

Annex 3: CREA Space Workshop

BEETLE

Biological and Ecological Evaluation
towards Long-Term Effects



Long-term effects of genetically modified (GM) crops on health, biodiversity and the environment: prioritisation of potential risks and delimitation of uncertainties

Reference: ENV.B.3/ETU/2007/0007



Contributors (in alphabetical order)

**Detlef Bartsch
Hans-Jörg Buhk
Christoph Ewen
Achim Gathmann
Christiane Koziolk
Anke Meisner
Gerd Neemann
Ulrich Rees
Elisabeth Schulte
Kristina Sinemus
Anja Vaasen**

Table of Contents

1.	Introduction	4
2.	Material & Methods	5
3.	Results	7
3.1.	Impacts in relation to cultivation and management of HT crops (Station 1)	7
3.2.	Impacts on Soil (Station 2)	9
3.3.	Stacked vs. Single Events (Station 3)	11
3.4.	Regional Aspects (Station 4)	12
3.5.	Points not addressed (Station 5)	15
3.6.	Final prioritization of methods and ways to delimit uncertainties	16
3.7.	Evaluation of the usefulness of the 'CREA Space' method	19
4.	Summary	22

1. Introduction

Within the BEETLE project the CREA Space Workshop (CSW) was dedicated to elaborating ways and methods for delimiting uncertainties arising from potential long-term effects of GMOs on the environment.

The CSW was the penultimate step in a multi-stage process for identifying potential effects of GMOs on the environment and the delimitation of remaining areas of scientific uncertainty. In preceding steps of the BEETLE project (see literature review and the online survey 'environment') processes causing adverse long-term effects of GMOs and several areas of scientific uncertainty were identified. These areas have been the starting points to the CREA Space Workshop in order to elaborate adequate methods and ways to get clarity about substantial adverse impacts.

Four topics had been previously selected for further discussion in the CREA Space Workshop.

Table 1: Topics for the CREA Space Workshop February 13, 2008, focussed on environmental aspects.

(i) potential impacts likely in relation to cultivation and management (in particular of HT crops)
(ii) potential impacts on soil
(iii) potential impacts caused by stacked versus single events
(iv) potential impacts caused by regional aspects

People from different stakeholder groups were invited to participate in the workshop and specific attention was drawn to the scientific expertise of the participants. All workshop participants were already involved in the project subjects as respondents to the preceding online survey. During the CSW the participants had the following tasks:

- to specify areas of still considerable scientific uncertainty,
- to work out what is needed to map the way forward to increase clarity in these areas, and
- to identify topics for future research.

2. Material & Methods

CREA Space is a method for the development of creative potential in teams and larger groups. This tool is methodologically derived from organisational development procedures and mainly serves to provide a framework for the achievement of sociological whole-group arguments and findings (El Hachimi & Stephan 2000)¹. The methodology can also be used outside of organisational development procedures and is most favourable when aimed at gaining a structured picture of a group's opinions and ideas out of a broad variety of political, professional or regional provenance.

These procedures offer the crucial advantage of gaining a manageable outcome in a relatively short period of time (El Hachimi & v.Schlipp 2003)². The aim of the CREA Space method within this project was:

- to unearth the creative potential of a group,
- to conduct a structured discussion within a group,
- to benefit from sharing knowledge and experience, and
- to amplify information in a transparent manner.

In the context of the BEETLE project, the CREA Space methodology was used to effectively check and validate issues derived from first findings of the literature review and the online survey in order to find out whether there were additional items, and whether there was clarity and consensus within the group. The workshop was structured in four parts: (i) a warming up with all participants, (ii) an introduction for the participants by presentation of the preliminary results from literature review and the online survey, (iii) the CREA Space 'in motion' at five stations (flipcharts) and (iv) the prioritization and final presentation of the most adequate ways and methods in the plenum.

27 experts³ participated at the CREA Space Workshop in Berlin. The majority of the experts were scientists from research institutions and universities. In addition representatives of three important stakeholder groups were invited: (i) companies developing GM plant applications

¹ El Hachimi M. & Stephan L. (2000) SpielArt – Kinästhetik und Konstruktion. Konzepte systemischer Supervision und Organisationsberatung. Instrumente für Trainer und Berater; Vandenhoeck & Ruprecht.

² El Hachimi M. & v. Schlippe A. (2003) Crea-Space – eine Methode zur Entwicklung des kreativen Potenzials in Teams und größeren Gruppen, OSC Jahresverzeichnis, 10: 137-144.

³ without members of the Beetle team

at the EU level, (ii) non-governmental organisations (NGOs) contributing scientifically to the GMO debate, and (iii) regulators, working in governmental bodies. The selection criteria for the experts were based on four major criteria: (a) known expertise substantiated by relevant scientific publications cited in the ICGEB database, (b) added value for the requested fields in the BEETLE project (due to the area of specific competence), (c) known representativeness for important stakeholder groups (for details see A2-8 and A2 Table 4.), and participation in the Online Survey Environment. For further discussions in the CSW it was essential that experts were familiar with the content of the Online Survey. The group of participants was completed by three members of the Peer Review Committee and one representative of DG Environment.

With the aim of obtaining adequate and representative participation, several reminders to attend to the CSW were posted. Representatives of all stakeholder groups provided feedback by participating in the CSW with the exception of NGOs. This missing engagement was attributed to time constraints in some cases.

Table 2: Participants of the CREA Space Workshop. Presented are number of invited and participating experts for each stakeholder group and the relative proportion.

Stakeholder	Number of participants		Percentage	
	invited	participating	invited	participating
Research institution	27	15	52 %	55 %
Regulation	8	4	15 %	15 %
Industry	5	4	9 %	15 %
NGO	5	-	9 %	-
Others ⁴	8	4	15 %	15 %
Sum	53	27	100 %	100%

⁴ In addition, members of the Peer Review Committee and DG Environment were invited to participate in the CSW.

The participants were divided into five randomized groups. Each group rotated through five working stations (flipcharts). Four working stations addressed the topics in Table 1. At each of these four stations several processes causing adverse effects were listed and one main question was asked: *In case you need to jointly explore this area what do you need to map the way forward?*

A fifth station was installed without a specified theme, where the participants had the opportunity to discuss issues which were not addressed in the other four stations.

At each working station, a moderator was present who introduced the topic by presenting the conclusions of the previous group. This served as the basis for the following discussion round. After 15 minutes each group switched to the next working station. At the end, each group had rotated through all stations.

The discussed methods and ideas were arranged and summarized by the moderators who were supported by members of the peer review committee (see section 2.3.3 of the BEETLE report document). Afterwards the participants were asked to prioritize for each “field of uncertainty” the most adequate way forward to clarify remaining uncertainties. This was done by labelling with sticker dots. The summary of this prioritization was presented in the plenum to the participants.

3. Results

3.1. Impacts in relation to cultivation and management of HT crops (Station 1)

Discussion at this station focussed initially on the following long-term processes derived from the Literature Review and Online Survey: (i) ‘changes in biodiversity’, (ii) ‘changes in crop rotation’, (iii) ‘changes in fertilizer use’ (iv) ‘changes in landscape structure’ and (v) ‘changes in pesticide use’. During discussion the processes ‘changes in water use’, ‘changes in tillage’ and ‘how coexistence measures influence cultivation and management’ were added by the experts. Most of the experts were of the opinion that the listed processes are linked. Consequently it was stated that separate views of the processes are not helpful. Altogether five ways (approaches) to increase clarity were discussed.

The first way was to meet the need for more data, in particular for more European data and better coverage of European regions. There was controversy regarding whether these needs should be met pre or post marketing. A farm-scale evaluation before marketing might be useful to assess the effects of processes (i)-(v) above, but might not always be practicable. The second way was to use modelling, in particular modelling of different scenarios of

cropping systems. Points for mapping the way forward were the modelling parameters which should be used as well as the performance time of such modelling (pre or post marketing). Starting points might be existing geographic information systems.

The third way related to the use of 'baselines and indicators'. The need for baseline data for different European regions was proposed by some experts, but others felt that it is impossible to define a baseline in highly dynamic systems such as agricultural environments. In general, the need for indicators was emphasized. Such indicators should preferably focus on functional groups or ecosystem functions. Additional analyses at the socio-economic level could be helpful to estimate the demand of the market and the reaction of stakeholders (e.g. farmers to potential economic benefits).

Finally, two other approaches for increasing clarity were discussed: the definition of general agricultural protection goals and the need for good agricultural practice rules including for the cultivation of GM plants. Agricultural protection goals should be defined and best measures should be chosen to achieve them. A reasonable tool might be qualified independent extension services. Good agricultural practice could include adopting recommended monitoring approaches and following guidance to farmers on decision-making in the context of GM plant cultivation.

Figure 1: Documentation of the flip chart “Cultivation management”



3.2. Impacts on Soil (Station 2)

Starting points for the discussion were the following long-term processes derived from the literature and online survey: (i) changes in nutrient cycling, (ii) changes in soil fertility, and (iii) changes in NTO effects. Some experts recommended summarizing (i) & (ii) into ‘changes in soil function’.

The contribution of the five expert groups concentrated on three major fields:

- Cultivation and management as the most important baseline and background activity that determines the major impact on soils
- Suitability of environmental risk assessment and monitoring
- Selection of appropriate indicators in relation to issue (i) & (ii), ‘changes in soil function’.

Figure 2: Documentation of the flip chart “Impacts on soil”, part 1 and 2



Concerning issue (i) most experts thought it important to define ‘soil functionality’ as the major focal point to address long-term effects. There was considerable disagreement on the exact definition of Environmental Risk Assessment (ERA) and the implications for Post Market Environmental Monitoring (PMEM). The participants stressed the importance of defining the endpoints (e.g. protection goals) for the ERA and PMEM before selecting appropriate indicator species or functionality parameters to ensure good selection.

The measurement of species and/or parameters needs to follow a clear timeline and a local specification for appropriate documentation. There was also a controversy about the timing of investigations into long-term effects: before market approval (within the ERA) or after market approval (within PMEM). Specific uncertainty was expressed regarding the generally low level of available information on ‘soil’ impacts. The way forward was finally mapped with regard to the question of where monitoring of long-term effects should take place. Here, the need for data e.g. from large scale cultivation was particularly emphasized.

3.3. Stacked vs. Single Events (Station 3)

Starting points for the discussion were the following long-term effect categories derived from the Literature Review and Online Survey: (i) ecological function, (ii) abiotic environment, (iii) Bt resistance development, (iv) cultivation & management, (v) intended vs. unintended stacks, (vi) NTO effects, and (vii) persistence & invasiveness. The discussions within the five groups of experts concentrated on four of the categories in the following order:

- intended vs. unintended stacks
- NTO effects,
- cultivation and management, and
- persistence and invasiveness.

The points raised in the category “NTO effects” were mainly driven by the examples of Bt maize (or other Bt plants), whereas the points raised in the category “persistence and invasiveness” were focused on HT plants. Viewed more generally, these points can also be considered under “intended vs. unintended” stacks.

As a way forward the following major recommendations were concluded from the discussions:

1. The knowledge of interactions incl. synergy of stacked events (intended and unintended) is limited. Therefore, more experience has to be acquired by practice (cultivation of single and stacked events) and research regarding
 - a) Population genetics,
 - b) Risk potential of stacked events,
 - c) Gene regulation (interaction of stacked events);
2. Possible synergistic effects of stacked events should be tested (intended stacks) at the level of gene products (e. g. mixture of proteins) or using appropriate plant tissue derived from a plant with a stacked event;
3. When doing a risk assessment of a GM plant to be placed on the market, the GM plants already on the market should be taken into account regarding the possibility of unintended stacks.

The groups also discussed possible long-term effects of stacked events that may arise due to the cumulative effects of gene products (e. g. Bt protein), as well as limiting the use of intended stacked events and the appearance of unintended stacked events, e. g. in order to ensure future weed control by modern herbicides (separation of HT genes by regions of gene pools). Future GM plants will probably have mostly stacked events.

Figure 3: Documentation of the flip chart “Stacked vs. Single events”.



3.4. Regional Aspects (Station 4)

The discussion focussed initially on the following long-term effect categories derived from the Literature Review and Online Survey: (i) abiotic environment, (ii) effects on NTO's, (iii) cultivation & management, (iv) ecological functions, (v) persistence and invasiveness, and (vi) resistance development. Some experts recommended adding the category "biodiversity".

General remarks were made regarding the importance of regional aspects for the ERA of further GM crops and the majority of the experts supported the consideration of regional aspects. However, these aspects represent a complex field of uncertainty with a high degree of variability that needs a case by case (crop/trait specific) approach. There was a range of opinions regarding whether pre-market ERA or PMEM is better suited to target regional long-term effects. The recommended ways forward varied from:

1. Design of regionally specific field trials as tools for covering long-term aspects before approval, to
2. General surveillance after approval for cultivation as the only realistic tool for identifying regional aspects in a case by case way, to
3. Identifying “worst case” regions for both pre- and post marketing studies to reduce the effort for regional ERA and monitoring

In addition, the experts supporting way 1 mentioned the need for specific approaches to identify agro-ecological regions and recommended standardized procedures. The experts supporting way 2 stated that no pre-market regionally dependent risk assessments should be necessary since data from experience with at least maize and soybean should allow extrapolation. Any potential regional effects could be accounted for by monitoring. “worst case” regions (way 3), these to be defined as regions where the likelihood of adverse environmental effects is judged to be high.

For detecting regionally differing Bt effects on NTOs many experts recommended using functional insect groups representative of specific EU regions. The identification of typical soil insect guilds could help to cover ecological functions that vary from region to region.

Monitoring the presence and phenology of wild relatives of GM crops is a way to address regional differences in persistence and invasiveness. Case-specific monitoring of resistance development in target insects will also need regional monitoring tools. Regionalization of biodiversity monitoring is another key aspect, whilst the range of receiving environments needs to be sufficiently covered.

Figure 4: Documentation of the flip chart "Regional aspects", part 1 and 2



3.5. Points not addressed (Station 5)

Starting points for the discussion were the individual views of experts which had not already been addressed in the workshop. The discussion input concentrated on the following major fields (from highest priority to lowest priority):

1. Benefits (economic/environment/health) which have not been addressed in the whole project by considering potential long-term effects of GMOs.
2. Definition of “adverse”: A clear definition of “adverse” in the context of biodiversity and environment was missing. Adverse effects of conventional crops were not considered in the project. The “vulnerability” of (eco-) systems has to be discussed in the context of adverse.
3. Role of society: Society seems to be divided into parallel societies (*good guys* [GMO is bad] and *bad guys* [GMO is good]). The GMO debate has to be accompanied by risk communication. Who are the “priests” in our society telling us the truth?

The following issues were discussed with interfaces to other discussion areas:

Baseline: The participants felt that a consensus about the methodology for defining baselines is missing. There is more than one baseline and no general baseline, and the dynamic of agriculture has to be kept in mind. For monitoring purposes a baseline is essential, whilst in studies contributing to the ERA there is automatically comparison between the GM plant and controls.

Modelling: Modelling of long-term effects is almost not possible yet and the interpretation of research models is limited.

The following issues were discussed but had a minor priority for the participants:

Nice to know/need to know: Do we have already enough data to assess long-term effects? Both, cultivation and field trials are necessary (“Without cultivation there could be no knowledge” and “No experience without field trials”). Are new data always necessary?

Success stories learned: The case-by-case approach was an important methodological step to assess long-term effects of GM crops. Important examples for creating clarity in the context of potential long-term effects were the results concerning cross pollination/out-crossing.

Figure 5: Documentation of the flip chart “Points not addressed”.



3.6. Final prioritization of methods and ways to delimit uncertainties

The aim of the “final exploration round” of the CSW was to prioritize the methods for increasing clarity in areas of uncertainty in relation to potential long-term effects of GMOs. To do this, the most adequate methods elaborated on in the first “round” of the workshop at each of the five working stations were prioritized using sticker dots by each participant. The summary of this prioritization was presented to the participants in a chart.

(1) Cultivation & Management

The approach “baselines/reference points” was ranked with the highest priority. Most experts were of the opinion that baselines or reference points are essential and should be a prerequisite to assess potential long-term effects.

- Baselines/reference points (12 sticker dots)
- Modelling (9 sticker dots)

- Agricultural protection goals (8 sticker dots)
- Good agricultural practice (6 sticker dots)
- Farm-scale evaluation (4 sticker dots)

(2) Impacts on soil

Soil functionality was identified as a major focus point for addressing potential long-term effects on ecosystems. Ahead of defining soil indicator species or parameters of soil functionality the important endpoints, e.g. protection goals need to be characterised.

- Soil functionality (9 sticker dots)
- Indicators (5 sticker dots)
- Data collection (1 sticker dot)

(3) Stacked vs. single events

Test of synergistic effects between proteins and within the whole plant for stacked events were prioritized as the most important way to get more clarity in the case of potential long-term effects of such GMOs.

- Test of synergistic effects (10 sticker dots)
- Research (5 sticker dots)
- Include unintended stacks in single events ERA (2 sticker dots)

(4) Regional aspects

The consideration of regional aspects in the assessment of potential long-term effects was supported by a majority of the workshop experts. However, opinions on whether pre-market ERA or PMEM is better suited to identify regional long-term effects ranged widely.

- Search for agro-ecological regions (9 sticker dots)
- Monitoring (3 sticker dots)

(5) Points not addressed?

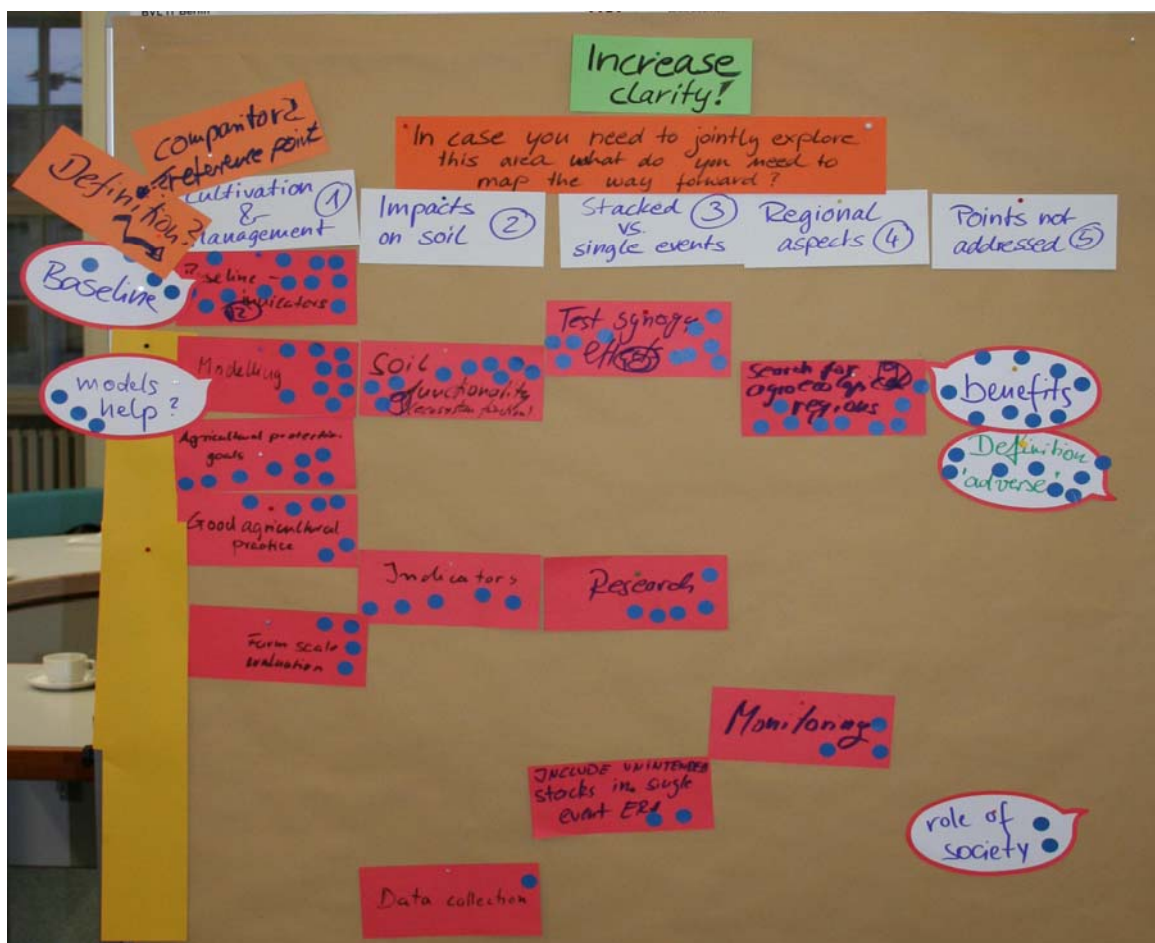
The prioritization by sticker dots showed that most of the participants stressed that potential benefits (economic/environment/health) of GMOs have been forgotten in the project concept when considering potential long-term effects of GMOs. In addition, general remarks were made that the “adversity” of long-term effects in the context of biodiversity and environment has to be compared with those of conventional crops.

- Benefits (economic/environment/health) (9 sticker dots)
- Definition of "adverse" (8 sticker dots)
- Role of society (2 sticker dots)

Interfaces to other discussion areas:

- Baseline (4 sticker dots)
- Modelling (3 sticker dots)

Figure 6: Documentation of the flip chart "Prioritization of ways and methods".



3.7. Evaluation of the usefulness of the 'CREA Space' method

The CSW was the penultimate step in a multi-stage process for identifying potential effects of GMOs on the environment and delimiting the remaining areas of scientific uncertainty. Within the BEETLE project the CREA Space Workshop was dedicated to elaborating ways of delimiting uncertainties arising from potential long-term effects of GMOs on the environment.

Due to the relatively short period of time available within a one-day workshop, a special method was chosen that made it possible to (i) unearth the creative potential of the participants, (ii) conduct a structured discussion within a heterogeneous group, (iii) benefit from sharing knowledge and experience, and (iv) amplify information in a transparent manner.

After the workshop the participants were asked to give their feedback on the usefulness of the CREA Space method in terms of the project goals. A questionnaire consisting of six questions was sent to the participants (see Table 3). 23 participants answered by filling out the questionnaire. Not all participants answered all the questions. Questions were asked on the (i) pre-selection of areas and central questions of the workshop (ii) group selection process (iii) communication process itself (iv) discussion method at the work stations (v) quality of moderators (vi) adequacy of the method for prioritising long-term effects? The evaluation was based on a scale of 1-4 (1= liked it; 4 = didn't like it).

Most of the participants (85 to 95 %) answered that the CREA Space method used was adequate for achieving the workshop goals. The participants thought the method was particularly well suited to the group selection process, the communication process itself, the discussion method at the stations and the adaptability to the process of prioritisation. Some minor reservations were noted with regard to the quality of the moderators (70 % acceptance) and the transparency of the presentation of the selected issues and central questions used as starting points for the CSW (71 % acceptance).

Overall, in view of the complex approach and very limited period of time, the CREA Space method fulfilled the expected tasks by initiating creativity, facilitating target-oriented discussions and by both amplifying and condensing knowledge in a transparent manner.

Table 3: Evaluation of the usefulness of the 'CREA Space' method on a scale of 1 (liked it) to 4 (didn't like it).

Questions	Number of answers on a scale 1 to 4				Additional comments
	Liked it (1)	(2)	(3)	Didn't like it (4)	
(i) Pre-selection of areas and central questions of the workshop	6	9	4	2	i.e. The combination of a literature study together with a questionnaire is to me a good approach for prioritising risks and identifying the areas of scientific uncertainty; always difficult to avoid bias in this – but from my experience the areas were about right; no other possibility with such a large and heterogeneous group;
	71 % ⁵		29 % ⁶		
(ii) Group selection process	7	13	1	0	i.e. People from eastern countries could be better represented, suitable, randomized, appropriate for the purpose; the methodology used for the group selection was refreshing and productive;
	95 %		5 %		
(iii) Communication process as such	10	8	2	0	i.e. Creative! More and better communication is possible in this way than in an "ordinary meeting"; refreshingly straightforward, relaxed and easy. I had doubts before the meeting that it could all be done in the time – but it worked; I would have appreciated more time at the stations; from the beginning to the end, the discussion developed in a proper way;
	90%		10 %		

⁵ Percentage of answers 'liked it' (scale (1) and (2) together)

⁶ Percentage of answers 'didn't like it' (scale (3) and (4) together)

Questions	Number of answers on a scale 1 to 4				Additional comments
(iv) Discussion method at the work stations	6	11	3	0	i.e. Maximum input of ideas on the topics at the station in a short time period; I felt 15 minutes was a bit to short. 20 minutes might have been better; it probably, if feasible at all, would be better to mix groups continuously since within the group hierarchical structures were developed within 2 stations that might overshadow some creative thinking;
	85 %		15 %		
(v) Quality of moderators	10	6	6	1	i.e. Enthusiastic people. Such approaches can only be successful with professional expertise, as chosen here; it was not uniform; most of them guided us towards a result without leading with their own views;
	70 %		30 %		
(vi) Is the method adequate for prioritising long- term effects?	Yes 19		No 4		i.e. YES Very efficient, however, redundancy cannot be avoided with such intuitive processes; a second round of the same process (e.g. on a second day) could have been beneficial; I find it a good method for finding a basic consensus. NO I do not really feel qualified to evaluate the prioritization process, so I cannot reply YES. But, it certainly was democratic: I do not like the idea that we have to prioritize. I prefer a holistic view; I think that one day is not enough to reflect upon how to prioritize which potential long-term effects need to be investigated;
	83 %		17 %		

4. Summary

Within the CSW it was possible to gain in a relatively short period of time helpful information on the third and last project goal: the identification of ways and methods to delimit uncertainties in the case of potential long-term effects. In the case of the four workshop issues (i) potential impacts expected in relation to cultivation and management (in particular of HT crops), (ii) potential impacts on soil, (iii) potential impacts caused by stacked versus single events, and (iv) potential impacts caused by regional aspects, a set of methods and ways was identified and prioritized.

In the case of potential impacts in relation to cultivation and management of HT crops modelling was selected as a most helpful tool to address long-term effects. An experimental approach like farm-scale-evaluations was considered to be useful to assess some impacts such as changes in pesticide use, but the discussion reflected controversy regarding whether these investigations should be performed pre or post marketing. According to the participants, baselines and reference points, and defined agricultural protection goals, are essential prerequisites for the assessment of long-term effects of GMOs in comparison to conventional crops. In addition, guidelines for “good agricultural practice” were prioritized as a useful tool to avoid potential adverse effects of GMOs.

In the case of potential adverse impacts of GMOs on soil, experts prioritized the soil functionality especially the soil integrity as the most relevant monitoring subject. The need to develop adequate indicators was emphasized. Such indicators should preferably focus on functional groups or ecosystem functions related to protection goals.

In the case of potential impacts caused by stacked events, tests of synergies between different proteins (from intended and unintended stacks) were highlighted as the most important way to address potential adverse effects. Possible synergistic effects of proteins from intended and unintended stacks should be considered during ERA.

The majority of the workshop experts regarded “regional aspects” as important. However, there was again controversy regarding whether pre-market Environmental Risk Assessment or Post Market Environmental Monitoring is better suited to identifying regional long-term effects. Research on identifying agro-ecological regions was prioritized.

The participants had the opportunity to add points to the discussion which were not addressed under the selected subjects and processes. The participants noted that

economic/environmental and health benefits of GMOs should be considered in the assessment of potential long-term effects as well. In addition the participants noted that the meaning of “adverse” in the context of evolving and dynamic ecosystems has still to be discussed. In addition a clear definition of “adverse” in relation to the environment and biodiversity is still missing.

Overall, the CREA Space Workshop fulfilled the expected tasks: The areas of scientific uncertainty were specified, some ways forward were more clearly mapped, and topics for future research were identified.