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**C3 - Management of scientific committees II; scientific co-operation and networks**

**SCIENTIFIC COMMITTEE ON PLANTS**

**SCP/GMO-SEED-CONT/002-FINAL  
13 March 2001**

**Opinion of the Scientific Committee on Plants concerning the  
adventitious presence of GM seeds in conventional seeds.**

(Opinion adopted by the Committee on 7 March 2001)

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## EXECUTIVE SUMMARY

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### **OPINION OF THE COMMITTEE ON QUESTION 1:**

#### **Question 1:**

As a threshold of 1% was established for the adventitious presence of (authorised) genetically modified material in food and food ingredients in respect of labelling under Commission Regulation N° 49/2000, the Commission is considering to propose the following thresholds for the adventitious presence of GM seeds covered by an authorisation under part C of Directive 90/220/EEC:

- 0.3% in the case of cross-pollinating crops,
- 0.5% in the case of self-pollinating crops and vegetatively propagated crops.

Does the Committee find any error or difficulty in this reasoning?

If so, what other threshold(s) would be justified?

#### **Opinion of the Committee:**

The SCP is of the opinion that with the scientific knowledge currently available the thresholds of 0.3% for cross-pollinated crops and 0.5% for self-pollinated and vegetatively propagated crops will only be achieved under ideal seed production conditions. There will be situations where achieving these thresholds will be problematic e.g. varietal association cultivars, production of hybrid seed. Achieving the 0.3 % and the 0.5 % thresholds will become increasingly difficult as GM crop production increases in Europe. In due course the 1% threshold set by the Commission may have to be revised. The SCP is also firmly of the opinion that, in addition to the thresholds of 0.3 % or 0.5 % defined for seed used to produce the crop, farm management and commercial production practices will influence the ability to achieve a 1% threshold in food and food ingredients. The relevant contribution of potential GM adventitious presence at various stages of farm production will vary with the crop. Cross pollinated crops propagated from seed but cultivated vegetatively (e.g. beet) could be placed in the 0.5% category.

### **OPINION OF THE COMMITTEE ON QUESTION 2:**

#### **Question 2:**

The Commission is considering to propose that no GM plants of the same species or of a closely related species have been grown in the field used for the production of seed of a non-GM variety in the previous:

- five years in the case of small seeded *Leguminosae* (fodder plants), oil and fibre plants,
- two years in the case of plants other than those under the previous point.

Does the Committee find any error or difficulty in our reasoning?

If so, what other time spans would be justified?

**Opinion of the Committee:**

The Committee, after examining the available information, finds there is difficulty in the reasoning for the following two main reasons:

- the grouping in the Commission proposal is too general to address the probability of gene flow from volunteer plants in some species and varieties;
- there is a lack of clear scientific data on persistence times for some species and therefore reliance is placed on anecdotal evidence and seed production experience.

It is recommended that previous cropping requirements be addressed according to current knowledge on seed longevity genus by genus. There appear to be three broad groupings requiring different break of rotation period:

1. short persistence (1 year; e.g. soya, maize and field peas);
2. medium persistence (2-3 years; e.g. wheat, field beans, barley);
3. long persistence (5 years; e.g. oilseed rape, potato, beet, grasses and herbage legumes).

**OPINION OF THE COMMITTEE ON QUESTION 3**

**Question 3**

As GM seeds not covered by an authorisation under part C of Directive 90/220/EEC should not be present in conventional plant varieties and if it is justified that GM seeds covered by an authorisation under part C of the said Directive should not exceed a threshold of 0.3% in the case of cross-pollinating species, the Commission is considering to propose:

- the doubling of the minimum distances currently applicable under the existing EU seed legislation for the isolation of the crop for the production of seed of cross-pollinating species in respect of neighbouring sources of pollen of GM plants which may result in undesirable foreign pollination.

Does the Committee find any error or difficulty in this reasoning?

If so, what other minimum distances would be justified?

**Opinion of the Committee:**

The SCP is of the opinion that with the scientific knowledge currently available the 0.3% standard for adventitious admixture in fully fertile swede (*Brassica napus*) oilseed rape can be achieved with currently implemented isolation distances. It is likely that current isolation distances in maize are adequate if other measures to reduce outcrossing (e.g. the use of physical or pollen barriers) are implemented. There is insufficient information to comment on isolation distances required for hybrid oilseed rape, turnip rape (*B. rapa*), and Beta species. However for hybrid oilseed rape evidence suggests that doubling the isolation distance would not be sufficient. The SCP is also of the opinion that, in addition to isolation distances, a range of other measures currently used in seed crop management practices (e.g. the use of physical and pollination barriers) will influence the ability to

achieve a 0.3% threshold in seed production. The importance of the various practices will be crop/species specific and will also be influenced by local environmental and agricultural circumstances.

#### **OPINION OF THE COMMITTEE ON THE SPECIFIC ISSUE RAISED**

##### **Issue:**

The Commission has indicated that GM seed not covered by an authorisation under part C of Council Directive 90/220/EEC should not be present in a commercial seed lot (zero tolerance). The Committee would like to comment on this issue.

##### **Opinion of the Committee:**

The Committee is of the opinion that a zero level of unauthorised GM seed is unobtainable in practice. A zero level would have severe consequences for part B GM field releases, for biosafety research and for evaluation of new GM plant varieties.

When establishing levels of tolerance, a major constraint is the limit of analytical sensitivity of available detection methods, which is currently at about 0.1% for routine analysis.

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## 1. TITLE

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### OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS CONCERNING THE ADVENTITIOUS PRESENCE OF GM SEEDS IN CONVENTIONAL SEEDS

(Opinion adopted by the Committee on 7 March 2001)

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## 2. TERMS OF REFERENCE

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The Committee is requested to provide answers to the following questions of the Commission regarding the adventitious presence of genetically modified (GM) seeds in lots of seeds for sowing of conventional plant varieties to be marketed in the EU.

1. As a threshold of 1% was established for the adventitious presence of (authorised) genetically modified material in food and food ingredients in respect of labelling under Commission Regulation N° 49/2000<sup>1</sup>, the Commission is considering to propose the following thresholds for the adventitious presence of GM seeds covered by an authorisation under part C of Directive 90/220/EEC<sup>2</sup>:

- 0.3% in the case of cross-pollinating crops,
- 0.5% in the case of self-pollinating crops and vegetatively propagated crops.

Does the Committee find any error or difficulty in our reasoning?

If so, what other threshold(s) would be justified?

2. The Commission is considering to propose that no GM plants of the same species or of a closely related species have been grown in the field used for the production of seed of a non-GM variety in the previous.

- five years in the case of small seeded *Leguminosae* (fodder plants), oil and fibre plants,
- two years in the case of plants other than those under the previous point.

Does the Committee find any error or difficulty in our reasoning?

If so, what other time spans would be justified?

3. As GM seeds not covered by an authorisation under part C of Directive 90/220/EEC should not be present in conventional plant varieties and if it is justified that GM seeds covered by an authorisation under part C of the said Directive should not exceed a threshold of 0.3% in the case of cross-pollinating species, the Commission is considering to propose:

- the doubling of the minimum distances currently applicable under the existing EU seed legislation<sup>3</sup> for the isolation of the crop for the production of seed of

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<sup>1</sup> EC OJ N° L 6 of 11. 1.2000, p. 13.

<sup>2</sup> EC OJ N° L 117 of 8. 5.1990, p. 15.

<sup>3</sup> According to the existing EU seed legislation, the crops for the production of seed of cross-pollinating species shall conform to defined standards as regards the distances from any neighbouring sources of pollen, which may result in undesirable foreign pollination. The current minimum distances vary according

cross-pollinating species in respect of neighbouring sources of pollen of GM plants which may result in undesirable foreign pollination.

Does the Committee find any error or difficulty in our reasoning?

If so, what other minimum distances would be justified?

In addition, the Committee identified a specific issue of concern, on which comments are provided in section 4.4 of the Opinion.

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### **3. BACKGROUND**

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The Commission White Paper on Food Safety, in position Number 77 of the Action Plan in the Annex thereto, requires amendments to be made to the Annexes of the current Directives on the marketing of seeds (six Council Directives<sup>4</sup>) in order to lay down:

- the growing conditions and other requirements necessary to ensure purity in seed lots of conventional plant varieties against the adventitious presence of genetically modified seeds;
- the details of the labelling requirement as established by Council Directive 98/95/EC<sup>5</sup> for seeds of genetically modified plant varieties;

The Commission services are preparing a draft Commission Directive aimed at achieving these objectives through the introduction of requirements in four areas:

- a) Genetically modified seeds not covered by an authorisation under part C of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, are not allowed and should therefore not be present in the seed lot.
- b) Genetically modified seeds covered by authorisations under part C of the above-mentioned Directive, should not exceed a specified tolerance threshold in a seed lot of a conventional variety.

This threshold should be consistent with the threshold of 1 % established for the adventitious presence of genetically modified material in food and food ingredients in respect of labelling under Commission Regulation (EC) No 49/2000.

- c) The previous cropping in fields utilised for the crop for the production of seed should not be incompatible (according to the current Community seed legislation) with the production of seed. The field should be sufficiently free from plants which are volunteers from previous cropping in so far as they belong to the same species or a closely related species.
- d) In the case of cross-pollinating seed crops, sufficient isolation is required according to Community seed legislation in respect of any neighbouring sources of pollen,

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to the species (in some cases, also to the type of variety of the seed crop or to the nature of the pollinator) and to the category of seed. For example, in the case of beet: 1000 m for the production of basic seed and from 300 m to 1000 m for the production of certified seed.

<sup>4</sup> I 66/400/EEC, 66/401/EEC;66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC.

<sup>5</sup> EC OJ N° L 25 of 1. 2.1999, p. 1.

which may result in undesirable foreign pollination by events authorised in the Community or not authorised in the Community.

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## **4. OPINION**

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### **Introduction**

The Scientific Committee on Plants stresses that this opinion is based on the current best scientific knowledge. This opinion may need to be revised in the light of new scientific data as it becomes available or to take into account the evolution of relevant technology.

The Committee in this opinion assumes that commercial seed is produced according to the statutory requirements of the Community and Member States so that it meets the required purity standards and that good agricultural practices are implemented by seed producers as well as farmers. Good practices for seed production include measures to minimise admixture and undesirable gene flow throughout crop growth and post harvest handling sometimes over and above the statutory requirements for isolation and segregation.

### **4.1 Question 1**

**As a threshold of 1% was established for the adventitious presence of (authorised) genetically modified material in food and food ingredients in respect of labelling under Commission Regulation N° 49/2000, the Commission is considering to propose the following thresholds for the adventitious presence of GM seeds covered by an authorisation under part C of Directive 90/220/EEC:**

- **0.3% in the case of cross-pollinating crops,**
- **0.5% in the case of self-pollinating crops and vegetatively propagated crops.**

**Does the Committee find any error or difficulty in this reasoning?**

**If so, what other threshold(s) would be justified?**

### **OPINION OF THE COMMITTEE:**

**The SCP is of the opinion that with the scientific knowledge currently available the thresholds of 0.3% for cross-pollinated crops and 0.5% for self-pollinated and vegetatively propagated crops will only be achieved under ideal seed production conditions. There will be situations where achieving these thresholds will be problematic e.g. varietal association cultivars, production of hybrid seed. Achieving the 0.3 % and the 0.5 % thresholds will become increasingly difficult as GM crop production increases in Europe. In due course the 1% threshold set by the Commission may have to be revised. The SCP is also firmly of the opinion that, in addition to the thresholds of 0.3 % or 0.5 % defined for seed used to produce the crop, farm management and commercial production practices will influence the ability to achieve a 1% threshold in food and food ingredients. The relevant contribution of potential GM adventitious presence at various stages of farm production will vary with the crop. Cross pollinated crops propagated from seed but cultivated vegetatively (e.g. beet) could be placed in the 0.5% category.**

## **SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED:**

In Table 1, oilseed rape, maize and sugar beet are used to provide examples of where inclusion of GM seed in the raw material used to produce food and food ingredients may arise, and therefore impact on the target threshold of 1%. The table assumes a 0.3% threshold for the source of oilseed rape and maize seed used and a 0.5% threshold in the case of sugar beet. With self pollinated crops no further possibility of gene transmission through cross pollination with GM varieties would occur, therefore a higher threshold of 0.5% could be accepted in seed used to produce the commercial crop.

**Table 1. Estimated average potential rates of adventitious presence occurring at various stages during on farm production.**

	<b>Oilseed rape (fully fertile)</b>	<b>Maize</b>	<b>Sugar beet</b>
<b>Seed</b>	0.3%	0.3%	0.5%
<b>Drilling</b>	0%	0%	0%
<b>Cultivation</b>	0%	0%	0%
<b>Cross pollination</b>	0.2%	0.2%	0%
<b>Volunteers</b>	0.2%	0%	0.05%
<b>Harvesting</b>	0.01%	0.01%	0.01%
<b>Transport</b>	0.05%	0.01%	0.01%
<b>Storage</b>	0.05%	0.05%	0.1%
<b>% achieved</b>	<b>0.81%</b>	<b>0.57%</b>	<b>0.67%</b>

These figures are mean values and assume good agricultural practice including reasonable attempts to isolate crops and segregate products. The figures are largely derived from the ongoing ESTO study<sup>6</sup> of the co-existence of GM and non-GM crops. The final % achieved is dependent on several variables.

With oilseed rape a problem in attaining the 1% threshold may arise if the influx of external pollen or volunteers are not adequately controlled. The 0.2% value for volunteers represents a scenario where good management practice has been followed, though values can be considerably higher. Simulations with GENESYS suggest that a 1% threshold in harvested seed may be difficult to obtain if field borders are left unmanaged instead of volunteer-free.

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<sup>6</sup> European Science and Technology Observatory network. More in <http://esto.jrc.es/>. The ESTO study is part of a project co-ordinated by the Institute for Prospective Technological Studies (IPTS) of the Joint Research Centre DG and requested by Agriculture DG. Data are unpublished. The final results are expected by July 2001.



In the case of maize, volunteers rarely cause a major problem and control of cross-pollination is more important. In the case of both crop species a threshold of 1% can be achieved with 0.3% GM adventitious presence in seed sown if good management practices are adhered to. However if non-GM crops of oilseed rape and maize are being grown on farms also growing a considerable proportion of GM crops of these species, and neighbouring farms are also growing GM crops, then achieving threshold levels below 1% becomes much more problematic.

In the case of crops where the consumed product is not derived from cross pollination e.g. beet and potatoes, then pollination of the crop by GM pollen has no impact on the GM content of the harvested product. Thus, while these crops may be considered open pollinating, it is proposed that the thresholds for seeds of these crops should be set at 0.5%. However additional measures may be needed in the seed production of these crops to ensure they achieve this 0.5% threshold (see sections 4.2 and 4.3 below)

For vegetative crops, such as potato, volunteers are likely to be the major source of occurrence of transgenes in the materials used in the food chain. Best management practices to avoid groundkeepers should be followed (nature of crops used in the rotation, time-scales of rotation, destruction of volunteers with herbicides). Under winter conditions in some European member states groundkeepers would be destroyed naturally by frost.

### **Segregation:**

Segregation of harvested GM and non-GM materials will be crucial in delivering the percentage thresholds required. With maize, for example, seed is dried using a continuous process and it will be important to ensure adequate cleaning of equipment to prevent seed mixing. Segregation in the harvesting, processing, transport and storage operations is emphasised as important ways to achieve the thresholds required.

### **Varietal Association Cultivars:**

A substantial proportion of the *B. napus* oilseed rape crop is now of a special type termed varietal association cultivars. These cultivars are made up of 80% of a male-sterile line and 20% of a pollinator line in the crop grown by farmers. There are particular difficulties devising alterations to the current Directives on the marketing of seeds to apply to varietal association cultivars of oilseed rape, which can be consistent with the 1% threshold set for the adventitious presence of GM material under Commission Regulation (EC) No 49/2000. These difficulties are due to 3 factors:

- i) a threshold of 0.3% in marketed seed in the case of cross-pollinating crops, if applied to crops of varietal association cultivars, could permit amplification in the subsequent generation through cross-pollination within the field to give GM admixture above the 1% threshold. This arises as, for small amounts of homozygous impurity, an approximately 5-fold amplification can be predicted as a result of the 5-fold reduction in total pollen produced in fields of such crops.
- ii) similarly, after the specified time span since the previous crop of that species, the low frequencies of volunteer plants occurring in seed production fields may permit amplification during the pollination of the seed crop above the 1% threshold.
- iii) the current statutory isolation distance of 300m for this and other types of hybrid is insufficient to meet a threshold of 0.3% due to the enhanced out-crossing to other

fields of the male sterile component of the hybrid system. Current evidence suggests that at least an order of magnitude increase in isolation distance would be required simply to reduce this component of admixture (see section 4.3).

These features of seed production for varietal association cultivars are reflected in the pragmatic figure of 90% purity required for certified seeds for this and other hybrid types of oilseed rape. Together, the three factors given above lead to the conclusion that meeting the requirement for GM admixture in the harvest from a farm crop is not possible without stringent additional measures.

### **Seed production for hybrids:**

A 99.7% purity value for certified seed is a legal requirement for some crops. This corresponding value for oilseed rape hybrids is 90%. Where hybrid seed production is involved stricter regimes must be employed to avoid cross-pollination from volunteers or neighbouring plants. Separation distances may need to be increased further where hybrids containing a high frequency of male sterile seed are involved. Similarly, where varietal associations are grown e.g. for oilseed rape, there is more opportunity for out-crossing (as described above).

Volunteer control will be crucial in crops such as oilseed rape. In a large cropping context problems derived from volunteers will be low if GM crops have not previously been grown on a farm. However, this will change with time and where co-cultivation of GM and non-GM crops occur. Ways forward would include increasing the rotational period (precautionary approach), managing inter-crop cultivation e.g. shallow cultivation to encourage germination of volunteer seed in the seed-bank, and weed control strategies *per se*.

Where machinery and transportation are concerned, operational cleanliness is essential to maintain low rates of mixing. Such practices would normally be followed for the production of certified seed of high purity.

For crops such as sugar beet, which are grown vegetatively, there would be no increase in gene transmission during normal production, but outcrossing during seed production is an important issue. Many beet varieties are hybrids and male sterile females are used in seed production. Separation distances will need to be reviewed to meet seed thresholds of 0.5% GM adventitious presence. Control of weed beet will also be paramount to minimise potential for transgene flow.

## **4.2 Question 2**

**The Commission is considering to propose that no GM plants of the same species or of a closely related species have been grown in the field used for the production of seed of a non-GM variety in the previous:**

- **five years in the case of small seeded *Leguminosae* (fodder plants), oil and fibre plants,**
- **two years in the case of plants other than those under the previous point.**

**Does the Committee find any error or difficulty in our reasoning?**

**If so, what other time spans would be justified?**

### **OPINION OF THE COMMITTEE:**

**The Committee, after examining the available information, finds there is difficulty in the reasoning for the following two main reasons:**

- the grouping in the Commission proposal is too general to address the probability of gene flow from volunteer plants in some species and varieties;**
- there is a lack of clear scientific data on persistence times for some species and therefore reliance is placed on anecdotal evidence and seed production experience.**

**It is recommended that previous cropping requirements be addressed according to current knowledge on seed longevity genus by genus. There appear to be three broad groupings requiring different break of rotation period:**

- 1. short persistence (1 year; e.g. soya, maize and field peas);**
- 2. medium persistence (2-3 years; e.g. wheat, field beans, barley);**
- 3. long persistence (5 years; e.g. oilseed rape, potato, beet, grasses and herbage legumes).**

### **SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED:**

The cropping intervals recommended are based on a target of the frequency of volunteer plants being no more than 0.1% in self-fertile seed crops. This figure is considered both achievable and far enough below the thresholds defined with respect to Question 1 to allow for limited impurities to arise by other means such as cross pollination. The figure of 0.1% GM volunteers also assumes that GM and seed crop plants have the same competitive ability, fecundity and rate of out-crossing.

At the present time, there is no evidence to indicate or to suppose that GM volunteers and conventional varieties differ intrinsically in competitive ability or fecundity in the environment of a seed crop that is a fully fertile. In the case of hybrid seed production fields, however, it is clear that the rate of pollination of the conventional seed crop variety by a male-fertile GM volunteer will be greater than it would be in a fully fertile seed crop. Hence the frequency of GM seed in the harvested seed will be several times higher than the frequency of GM volunteers in the crop. In such circumstances, the frequency of GM volunteers might need to be as much as five times less than the 0.1% recommended in self-fertile crops, and such low volunteer frequencies might be difficult or impossible to achieve.

The recommendations assume the adoption of normal good seed growing practices for the control of volunteers during the crop rotation. This includes, for example, strategies to minimise seed shedding, post-harvest germination of shed seed and elimination of volunteers in succeeding crops within the rotation. Table 1 indicates that, in order not to exceed the threshold of 1% of GM impurity in a commercial yield, the frequency of GM volunteers in the commercial crop will similarly have to remain around 0.1- 0.2%. Therefore the practices for commercial growing of conventional varieties where GM crops are common would have to be as stringent as those for seed crops.

It is stressed that, although the number and viability of shed seeds in soil declines over time, a very small number may persist for long periods, even for species in which the bulk of seed is short lived. This has implications for any threshold set for non-approved GM events since a level of zero volunteers cannot be guaranteed after any time interval.

### **Specific recommendations:**

**Oilseed rape:** Volunteer weeds in oilseed rape provide potentially serious problems but have been subject to much scientific study. Quantities of seed shed at harvest of oilseed crops of *Brassica napus* and *B. rapa* leave a substantial population in the soil seedbank that can persist for many years. The decline in seed numbers over the first two years is steep and more or less exponential, but thereafter a residue persists from which volunteers may arise for up to 10 years, possibly longer. The main factors encouraging persistence include primary (genetic) dormancy (which is variety specific), secondary dormancy and burial of seed. Volunteers can be reduced to below 1 per 1000 plants in a succeeding rape crop (equivalent to 1 plant in a 10m by 10m square) after 5 years by the best practice. This includes post-harvest killing of germinated seed before cultivation and not planting crops (e.g. set-aside, some legumes) in which volunteers can flower and re-seed. In practice, seed producers in some Member States take a more cautious view and do not plant a seed crop until 7 years after a previous oilseed rape crop.

**Potato:** Potato volunteers arise both from vegetative parts of the plant (tubers or whole tubers) left in the ground after harvest or from seed which is shed if plants are allowed to reach reproductive maturity. Most of the tubers decay rapidly but living residues can persist for several years. Seed can persist for more than 10 years. On the condition that very little seed has been shed by previous crops, and that none of the vegetative material has been allowed to increase in mass during the intervening crops, it is reasonable to assume that the target frequencies can be attained after 5 years. However, there are other reasons (e.g. to reduce harmful organisms) why potato seed producers will probably leave an interval longer than 5 years in many instances.

**Beans and peas:** Seed is sometimes shed from both these crops but decays rapidly. Seedbank studies indicate beans (*Vicia*) persist for slightly longer than peas, but with best practice – which includes not allowing volunteers to re-seed in the intervening period – the target frequency can be attained after an interval of two years for beans and one year for peas.

**Maize:** Volunteer maize plants are known not to occur in significant numbers in fields following maize crops. In seed growing regions of France, continuous maize seed production on the same fields is a common practice, with no significant adverse affect on seed quality. That is, even if seed of one variety is grown after a crop of another variety there is very little varietal undesirable presence in the second crop. This is despite the fact that the seed-bearing component of seed crops is male-sterile and susceptible to pollination from male-fertile volunteer plants. Adopting best practice, it is suggested that a requirement of one year free from GM maize is a reasonable safeguard.

**Soya:** Seeds of soya bean have short longevity in soils. It is unusual for soya crops to be grown in succession but seed production experience of short intervals between crops indicates that the incidence of volunteers in such cases is extremely low. Soya is self-fertile and the frequency of genes from volunteers is unlikely to increase due to cross-pollination within seed crops. For this reason, adopting best practice, it is suggested that a requirement of one year free from GM soya is a reasonable safeguard.

**Wheat, barley, oats, rye and triticale:** These cereal seeds are known to survive in soil for several years if buried in dry conditions. However normal seed production practice is to avoid this by encouraging germination of shed seed after harvest. Experience of seed production in the UK is that a 1 year interval is normally sufficient to achieve a 0.3% varietal impurity threshold and that a 2 year break is normally enough to achieve a 0.1% threshold. Seeds of any of these crops can exist as species impurities in seed of any other crop as they are difficult to remove at harvest and in seed processing. However, there are seed purity standards that ensure the level of such impurities should not exceed 0.1%. Seed with more than this level may not be certified, so it is not necessary to address this issue through previous cropping provisions.

Adopting best practice, it is suggested that a requirement of 2 years free from a GM cereal of the same species is a reasonable safeguard.

**Grass and herbage legumes:** Grass seeds are known to survive in soil for several years and will appear in succeeding arable crops in a rotation. Current seed production practice is to require a 4-6 year interval between grass seed crops of the same species. During this time some re-seeding by volunteers can be expected but this will decline if successive crops are appropriately managed. Herbage legumes, e.g. clover, have high rates of inherent dormancy and survive in the soil for several years, although reseeding in arable crops is unlikely. It is suggested that a requirement of 5 years free from GM crops of the same species is a reasonable safeguard.

**Vegetables:** There is too wide a range of vegetable genera and species to cover here. Appropriate previous cropping intervals can be inferred from the principles established above, e.g. 5 years for Brassica spp., 1-2 years for peas and beans.

### 4.3 Question 3

**As GM seeds not covered by an authorisation under part C of Directive 90/220/EEC should not be present in conventional plant varieties and if it is justified that GM seeds covered by an authorisation under part C of the said Directive should not exceed a threshold of 0.3% in the case of cross-pollinating species, the Commission is considering to propose:**

- **the doubling of the minimum distances currently applicable under the existing EU seed legislation for the isolation of the crop for the production of seed of cross-pollinating species in respect of neighbouring sources of pollen of GM plants which may result in undesirable foreign pollination.**

**Does the Committee find any error or difficulty in this reasoning?**

**If so, what other minimum distances would be justified?**

#### **OPINION OF THE COMMITTEE:**

**The SCP is of the opinion that with the scientific knowledge currently available the 0.3% standard for adventitious admixture in fully fertile swede (*Brassica napus*) oilseed rape can be achieved with currently implemented isolation distances. It is likely that current isolation distances in maize are adequate if other measures to reduce outcrossing (e.g. the use of physical or pollen barriers) are implemented. There is insufficient information to comment on isolation distances required for hybrid oilseed rape, turnip rape (*B. rapa*), and Beta species. However for hybrid**

**oilseed rape evidence suggests that doubling the isolation distance would not be sufficient. The SCP is also of the opinion that, in addition to isolation distances, a range of other measures currently used in seed crop management practices (e.g. the use of physical and pollination barriers) will influence the ability to achieve a 0.3% threshold in seed production. The importance of the various practices will be crop/species specific and will also be influenced by local environmental and agricultural circumstances.**

**SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED:**

Isolation distances have been prescribed for certified seed production in the EU for oilseed rape, maize and sugar beet. Member States and plant breeders have, in many cases, extended these distances to further minimise the probability of varietal impurities. This precautionary approach takes account of local circumstances and environmental factors which might increase the probability of cross pollination.

Current isolation distances may need to be reviewed since the 0.3% and 0.5% thresholds do not necessarily equate with current purity standards for certified seeds (e.g. hybrid oil seed rape). Isolation should take into account local environmental and cropping patterns which may influence both amounts and flux of pollen. On large farms adequate separation distances to minimise cross-pollination problems are more easily controlled by a single grower than would be the case for many small fields on adjacent farms controlled by different growers. In this case communication and local co-operation between farmers will be important. The greater the distance will be the better it is.

The amount of pollen coming from a source depends on the size of the source and pollen flow declines leptokurtically with distance and thus isolation distances of 100m can be used to reduce amounts of pollen to 1-2% of those measured at the source for oilseed rape and maize. However, if the source of pollen is relatively large compared to the recipient crop then this can still present a major outcrossing problem. In addition, there is evidence that oilseed rape pollen can be detected at low levels at considerable distances from sources, especially if the sources of pollen are large. Thus isolation can only be used to reduce cross pollination and not to exclude it. Isolation can be used to achieve "non-hybrid" oilseed rape seed crops with a 0.3% threshold, but achieving lower levels becomes more problematic.

Isolation distances will also depend on field areas. Simulations with GENESYS and other dispersal models show that the larger the field is, the further the pollen is dispersed. GENESYS simulations (which currently still underestimate gene dispersal in space) have shown that, with a 6 ha field, isolation distances of 100m are insufficient to avoid cross pollination of non GM oilseed rape by GM oilseed rape. This is the case even if the 100m were cultivated with a pollen barrier (conventional oilseed rape variety flowering simultaneously but not used for seed production). Gene flow can also be easily doubled by using long and narrow fields instead of square ones.

***Pollination barriers:*** Alien pollen entering a crop is rapidly diluted by the crop's own pollen and has to compete with it to pollinate flowers. Thus alien pollination also declines rapidly with distance into the crop. It is for this reason that seed crops are often surrounded by barriers of male fertile pollinator plants or the outer rows of the seed crop are discarded since the majority of alien pollination will be in these plants. Experiments in France and UK with GM oilseed rape immediately adjacent to fully fertile non-GM crops have shown that outcrossing with GM varieties declines to 1% within 25m of the

crop and to 0.5% at 50m. These figures are considerably reduced if the crops are separated by standard 100m isolation distances.

**Compatibility:** Some turnip rape (*Brassica rapa*) varieties have higher levels of cross compatibility than self compatibility. Research in Canada has shown higher levels of cross pollination with GM rape since turnip rape is more likely to be fertilised by alien pollen. Thus it is currently not possible to define isolation distances for turnip rape seed production.

**Fertility and hybrids:** Experiments with oilseed rape varieties with reduced male fertility have shown that considerably higher levels of outcrossing can occur. Varietal associations commonly have only 20% of plants producing pollen and subsequently have a greater level of outcrossing at any given distance. In addition recent information from North America on the production of hybrid oilseed rape seed, where male sterile plants are grown in conjunction with pollinators, has shown that these crops have been pollinated by GM crops growing at several kilometres distance. Some samples of imported hybrid rape seed contained levels in excess of 0.3% GM presence. Thus, recommendations on isolation requirements for seed crops of hybrid oilseed rape and beet (which is also commonly produced from hybridisation of male sterile mother plants) to meet 0.3% thresholds cannot currently be made.

Comments from plant breeders suggest that doubling isolation distances of male sterile mother plants of sugar beet to 2000m will be needed to achieve the threshold for sugar beet seed, assuming that the mother plants are surrounded by non-GM pollinators. Similar or larger distances will also be needed for hybrid rape seed production depending on the scale of GM crop production in the same region. However, research data on which to base firm recommendations are not currently available for these hybrid crops.

Most maize varieties are hybrids with male sterile seed producing plants inter-planted with rows of pollinators and surrounded by pollinators. This surrounding block of pollinators forms an effective screen against alien pollen since maize pollen is large and flow declines rapidly with distance. French and UK experiments have shown that alien cross pollination is reduced to 0.1% at distances between 20 and 50m into these male fertile barriers. Thus we can advise that current isolation distances can be used to achieve the 0.3% threshold in maize provided current seed production methods continue to be used which include the use of surrounding barriers of pollinators. While these isolation measures may be appropriate in some circumstances, seed producers will need to take account of the density of potential contaminating GM crops in a region, the flowering period of these crops in relation to the seed crop and environmental factors such as wind speed and direction, and adjust isolation measures accordingly.

However maize female flower fertility periods do not always coincide with male flower (tassel) pollen dehiscence. There is thus some possibility that alien pollen can fertilise female flowers during this fertility interval. GM adventitious presence has been detected in maize seed imported from North America and some of the presence may be due to problems of this type. Thus seed production in maize should be closely monitored for problems of this nature and seed production requirements reviewed where necessary.

**Potatoes:** Most potato 'seed' are vegetative tubers and thus not subject to gene transfer through pollination of the mother plant. Small amounts of true seed are produced especially during the breeding or early multiplication of varieties. Potatoes will cross pollinate at low frequencies so that effective isolation is required to minimise this.

#### **4.4 Specific issue identified by the Committee**

**The Commission has indicated that GM seed not covered by an authorisation under part C of Council Directive 90/220/EEC should not be present in a commercial seed lot (zero tolerance). The Committee would like to comment on this issue.**

##### **OPINION OF THE COMMITTEE:**

**The Committee is of the opinion that a zero level of unauthorised GM seed is unobtainable in practice. A zero level would have severe consequences for part B GM field releases, for biosafety research and for evaluation of new GM plant varieties.**

**When establishing levels of tolerance, a major constraint is the limit of analytical sensitivity of available detection methods, which is currently at about 0.1% for routine analysis.**

##### **SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED:**

From experience of research on unintentional seed mixing, on gene-flow, and from, long experience of commercial seed production, it is clear that a zero level of unauthorised GM seed is unobtainable in practice. Field grown crops are always subject to unintended pollen and seeds from various sources.

A zero level would have severe consequences for part B GM field releases, for biosafety research and for evaluation of new GM plant varieties.

The nature of any non part C material introduced into a seed crop is most likely to be from part B release experiments in the EU or from GM crops that have received some level of regulatory approval in a third country. GM material that has not passed through any international regulatory process is unlikely to be detected, because the DNA sequence data is probably not available for analysis to be possible.

A major constraint on defining levels of tolerance of the presence of non-part C seeds, is the limit of analytical sensitivity. The analytical method adopted must be capable of routine use, with appropriate sampling procedures and confidence limits. The sensitivity of PCR and antibody-based analytical procedures is currently at about 0.1 %. It is possible routinely to detect one GM seed in a sample of 1000 seeds. Certain GM characters, such as herbicide tolerance will be easier to test for. However, it is likely that PCR and associated technologies will form the basis of most routine analysis. Whatever level of tolerance is decided upon it is important that it is within the sensitivity of routine analytical procedures.

To have the capability of analytical detection it will be important to establish an international database of DNA sequences and analytical procedures to be able to detect unauthorised GM material.

It may be appropriate to give special consideration to the presence of GM seeds as the spectrum of GM crops changes, for example GM modification for the production of pharmaceutical and industrial processing.



## 4.5 Overall Conclusion

With regard to Question 1, the 0.3% and 0.5% thresholds suggested by the Commission are achievable only with best growing and commercial practices which are best defined on a crop by crop or species by species basis. However, achieving these thresholds in varietal association cultivars and production of hybrid seed will be problematic. With regard to Question 2 it is recommended that previous cropping requirements are addressed according to current knowledge on seed longevity genus by genus. The Committee suggests three broad groupings of crops which require different rotation breaks. With regard to Question 3 and separation distances the Committee is of the opinion that current distances are adequate for some crop species if additional measures are taken to reduce outcrossing. For other species/crops doubling the current separation distances would not be sufficient. The importance of various management practices will be crop/species specific and influenced by local environmental and agricultural consideration.

The Committee advises that research into outcrossing frequencies in hybrid crops is required so that isolation distances can be recommended and that research on the impact of volunteers on gene flow in seed crops is required in order to determine numbers that can be tolerated in seed and food crops.

The Committee further advises that the recommendations provided in this opinion should be continuously reviewed especially in the light of on-going research in this area and that there may be need to revisit the 1% threshold in the light of ongoing experience with GM crops.

In addition, the Committee is of the opinion that a zero level of unauthorised events is unobtainable in practice.

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## 6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

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