency	Region	Frequency	Development phase NBF	Frequency
Government	10	Africa	4	Drafting	10
NGO	2	Asia-Pacific	3	Completed	7
Industry	0	Eastern and Central Europe	9		
Academia	5	Latin America and Caribbean	1		
Total	17	Total	17		17

Table 1b: Second round. *Distribution of respondents over stakeholders, region and developing phase.*

In the first round, informants in 30 countries were approached, but only 27 countries were eventually included. Within these 27 countries the number of respondents varied between 1 and 10. Of the 27 National Project Coordinators that were contacted, 17 eventually filled out the questionnaire.

All respondents were asked in what development phase their countries NBF were. Respondents of 60 countries stated that they were in the process of drafting a NBF, and 42 respondents indicated that their country had already completed the draft NBF (10 out of 102 respondents did not have an answer. These were assigned to a phase by making use of the National Project Coordinator and UNEP-GEF information).

At the outset of the evaluation it was planned to incorporate at least four respondents representing different stakeholders from each country. This aim is unfortunately not met. There were only two countries for which there were four different stakeholder categories.

The respondents stated that they were well informed regarding the Cartagena Protocol (91%), regarding the NBFs (95%) and regarding the UNEP/GEF Toolkits (78%). Those respondents who did not regard themselves as knowledgeable on detailed aspects of the Toolkits limited themselves to more general remarks and observations and answered the more technical questions on the Toolkits with 'do not know' or left them unanswered. The statistical analyses per question were done leaving out these respondents. However, whenever frequencies and percentages are given in this report all respondents were taken into account.

In general the background of the informants was evenly distributed over the options for the answers. In other words, being a specific stakeholder, coming from a specific region, or differing with respect to development phase of the NBF did not make a difference in the (positive) way these respondents answered the questions. Only when there is a significant difference in answers between these groups of respondents the report will make an explicit note.

<u>Results Part I: Main answers on the three evaluation topics:</u> <u>consistency, country needs and professional quality</u>

Consistency with the Cartagena Protocol

In the questionnaire there is one question that addresses the consistency with the Cartagena Protocol directly and 7 questions that address it indirectly. On all of these questions a majority of respondents stated that the UNEP-GEF Toolkits are consistent with the Cartagena Protocol. On the question "How consistent are the UNEP-GEF Toolkits with the Cartagena Protocol?" 78% of the respondents answered very consistent or consistent and only one respondent answered 'not so consistent'. All other respondents had no opinion or did not know. This positive evaluation of the consistency with the Protocol was also illustrated by the indirect questions. For example, a majority of respondents stated that the Toolkits are/were useful to set up risk management, ensure full protection of biological diversity and human health, and approach LMO applications with precaution. Moreover, relatively many respondents were quite positive (45%) about the impact of the NBF on transboundary movement of LMOs (28% neutral/10% negative/17% did not know or gave no answer).

Furthermore, there were two questions that looked at the wider aspects of the Protocol and the Toolkits. These evaluated the relation between the Cartagena Protocol and the National Biosafety Frameworks with respect to broadness of issues and strictness. The question was: "the Cartagena Protocol covers only a specific small range of issues relating to LMOs, but allows countries to adopt laws on a broader range of issues, or to impose stricter standards. How do you evaluate the coverage of your country's NBF?" The following table gives the answers of the respondents to this question.

	Too broad/strict	Neither	Not broad/strict enough	Do not know/No answer
Broadness	32%	43%	18%	7%
Strictness	26%	47%	11%	16%

Table 2: Opinions on broadness and strictness of the NBF

The Kruskal-Wallis test showed that all respondents, no matter which region they come from, were like minded on these questions. However, stakeholder background and development phase relate to some slight but significant deviations of the general pattern. Figure 1 shows a small tendency that government representatives were more likely to consider the NBF too strict than Academia and NGO representatives (p<0.005).

Figure 1: Evaluation of strictness of the NBF by stakeholder



Furthermore, there is a relationship between a later development phase of the NBF and considering the NBF too strict (Figure 2). Also, a later development phase is related to a more positive evaluation of the impact of the NBF on transboundary movement of LMOs (Figure 3).

Figure 2: Evaluation of strictness of the NBF by Development Phase



Evaluation of the coverage of the NBF strictness





Overall, the above analysis shows that on all questions concerning 'consistency' with the Cartagena Protocol a majority of respondents is neutral to (very) positive or satisfied. However, especially government representatives and respondents representing a country with a fully developed NBF indicate more frequently that the NBF is too strict in its interpretation of the Cartagena Protocol. The respondents representing a country with a fully developed NBF are also relatively more positive about the impact of the NBF on transboundary movement of LMOs.

Country Needs

There are 7 questions that give an indication of country needs of which 2 relate specifically (and 5 indirectly) to the UNEP-GEF Toolkits. A large proportion of the respondents (79%) stated the Toolkits have been (very) useful for their country. Also, the majority of the respondents felt that the Toolkits are/were sensitive to their country's needs with respect to available scientific expertise (65% pos, 15% neg, 20% did not know/no answer) and the socio-economic situation (53% pos, 29% neg, 18% did not know/no answer). With respect to the cultural values a more divided image emerges (46% pos, 32% neg, 22% did not know/no answer).

If the Kruskal-Wallis test is applied, it appears that there is a tendency for respondents with a fully developed NBF to be more satisfied with how the Toolkits fit/fitted their country's situation (with respect to available scientific expertise, socio-economic situation, and cultural values).

Figure 4 illustrates, by showing the mean-scores over the sub-questions, that there was a different distribution between development phases.

Figure 4: Distribution of scores on Toolkits sensitivity to country needs by development phase NBF.(Summated over 3 sub-questions)



It is interesting to note that there is a significant deviation from these mean scores on 'available scientific expertise' and 'cultural values' for respondents representing a country with a NBF that is not yet developed. This group of respondents are relatively less satisfied with the Toolkits' sensitivity to cultural values and relatively more satisfied with the Toolkit's sensitivity to the country's situation with respect to the available scientific expertise.

On the question whether the Toolkits find a balance between international harmonization and the country specific situation respondents (43%) stated either that there is neither too much emphasis on international harmonization nor too much emphasis on the country specific situation. Another group (36%) stated that there is too much emphasis on international harmonization/legislation. Only 3% stated that the emphasis lies on countries and 18% of the respondents scored "do not know".

An indication of the actual country needs, is the question "How difficult was it to begin the development of the NBF in your country in general?". Around a quarter (28%) of the respondents considered it (very) difficult and 55% considered it not so difficult (18% indicated 'not applicable' or 'no answer'). Furthermore, 82% of the respondents were (very) satisfied with the general support UNEP-GEF gave during the process of setting up a NBF (5% was not satisfied, and 13% did not have an answer).

The Kruskal-Wallis test on the impact of NBF development shows that there is a difference in answering patterns between regions and NBF development phase. As figure 5 indicates, respondents from Africa and Asia-Pacific are slightly more positive than especially respondents from Latin America and the Caribbean. This difference in

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answers can be found on all three sub-questions (the impact of the NBF on research and development of LMO, on administrative handling of LMOs, and on transboundary movement of LMOs.). Only respondents from Africa tend to be more positive than respondents from other regions about the impact of the NBF on the transboundary movement of LMOs.





Furthermore, there is again a trend that respondents with fully developed NBFs are relatively more positive about the impact of NBF development than other respondents. This is illustrated in figure 6. The Kruskal-Wallis test shows that the answering patterns of the respondents do not differ significantly from the mean answering pattern that is given in figure 6. In other words, a majority of the respondents is quite positive about the impact of the NBF on research and development of LMO, administrative handling of LMOs, and transboundary movement of LMOs.

Figure 6: Distribution of the impact of development NBF by development phase NBF. (Summated over 3 sub-questions)



If only the closed questions are analyzed the UNEP-GEF Toolkits and the process of setting up of the NBF seem to respond well to the country needs. Most respondents are satisfied with the way the Toolkits are sensitive to their country's needs and the way the NBF development impacted on various aspects in their country. Overall, respondents who indicated that their country has a fully developed NBF are more positive than other respondents.

Professional Quality

In the questionnaire there are nine questions that are related to professional quality of the Toolkits. Six of these are specifically on professional quality and three are linked indirectly. A large majority of the respondents were (very) satisfied about the professional quality of the Toolkits. All aspects of professionalism were evaluated positively as is illustrated in figure 7. More than 70% indicated to be (very) satisfied about the clarity of aims, the selection of topics, and the depth and comprehensiveness of guidance on selected topics. Fewer respondents were (very) satisfied about the timeframe and planning of the different phases of the Toolkit (64%). About 18% of respondents did not have an opinion about the professional quality of the Toolkits.





Controlling for the individual pattern of mean scores on all questions regarding professional quality, the Kruskal-Wallis test shows that there are only few slight differences between stakeholders, regions, and development phase of the NBF on how they assess professional quality. These differences, however, are minor and between "very satisfied" and "satisfied". However, there is a significant difference (p<.05) between the high mean score on all grouped professional quality sub-questions and the lower score on the sub-questions on timeframe and guidance on selected topics. It is interpreted as that the respondents are *relatively* less satisfied with the professional quality of the Toolkits with respect to planning and timeframe of the different phases, and with respect to the depth and comprehensiveness of guidance on selected topics. Still, overall there are few differences between categories of respondents and almost all were satisfied with the professional quality of the Toolkits in general.

In addition to satisfaction with the professional quality of the Toolkits, 75% of the respondents also indicated that the Toolkits are or have been (very) useful to them.

Another aspect of quality is the coverage of topics in the Toolkits. In the questionnaire respondents were asked to assess how much attention the Toolkits *actually give* to 14 topics and how much they *would want* the Toolkits to give attention to that topic. These two aspects are given in the following graphs. It can be seen that there are 7 topics to which more than 36% of the respondents indicated that they desired more attention in the Toolkits than they thought is actually given (Figure 8: while looking at the graph it should be kept in mind that about 20% of the respondents – equally distributed over all categories - did not fill out these questions). These topics are 'protection of biodiversity and human health' (39%) , 'public awareness programs' (37%), 'risk assessment' (37%) , 'organizing procedures in decision making' (38%),

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'designing a regulatory regime (36%), 'illegal introduction of LMOs into the country' (53%), and 'systems for monitoring, inspections, and enforcement'(50%). Within five of these seven aspects the respondents indicate that a major increase in attention is desired (figure 9): 'protection of biodiversity and human health', 'public awareness programs', 'risk assessment', 'illegal introduction of LMOs into the country', 'systems for monitoring, inspections, and enforcement'. There are no significant differences between respondent categories (stakeholders, regions, and NBF development phase) with respect to views on these different topics.









In addition to looking at the differences between indications of desired and actual attention of various topics in the Toolkits, the differences in assessment were also

³ The difference between desired and actual attention is calculated by subtracting the scores on "how much attention should the Toolkits give to a certain topic" by "how much attention do the Toolkits give to that certain topic". For example, if a respondent indicated that the Toolkits *do not give much* attention at all to monitoring and enforcement and that they should give *very much* attention to this topic, the calculated difference is large. If a respondent said that the Toolkits give *much* attention to, for example the involvement of stakeholders, and that they should give *very much* attention to this topic, the difference is small. The bars in the figure represent the total count of differences of all respondents: short bars indicate relative satisfaction with the attentions these topics receive in the Toolkits (or a balance between positive and negative scores), longer bars indicate that more respondents would like to see (also a larger) shift in attention

studied while controlling for the individual mean score. This was done to find out whether certain topics were evaluated consistently different from the others irrespectively individual positive or negative scoring patrons. For every respondent a mean score was calculated of all answers on the sub-questions concerning the attention the Toolkits actually give to various topics. Then it was analysed which topic differed significantly from this mean score. Finally, it was tested whether these topics are consistently occurring within the whole sample of respondents. It was found that two variables differed negatively and three positively (p<.05). Respondents were relatively more satisfied about the amount of attention the Toolkits give to organizing workshops, involvement of stakeholders, and setting up of an institutional structure. On the other hand, respondents were relatively less satisfied with the attention given to the illegal introduction of LMOs, and monitoring and enforcement.

Overall the results indicate that a large majority of respondents is satisfied about the professional quality of the toolkits. The differences between questions are minor. Respondents were relatively well satisfied about the amount of attention the Toolkits give to organizing workshops, involvement of stakeholders, and setting up of an institutional structure. Respondents were slightly less satisfied about the planning and timeframe of the different phases of the Toolkits and the depth and comprehensiveness of guidance on the selected topics. Especially they indicated that the Toolkits should give more attention to monitoring and enforcement, and the illegal introduction of LMOs.

Results Part II: Challenges and issues for improvement

In addition to the multiple choice questions there were four open questions at the end of the questionnaire. These questions were added to create an option to elaborate upon the closed questions and to solicit for issues not yet covered in the questionnaire. In addition, the open questions indicate what issues are considered most important by the respondents and therefore justify further analysis.

There were four open questions that were coded for keywords:

- What do you consider to be the advantages of the UNEP-GEF Toolkits for your country?
- What do you consider to be the disadvantages of the UNEP-GEF Toolkits for your country?
- What in your opinion are/have been the three main challenges with respect to the application of the UNEP-GEF Toolkits for the development of the National Biosafety Framework in your country?
- How would/did you deal with these challenges?

It should be noted that not all respondents filled out the open questions. Out of 102 respondents, 79% filled out the question on advantages, 67% the question on disadvantages, 67% gave three challenges, and 58% gave examples of solutions. These respondents had a similar distribution over all stakeholder categories and regions as the whole sample. Thus, no stakeholder category or region had a disproportional high or low representation in the open questions compared to the closed questions.

The following tables give the frequencies of issues discussed in the open questions. Only those words/phrases/issues that were mentioned more than three times are taken up in the tables.

Advantages of the UNEP-GEF Toolkits

Table 3. Answers to the question: "What do you consider to be the advantages of the UNEP-GEF Toolkits for your country?"

Topic/ Category	Subtopic/ Category		Number of times mentioned
Overall assessment	Guidance	Good/Useful/Helpful/Important/Crucial	42
	Crucial guiding document	Modest tool	4
Toolkits approach	Provides	Framework/Coordinates work	14
		Step-by-step approach	8
		Flexibility to specific conditions	9
		Clear explanations	6
		Timeline/planning	4
		Harmonization of LMO legislation/procedures	3
	Stakeholders	Helps stakeholders understand important issues	5
		Helps to involve stakeholders	4
	LMO legislation	Increases speed LMO legislation	4
	_	Increases interests in and awareness of LMO issues	3

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As can be seen in the above table, many respondents considered the Toolkits an advantage because they provide/provided guidance and the Toolkits approach has been advantageous to their country. This is in line with the positive view of the Toolkits that was discussed in part I of this report.

Disadvantages of the UNEP-GEF Toolkits and challenges during NBF development

Even though the question on disadvantages of the Toolkits and challenges experienced during the process of setting up a NBF are quite different, they have been analyzed simultaneously. The same issues were sometimes written down as a disadvantage and sometimes as a challenge. Some issues were related to the Toolkits and others were more general issues that respondents/countries deal with.

Disadvantages and challenges that are specifically related to the Toolkits

Topic/Category	Sub-topic	Number of times mentioned
Timing	Coordinating availability/introduction different Toolkits with the development of the NBF	13
Coverage	No country specifics taken into account	8
	Too narrow focus	6
	No attention given to issues of NBF Implementation	5
	Not enough focus on science/LMO Development	4

Table 4: The disadvantages and challenges that are specifically related to theToolkits, divided in two categories, namely Timing and Coverage.

The issues timing is brought up 13 times in the open questions by 10 respondents from all regions. Remarkably, eight of whom happened to be the National Project Coordinator. Regarding the fact that our survey includes 17 National Project Coordinators, it implies that a large proportion of coordinators struggled with the time logistic aspects of the introduction and phases of the Toolkits. On the other hand, as discussed earlier, the rest of the respondents indicated to be (very) satisfied about this aspect of the Toolkits (although they were *relatively* less satisfied about planning and timeframe of the different phases of the Toolkits: between 'very satisfied' and 'satisfied'). Therefore, the explicit critic on timing in the open questions seems to be in contradiction and was further investigated in the second round.

Respondents of the first round were asked what they estimated to be a realistic timeframe to accomplish the draft NBF (from the moment that the project is signed/started until the NBF draft is completed) and what they thought about the timing of the introduction of the five Toolkits. The question on the timeframe was answered by 16 out of 17 respondents. Of whom 2 estimated 18 months, 8 of them estimated 27 months and 5 said 36 months. One person estimated more than 36 months. Most of the respondents indicated that at least 27 months is needed to develop the NBF.

Seven out of 17 respondents agreed with the following observation: 'Many respondents indicated that the availability and introduction of the different phases of the Toolkits did not match adequately with the actual development of the NBF'. Four

of these respondents commented that some countries were already in an advanced stage of NBF development when the Toolkits were introduced. Seven out of 17 (41%) is again a relatively low number of respondents, which seems to correspond with the high number of respondents who indicated to be satisfied with this aspect of professional quality in the first round.

Based on the findings in both the first and the second round it can be concluded that mainly those who are in charge of the coordination of the Toolkit-project do experience problems related to timing and planning. Depending on the local situation respondents indicate that the development of the NBF needs more time (27-35 months). However, since a majority of the respondents, who are all part of (or close related to) National Coordinating Committees, did not express these concerns might be interpreted as the result of an adequate, but apparently demanding, management of the coordinators to cope with these timing aspects

Disadvantages and challenges that need not be related to the Toolkits

Table 5 illustrates that relatively few respondents have mentioned specific difficulties with the Toolkits. However, many respondents (67%) have brought up wider issues and difficulties that they/their country encountered during the process of setting up a National Biosafety Framework. These difficulties need not necessarily be related to the Toolkits. It might be just difficult in the given national situation to raise public awareness, to build capacity, or to obtain the involvement of stakeholders.

Торіс	Topic Sub-topic	
Public Awareness & Participation	Realizing public awareness	24
	Realizing public participation	16
Capacity building	Lack of human resources	13
	Capacity for risk assessment	8
	Setting up of an institutional structure	8
	Increase scientific and technical capacity	9
	Capacity training in general	8
	Allocating financial resources	4
Stakeholder involvement	Cooperation different stakeholders	12
	Participation of stakeholders	13

Table 5: *The disadvantages and challenges that are not specifically related to the Toolkits*

There are three issues that stand out as problems, namely public participation and awareness, capacity building, and stakeholder involvement. More insight can be gained in these topics by relating them to the answering patterns of the closed questions.

Public awareness and participation

Table 5 shows that public awareness and participation are especially considered a challenge. This is interesting since Public awareness and participation is specifically called for in the Cartagena Protocol under Article 23. This Article states in part that "parties shall promote and facilitate public awareness, education and participation

concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health". Almost a third (31%) of the respondents stated in the closed questions that it was difficult to begin the development of the NBF in relation to public awareness and participation; 47% did not consider it difficult and 21% did not have an opinion. In addition, 19% of the respondents stated that they are not satisfied with the support UNEP-GEF provides on public awareness and participation. However, 61% indicated they were satisfied and 20% did not have an opinion.

Furthermore, 37% of the respondents indicated that the Toolkits should give more attention to public awareness programs than they do at the moment. This percentage is lower, but still substantial, for Public Participation, namely 28%. This goes hand in hand with the observation that 29% of these 80 respondents indicated that the Toolkits do not give (very) much attention to Public Awareness and 22% indicated that not (very) much attention is given to Public Participation.⁴

Interesting to note is that there seems to be a discrepancy between the concern about public awareness and participation, and the positive evaluation of the Toolkits with respect to organizing workshops and involving stakeholders.

The outcomes of the Kruskal-Wallis test show that there are few differences between stakeholders, regions, and developments phase of the NBF in the way they assess public participation and awareness. One observation that stands out is the differences between regions on how they view UNEP-GEF support on public participation and awareness. Especially respondents from Latin America and the Caribbean are relatively less satisfied with the support than other respondents (see figure 10). Moreover, in general it was also found that all respondents answer significantly less positively on the specific support question on public participation and awareness than on other sub-questions on UNEP-GEF support.

⁴ In the open questions, a total of 28 respondents expressed concerns about either public awareness or public participation, or about both. However, no strong link is found between the respondents who were concerned or negative about public awareness and participation in the closed questions, and those who expressed these concerns in the open questions.

Figure 10: Satisfaction with UNEP-GEF support with respect to public participation and awareness by region.



How satisfied are you with support given by UNEP-GEF to public participation and awareness programs

Public awareness and participation were mentioned frequently in the open questions. However, at the same time a large number of respondents indicated to be (very) satisfied with UNEP-GEF support and progress in national capacity in this field in the closed questions. An element that stands out is that respondents from Latin America and the Caribbean are relatively less satisfied with the support than other respondents

Capacity

Capacity building is covered under Article 22 in the Cartagena Protocol. In the article is written that Parties shall cooperate in development and/or strengthening of human resources and institutional capacities in Biosafety. Some respondents have indicated in the open questions that they see capacity, or aspects of capacity, as an important issue/difficulty in the process of setting up a NBF. Most often are mentioned the lack of human (13x) and technical resources (9x), the capacity for risk assessment (8x), and the capacity for setting up an institutional structure (8x). There are closed questions that shed light on to what extend this opinion is shared among the wider circle of respondents. The topics within capacity building are: risk assessment, institutional structure, regulatory regime, systems for handling LMO applications, monitoring and enforcement, and illegal introduction of LMOs in country. Table 6a-e gives a summary of the distribution of scores on all related questions.

Tables 6a to 6e: *Distribution of the balance between positive and negative scores regarding different topics within capacity building (over all respondents)*

Торіс	Question	Positive	%	Neutral (%)	Negative	%	No answer (%)
Risk assessment	Actual situation: Do the Toolkits give much attention to risk assessment?	Yes	54	20	No	10	16
	Desired situation: Should the Toolkits give more attention to risk assessment?	No	5	38	Yes	37	20
	Satisfaction support UNEP-GEF on risk assessment	(very) satisfied:	65	-	Not so satisfied:	13	22
	Satisfaction progress national capacity risk assessment	(very) satisfied:	38	-	Not so satisfied:	49	13

Table 6a: Risk assessment

 Table 6b: Setting up a regulatory regime

Торіс	Question	Positive	%	Neutral (%)	Negative	%	No answer (%)
Regulatory regime	How difficult to begin development NBF	Not so difficult	23	-	(very) difficult	54	23
	Actual situation: Do the Toolkits give much attention to setting up a regulatory regime?	Yes	55	21	No	9	15
	Desired situation: Should the Toolkits give more attention to setting up a regulatory regime?	No	7	38	Yes	36	19
	Satisfaction support UNEP-GEF	(very) satisfied:	70	-	Not so satisfied:	9	21

Table 6c: Systems for handling LMO applications

Торіс	Question	Positive	%	Neutral (%)	Negative	%	No answer (%)
Systems for handling	How difficult to begin development NBF	Not so difficult	27	-	(very) difficult	45	28
LMO applications	Actual situation: Do the Toolkits give much attention to systems for handling LMO applications?	Yes	54	21	No	8	17
	Desired situation: Should the Toolkits give more attention to systems for handling LMO applications	No	8	45	Yes	27	20

2005: UNEP-GEF Toolkits Evaluation: Stakeholder Review. *de Cock Buning, Haker, Bereano, de Boer, Bunders*

Table 6a-6c give a summary of all questions and answers on risk assessment, setting up of a regulatory regime, and setting up systems for handling LMO applications. It shows that the difficulties that are experienced with the starting of the NBF and the progress in national capacity are not linked to respondent satisfaction of support given by UNEP-GEF. For example, most respondents who indicated that the Toolkits should give more attention to risk assessment and who were not so satisfied with progress in national capacity, do not relate this to the Toolkits or to UNEP-GEF support. However, table 6d and 6e show a slightly different pattern.

Торіс	Question	Positive	%	Neutral (%)	Negative	%	No answer (%)
Monitoring and	How difficult to begin development NBF	Not so difficult	34	-	(very) difficult	40	26
Enforcement	Actual situation: Do the Toolkits give much attention to Monitoring and Enforcement?	Yes	41	25	No	18	16
	Desired situation: Should the Toolkits give more attention to Monitoring and Enforcement?	No	4	28	Yes	50	18
	Satisfaction support UNEP-GEF	(very) satisfied:	52	-	Not so satisfied:	26	22
	Satisfaction progress	(very) satisfied:	28	-	Not so satisfied:	52	20

Table 6d: Monitoring and Enforcement

Table 6e:	Illegal	introduction	of LMOs
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Торіс	Question	Positive	%	Neutral (%)	Negative	%	No answer (%)
Illegal introduction of LMOs	Actual situation: Do the Toolkits give much attention to the illegal introduction of LMOs	Yes	32	26	No	26	16
	Desired situation: Should the Toolkits give more attention to the illegal introduction of LMOs?	No	4	26	Yes	52	18

The tables 6d and 6e show that monitoring and enforcement and illegal introduction of LMOs have a pattern that differs slightly from the other capacity building aspects so far (tables 6a-6c). As discussed in relation to the closed questions in part I, there is a significant difference between mean scores on all topics that were assessed and the two specific questions on monitoring and enforcement, and illegal introduction of LMOs in the country. This same significant difference is illustrated by the fact that relatively many respondents indicated that there were or had been starting difficulties with respect to monitoring and enforcement (40%) and that many were not so satisfied about progress in this respect (50%). Also, 18% indicated that the Toolkits do not give much attention to this aspect. In addition, a relatively high number of

respondents (26%) were not satisfied with UNEP-GEF support. A similar pattern is seen for the illegal introduction of LMOs. 26% of the respondents thought that not enough attention is currently given by the Toolkits to this issue. Also, 52% indicated that the Toolkits should pay more attention to this issue.





(Mean-score over sub-questions)

A similar pattern can be found for the mean score on all sub-questions on progress made in national capacity (figure 12). A fully developed NBF is related to more satisfaction regarding progress. All sub-questions on progress in national capacity have similar answering patterns.

Figure 12: Distribution of progress in national capacity of various aspects by development phase of the NBF. (Summated over 4 sub-questions)



2005: UNEP-GEF Toolkits Evaluation: Stakeholder Review. *de Cock Buning, Haker, Bereano, de Boer, Bunders*

The open questions showed that countries struggle with capacity in terms of human and technical resources, capacity for risk assessment, and the capacity for setting up an institutional structure. The closed questions underlined these concerns to some extent. Worries about resources and capacity are reflected in the fact that especially monitoring and enforcement, and the illegal introduction of LMOs into the country were seen as issues that require more attention in the Toolkits.

Stakeholder involvement

Stakeholder involvement is an important component of UNEP-GEF Biosafety Project and thus an important topic in the Toolkits. In the open questions the issues of stakeholder involvement (13x) and cooperation (12x) was mentioned relatively frequently. This is interesting since the respondents were relatively more satisfied with the attention given to involvement of stakeholders in the Toolkits than with most other issues in the Toolkits.

A majority of the respondents indicated in the closed questions that the Toolkits are or were of great use to involve the following stakeholders in the development process of the NBF: the national government (useful:75% /not so useful:10% /missing:15%), community based organizations (useful:57% /not so useful:25% /missing:18%), public sector (useful:55% /not so useful:28% /missing:17%), and respondents are clearly divided with respect to the involvement of the private sector (useful:47% /not so useful:36% /missing:17%), and local government (useful:36% /not so useful:42% /missing:22%), However, most respondents thought that the Toolkits have not been useful in involving traditional and spiritual leaders (useful:24% /not so useful:52% /missing:24%) in the development of the NBF.

The results of the Kruskal-Wallis test show that there were no significant differences between stakeholders and development phase of the NBF. However, respondents from Latin America and the Caribbean are relatively less positive about the usefulness of the Toolkits in involving stakeholders than respondents from other regions. This is illustrated in figure 13. Comparing the overall mean-score over the set of sub-questions with the respective sub-questions, especially the involvement on the local government and traditional and spiritual leaders are significantly different. Relatively more people consider the Toolkits not so useful in involving these groups. Figure 14 shows that especially respondents from Latin America and the Caribbean considered the Toolkits not useful in involving local government.

Figure 13: Distribution of the usefulness of Toolkits in involving different stakeholders by region (Summated over 6 sub-questions)



Figure 14: Distribution of usefulness Toolkits in helping to involve local government by region.



Usefulness Toolkits in helping to involve the local government in the development of the NBF

The analysis of the open questions showed that stakeholder involvement and stakeholder communication and cooperation is often seen as a problem. The closed questions suggest that especially traditional and spiritual leaders and local governments are often underrepresented in the development process of the NBF.

Solutions

The last open question, "*How would/did you deal with these challenges?*" was only answered by about half of the respondents (58%). Most answers were proposals to put energy into the challenges listed above (like capacity building). Some respondents gave a personal account of how they have dealt with challenges professionally. Others gave suggestions for improvement on the national level⁵.

Table 7: Solutions/recommendation proposed by the respondents to cope with the
problems countries encounter during the process of setting up a NBF.

Topic/Category	Sub-topic		Number of times mentioned
Capacity building	Increase capacity building in general		11
	Improve communication between stakeholders		10
	Finding financial resources		3
	Education	To increase public awareness	6
	Organize workshops		5
	Surveys/consultations		3
	Working with/hiring experts		8
International/regional focus	Learn from other countries		6
	Regional cooperation/workshops		8
Using Toolkits	Adjust Toolkits to country situation		3
	Follow steps as indicated by the Toolkits		5
	Proceed with the (hard) work that is already being done		7

As can be seen in the table above, most respondents regard capacity building and knowledge sharing as the key to deal with the challenges they encounter during the development of the NBF. This is supported by the closed question in which 90% of the respondents considered regional cooperation (very) important. However, it seems in contrast with the question on the Roster of Experts ("Has your country requested the assistance of the Roster of Experts in order to get additional expertise to assist with the development of the National Biosafety Framework?"). Only 21% of the 102 respondents indicated that their country has made use of the Roster of Experts. In the second round 16 out of 17 respondents filled out the question(s) on the Roster of Experts discussed in your country as one of the options for capacity building?' 12 answered affirmative.

⁵ This duality indicates an ambiguity in the question that had to be taken into account in the qualitative analysis. Since the aim of this question was to get possible solutions On the national level, the 'personal accounts' were also analyzed as such. For example, if respondent indicated that he or she organized workshops to deal with the challenge of public awareness, this has been interpreted as if the respondent suggested doing workshops as a solution (e.g. for too little capacity building).

When asked what advice was given by the UNEP-GEF team regarding the Roster of Experts, 10 respondents indicated that the UNEP-GEF team gave various sorts of advices on how and when to involve experts. Two respondents indicated that the discussion on the Roster of Experts was only held at the national level. Also, two respondents indicated that they were specifically advised to make use of regional experts. None of the respondents indicated to be dissatisfied with the advice given by the UNEP-GEF Team.

The respondents indicated that as a result of the advice given by the UNEP-GEF team not much action was taken. Only two respondents said that they hired an expert from the Roster of Experts. Two said that they are planning to hire experts during the implementation project of the NBF.

On the question whether there is a specific reason why no use has been made of the Roster of Experts, two respondents indicated that they did not know why their country did not make use of the Roster of Experts. Four respondents give the reason that their country already has enough expertise. One respondent indicated that hiring expertise would be too expensive (Seemingly this person was unaware that there was a UNEP-GEF fund to subsidize the Roster of Experts). Another 10 respondents did not give a reason.

The respondents regard capacity building and knowledge sharing as the key to deal with the challenges they encounter during the development of the NBF. Although countries are in need of various types of information, the consultation of the Roster of international Experts seemed to be underutilized as a tool to assist the countries, although specific funds are at the same time available.

<u>Results Part III: Analysis of the additional questionnaire for the Global perspective</u>

Only a limited number of questionnaires (eight) were returned by informants who play a role at the international level and who are familiar with the Cartagena Protocol and the options to implement a National Biosafety Framework in a non-western country. Despite intensive efforts to involve a balanced variety of global players, there were only few that filled out the questionnaire.⁶

Although the number of such respondents was too small to apply statistical analysis, the points raised show a spectre of positive and critical positions. Some of the global industry informants portray even a position opposite to the received responses from the countries. Three representative statements:

Each of the Toolkits was delivered too late be of timely help to countries trying to develop an NBF (Six out of eight "global" respondents).

The UNEP/GEF Toolkits did not provide enough practical and useful guidance. They were often too general to be helpful and were sometimes confusing. (Six out of eight "global" respondents)

The scope of the UNEP/GEF Toolkits was too limited. Focus was placed on the development of NBFs but little attention was given to coming into force of the Cartagena Protocol and the tuning with additional modalities. (some "industry" respondents))

By "timely" at least three aspects are meant: too late (countries had already started the NBF development), the sequence of modules/activities is not always functional (especially phase two came too late) and too short (the planned 18 months is not realistic). This last comment is in line with the comments of a part (7 out of 17) of the National Project Coordinators indicating that 27 or more months are more realistic. At the same time it opposes the responses of the country-level actors (e.g. "How satisfied are you with the professional quality of the UNEP-GEF Toolkits: With respect to the planning and timeframe of the different phases of the UNEP-GEF Toolkits?": 64% responded "very/quite satisfied").

With respect to the answers to the closed questions, some remarkable differences can be observed between the rather positive answers received from the country level actors themselves and the assessment from the side of industry at a global level. The most contrasting questions and answers are listed in table 8.

⁶ Organizations/Industries/Donors that were contacted: Global Industry Coalition,

Croplife International, IBRS, Bayer Cropscience, Monsanto, Third World Network, Greenpeace, FAO, IRRI, Harvestplus, Golden rice network, IPPC, BIOEARN (Sweden), DGIS (The Netherlands), IFPRI (United States), Global Justice Ecology Project, European Commission, ICTSD (International centre for trade and sustainable development), German Development Agency

Question	Response by the countries	Response by some of global industry
Toolkits help to develop appropriate mechanisms for the impartial assessment of risk of LMOs	Very/quite much 58% (do not know/no answer 18%)	Not at all
Ensuring full protection of the biological diversity	Very/quite sufficient 55% (do not know/no answer 17%)	Not at all sufficient
Ensuring full protection of the human health	Very/quite sufficient 47% (do not know/no answer 18%)	Not at all sufficient
Toolkits is responsive to countries available scientific expertise	Very/quite satisfied 65% (do not know/no answer 20%)	Not at al satisfied
Support for setting up systems for risk assessment	Very/quite satisfied 65% (do not know/no answer 23%)	Not at all satisfied
Support for setting up a regulatory regime	Very/quite satisfied 70% (do not know/no answer 22%)	Not at all satisfied
Support for setting up systems for monitoring and enforcement	Very/quite satisfied 52% (do not know/no answer 23%)	Not so/at all satisfied
Toolkits helps to identify expertise needed	Very/quite satisfied 60% (do not know/no answer 23%)	Not so/at all satisfied

Table 8 Contrasting statements between answers on closed question by stakeholders in the 30 countries under study and some global players from.

There are two optional hypotheses to explain this contrast. One is that the global respondents have more knowledge about alternative instruments to set up a NBF. Therefore their comments refer in a relative way to other "Toolkits" that perform better on these aspects of timing. This hypothesis receives some support from the observation that the respondents at the country level have only limited awareness of alternative programs to set up NBFs (see appendix C for the list of alternative "tools" listed by the respondents). Second, the global respondents might have a legitimate position here, and the difficulties expressed by the country-level actors about getting started in the first three phases, might indirectly confirm such comments (although the UNEP-GEF Toolkits are still regarded by the countries as helpful assistance in these difficult phases). Without further inquiry it is hard to decide whether one or the other perspective corresponds with reality, or that both observations belong to both sides of the same coin.

Both interpretations seem to warrant a recommendation (if the UNEP-GEF Toolkits are to be continued) to expand the activities connected to the Toolkits in such a way that more options and adequate detailed suggestions are provided to guide starting countries through these phases.

Summary and discussion of the results

Overall it can be said that the UNEP-GEF Toolkits are evaluated positively as a first instrument to start and frame the process to develop a NBF. When asked directly respondents declare to be satisfied about their consistency with the Cartagena Protocol, professional quality, and their sensitivity to country needs. On almost all questions the highest frequency was on the option 'satisfied', 'useful', or 'much'. However, respondents also indicated in the open questions that timing was seen as a weakness of the Toolkits. Also, *public participation and awareness, capacity*, and *stakeholder involvement were* mentioned as challenges that the Toolkits do not resolve.

Summarizing the findings for the main research questions

Consistency: Overall, the analysis shows that on all questions concerning 'consistency' with the Cartagena Protocol a majority of respondents is neutral to (very) positive or satisfied. However, especially government representatives and respondents representing a country with a fully developed NBF indicate more frequently that the NBF is too strict in its interpretation of the Cartagena Protocol. The respondents representing a country with a fully developed NBF are also relatively more positive about the impact of the NBF on *transboundary movement of LMO* (estimated in absence of concrete cases of transboundary movement).

Country needs: If only the closed questions are analyzed the UNEP-GEF Toolkits and the process of setting up of the NBF seem to respond well to the country needs. Most respondents are satisfied with the way the Toolkits are sensitive to their country's needs and the way the NBF development impacted on various aspects in their country. Overall, respondents who indicated that their country has a fully developed NBF are more positive than other respondents. The analysis of the open questions showed that stakeholder involvement and stakeholder communication and cooperation is often seen as a problem. The closed questions suggest that especially *traditional and spiritual leaders* and *local governments* are often underrepresented in the development process of the NBF.

Professional quality: Overall the results indicate that a large majority of respondents is satisfied about the professional quality of the Toolkits. The differences between questions are minor. Respondents were relatively well satisfied about the amount of attention the Toolkits give to organizing workshops, setting up of an institutional structure and involvement of stakeholders. Respondents were slightly less satisfied about the depth and comprehensiveness of guidance on the selected topics. Especially they indicated that the Toolkits should give more attention to *monitoring and enforcement*, and *the illegal introduction of LMOs*. The open questions showed that countries struggle with *capacity for setting up an institutional structure*. Although countries are in need of various types of information, the consultation of the Roster of international Experts seemed to be underutilized as a tool to assist the countries

Discussion point: Paradox in the data?

There seems to be a discrepancy between on the one hand concerns about stakeholder involvement and public awareness and participation expressed in the open questions, and on the other hand the positive evaluation of the Toolkits with respect to the

2005: UNEP-GEF Toolkits Evaluation: Stakeholder Review. *de Cock Buning, Haker, Bereano, de Boer, Bunders*

attention they pay to organizing workshops and involving stakeholders. One reason for this discrepancy could be the difference between theory and practice. Respondents can be very satisfied with the way the Toolkits pay attention to the involvement of stakeholder and the public, but in practice there could be many obstacles to realizing actual involvement. In addition, most of the workshops that are organized by UNEP-GEF are separate expert meetings for separate stakeholders. These workshops do not appear to have the purpose of joining stakeholders in a participative learning process.

<u>Discussing the hypotheses:</u> <u>Stakeholders, regions, and development phase as sources of variation</u>

In general, few differences between stakeholders, regions, and development phase of the NBF were identified. Still, the following significant differences were found:

Differences between regions:

Respondents from Latin America and the Caribbean seem to be less satisfied with the impact of NBF development on, for example, transboundary movement and support given by UNEP-GEF on public participation and awareness. This group of respondents also differed significantly from other respondents because they indicated relatively more often that the Toolkits were less useful for involving local government.

Differences between stakeholders:

Relatively many government representatives consider the NBF in their country too strict. This seems to contradict the fact that almost all respondents indicated that protection of biological diversity and human health is of great importance. This contrast can be understood as the tension between those who design the NBF and those who have to execute the NBF, in the sense of the difficulties and challenges to fulfil the needed administrative, legal and technical infrastructure to develop a strict NBF

Differences between NBF development phase

Respondents who indicate that their country is at an early phase in the NBF development differ from respondents from countries with a fully developed NBF. Having a fully developed NBF is related to fewer worries about progress in national capacity and the notion that it was not so difficult to start the development of the NBF. Also, they are comparatively more positive about the Toolkits responsiveness to various country needs and the impact of the development of the NBF on various aspects, such as the transboundary movement of LMOs. Moreover, respondents who represent a country with a fully developed NBF more often indicate that the NBF is too strict than respondents from countries who are still in the process of developing a NBF.

Discussion point: understanding differences between categories of respondents There are two explanations for the fact that respondents representing different development phases of the NBF evaluate starting difficulties and progress differently. Firstly, it could be that respondents who represent a country with a fully developed NBF are influenced by a type of hind side-bias. Looking back, the process of setting up the NBF can look easier than it looked before. In other words, respondents who represent a country that is still drafting its NBF might consider the task more demanding. Another reason could be that some of the countries with a fully developed NBF started from a relatively advanced situation in which some regulations were already in place (set up in the late 90). They might have enrolled in the Toolkits program for various reasons like additional coaching, additional harmonization or perhaps just because it was offered along with a package of financial support. Although this survey is limited in its options to interpret the data due to the absence of parallel in-depth interviews, the extent to which some biosafety frameworks were operational at the onset is a variable we could not control for.

The fact that respondents representing a country with a fully developed NBF, and stakeholders representing government, relatively often consider the NBF too strict, might be interpreted as a consequence of the approach chosen by the UN-GEF. The UNEP-GEF Toolkits are tools to help a country to develop an institutional and legal structure that governs a cautious and standardised handling of LMOs. The essence of this approach is that primarily an administrative 'structure' is developed, whereas the 'content', i.e. the first concrete LMO products, the first risk assessment on scientific grounds, are postponed to a later, so called "implementation phase". It is very well conceivable that a country in absence of concrete LMO cases might opt too much for the inclusive potentiality of the NBF under construction. This might lead to a situation in which a NBF is constructed that is potentially well suited to handle a diversity of LMO-cases, but will at the same time loose efficacy and increase bureaucracy. Having said this, it has to be realized that the protection of biodiversity is a policy issue that has to be managed at trans-national level. Individual actors like industry and national governments do not regard it their direct interest and cannot carry the burden and responsibility to guard the global biodiversity. Therefore, a NBF will always be an "additional" activity to the main priorities of national politics, private enterprises, and academic research. Some will experience this as a cumbersome burden, some as a duty towards the global society.

Challenges to interpretation of the results

In this section the caveats will be discussed that should be kept in mind while interpreting the results. First of all, it is investigated why some respondents participated, while others did not. Secondly, the general background of respondents in relation to the findings in this research is studied. Finally, the methodology used and its consequences are discussed.

The respondents vs non-respondents

An important question is to what extent the returned questionnaires give a representative picture of the development of NBFs with the help of the UNEP-GEF Toolkits in the selected countries. Clearly fewer questionnaires were returned than planned. There are some possible reasons why potential respondents declined from active participation in this evaluation.

First of all, there are technical reasons, such as insufficient internet connection that resulted in about hundred persistent failures (from the 600 addresses) to reach potential informants. Secondly, people are often absent from their offices in the summer (about half of the approached countries are situated in the northern
hemisphere). Thirdly, language proficiency is a limitation for many. The questionnaires were translated in Spanish and French, but not in Russian and Arabic. Fourthly, a frequently heard argument (also from the group of "global players") was that the questionnaire addressed detailed topics that could only be answered by someone who has direct experience with the Toolkits and/or is somehow involved in the UNEP-GEF projects that uses them. It could be that those informants who get the impression that they have to answer many times "do not know" might be reluctant to return the questionnaires. It was difficult to convince those informants that the team was happy to receive at least the answers they could give from their experience (i.e. the open questions). Furthermore, most of the international operating organisation (such as Greenpeace, industries, and research organisations) are hardly involved in national Toolkit projects and made clear that their interest is not primarily the regulatory regime but concrete risk management of concrete LMOs. Finally, there might be respondents/stakeholders who are hesitant to commit themselves to evaluations that are connected to an approach or organization/institute (i.e. UNEP/GEF) that they criticize. As a consequence of these possible reasons, the sample is probably quite representative for those who are closely involved in the **UNEP-GEF** Toolkits project.

Respondents

The sample of respondents that did participate in this evaluation has certain characteristics which should be kept in mind interpreting the results. First of all, an overwhelming majority of the respondents are members of National Coordinating Committees. Secondly, there is a strong representation of government representatives and an under representation of industry and NGOs. Furthermore, Eastern and Central Europe and Africa are well represented, while Asia-Pacific has the least representatives.

In addition to these differences between respondents on a micro level, there are also macro or country-level factors that should be taken into account. For example, the combination of a variety of national, cultural, and political conventions could influence the way in which respondents interpret and fill out the questions. An example of this could be that there are different notions of "directness" in different cultures. Also, the country situation, e.g. political climate, could be strongly related to the issues respondents mention. For example, "raising awareness for biotechnology" might be interpreted in difference ways, i.e. as education, as propaganda, and/or as a nature conservation movement. Since this research was conducted by an internet survey it was impossible to check these cultural connotations, as could be done in a face tot face interview.

Understanding the positive evaluation

Since a large majority of the respondents are "quite positive" to "very positive" about all aspects of the Toolkits and the NBF development project, it can be concluded that either there are hardly negative opinions or those informants who have negative sentiments did not take this opportunity to voice their criticism. It could be hypothesized that the informants who are involved in the process of NBF development may have seen this evaluation as a grading of their own performance or their institution's/country's performance. It is difficult to separate the tool (theory) from how it is used and worked with in the country itself (practice). This hypothesis cannot easily be tested, however, the research team took preventive measures, namely guaranteeing anonymity and explicitly stating in the letter to all respondents that this was not an evaluation of their or their country's performance.

Another reason why few respondents express negative opinions could be the political and financial interests that are at stake. Firstly, the UNEP-GEF Development Project offers both financial and logistic support to countries. Secondly, the field of legal aspects of biotechnology is highly politicized. Biotechnology is an example of a technology that, if successful, could induce landslides in all societies over the world: traditional chemical industries could be replaced by high technological bio-science industries, higher yields of a specific crop could induce imbalances on markets and crop processing industry, consumers could alter their behaviour and governments would rearrange their policies.

Understanding the 'missings'

The analyses were done for all respondents who gave an answer to the questions (positive, neutral, or negative). On average there were about 18-20 respondents per closed question who either left the question unanswered or answered 'not applicable' or 'do not know'. There are several possibilities why there was such a high percentage of 'missings'. First of all, respondents might not have known the answers to the questions. This option would suggest an inconsistency in the findings since almost all respondents indicated that they were either very well informed (70) or informed (25) of the NBF development process in their country. A second reason for not answering all questions could be that respondents got tired of the lengthy and in-depth questionnaire. Thirdly, it could be that the questions were unclear to them or that their understanding of the English, French, or Spanish languages was not sufficient to grasp the meaning of the questions. Finally, despite language barriers, it could be that some respondents regarded certain questions to be unclear or ambiguous.

Discussion of the methodology

In order to increase reliability of the results the method of triangulation was used. Triangulation is a methodology in which three (or more) data collection methods are used on the same topic. When these different data sets point to the same direction it is regarded as a reliable conclusion. In other words, consistency is an important criterion. We applied triangulation in our data sources (questionnaire, expert consultation, participative observation COP/MOP meeting Montreal), and in our analytical tools. The whole sample appeared to be consistently positive. Only those deviations from this general pattern that appeared to stay significant under various tests =(triangulation) are described and interpreted in part I. Apparent discrepancies between answers of closed and open questions have been analyzed in part II and III with contextual information obtained from experts and own participative observations.

Even though this study made use of triangulation, a note on the positioning and value of is relevant. This study is only one part of the UNEP-GEF evaluation 2005. The other part of the evaluation was done in 10 countries through visits and in-depth interviews. Ten other countries are being evaluated by telephone interviews. Usually, in-depth interviews precede a wider quantitative based survey. The UNEP-GEF decided to assign these two phases to two different research teams and scheduled them

simultaneously. Although this might be efficient in time, it is not efficient in a scientific way. Six of our 27 countries were also included in the survey of the other research team. Both studies can be calibrated upon each other by these six overlapping countries. For instance, it could be that the interview team managed to interview a more representative proportion of the four stakeholders. Also, it could be that those six countries assess, by means of a different methodology, namely in-depth interviews, their experiences with UNEP-GEF Toolkits systematically different (i.e. more negatively) in relation to our questions. Under these conditions there are good grounds to reconsider the generalisability of the answers collected by our internet survey.

Concluding messages and remarks

Having in mind the politicized context, the narrow focus of the 5 UNEP-GEF Toolkit documents, and the relative high number of governmental stakeholders who returned the questionnaire, the results should be interpreted with caution. It is unwise to go further than to summarize some indicative messages, and to describe the contrasting of opinions between the returned questionnaires from the respondents in the 27 countries and the opinions of the international and global stakeholders.

Concluding Messages

Message 1

A large majority of the country-level actors declared to be satisfied with the UNEP-GEF Toolkits with regards to their consistency with the Cartagena Protocol, their professional quality, and their sensitivity to country needs.

Message 2

Support is needed to organize public participation and awareness, as well as capacity building aspects, in fields, such as monitoring & enforcement and human resources. This message is supported by all stakeholders, regions and is independent of the level of development.

Message 3

A message given by a relatively high number of respondents through the open questions is that the timeframe of setting up a NBF should be set about 27-36 months.

Message 4

In the open questions respondents indicated that capacity building is an important way to deal with difficulties that are encountered during the NBF development process. Through especially the second round it was learned that a potential solution, the Roster of Experts, is not yet fully utilized.

Message 5

There is a contrast between the answers of country-level actors and global industry informants. The latter evaluated the Toolkits more negatively. Indicating that the Toolkits came too late, have a too narrow focus, and do not provide enough practical and useful guidance.

Concluding remarks

These messages that signal problems in the practical management/logistics of the provided Toolkits (message 2-5) might be understood as four symptoms rooted in a single assumption at the basis of the design of the UNEP-GEF Toolkits. The questionable assumption is that "content (proper risk management of LMOs) follows structure (NBF)". Within the context of philosophy of law almost all national legal systems grow organic (and responsive to the country's specific needs) as separate patchworks. This notion is referred to in the literature as "common law". In contrast to this the modern supra national acts, agreements and protocols are negotiated in international arenas. Subsequently, supra national agreements have to be implemented at national levels and this process has a predominant top-down character. These topdown demanded implementation trajectories clash with the imbedded tradition of national "common law". They will clash with the national timeframe in which legal revisions used to have their life cycle (message 3 and 5). They will clash with the common law mechanism; in which societal debate about nationally emerging problems generate pragmatic legal framing (structure follows contents). Except for small island countries with a long standing tradition on conservation and protection of natural diversity, many of the investigated countries do not possess laboratories to generate LMOs (n)or they encounter LMO risks that outweigh (yet) the daily risk of social destabilization, epidemics and hunger. It is thus evident that the NPCs struggle with the demand to comply with this hard quest to raise public awareness and stimulate stakeholder participation (message 2) in the absence of concrete cases. However, concrete cases to handle import/export and all other transboundary movements of LMOs are matters of administrative responsibility and need foremost 'best practice' advices to organize it properly (structure follows contents) (message 4 and 5).

This meta-analysis concerns only the mutual relations at a deeper level behind the deduced messages from stakeholders working with the UNEP-GEF Toolkits. The lesson to be learned is, in our view, that top down implementation of new and "western" legislation could gain momentum when general as well as country specific "actual LMO cases" are used, from the very beginning, as crystallisation points to develop a country specific NBF: licensing procedures at the border (sharing knowledge in regional context), how to handle administrative responsibility by means of risk assessment on international data (clearing house), risk management of crops and medical biologicals (roster of national and international experts, participation of NGOs and citizens).

Appendix A: The Questionnaire, including the results

UNEP-GEF Toolkits Evaluation

Stakeholder Review

vrije Universiteit

amsterdam



Α	Personal I	nformation							
A1	Name:								
	Total number of respondents: $102 (102 = 100\%)$								
A2	For which country do you fill out this questionnaire?	Country: Africa (29,4%) Asia/Pacific (16,7%) Eastern & Central Europe (33,3%)							
A3	Stakeholder	Latin America/Caribbean (20,6%)							
	National Government (54,9%) NGO (16,7%) Industry (4,9%) Academia (23,5%) n.b. There were some respondents who fill They were put into the category with which	ed out more than one stakeholder category. h they seemed to be most affiliated.							
A4	For how many years have you been involved in issues related to:								
	Biotechnology	Average Nr. of years: 8,8							
	Nature Conservation	Average Nr. of years: 9,0							
	Biodiversity	Average Nr. of years: 9,6							
	Social Welfare	Average Nr. of years: 3,1							
	Human health issues	Average Nr. of years: 2,9							
A5	For how many years have you been involved in issues related to the Cartagena Protocol?	n Average Nr. of years: 3,8							
A6	How informed are you of your country's development of a Nation Biosafety Framework?	Very informed (68,6%)Quite informed (24,5%)Not so informed (3,9%)Not at all informed (1,0%)No answer (2,0%)							

	The UNEP-GEF Toolkits and the dev Biosafety Framework	velopment of a National
A7	Are you aware of the existence of the UNEP-GEF Toolkits?	Yes (90,2%) No (8,8%) No answer (1,0%)
A8	Have you ever looked at the UNEP-GEF Toolkits?	Yes (77,5%) No (21,6%) No answer (1,0%)
A9	Has your country made use of the UNEP- GEF Toolkits?	Yes (84,3%) No (9,8%) No answer (5,9%)
A10	If Yes, in what stage of development is the Framework in your country? Not started (0%) Phase 0 (Starting) (0%) Phase 1 (Data Collection) (3,9%) Phase 2 (Analysis & Consultation) (8,8%) Phase 3 I or II (Drafting a National Biosafety Fr Fully developed (31,4%) Started the implementation project. (4,9%) Fully operational (2,0%) Do not know (4,9%) No answer (5,9%)	
	Experience with workshops	
A11	How many workshops on the development of a National Biosafety Framework have taken place in your country?	Average nr. 8,3
A12	How many have you attended?	Average nr. 6,0
A13	How many workshops on the development of a National Biosafety Framework did you attend that were organized by UNEP-GEF and based on the UNEP-GEF Toolkits?	Average nr. 3,2

A14	How many workshops on the development of a National Biosafety Framework did you attend that were organized by other organizations?	Average nr. 2,2
A15	In addition to the UNEP-GEF projects and you, or has your country made use of other manuals and/or programs for the develop Biosafety Framework made by other organ	r comparable activities, nent of the National
	Yes (49,0%) No (46,1%) No answer (4,9%)	
	If Yes, please list:	
		•••••

B

Evaluation of the UNEP-GEF Toolkits

	Consistency with the Cartagena Protocol						
	"The Parties shall ensure that the development, handling, transport, use, transfer, and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health" (Cartagena Protocol, Article 2(2)).						
	"Nothing in the Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol, provided that such action is consistent with that objective and the provisions of the protocol and is in accordance with that Party's other obligations under international law" (Cartagena Protocol, Article2(4)).						
B1	How familiar are you with the specific requirements imposed on countries, and the other options available to them, under the Cartagena Protocol?						
	Very familiar (32,4%) Quite familiar (56,9%) Not familiar (5,9%) Not at all familiar (0%) Do not know (2,9%) No answer (2,0%)						
B2	Considering the quote above, in your opinion how consistent are the UNEP-GEF Toolkits with the Cartagena Protocol?						
	Very consistent (29,4%) Quite consistent (48,0%) Not consistent (1,0%) Not at all consistent (0%) Do not know (14,7%) No answer (6,9%)						
	Please explain your opinion:						

	Usefulness
B3	How useful are/were the UNEP-GEF Toolkits to you?
	Very useful (41,2%)
	Quite useful (34,3%)
	Not useful (3,9%)
	Not at all useful (1,0%)
	Do not know (13,7%)
	No answer (5,9%)
B4	
B4	How useful are/were the UNEP-GEF Toolkits to your country?
B4	
B4	Very useful (43,1%)
B4	Very useful (43,1%) Quite useful (36,3%)
B4	Very useful (43,1%) Quite useful (36,3%) Not useful (2,0%)
B4	Very useful (43,1%) Quite useful (36,3%) Not useful (2,0%) Not at all useful (1,0%)
B4	Very useful (43,1%) Quite useful (36,3%) Not useful (2,0%)

	Professional quality
В5	How satisfied are you with the way that the UNEP-GEF Toolkits and other relevant documents were made available to you? eg, by hand, at workshops, by CD-ROM, through email, fax, on paper, from the website, etc
	Very satisfied (29,4%) Quite satisfied (46,1%) Not so satisfied (4,9%) Not at all satisfied (2,0%) Do not know (11,8%) No answer (5,9%)
B6	How satisfied are you with the professional quality of the UNEP- GEF Toolkits:
	With respect to <i>clarity of aims</i> ?
	Very satisfied (36,3%) Quite satisfied (41,2%) Not so satisfied (4,9%) Not at all satisfied (1,0%) Do not know (11,8%) No answer (4,9%)
B7	With respect to <i>selection of topics</i> ?
	Very satisfied (22,5%) Quite satisfied (53,9%) Not so satisfied (3,9%)

Not at all satisfied (1,0%)Do not know (11,8%) No answer (6,9%)With respect to the depth and comprehensiveness of guidance on the **B8** selected topics? Very satisfied (19,6%) Quite satisfied (50,0%) Not so satisfied (11,8%) Not at all satisfied (1,0%)Do not know (11,8%) No answer (5,9%)**B9** With respect to *the planning and timeframe of the different phases of* the UNEP-GEF Toolkits? Very satisfied (18,6%) Quite satisfied (45,1%) Not so satisfied (11,8%) Not at all satisfied (2,9%)Do not know (15,7%) No answer (5,9%)**B10** How satisfied are you with the professional quality of the UNEP-**GEF** Toolkits in general? Very satisfied (27,5%) Quite satisfied (52,9%) Not so satisfied (1,0%)Not at all satisfied (2,0%)Do not know (11,8%) No answer (4,9%)

	Starting
B11	How difficult was it to begin using the UNEP-GEF Toolkits to develop the draft National Biosafety Framework in your country:
	In relation to <i>The regulatory regime?</i>
	Very difficult (8,8%) Quite difficult (13,7%) Not so difficult (42,2%) Not at all difficult (11,8%) Not applicable (16,7%) No answer (6,9%)
B12	In relation to systems for handling of LMO applications?
	Very difficult (4,9%) Quite difficult (21,6%) Not so difficult (31,4%) Not at all difficult (13,7%) Not applicable (19,6%) No answer (8,8%)
B13	In relation to <i>monitoring and enforcement?</i>
	Very difficult (12,7%) Quite difficult (21,6%) Not so difficult (34,3%) Not at all difficult (5,9%) Not applicable (17,6%) No answer (7,8%)
B14	In relation to <i>public participation and awareness?</i>
	Very difficult (6,9%) Quite difficult (24,5%) Not so difficult (27,5%) Not at all difficult (19,6%) Not applicable (13,7%) No answer (7,8%)
B15	In relation to the state of science in your country?
	Very difficult (7,8%) Quite difficult (14,7%) Not so difficult (36,3%) Not at all difficult (19,6%) Not applicable (14,7%) No answer (7,8%)

B16 In relation to *the state of biotechnology in your country?*

Very difficult (8,8%) Quite difficult (9,8%) Not so difficult (42,2%) Not at all difficult (16,7%) Not applicable (14,7%) No answer (7,8%)

B17 How difficult was it *in general* to begin using the UNEP-GEF Toolkits to develop the National Biosafety Framework in your country?

Very difficult (2,9%) Quite difficult (24,5%) Not so difficult (41,2%) Not at all difficult (13,7%) Not applicable (10,8%) No answer (6,9%)

	Assessment of the issue Toolkits	es hig	hl	ight	ed in	the	UN	EP-(GE	'F	
B18	How much attention do taspects?	he UN	E	P-GE	EF To	olkit	ts giv	e to t	the	foll	C
	Protection of biodiversity and human health	Very much	<	32,4	23,5	17,6	7,8	2,9	>	Not at all	Missing 15,7
	Setting up an Institutional structure	Very much	<	43,1	19,6	18,6	1,0	2,0	>	Not at all	15,7
	Conducting surveys	Very much	<	32,4	25,5	18,6	2,9	3,9	>	Not at all	16,7
	Involvement of Stakeholders	Very much	<	39,2	23,5	10,8	2,9	2,9	>	Not at all	20,6
	Public Participation	Very much	<	39,2	19,6	11,8	6,9	3,9	>	Not at all	18,6
	Public awareness program	Very much	<	29,4	21,6	21,6	5,9	3,9	>	Not at all	17,6
	Hiring of expertise	Very much	<	33,3	21,6	15,7	7,8	4,9	>	Not at all	16,7
	Risk assessment	Very much	<	37,3	16,7	20,6	5,9	3,9	>	Not at all	15,7
	Organizing workshops	Very much	<	38,2	23,5	18,6	2,9	1,0	>	Not at all	15,7
	Organizing procedures in decision making	Very much	<	29,4	26,5	19,6	5,9	2,9	>	Not at all	15,7
	Administrative steps in processing LMO applications	Very much	<	30,4	23,5	20,6	3,9	3,9	>	Not at all	17,6
	Designing a regulatory regime	Very much	<	30,4	24,5	20,6	6,9	2,0	>	Not at all	15,7
	Illegal introductions of LMOs into the country	Very much	<	18,6	13,7	25,5	11,8	14,7	>	Not at all	15,7
	Systems for monitoring, inspections, and enforcement	Very much	<	26,5	14,7	24,5	8,8	9,8	>	Not at all	15,7

^{B19} How much attention *should* the UNEP-GEF Toolkits give to the following aspects?

tonowing aspects:										Missing
Protection of biodiversity and human health	Very much	<	69,6	10,8	4,9	0	2,0	>	Not at all	12,7
Setting up an Institutional structure	Very much	<	52,9	16,7	12,7	3,9	2,0	>	Not at all	11,8
Conducting surveys	Very much	<	48,0	25,5	9,8	4,9	0	>	Not at all	11,8
Involvement of Stakeholders	Very much	<	59,8	16,7	7,8	1,0	2,9	>	Not at all	11,8
Public Participation	Very much	<	58,8	20,6	6,9	0	2,0	>	Not at all	11,8
Public awareness program	Very much	<	65,7	15,7	4,9	0	2,0	>	Not at all	11,8
Hiring of expertise	Very much	<	44,1	19,6	18,6	3,9	0	>	Not at all	13,7
Risk assessment	Very much	<	66,7	11,8	3,9	0	2,0	>	Not at all	15,7
Organizing workshops	Very much	<	46,1	25,5	11,8	2,9	0	>	Not at all	13,7
Organizing procedures in decision making	Very much	<	52,9	22,5	7,8	1,0	2,0	>	Not at all	13,7
Administrative steps in processing LMO applications	Very much	<	49,0	22,5	11,8	2,9	1,0	>	Not at all	12,7
Designing a regulatory regime	Very much	<	51,0	27,5	5,9	1,0	1,0	>	Not at all	13,7
Illegal introductions of LMOs into the country	Very much	<	58,8	17,6	8,8	2,9	0	>	Not at all	11,8
Systems for monitoring, inspections, and enforcement	Very much	<	65,7	16,7	2,9	2,0	0	>	Not at all	12,7

	Risk assessment
B20	How much did the UNEP-GEF Toolkits help your country to develop appropriate mechanisms for the impartial assessment of risks of particular LMOs?
	Very much (17,6%) Quite much (40,2%) Not so much (19,6%) Not at all (4,9%) Do not know (11,8%) No answer (5,9%)
B21	Do you feel that the way the UNEP-GEF Toolkits approach the issue of risk assessment is sufficient in ensuring the full protection of:
	Biological diversity?
	Very sufficient (5,9%) Quite sufficient (49,0%) Not so sufficient (23,5%) Not at all sufficient (4,9%) Do not know (10,8%) No answer (5,9%)
B22	Human health?
	Very sufficient (5,9%) Quite sufficient (41,2%) Not so sufficient (29,4%) Not at all sufficient (4,9%) Do not know (11,8%) No answer (6,9%)
B23	How much did the UNEP-GEF Toolkits help your country to approach LMO applications with precaution (i.e. to take preventive
	measures in situations of scientific uncertainty or before full scientific proof has been provided)?
	Very much (16,7%) Quite much (36,3%) Not so much (16,7%) Not at all (4,9%) Do not know (18,6%) No answer (6,9%)

B24	Risk assessment often reveals scientific uncertainties. However, the way
	in which biosafety regulation is formulated to deal with these
	uncertainties, i.e. through risk <i>management</i> , may vary among countries.
	At the one end stands an extensive option of precautionary procedures to
	monitor unexpected toxic and adverse biodiversity effects (e.g. super
	weeds). On the other end of the spectrum one finds a risk management
	approach that regards LMOs in principle as safe as its unmodified
	ancestor (by which we are familiar for many generations and other
	relevant regulations may already be in place) and as long as the
	(bio)chemical content is not substantially changed.
	What emphasis has the policy of LMO risk management regulation
	in your country (or is the policy heading for)?
	Missing

u u		•	v		0	,		Missing
LMOs are never considered safe. Extensive Risk management/monitoring is required in each case	22,5	28,4	26,5	9,8	3,9	>	LMOs are always considered safe as long the LMO has similar composition/ characteristics as the unmodified plant	8,8 as

B25	If applicable, do you feel that the representation of different stakeholders in the National Coordinating Committee is adequate and balanced?												
	National Government	Over- represented	<	18,6	25,5	38,2	4,9	2,9	>	Under- represented	Missing 9,8		
	Community-based organizations	Over- represented	<	5,9	11,8	34,3	23,5	15,7	>	Under- represented	8,8		
	The public sector	Over- represented	<	17,6	15,7	34,3	17,6	3,9	>	Under- represented	10,8		
	The private sector	Over- represented	<	4,9	13,7	25,5	25,5	20,6	>	Under- represented	9,8		
	Traditional and spiritual leaders	Over- represented	<	2,9	3,9	14,7	12,7	49,0	>	Under- represented	16,7		
	Local government	Over- represented	<	3,9	5,9	27,5	18,6	29,4	>	Under- represented	14,7		
326	How useful were different stakeho Biosafety Frame	olders in th											

										Missing
National Government	Useful	<	51,0	23,5	5,9	2,9	2,0	>	Not useful	14,7
Community-based organizations	Useful	<	23,5	33,3	11,8	8,8	4,9	>	Not useful	17,6
The public sector	Useful	<	34,3	20,6	18,6	7,8	2,0	>	Not useful	16,7
The private sector	Useful	<	29,4	17,6	20,6	12,7	2,9	>	Not useful	16,7
Traditional and spiritual leaders	Useful	<	14,7	8,8	11,8	16,7	24,5	>	Not useful	23,5
Local government	Useful	<	14,7	21,6	10,8	16,7	14,7	>	Not useful	21,6

	Country needs in working with the UNEP-GEF Toolkits
B27	How satisfied are you with the way the UNEP-GEF Toolkits are responsive to:
	Your country's available scientific expertise?
	Very satisfied (11,8%) Quite satisfied (53,9%) Not so satisfied (11,8%) Not at all satisfied (2,9%) Do not know (12,7%) No answer (6,9%)
B28	Your country's socio-economic situation?
	Very satisfied (4,9%) Quite satisfied (48,0%) Not so satisfied (26,5%) Not at all satisfied (2,9%) Do not know (11,8%) No answer (5,9%)
B29	Your country's cultural values?
	Very satisfied (2,0%) Quite satisfied (44,1%) Not so satisfied (26,5%) Not at all satisfied (5,9%) Do not know (15,7)

	No answer (5,9%)							
B30	Do you consider that the UNEP-GEF Toolkits provide a suitable balance between on the one hand a focus on international harmonization and regulation of LMO legislation, and on the other hand the country's specific situations?								
									Missing
	Too much emphasis on international LMO regulations	< 13,7	22,5	43,1	2,9	2,0	>	Too much emphasis on country's specific situations	15,7

B31	relating to I range of issu	LMOs, but ies, or to in	allows npose	s coun strict	tries t er stai	o ado ndard	pt l s. F	all range of is aws on a broa low do you ev / Framework?	der aluat
	Too broad	< 8,8	23,5	43,1	13,7	3,9	>	Not broad enough	6,9
	Too strict	< 7,8	18,6	47,1	6,9	3,9	>	Not strict enough	15,7
	upon the fol Research & Very positive	Developme e (8,8%)				ffectir	ng y	our country:	
	Quite positiv Neutral (22, Quite negativ Very negativ Do not know No answer (4	5%) ve (9,8%) re (2,0%) v (5,9%)							

B34 *The transboundary movement of LMOs (import, export, etc)?*

Very positive (7,8%) Quite positive (37,3%) Neutral (28,4%) Quite negative (7,8%) Very negative (2,0%) Do not know (12,7%) No answer(3,9%)

UNEP-GEF Support and Expertise

	UNEP-GEF overall support
C1	How satisfied are you with the support given by UNEP-GEF on:
	Setting up systems for risk assessment?
	Very satisfied (23,5%) Quite satisfied (41,2%) Not so satisfied (11,8%) Not at all satisfied (1,0%) Do not know (14,7%) No answer (7,8%)
C2	Creation of a National Coordinating Committee, and a National Executing Agency?
	Very satisfied (34,3%) Quite satisfied (38,2%) Not so satisfied (4,9%) Not at all satisfied (1,0%) Do not know (8,8%) No answer (12,7%)
C3	Setting up a regulatory regime?
	Very satisfied (26,5%) Quite satisfied (43,1%) Not so satisfied (6,9%) Not at all satisfied (2,0%) Do not know (12,7%) No answer (8,8%)
C4	Setting up systems for monitoring and enforcement?
	Very satisfied (16,7%) Quite satisfied (35,3%)

Not so satisfied (21,6%) Not at all satisfied (3,9%) Do not know (15,7%) No answer (6,9%)

C5 Setting up Public Participation and Awareness programs?

Very satisfied (21,6%) Quite satisfied (40,2%) Not so satisfied (16,7%) Not at all satisfied (2,0%) Do not know (11,8%) No answer (7,8%)

C6 How satisfied are you *in general* with the support given by UNEP-GEF?

Very satisfied (36,3%) Quite satisfied (46,1%) Not so satisfied (3,9%) Not at all satisfied (1,0%) Do not know (6,9%) No answer (5,9%)

	Roster of Experts
C7	To what extent did the UNEP-GEF Toolkits help your country to identify the types of expertise needed for the development of a National Biosafety framework?
	Very much (22,5%) Quite much (37,3%) Not so much (14,7%) Not at all (2,9%) Do not know (16,7%) No answer (5,9%)
C8	The Roster of Experts is compiled by the CBD Secretariat, and is available online at http://www.biodiv.org/roster/default.asp Has your country requested the assistance of the Roster of Experts in
	order to get additional expertise to assist with the development of the National Biosafety Framework?
	Yes (20,6%) No (60,8%) No answer (18,6%)

D	Evaluation of progress
	Progress in national capacity
D1	How satisfied are you with the progress made up till now towards strengthening national capacity for decision-making and administration of Biosafety procedures:
	With respect to Systems for risk management and risk assessments?
	Very satisfied (7,8%) Quite satisfied (30,4%) Not so satisfied (36,3%) Not at all satisfied (12,7%) Do not know (7,8%) No answer (4,9%)
D2	With respect to <i>The coordination between the different participating agencies in the LMO procedures?</i>
	Very satisfied (8,8%) Quite satisfied (29,4%) Not so satisfied (29,4%) Not at all satisfied (14,7%) Do not know (12,7%) No answer (4,9%)
D3	With respect to Systems for monitoring and enforcement?
	Very satisfied (4,9%) Quite satisfied (23,5%) Not so satisfied (39,2%)

Not at all satisfied (12,7%) Do not know (13,7%) No answer (5,9%)

D4 How satisfied are you with the progress made up till now towards strengthening national capacity for decision-making and administration of Biosafety procedures *in general*?

> Very satisfied (10,8%) Quite satisfied (33,3%) Not so satisfied (37,3%) Not at all satisfied (6,9%) Do not know (7,8%) No answer (3,9%)

	Regional cooperation					
D5	How important do you consider regional cooperation with regard to LMO legislation for your country?					
	Very important (61,8%) Quite important (28,4%) Not so important (3,9%) Not at all important (0%) Do not know (2,9%) No answer (2,9%)					
D6	What has been the usefulness of the UNEP-GEF Toolkits with respect to regional cooperation <i>in general</i> ?					
	Very useful (17,6%) Quite useful (40,2%) Not so useful (15,7%) Not at all useful (1,0%) Not applicable (20,6%) No answer (6,9%)					
D7	What elements of regional cooperation, in your opinion, require more attention in the Toolkits?					

	Other approaches to the development of a National Biosafety Framework
D8	In addition to the UNEP-GEF Toolkits are there other or similar guidelines available in your country?
	Yes (16,7%) No (64,7%) No answer (18,6%)
	If Yes, please list them:
D9	If applicable, are the UNEP-GEF Toolkits effective in developing a National Biosafety Framework compared to similar guidelines and materials in your country/region? Very effective (7,8%) Quite effective (27,5%) Not so effective (3,9%)
	Not at all effective (1,0%) Do not know (21,6%) No answer (38,2%)
	Please explain your answer:
	······
D10	If any, from which country's National Biosafety Framework does/has your country learn(ed) from?
	No insight in NBFs from other countries (13,7%) No country (11,8%) Various countries (59,8%) No answer (14,7%)

E	Open question	IS				
E1	What do you consider to be the advantages of the UNEP-GEF Toolkits for your country?					
	79,4% of respondents gave an answer to this question					
E2	What do you consider to be the disadvantages of the UNEP-GEFToolkits for your country?					
	66,7% of respondents gave an answer to this question					
E3	What in your opinion are/have been the three main challenges with respect to the application of the UNEP-GEF Toolkits for the development of the National Biosafety Framework in your country?					
	66,7% of respondents gave an answer to this question					
E4	How would/did you deal with these challeng	es?				
	57,8% of respondents gave an answer to this question					
E5	What is your estimated time to complete the development of the National Biosafety	In the year:				
	Framework and making it operational?	63,7% answered 2005 (14,7%)				
		2005 (14,7%) 2006 (20,6%)				
		2007 (11,8%)				
		2008 (7,8%)				
		2009 or later (8,8))				

Appendix B: Additional Questions

Round Two: Additional Questions

Roster of Experts

The results of the study show that countries have a need for more capacity building. The Roster of Experts was designed "to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms" (Decision EM 1/3, Extraordinary COP, Montreal, January 2000). According to the respondents, not many countries made use of the provided roster of experts. We would therefore like to ask the following questions:

- 1) Was the Roster of Experts discussed in your country as one of the options for capacity building?
 - o Yes
 - o No
- 2) If Yes, what advice was given to you by the UNEP-GEF team?
- 3) As a result did you/your country take action?
- 4) Is there a specific reason why your country has not made use of the Roster of experts?

Timing

Regarding the socio-economic, political, and cultural situation in your country, what do you estimate as a realistic timeframe to accomplish the draft NBF (from the moment that the project is signed/started until the NBF draft is completed)?

- \circ less than 18 months
- \circ 18 months
- \circ 27 months
- \circ 36 months
- \circ More than 36 months

Many respondents indicated that the availability and introduction of the different phases of the Toolkits did not match adequately with the actual development of the NBF. Do you agree with this observation?

o Yes

 \circ No

If Yes, please comment:

Appendix C:

Some additional guidelines, publications, and activities to the UNEP-GEF Toolkits indicated by the respondents, who mentioned to be aware and/or to use them in the development of the NBF

Category	Guidelines/manuals	Description
Risk Assessment	Risk assessment manual by the Edmonds Institute T. Jewell, A. Stirling	technical manual setting out a clear step-by- step bioassessment process
Risk Assessment	Workbook on Biosafety and risk assessment in agricultural biotechnology Patricia L. Traynor, Robert J. Frederick, Muffy Koch	This workbook provides a background for the practical application of biosafety review procedures using a case study approach.
Guidance to develop procedures	Aarhus Convention Guidelines	Convention on access to information, public participation in decision making and access to justice in environmental matters (1998)
Guidance to develop procedures	Biosafety Protocol Model law Abramson & Reifschneider, Nov 2004	www.arentfox.com/modelbiosafetyact.pdf
Guidance to develop procedures	CropLife International Reference Guide	The Reference Guide is intended to help governments around the world develop national science-based risk assessment and risk management measures for the intentional release of plants that have been improved using modern biotechnology.
Risk Assessment & Guidance to develop procedures	International Plant Protection Convention (IPPC)	Pest Risk analysis for LMOs

Category	Regional programs	Description
Regional Program	AfricaBio	AfricaBio is a non-political, non-profit
	(www.africabio.com)	biotechnology association for the safe, ethical
		and responsible research, development and
		application of biotechnology and its products.
		The Association also serves as a forum for
		informed dialogue on biotechnological issues
		in Africa.
Regional Program	BIOEARN	The mission of the BIO-EARN Program is to
	(www.bio-earn.org)	build capacity in biotechnology in Ethiopia,
		Kenya, Tanzania and Uganda and promote
		appropriate research and related policies. The
		Program aims to use biotechnology in a
		sustainable manner in order to help improve
		livelihoods, ensure food security and
		safeguard the environment.

Category	Publications	Description
Guidance documents	Joint FAO/WHO Publications	 Safety Aspects of Genetically Modified Foods of Plant Origin (Report of a joint WHO/FAO expert consultation on foods derived from biotechnology) Joint WHO/FAO activities on risk assessment of microbiological hazards in foods
Guidance documents	ISNAR publication	 A Framework for Biosafety Implementation (ISNAR, briefing paper No. 47) examples of country-level publications: Analysis of the Biosafety System for Biotechnology in Kenya: Application of a Conceptual Framework (ISNAR, Country report No. 65) Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina (ISNAR, country report No. 63)
Guidance documents	Explanatory guide to the Cartagena Protocol (IUCN) Mackenzie, R. et al /2004	
General Information	Agbios Publications (www.agbios.com)	AGBIOS is a Canadian company dedicated to providing public policy, regulatory, and risk assessment expertise for products of biotechnology.

Z.Teqja	Albania
E. Kongjika	Albania
A. Aissa	Algeria
C. Rebzani-Zahaf	Algeria
M.S. Belaustequi	Argentina
M. Burachik	Argentina
C. Vicien	Argentina
S. Wells-Moultrie	Bahamas
K. Richardson	Bahamas
K.C. Nyedrup	Bhutan
J.C. Medaglia	Costa Rica
K.M. Ordenana	Costa Rica
M. Valdez	Costa Rica
I. Rojas	Costa Rica
M. Montero Alex	Costa Rica
Z.Zgaga	Croatia
M.Bosni	Croatia
M. Cepo	Croatia
M. Jost	Croatia
D. Curic	Croatia
B. Vrkljan	Croatia
D. Simlesa	Croatia
S. Rakousky	Czech
J. Marsalek	Czech
T. Marik	Czech
M. Roudna	Czech
J. Ampofo	Ghana
A. Owusu-Biney	Ghana
J.A. Dziwornu	Ghana
L.K. Alorvor	Ghana
E.C. Quaye	Ghana
E.A. Okoree	Ghana
E. Suglo	Ghana
D. Brandful	Ghana
G. Issahaque	Ghana
P. Sekyi	Ghana
D.S.D. Sastrapradja	Indonesia
E. J. Sattout	Lebanon
D. Jamali	Lebanon
R. Baalbaki	Lebanon
B.T. Donnie	Liberia
?	Liberia
J.T. Voker	Liberia

Appendix D: List of Participants

G. Jodinskas	Lithuania
D. Lygis	Lithuania
O. Ivascenko	Lithuania
B. Rakouth	Madagascar
A. Chantal	Madagascar
N. Lanzon	Malta
A. Baldacchino	Malta
D. Stevens	Malta
V. Farrugia	Malta
A. Dascaliuc	Moldova
I. Trombitsky	Moldova
T. Siniaeva	Moldova
V. Gherciu	Moldova
V. Crismaru	Moldova
C. Beatriz	Mozambique
M. dos Anjos	Mozambique
J. Massingue	Mozambique
N. Bassey	Nigeria
G. Ogbadu	Nigeria
M. Dore	Nigeria
V. Kula	Papnegui
D. Henao	Papnegui
A. Mendoza-Garces	Philippine
B. Peczon	Philippine
E. Badea	Romania
C. Sin	Romania
A. Popescu	Romania
M. Falca	Romania
M.A. Antofie	Romania
R. Joseph	Rwanda
A. Mutesa	Rwanda
E. Ndamyimana	Rwanda
K. Misa	Samoa
P. Matalavea	Samoa
R.C. Voigt	Samoa
S.M. Zuke	Swaziland
A. Dlamini	Swaziland
S. Maphalala	Swaziland
N. Tatyana	Tatjikis
A. Idrisova	Tatjikis
S. Neimatullo	Tatjikis
M. John	Trin & To
K.Balramsingh	Trin & To
L. Superville	Trin & To
B.S. Ali	Trin & To
V. Eser	Turkey
H. Kilin	Turkey
S. Seval	Turkey
5. 55Val	Ιμικύ

M. Kizilt	Turkey
I.H. Esin	Turkey
C. Miche	Venezuela
J. Ramos	Venezuela
C. Molina	Venezuela
S.F. Acosta	Venezuela
A. Sangronis	Venezuela
L.M. Carrero G.	Venezuela
L. Haynes	Venezuela
N. Van Tai	Vietnam
Le Minh Sat	Vietnam