

UDENRIGSMINISTERIET

EUROPAUDVALGET

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Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets grundnotat vedrørende forslag til kommissionsdirektiv om ændring af rådsdirektiverne 66/400/EØF, 66/401/EØF, 66/402/EØF, 66/403/EØF, 69/208/EØF, 70/458/EØF om handel med bedefrø, frø af foderplanter, sædekorn, læggekartofler, frø af olie- og spindplanter og grønsagsfrø, Dokument SANCO/1542/00 rev 1 og rev 2.

Ministeriet for Fødevarer, Landbrug og Fiskeri

1. afdeling, 1. kontor

Den 31. august 2001

TDN

LFM 0550

GRUNDNOTAT TIL FOLKETINGETS EUROPAUDVALG

om forslag til kommissionsdirektiv om ændring af rådsdirektiverne 66/400/EØF, 66/401/EØF, 66/402/EØF, 66/403/EØF, 69/208/EØF, 70/458/EØF om handel med befrø, frø af foderplanter, sædekorn, læggekartofler, frø af olie- og spindplanter og grønsagsfrø

Dokument SANCO/1542/00 rev 1 og rev 2

Resumé

Direktioforslaget omfatter fastsættelse af grænseværdier for tilladt indhold af godkendte genmodificerede frø i frøpartier af traditionelle plantesorter samt de deraf følgende krav til isolationsafstande til marker med genmodificerede afgrøder, dyrkningsintervaller efter genmodificerede afgrøder, samt hensigtsmæssig praksis med hensyn til såning, dyrkning, høst, transport og oplagring.

Med hensyn til fastsættelse af grænseværdier, omfatter forslaget indførelse af tre grænseværdier gældende for forskellige afgrødekategorier. Dog skal der tages hensyn til, at såfremt der for nogle arter allerede i dag findes højere renhedskrav, skal disse fortsat gælde.

Der indføres, i modsætning til de hidtil gældende regler, specifikke dyrkningsintervaller mellem afgrøder af samme art eller nært beslægtede arter for dyrkning på den samme mark. Dyrkningsintervallerne varierer fra et til fem år afhængigt af planteart. Den hidtidige formulering i frøhandelsdirektiverne har været, at "marken i tilstrækkelig grad skal være fri for selvsåede planter fra tidligere dyrkning".

Forslaget omfatter endvidere nærmere krav til mærkning af genetisk modificerede plantesorter på frøpakkninger og etiketter. Mærkningen skal således omfatte ordene "genetisk modificeret sort" sammen med navnet på den genetisk modificerede organisme.

Baggrund

Kommissionen har ved SANCO/1542/00 rev 1 fremlagt et arbejdsdokument om forslag til et kommissionsdirektiv om ændring af følgende rådsdirektiver:

- Rådsdirektiv 66/400/EØF 14. juni 1966 om handel med bederoefrø¹. Forslaget er fremsat med hjemmel i artikel 21 (a) i direktivet.
- Rådets direktiv 66/401/EØF 14. juni 1966 om handel med frø af foderplanter¹. Forslaget er fremsat med hjemmel i artikel 21 (a) i direktivet.
- Rådets direktiv 66/402/EØF af 14. juni 1966 om handel med sædekorn². Forslaget er fremsat med hjemmel i artikel 21 (a) i direktivet.
- Rådets direktiv 66/403/EØF 14. juni 1966 om handel med læggekartofler³. Forslaget er fremsat med hjemmel i artikel 19 (a) i direktivet.
- Rådets direktiv 69/208/EØF 30. juni 1969 om handel med frø af olie- og spindelplanter¹. Forslaget er fremsat med hjemmel i artikel 20 (a) i direktivet.
- Rådets direktiv 70/458/EØF af 29. september 1970 om handel med grøntsagsfrø¹. Forslaget er fremsat med hjemmel i artikel 40 (a) i direktivet.

Kommissionen har endvidere udarbejdet et memorandum, som er indeholdt i dokument SANCO/1542/00 rev. 2. Arbejdsdokumenterne er fremsendt den 15. juni 2001. Arbejdsdokumenterne er drøftet i Den Stående Komité for Frø og Plantemateriale den 4. juli 2001, hvor det blev fremhævet, at der er tale om arbejdsdokumenter. Et formelt forslag forventes at foreligge i oktober d.å.

Forslaget behandles i en Ila-procedure i Den Stående Komité for Frø og Plantemateriale. Kommissionen kan udstede direktivet, medmindre komitéen udtaler sig mod forslaget med kvalificeret flertal. I så fald forelægger Kommissionen sagen for Rådet. Kommissionen kan samtidig beslutte at udsætte gennemførelsen af reglerne i en måned. Træffer Rådet ikke inden en frist på en måned med kvalificeret flertal en anden afgørelse, kan Kommissionen udstede direktivet.

¹ Senest ændret ved direktiv 1998/95/EØF og 1998/96/EØF.

² Senest ændret ved direktiv 1999/54/EØF.

³ Senest ændret ved beslutning 1999/742/EF.

Nærheds- og proportionalitetsprincippet

I Kommissionens Hvidbog om Fødevarer sikkerhed er der i bilaget gengivet en handlingsplan om fødevarer sikkerhed, hvorefter der ifølge foranstaltning nr. 77 skal gennemføres ændringer af bilagene til direktiverne om handel med frø.

Ændringerne omfatter 1) fastsættelse af højere krav til renhed med hensyn til tilfældigt forekommende tilstedeværelse af genetisk modificerede frø i frøpartier af traditionelle plantesorter samt 2) fastsættelse af de nærmere regler for det krav om mærkning, der i Rådets direktiv 98/95/EF blev fastsat for frø fra genetisk modificerede landbrugsplantearter og grøntsagsarter.

I foråret 2000 blev der i flere medlemsstater konstateret iblanding af genetisk modificerede frø i partier med konventionel udsæd af raps, majs og bomuld importeret fra USA og Canada. Som følge heraf blev der i Den Stående Komité for Frø og Plantemateriale udarbejdet en midlertidig handlingsplan for kontrol af traditionel udsæd for tilstedeværelse af genetisk modificeret frø.

Handlingsplanen fastsatte bl.a. en midlertidig grænseværdi for tilladt indhold af godkendte genmodificerede frø i traditionel udsæd. Imidlertid udgjorde handlingsplanen ikke noget juridisk grundlag for at gribe ind i de tilfælde, hvor grænseværdien ikke blev overholdt.

Direktivforslaget skal således tjene til at opfylde foranstaltning nr. 77 i Hvidbogen om fødevarer sikkerhed samt implementere den midlertidige handlingsplan i frødirektiverne.

Formål og indhold

Direktivforslaget omfatter fastsættelse af grænseværdier for tilladt indhold af godkendte genmodificerede frø i frøpartier af traditionelle plantesorter samt de deraf følgende krav til isolationsafstande til marker med genmodificerede afgrøder, dyrkningsintervaller efter genmodificerede afgrøder, samt hensigtsmæssig praksis med hensyn til såning, dyrkning, høst, transport og oplagring.

Med hensyn til fastsættelse af grænseværdier, omfatter forslaget indførelse af tre grænseværdier gældende for forskellige afgrødekategorier. Dog skal der tages hensyn til, at såfremt der for nogle arter allerede i dag findes højere renhedskrav, skal disse fortsat gælde.

Gældende for første afgrødekategori er grænseværdien 0.3 pct. Kategorien omfatter krydsbestøvende arter, bortset fra majs og roer og visse krydsbestøvende grønsager der formeres ved frø men alene dyrkes vegetativt.

Grænseværdien for anden afgrødekategori er 0.5 pct. Kategorien omfatter frø fra majs og roer samt visse krydsbestøvende grønsager, der formeres ved frø men alene dyrkes vegetativt. Endvidere omfatter gruppen frø fra selvbestøvende arter, bortset fra soja og markært, samt frø fra arter som formeres vegetativt⁴ (i praksis kun kartofler).

Grænseværdien for tredje afgrødekategori er 0.7 pct. og omfatter soja og markært.

For så vidt angår isolationsafstande, foreslås for de fleste afgrøder ingen ændringer i de eksisterende isolationsafstande, forudsat at yderligere foranstaltninger som fysiske barrierer eller pollenbarrierer tages i anvendelse. Undtaget herfra er bederoer, henholdsvis raps- og rybshybrider, hvor isolationsafstandene foreslås øget betragteligt. Konkret foreslås isolationsafstandene øget for bederoer med en faktor 2, for raps- og rybshybrider med en faktor 10.

Derimod indføres der i modsætning til de hidtil gældende regler specifikke dyrkningsintervaller mellem afgrøder af samme art eller nært beslægtede arter for dyrkning på den samme mark. Dyrkningsintervallerne varierer fra et til fem år afhængigt af plantearart. Den hidtidige formulering i frøhandelsdirektiverne har været, at "marken i tilstrækkelig grad skal være fri for selvsåede planter fra tidligere dyrkning".

Forslaget omfatter endvidere nærmere krav til mærkning af genetisk modificerede plantesorter på frøpakninger og etiketter. Mærkningen skal således omfatte ordene "genetisk modificeret sort" sammen med navnet på den genetisk modificerede organisme.

⁴ Vegetativ formering: Ukønnet formering ved udplantering af plantemateriale fra moderplanten, f.eks. i form af stiklinger eller knolde.

Ændringerne indføres i bilagene til rådsdirektiv 66/400/EØF om handel med bederøer, rådsdirektiv 66/401/EØF om handel med frø af foderplanter, rådsdirektiv 66/401/EØF om handel med sædekorn, rådsdirektiv 66/403/EØF om handel med læggekartofler, rådsdirektiv 69/208/EØF om handel med frø af olie- og spindplanter og rådsdirektiv 70/458/EØF om handel med grønsagsfrø.

Det fremgår af forslaget, at indhold af genetisk modificerede frø, som ikke er godkendt til markedsføring i EU efter direktiv 90/220/EØF om udsætning i miljøet af genetisk modificerede organismer (som afløses af direktiv 2001/18/EF), ikke er tilladt.

Imidlertid nævnes det i præamblen til forslaget, at dette krav bør ændres i overensstemmelse med forslag til forordning vedrørende sporbarhed og mærkning af genetisk modificerede organismer og sporbarhed af fødevarer og foder afledt fra genetisk modificerede organismer samt den tilhørende ændring af direktiv 2001/18/EF.

Det kan således ikke udelukkes, at forordningen vedrørende sporbarhed og mærkning henholdsvis ændringen af direktiv 2001/18/EF kommer til at indeholde bestemmelser, som tillader tilstedeværelse af teknisk uundgåelige eller tilfældige spor af ikke-godkendte genmodificerede organismer, såfremt visse betingelser er opfyldt og såfremt EU's sikkerheds- og sundhedsvurdering er gennemført (af Fødevaraautoriteten).

Udtalelser

Europa-Parlamentet skal ikke udtale sig om forslaget.

Gældende dansk ret

De berørte områder er omfattet af lov om frø, kartofler og planter, jf. lovbekendtgørelse nr. 261 af 26. april 1999, som ændret ved lov nr. 279 af 25. april 2001 om ændring af lov om fødevarer m.fl.

I medfør af lov om frø, kartofler og planter er udstedt:

- Bekendtgørelse nr. 51 af 24. januar 2000 om en fortegnelse over godkendte sorter af landbrugsplante- og grønsagsarter (sortslisten), der gennemfører rådsdirektiv 70/457/EØF om den fælles sortliste over landbrugsplanter og delvist 70/458/EØF om handel med grønsagsfrø samt ændringer.

- Bekendtgørelse nr. 52 af 24. januar 2000 om markfrø som senest ændret ved bekendtgørelse nr. 933 af 10. oktober 2000, der gennemfører rådsdirektiv 66/400/EØF om handel med bederoefrø, rådsdirektiv 66/401/EØF om handel med frø af foderplanter og rådsdirektiv 69/208/EØF om handel med olie- og spindplanter samt ændringer.
- Bekendtgørelse nr. 53 af 24. januar 2000 om sædekorn som senest ændret ved bekendtgørelse nr. 412 af 21. maj 2001, der gennemfører rådsdirektiv nr. 66/402/EØF om handel med sædekorn samt ændringer.
- Bekendtgørelse nr. 54 af 24. januar 2000 om grønsagsfrø, der gennemfører rådsdirektiv nr. 70/458/EØF om handel med grønsagsfrø.

Bekendtgørelse nr. 124 af 1. marts 1999 om kartofler som senest ændret ved bekendtgørelse nr. 727 af 27. juli 2000, der gennemfører rådsdirektiv nr. 66/403/EØF om handel med læggekartofler samt ændringer.

Konsekvenser

Forslaget har ingen lovgivningsmæssige konsekvenser. Såfremt forslaget vedtages, skal der foretages ændringer i ovennævnte bekendtgørelser.

Forslaget har ingen statsfinansielle konsekvenser, idet kontrollen er brugerfinansieret.

En vedtagelse af direktivet skønnes ikke direkte at berøre beskyttelsesniveauet i Danmark, idet der alene er tale om en tærskelværdi for allerede godkendte genmodificerede frø.

Høring

Forslaget har været sendt til høring i §2-udvalget (landbrug)

Landbrugsraadet finder i en foreløbig udtalelse, at forslaget indeholder en række spørgsmål, hvis baggrund ikke er nærmere belyst, hvorfor Landbrugsraadet ikke kan tage endelig stilling til forslaget på nuværende tidspunkt.

Tidligere forelæggelse for Folketingets Europaudvalg

Forslaget har ikke tidligere været forelagt Folketingets Europaudvalg.

Orienterende notat om handlingsplanen for kontrol med konventionelle frø for urenheder af GMO er fremsendt den 31. august 2000.

EN

SANCO/1542/00 rev 2 – 25 mai 2001

Fejl! Ukendt argument for parameter.

**WORKING DOCUMENT
DOES NOT NECESSARILY
REPRESENT THE VIEWS
OF THE COMMISSION
SERVICES**

MEMORANDUM TO THE COMMISSION

1. Aim

The Commission's White Paper on Food Safety, in item 77 of the Action Plan in the Annex, requires amendments to be made to the Annexes of the current Directives on the marketing of seeds (six Council Directives¹) in order to lay down

- the growing conditions and other requirements for purity concerning the adventitious presence of genetically modified (GM) seeds in seed lots of conventional plant varieties;
- the details of the labelling requirements introduced by Council Directive 98/95/EC² for seeds of genetically modified (GM) plant varieties.

It should be stressed that these two provisions are not interconnected, in that the first one relates to non-genetically modified varieties and the second one to genetically modified varieties.

2. Adventitious presence of GM seeds in seed of conventional plant varieties

The seed marketing Directives lay down minimum conditions to be met by the crop and by the seed, including those relating to varietal purity of the seed. However, until now these conditions did not include specific growing conditions and other requirements for purity concerning the presence of genetically modified (GM) seed, in particular in seed lots of non-genetically modified varieties.

Because the cultivation of GM plants has increased considerably during the last few years, in particular in some third countries, the possibility of finding GM seeds in seed lots of conventional varieties due to contamination in the field or during the processing stages of the seed has passed from hypothesis to reality. In spring 2000, the Commission services were for the first time informed of interceptions of imported seed of conventional varieties of cotton,

¹ 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC.

² This Directive of 14 December 1998 amended the Directives mentioned in footnote 1 and inter alia introduced provisions to avoid adverse effects on human health and the environment as well as on food safety which may result from the placing on the market or the use of seeds of genetically modified plant varieties. Furthermore, it requires that genetically modified varieties have to be labelled as such.

oilseed rape and maize imported from USA and Canada containing traces of GM seeds. Member States reacted differently to these interceptions.

In order to harmonise the actions of Member States, the Commission proposed within the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry that co-ordinated action should be taken as regards monitoring and testing of seed lots under certain criteria, with interim thresholds for authorised GM impurities. This "Interim Action" has the disadvantage of being only a "gentleman's agreement" and does not constitute a legal base for actions to be taken in cases where the threshold values are not respected.

It thus became clear that legislative action to lay down an acceptable level for the presence of genetically modified seed ("GM seed") in seed lots of conventional varieties was urgently needed.

Proposed elements

The attached draft Commission Directive aims at achieving these objectives for purity regarding the presence of genetically modified seeds in seed of conventional plant varieties through the introduction of requirements in five areas. The first two requirements are obligations of result, while the three others are obligations of means, essential for achieving the obligations of result.

In this context, an important factor to consider is that the Commission has asked the Scientific Committee on Plants for advice and that this Committee delivered an opinion on 7 March 2001 concerning the adventitious presence of GM seeds in conventional seeds.

a) Thresholds for authorised GM seed

In a seed lot of a conventional variety, genetically modified seed having received authorisation under part C of Council Directive 90/220/EEC replaced by Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms should not exceed a specified tolerance threshold.

The aim is thus to introduce such a threshold for lots of conventional seed. However, in doing so, one has to take into account the threshold of 1% established for the adventitious presence of genetically modified material in food ingredients and foodstuffs for labelling purposes under Commission Regulation (EC) No 49/2000, which is in fact a derogation from labelling the food ingredient or foodstuff as being genetically modified.

Because of the well-known increase of impurities from one generation of seed to the next, due to the fact that contamination can occur in the field and also at harvesting and further processing of the seed, lower thresholds than 1% have to be set for seeds in order to ensure that the final product derived from the harvest will not have to be labelled. This is very clearly set out in the opinion of the Scientific Committee on Plants.

A distinction needs to be made between self-pollinating plants (as well as vegetatively propagated species) and cross-pollinating plants.

Furthermore, cross-pollinated crops cultivated vegetatively (e.g. beet) should be considered, from the point of view of the commercial grower, as self-pollinated crops (since pollination by GM pollen has no impact on the GM content of the harvested product).

One of the sources of contamination in the field comes from dormant seeds which germinate after some years (i.e. producing volunteer plants). In some case (e.g. soya, maize and field pea), these remaining seeds have a very low chance of germinating and this fact should be taken into account when setting thresholds.

As a consequence of this, and taking into account the opinion of the Scientific Committee on Plants, it is proposed to introduce thresholds of :

- 0.3% for seed of a cross-pollinating species other than maize (for which the probability of volunteers is very low) and beet and certain vegetable plants (cross-pollinated crops propagated from seed but cultivated vegetatively),
- 0.5% for seed of maize, beet and certain vegetable plants (see above), for seed of a self-pollinating species other than soya and field pea (see below), for seed of vegetatively propagated species (in practice only potato),
- 0.7 % for soya and field pea (for which the probability of volunteers is very low).

Because of the fact that in some cases the normal varietal purity standards are lower, thus stricter, these should continue to apply (e.g. the actual standard for basic seed potato is 0.35 while the corresponding one indicated above would be 0.5).

b) Threshold for unauthorised GM seed

Genetically modified seeds having not received an authorisation under part C of Directive 90/220/EEC now replaced by Directive 2001/18/EC should not be present in a seed lot. Directive 2001/18/EC does not foresee the establishment of thresholds for presence of unauthorised genetically modified organisms.

However, it is the intention to amend Directive 2001/18/EEC to provide for the possibility of establishing thresholds for technically unavoidable or adventitious presence of minute amounts of genetically modified organisms as or in products not authorised in accordance with Community legislation provided that certain conditions are fulfilled. The annexes of the seed Directive will have to be changed accordingly once the amendment of Directive 2001/18/EC enters into force.

In order to be able to monitor the thresholds under a) and b) above in a harmonised way, conditions for sampling, testing plans with associated statistical confidence levels and decision rules have to be defined.

Therefore, a protocol for sampling and detection of seed lots of conventional seed for the presence of GM seed in relation to the established thresholds has been worked out and should be adopted in a separate legal act, simultaneously with this Directive setting the requirements for purity of seed.

c) Break in crop production

In order to achieve the stipulated thresholds in seed lots, action has to be taken at the level of the growing of the crop which will produce the seed. In particular, the frequency of volunteer plants in the seed crop should be limited by setting minimum breaks of rotation period.

This is because seeds, including GM seeds, from previous crops on the same field may still be capable of germinating and giving rise to gene flow from these GM plants. This has to be avoided as much as possible.

A way to achieve this is to impose the rule, based on current knowledge of seed longevity, that no GM plants of the same species or of a closely related species should have been grown in the field used for the production of seed of a non-GM variety during

- the previous year in the case of species such as soya, maize and pea,
- the previous five years in the case of species such as Brassica sp (e.g. swede rape), potato, beet, grasses and herbage legumes,
- the previous two years in all other cases (e.g. wheat, field beans and barley).

d) Isolation distances

In the case of cross-pollinating seed crops, isolation is already required in the current seed legislation in respect of any neighbouring sources of pollen which may result in undesirable foreign pollination.

It is felt likely that current isolation distances are in general adequate if other measures to reduce outcrossing are implemented (in particular the use of physical or pollen barriers).

As suggested in the opinion of the Scientific Committee on Plants, the normal distance should however be increased

- for hybrids of swede rape and turnip rape by a factor of 10 (5000m for basic seed and 3000m for certified seed),
- for beet to 2000m.

It should be noted that Council Directive 69/208/EEC on seed of oil and fibre plants does not cover the seeds of hybrids of swede rape and turnip rape. However, a temporary measure does provide for the conditions and requirements to be satisfied, inter alia, by the seed of such hybrids. This draft Commission Directive will bring hybrids of swede rape and turnip rape within the scope of Council Directive 69/208/EEC.

e) Good practice for seed production

Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling, in particular in respect of drilling, cultivation, harvesting, transport and storage, are to be implemented by seed growers.

However, the above determinations need not be carried out if the seeds have been produced in an area for which it has been officially ensured (official measures are defined as measures taken by state authorities or by any legal person acting under the responsibility of the State) that genetically modified plants of the same species or of a closely related species are not grown.

3. Labelling requirement for seeds of genetically modified (GM) plant varieties

Council Directive 98/95/EC, which in December 1998 amended the various Directives on the marketing of seeds, requires that genetically modified varieties must be labelled as such on packages of seeds.

However, the details of the indications to be put on the label were not given in this Directive. Therefore, in order to have harmonised labelling, it is proposed in the present Directive to require precise information on the official label as follows:

- "genetically modified variety" together with the name of the genetically modified organism.

4. Other points

There are no financial implications for the EC budget.

The Commission is asked to adopt the draft Commission Directive and to publish it in the Official Journal.

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SANCO/1542/00.rev 1



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.05.2001

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**Working document does not
necessarily represent the views of
the Commission services**

Draft

COMMISSION DIRECTIVE/.../EC

of [...]

**Commission Directive amending Council Directives 66/400/EEC, 66/401/EEC,
66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC on the marketing of beet seed,
fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable
seed**

Draft

COMMISSION DIRECTIVE/EC

of

Commission Directive amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable seed

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/400/EEC of 14 June 1966 on the marketing of beet seed¹, and in particular Article 21(a) thereof,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed², and in particular Article 21(a) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed³, and in particular Article 21(a) thereof,

Having regard to Council Directive 66/403/EEC of 14 June 1966 on the marketing of seed potatoes⁴, and in particular Article 19(a) thereof,

Having regard to Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre plants⁵, and in particular Article 20(a) thereof,

Having regard to Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed⁶, and in particular Article 40(a) thereof

¹ OJ L 25, 11.7.1966, p. 2290/66, as last amended by Council Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

² OJ L 25, 11.7.1966, p. 2298/66, as last amended by Council Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

³ OJ L 25, 11.7.1966, p. 2309/66, as last amended by Commission Directive 1999/54/EC (OJ L 142, 5.6.1999, p. 30).

⁴ OJ L 25, 11.7.1966, p. 2320/66, as last amended by Commission Decision 1999/742/EC (OJ L 297, 18.11.1999, p. 39).

⁵ OJ L 169, 10.7.1969, p. 3, as last amended by Council Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

⁶ OJ L 225, 12.10.1970, p. 7, as last amended by Council Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

Whereas:

- (1) The six seed marketing Directives lay down minimum conditions to be satisfied by the crop and by the seed, including those relating to varietal purity of the seed; these conditions do not include specific growing conditions and other requirements for purity regarding the presence of genetically modified seed, in particular in seed lots of non-genetically modified varieties.
- (2) Council Directive 69/208/EEC does not cover the seed of hybrids of swede rape and turnip rape. However, Commission Decision 95/232/EEC⁷ provides for the conditions and requirements to be satisfied, inter alia, by the seed of hybrids of swede rape and turnip rape.
- (3) It is therefore appropriate to include hybrids of swede rape and turnip rape within the scope of Directive 69/208/EEC and to complement the aforesaid minimum conditions in the six seed marketing Directives with a set of additional conditions and requirements concerning the presence of genetically modified seed in seed crops and in seed lots of non-genetically modified varieties.
- (4) Fields used to grow seed of non-genetically modified varieties should be free from seed of genetically modified plants from previous cropping which are still capable of germinating.
- (5) In the case of seed crops of cross-pollinating plants, sufficient isolation should be required in respect of any neighbouring sources of pollen of genetically modified plants which may result in undesirable foreign pollination.
- (6) It should be ensured that, under defined seed sampling and testing conditions, genetically modified seeds having not received an authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms are not present in seed lots.
- (7) The latter requirement should be adapted following the adoption of the proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products derived from genetically modified organisms and amending Directive 2001/18/EC on the deliberate release into the environment which foresees that presence of technically unavoidable or adventitious traces of genetically modified organisms in minute amounts should not require authorisation, if certain conditions are fulfilled.
- (8) It should also be ensured that the level of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms in seed lots of non-genetically modified varieties comply with established standards on varietal purity and, within these limits, do not exceed an appropriate tolerance threshold; the level should be consistent with the thresholds established by Community legislation for the adventitious presence of genetically modified organisms in food ingredients and foodstuffs, taking account of the reproductive system of the plants concerned.

⁷ OJ L 154, 5.7.1995, as last amended by Commission Decision 2001/18/EC (OJ L 4, 9.1.2001, p. 36).

- (9) According to the Directives, in the case of seed of a variety which has been genetically modified, any label or document, official or otherwise, which is affixed to or accompanies the seed lot must clearly indicate that the variety has been genetically modified.
- (10) It is therefore appropriate to establish the details of the information required for labelling in the case of seeds of varieties which have been genetically modified.
- (11) The Commission has consulted the Scientific Committee on Plants and this Committee delivered an opinion on 7 March 2001 concerning the adventitious presence of GM seed in conventional seed.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Article 2(1), points B and Ba, of Directive 69/208/EEC the words "of sunflower" shall be deleted.

Article 2

Annexes I, III and IV to Directive 66/400/EEC are amended as set out in Annex I hereto.

Article 3

Annexes I, II, IV and V to Directive 66/401/EEC are amended as set out in Annex II hereto.

Article 4

Annexes I, II, IV and V to Directive 66/402/EEC are amended as set out in Annex III hereto.

Article 5

Annexes I, II and III to Directive 66/403/EEC are amended as set out in Annex IV hereto.

Article 6

Annexes I, II, IV and V to Directive 69/208/EEC are amended as set out in Annex V hereto.

Article 7

Annexes I, II, IV and V to Directive 70/458/EEC are amended as set out in Annex VI hereto.

Article 8

Section 1(c) of the Annex to Commission Decision 95/232/EEC shall be repealed with effect from the date referred to in Article 9 of this Directive.

Article 9

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 10

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 11

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission

Member of the Commission

ANNEX I

(Council Directive 66/400/EEC)

The Annexes to Directive 66/400/EEC are amended as follows:

Annex I, Part A:

1. In section 1 the following shall be added:

"In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species or of a closely related species shall have been grown in the field in the previous five years."

2. The following sections shall be inserted after section 5:

"6. In relation to any neighbouring sources of pollen of genetically modified plants which may result in undesirable foreign pollination, the minimum distance of the crop for the production of seed shall be at least 2000 meters. Furthermore appropriate measures to reduce foreign pollination shall be taken in particular the use of physical or pollen barriers.

7. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented by seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

8. The determination of the conditions under section 01, second sentence, and 6 above need not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex I, part B:

The following section 1a shall be inserted after section 1:

"1a. Presence of genetically modified seed:

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than 0,5 %.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 21.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex III:

1. The following point 5a shall be inserted in part A I:

"5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following point 7a shall be inserted in part B:

"7a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

Annex IV:

1. The following shall be inserted after the third indent in part A:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be inserted after the third indent in part C:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

ANNEX II

(Council Directive 66/401/EEC)

The Annexes to Directive 66/401/EEC are amended as follows:

Annex I:

1. In section 1 the following shall be added:

"In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species, or of a closely related species, shall have been grown in the field during

- the previous year in the case of field peas,
- the previous two years in the case of large seeded legumes other than field peas,
- the previous five years in the case of the plants other than those listed above.

2. The following section 2a shall be inserted after section 2:

"2a. In the case of any neighbouring sources of pollen of genetically modified plants which may result in undesirable foreign pollination, appropriate measures to reduce foreign pollination shall be taken, in particular the use of physical or pollen barriers."

3. The following sections shall be inserted after section 6:

"7. Good practice for seed production to minimise admixture and undesirable gene flow throughout crop growth and post-harvest handling, shall be implemented by seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

8. The determination of the conditions under sections 1, second sentence, and 2a above needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex II:

1. The following section 1a shall be inserted in part I after section 1:

"1a. Presence of genetically modified seed:

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than

- 0,3 % for seed of a cross-pollinating species or variety,
- 0,5 % for seed of a self-pollinating species or variety other than field peas,
- 0,7 % for seed of field peas.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 21.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

2. The following section 01 shall be inserted in Part III, before section 1:

"01. Presence of genetically modified seed

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than
 - 0,3 % for seed of a cross-pollinating species,
 - 0,5 % for seed of a self-pollinating species.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 21.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified varieties of the same species, or of a closely related species, are not grown."

Annex IV:

1. The following point 5a shall be inserted in part A I (a):

“5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism.”

2. The following shall be added to point 4 in part A I (c):

“In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism.”

3. The following point 7a shall be inserted in part B (a):

“7a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism.”

4. The following shall be added to point 11 in part B (c):

“In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism.”

Annex V:

1. The following shall be inserted after the third indent in part A:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be inserted after the third indent in part C:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

ANNEX III

(Council Directive 66/402/EEC)

The Annexes to Directive 66/402/EEC are amended as follows:

Annex I:

1. In section 1 the following shall be added:

"In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species or of a closely related species shall have been grown in the field in the previous year in the case of maize and the previous two years in the case of other plants."

2. The following section 2a shall be inserted after section 2:

"2a. In the case of any neighbouring sources of pollen of genetically modified plants which may result in undesirable foreign pollination, appropriate measures to reduce foreign pollination shall be taken, in particular the use of physical or pollen barriers."

3. In section 3, second subparagraph, the words "of Sorghum spp. and Zea mays" shall be deleted, and the words ", where relevant," shall be inserted between "including" and "male sterility".

4. The following sections shall be inserted after section 5:

"6. Good practices for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented by the seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

7. The determination of the conditions under sections 1, second sentence, and 2a above needs not be carried out, if the seeds have been produced in an area, for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex II:

The following section 1a shall be inserted after section 1:

"1a. Presence of genetically modified seed:

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than

- 0,3 % for seed of a cross-pollinating species or variety other than maize,
- 0,5 % for seed of maize and of a self-pollinating species or variety.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 21.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex IV:

1. The following point 5a shall be inserted in part A (a):

"5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be added to point 4 in part A (b):

"In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

Annex V:

1. The following shall be inserted after the third indent in part A:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be inserted after the third indent in part C:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

ANNEX IV

(Council Directive 66/403/EEC)

The Annexes to Directive 66/403/EEC are amended as follows:

Annex I:

1. The following section 01 shall be inserted before section 1:

"01. The previous cropping of the field shall not have been incompatible with the production of seed potatoes of the variety of the crop, and the field shall be sufficiently free from plants which are volunteers from previous cropping. In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species or of a closely related species shall have been grown on the field in the previous five years."

2. The following sections shall be inserted after section 6:

"7. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented by the seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

8. The determination of the conditions under section 1, second sentence above needs not be carried out, if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex II:

The following section 1a shall be inserted under part A after section 1:

"1a. Presence of genetically modified seed potatoes:

- (a) Genetically modified seed potatoes which have not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed potatoes of a non-genetically modified variety, the presence of genetically modified seed potatoes having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organism shall not exceed the standards laid down for varietal purity, and in any case not more than 0,5 %.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 19.

The determination of these requirements needs not be carried out if the seed potatoes have been produced in an area, for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex III:

The following point 4a shall be inserted in part A:

"4a. in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

ANNEX V

(Council Directive 69/208/EEC)

The Annexes to Directive 69/208/EEC are amended as follows:

Annex I:

1. In section 1 the following shall be added:

"In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species, or of a closely related species shall have been grown on the field during

- the previous year in the case of soya bean ,
- the previous two years in the case of plants other than soya bean and Brassica sp.,
- the previous five years in the case of Brassica sp.

2. The following section 2a shall be inserted after section 2:

"2a. In the case of any neighbouring sources of pollen of genetically modified plants, which may result in undesirable foreign pollination, appropriate measures to reduce foreign pollination shall be taken, in particular the use of physical or pollen barriers. For the production of seed of hybrids of swede rape and turnip rape the minimum distance shall be at least 5000 metres for the production of basic seed and 3000 metres for the production of certified seed."

3. In section 3, second subparagraph, the words "of Helianthus annuus" shall be deleted, and the words ", where relevant," shall be inserted between "including" and "male sterility".

4. In section 5 part B, the words "hybrid sunflower" and "hybrids of sunflower" shall be replaced by the words "hybrid varieties" respectively.

5. The following section 6 shall be inserted after section 5:

"6. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented by the seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

7. The determination of the conditions under sections 1, second sentence, and 2a above needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex II:

1. The following section 1a shall be inserted in part I after section 1:

"1a. Presence of genetically modified seed:

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than
 - 0,3 % for seed of a cross-pollinating species or variety,
 - 0,5 % for seed of a self-pollinating species or variety other than soya bean ,
 - 0,7 % for soya bean .

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 20.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

- 2. Current section 1a shall become section 1b.
- 3. In part II COMMERCIAL SEED the words "subject to the provisions below" shall be added to the first sentence.
- 4. In part II COMMERCIAL SEED the following shall be added:

"Presence of genetically modified seed

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.
- (b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than
 - 0,3 % for seed of a cross-pollinating species,
 - 0,5 % for seed of a self-pollinating species.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 21.

The determination of these requirements needs not be carried out if the seeds have been produced in an area for which it has been officially ensured that genetically modified varieties of the same species, or of a closely related species, are not grown."

Annex IV:

The following point 6a shall be inserted in part A (a):

"6a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

Annex V:

1. The following shall be inserted after the third indent in part A:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be inserted after the third indent in part C:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

ANNEX VI

(Council Directive 70/458/EEC)

The Annexes to Directive 70/458/EEC are amended as follows:

Annex I:

1. The following section 01 shall be inserted before section 1:

"01. The previous cropping of the field shall not have been incompatible with the production of seed of the species and variety of the crop, and the field shall be sufficiently free from plants which are volunteers from previous cropping.

In the case of a crop of a non-genetically modified variety, no genetically modified plants of the same species or of a closely related species shall have been grown in the field during

— the previous year in the case of peas,

— the previous two years in the case of plants other than peas, *Beta vulgaris* and *Brassica* sp.,

— the previous five years in the case of *Beta vulgaris* and *Brassica* sp.

2. The following sections shall be added after section 4:

"5. In the case of any neighbouring sources of pollen of a genetically modified plant which may result in undesirable foreign pollination, appropriate measures to reduce foreign pollination shall be taken, in particular the use of physical or pollen barriers. For the production of seed of *Beta vulgaris* the minimum distance shall be at least 2000 meters."

6. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented by the seed growers, in particular in respect of drilling, cultivation, harvesting, transport and storage.

7. The determination of the conditions under sections 01, second sentence, and 5 above needs not be carried out, if the seeds have been produced in an area for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex II:

The following section 1a shall be inserted after section 1:

"1a. Presence of genetically modified seed:

- (a) Genetically modified seed having not received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not be present.

(b) In the case of seed of a non-genetically modified variety, the presence of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms shall not exceed the standards laid down for varietal purity, and in any case not more than

- 0,3 % for seed of a cross-pollinating species or variety other than those propagated from seed but cultivated vegetatively,
- 0,5 % for seed of a self-pollinating species or variety and a cross-pollinating species or variety of crops propagated from seed but cultivated vegetatively.

Compliance with these requirements shall be ensured by seed testing carried out in accordance with the protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed, to be established in accordance with the procedure laid down in Article 40.

The determination of these requirements needs not be carried out if the seeds have been produced in an area, for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown."

Annex IV:

1. The following point 6a shall be inserted in part A (a):

"6a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following point 5a shall be inserted in part B (a):

"5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

Annex V:

1. The following shall be inserted after the third indent in part A:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."

2. The following shall be inserted after the third indent in part C:

"- in the case of a genetically modified variety: the words 'genetically modified variety' together with the name of the genetically modified organism."