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Medlemmerne af Folketingets Europaudvalg
og deres stedfortrædere

Astors Plads 2
DK-1448 København K
Tel. +45 33 92 00 00
Fax +45 32 54 05 33
E-mail: um@um.dk
Telex 31292 ETR DK
Telegr. adr. Etrangeres
Girokonto 300-1806



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Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets reviderede grundnotat om forslag til kommissionsdirektiv om ændring af rådsdirektiverne 66/400/EØF, 66/401/EØF, 66/402/EØF, 66/403/EØF, 69/208/EØF og 70/458/EØF om handel med bedefrø, frø af foderplanter, sædekorn, læggekartofler, frø af olie- og spindplanter og grønsagsfrø og beslutning 95/232/EF om gennemførelse af et tidsbegrænset forsøg for at fastsætte de betingelser, som frø af hybrider og af sammensatte sorter af raps og rybs skal opfylde, dokument SANCO/1542/02.

Anders Fogh Rasmussen

Ministeriet for Fødevarer, Landbrug og Fiskeri

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REVIDERET GRUNDMOTAT 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 be-
defrø, frø af foderplanter, sædekorn, læggekartofler, frø af olie- og spindplanter og
grønsagsfrø og beslutning 95/232/EF om gennemførelse af et tidsbegrænset forsøg
for at fastsætte de betingelser, som frø af hybrider og af sammensatte sorter af raps
og rybs skal opfylde

Dokument SANCO/1542/02

Resumé

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

*Med hensyn til fastsættelse af grænseværdier, omfatter forslaget indførelse af tre grænseværdi-
er 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
modsatning til de hidtil gældende regler, specifikke dyrkningsintervaller mellem afgrøder af
samme art eller nært beslægtede arter for dyrkning på den samme mark. Dyrkningsinterval-
lerne varierer fra et til fem år afhængigt af planteart. Den hidtidige formulering i frøhandels-
direktiverne 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 fropakninger og etiketter. Mærkningen skal således omfatte ordene "genetisk modificeret sort" sammen med navnet på den genetisk modificerede organisme.

Endelig omfatter forslaget en beslutning om gennemførelse af et tidsbegrænset forsøg for at fastsætte de betingelser, som frø af hybrider og af sammensatte sorter af raps og rybs skal opfylde.

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

Baggrund

Kommissionen har ved SANCO/1542/02 dateret 29. januar 2002 fremlagt et arbejdsdokument om forslag til et kommissionsdirektiv om ændring af bilagene til følgende rådsdirektiver hhv. beslutning:

- Rådets direktiv 66/400/EØF af 14. juni 1966 om handel med bederoefrø¹. Forslaget er fremsat med hjemmel i artikel 21 (a) i direktivet.
- Rådets direktiv 66/401/EØF af 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 af 14. juni 1966 om handel med læggekartofler³. Forslaget er fremsat med hjemmel i artikel 19 (a) i direktivet.
- Rådets direktiv 69/208/EØF af 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.

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.

- Kommissionens beslutning 95/232/EF af 27. juni 1995 om gennemførelse af et tidsbegrænset forsøg i henhold til Rådets direktiv 69/208/EØF for at fastsætte de betingelser, som frø af hybrider og af sammensatte sorter af raps og rybs skal opfylde. Forslaget har hjemmel i Rådets direktiv 69/208/EØF.

Kommissionen har endvidere udarbejdet forklarende noter til dokumentet. Forslaget er revision af en tidligere version af arbejdsdokumentet - SANCO/1542/00 rev.1 og rev. 2.

Forslaget behandles i en IIa-procedure i Den Stående Komité for Frø og Plantemateriale. Kommissionen kan udstede direktivet, medmindre komiteen 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.

Nærheds- og proportionalitetsprincippet

Der er ikke redegjort for nærheds- og proportionalitetsprincippet, idet der er tale om gennemførelsesbestemmelser til en allerede vedtaget retsakt. Det skal dog bemærkes, at der i Kommissionens Hvidbog om Fødevarerikkerhed, KOM(1999)719 endelig, i bilaget er gengivet en handlingsplan om fødevarerikkerhed, 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. Forslaget skal tjene til at opfylde foranstaltning nr. 77 i Hvidbogen om Fødevarerikkerhed samt implementere den midlertidige handlingsplan i frødirektiverne.

Formål og indhold

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 midler-

tidig 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.

Forslagets formål er at fastsætte grænseværdier for tilladt indhold af godkendte genmodificerede frø i frøpartier af traditionelle plantesorter, hvor der er udviklet genmodificerede sorter. Forslaget omfatter endvidere krav til isolationsafstande til marker med genmodificerede afgrøder, dyrkningsintervaller efter genmodificerede afgrøder, samt hensigtsmæssig praksis med hensyn til såning, dyrkning, høst, transport og oplagring.

Forslaget lægger op til, at såsæd med indhold af GMO'er under de foreslåede grænseværdier ikke skal mærkes. Kommissionen har således ved udformningen af forslaget henholdt sig til princippet i Novel Foods-lovgivningen (Kommissionens forordning (EF) nr. 49/2000 af 10. januar 2000), hvorefter der ikke skal ske mærkning ved utilsigtet iblanding af GMO'er under 1 %. Grænseværdierne er fastsat med henblik på, at indholdet af GMO i afgrøden fra de anvendte frø vil være under 1 %.

De omfattede arter er p.t. bederoe, majs, raps, kartoffel, soja, bomuld, cikorie og tomat. Nye plantearter kan blive omfattet på et senere tidspunkt ved ændring af det relevante frødirektiv. Forslaget omfatter indførsel af 3 grænseværdier gældende for forskellige afgrødekategorier. Imidlertid tages der hensyn til, at der for nogle arter allerede i dag findes højere renhedskrav for så vidt angår de normale sortsrenhedskriterier. Grænseværdierne er fastsat på baggrund af bestemmelserne i Europa-Parlamentets og Rådets forordning (EF) nr. 258/97 af 27. januar 1997 om nye levnedsmidler og nye levnedsmiddelsintegredienser om, at der for fødevarer med et utilsigtet indhold på op til 1% GMO'er ikke kræves mærkning for GMO-indhold.

Gældende for første afgrødekategori er grænseværdien 0,3 %. Kategorien omfatter raps og bomuld. Grænseværdien for anden afgrødekategori er 0,5 %. Kategorien omfatter majs, bederoer, kartoffel, cikorie og tomat. Grænseværdien for tredje afgrødekategori er 0,7 % og omfatter soja. Såfremt de angivne grænseværdier overskrides, vil frøene stadigvæk kunne markedsføres, men på den betingelse, at det på etiketter eller dokumenter, som ledsager frøpartiet, angives at partiet indeholder genmodificerede frø over den pågældende grænseværdi.

For så vidt angår isolationsafstande, foreslås for de fleste afgrøder ingen ændringer i de eksisterende isolationsafstande i henhold til frøhandelsdirektiverne, 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, fordi risikoen for indkrydsning med udefra kommende pollen er særlig stor for disse afgrøder. Konkret foreslås isolationsafstandene øget for bederoer fra 1.000 til 2.000 m, for raps- og rybshybrider fra 500 til 5.000 m for basisfrø og fra 300 til 3.000 m for certificeret frø. Disse isolationsafstande baserer sig på udtalelser fra EU's Videnskabelige Komité for Planter.

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 planteart. Den hidtidige formulering i frøhandelsdirektiverne har været, at "marken i tilstrækkelig grad skal være fri for selvsåede planter fra tidligere dyrkning". Det nævnes i forslaget, at en undtagelse fra opfyldelse af kravene kan komme på tale for geografiske områder, hvor der påviseligt ikke dyrkes GMO-afgrøder. Betingelserne herfor vil skulle fastlægges ved en efterfølgende komitéprocedure.

Forslaget omfatter endvidere nærmere krav til mærkning af genetisk modificerede plantesorter på frøpakninger og etiketter, som oprindeligt fastsat i Rådets direktiv 98/95/EF. Mærkningen skal således omfatte ordene "genetisk modificeret sort" sammen med information om den genetiske modifikation.

Ændringerne indføres i bilagene til rådsdirektiv 66/400/EØF om handel med bederoer, 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, rådsdirektiv 70/458/EØF om handel med grønsagsfrø, samt i artikel 3 og bilaget til kommissionsbeslutning 95/232/EF om gennemførelse af et tidsbegrænset forsøg for at fastsætte de betingelser, som frø af hybrider og af sammensatte sorter af raps og rybs skal opfylde.

Det fremgår af forslaget, at indhold af genetisk modificerede frø, som ikke er godkendt til markedsføring i EU efter Rådets direktiv 90/220/EØF om udsætning i miljøet af genetisk modificerede organismer, som pr. 17. oktober 2002 afløses af Europa-Parlamentets og Rådets direktiv 2001/18/EF, ikke er tilladt. Imidlertid nævnes det i

præambelen til forslaget, at dette krav bør ændres i overensstemmelse med en kommende ændring af direktiv 2001/18/EF til at tillade tilfældig eller teknisk uundgåelig iblanding af spormængder af ikke-godkendte GMO'er. Det kan således ikke udelukkes, at ændringen af direktiv 2001/18/EF kommer til at indeholde bestemmelser, som tillader tilstedeværelse af teknisk uundgåelige eller tilfældige spor af ikke-godkendte GMO'er, såfremt visse betingelser er opfyldt, (positiv vurdering fra en videnskabelig komité eller fra Den Europæiske Fødevarer sikkerhedsautoritet).

Herudover omfatter forslaget en bestemmelse om, at ændringerne skal tages op til revision senest den 31. december 2006.

Det bemærkes endeligt, at kravene til dyrkningsafstande og dyrkningsintervaller ikke gælder for frøavlsbestande, som er blevet etableret inden offentliggørelsen af direktivændringerne. Endelig skal kontrollen med overholdelse af bestemmelserne foretages ved hjælp af prøvetagnings- og analysemetoder, som vil blive beskrevet i en kommissionsforordning, der skal træde i kraft samtidig med direktivændringerne.

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 senere 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 foderplan-

ter og rådsdirektiv 69/208/EØF om handel med olie- og spindplanter samt senere 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 senere ændringer.

Bekendtgørelse nr. 54 af 24. januar 2000 om grønsagsfrø, der gennemfører rådsdirektiv nr. 70/458/EØF om handel med grønsagsfrø samt senere ændringer.

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 senere 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 at berøre beskyttelsesniveauet i Danmark, idet der i medfør af forslaget alene er tale om fastsættelse af en tærskelværdi for allerede godkendte genmodificerede frø. Beskyttelsesniveauet og herunder spørgsmålet om godkendelse af GMO'er reguleres p.t. af direktiv 90/220/EØF om udsætning i miljøet af genetisk modificerede organismer.

Forslaget ændrer ikke på, at det således fortsat påhviler frøfirmaet at sikre sig, at de relevante isolationsafstande overholdes. Såfremt frøfirmaet lægger avlen ud til en frøavler, skal firmaet fortsat sikre sig dette i kontrakten med avleren.

Høring

Det reviderede forslag har været sendt til høring i §2-udvalget (landbrug). Landbrugsrådet har ved brev af 19. april 2002 fremsendt sit høringssvar på vegne af

Landboforeningerne, Dansk Familielandbrug, Økologisk Landsforening og Landbrugsraadet. Organisationerne finder det særdeles vigtigt, at der etableres rammer for regulering og håndtering af GMO i non-GMO sorter. De foreslåede elementer vil være et hensigtsmæssigt instrument til at sikre dette. Organisationerne hilser derfor forslaget velkommen, idet det tager hånd om de praktiske problemstillinger, der er forbundet med foranstaltninger til at sikre mod indkrydsning i udsæd af non-GMO sorter i forbindelse med eventuel dyrkning af GMO afgrøder.

Organisationerne støtter Kommissionens forslag, men tilføjer, at organisationerne anbefaler, at der for kartofler stilles samme krav som for sortsrenhed i læggekartofler. Kravet er i Danmark 0,1 pct.

Organisationerne støtter intentionerne med dyrkningsfri år i forbindelse med fremavl med henblik på at forebygge problemer med spildfrø. Der foreslås generelt 5 år. Dette bør ifølge organisationerne være en minimumsbestemmelse, da der i de gældende danske regler er krav om 6 år for raps og 8 dyrkningsfri år for bederoer.

Organisationerne finder, at den foreslåede isolationsafstand og de foreslåede procentvise grænseværdier for fremavl af raps bør vurderes nærmere på et videnskabeligt grundlag.

En tidligere version af arbejdsdokumentet SANCO/1542/00 rev. 1 og rev. 2 har været sendt til høring i §2-udvalget (landbrug). Landbrugsraadet fandt i en foreløbig udtalelse af 6. august 2001, at forslaget indeholdt en række spørgsmål, hvis baggrund ikke var nærmere belyst, hvorfor Landbrugsraadet ikke kunne tage stilling til forslaget på daværende tidspunkt.

Tidligere forelæggelse for Folketingets Europaudvalg

Der er fremsendt grundnotat om en tidligere version af arbejdsdokumentet den 4. september 2001.

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

EXPLANATORY NOTE

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 non-genetically modified 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 or technically unavoidable presence of GM seeds in seed lots of non-genetically modified plant varieties

The seed marketing Directives lay down minimum conditions to be met by the seed crop and by the seed lots to be marketed, 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 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 non-genetically modified varieties due to adventitious or technically unavoidable presence in the seed crop 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 traces of GM seeds in seed lots of non-genetically modified varieties of cotton, oilseed rape and maize imported from USA and Canada. Member States reacted differently to these interceptions.

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.

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 non-genetically modified varieties was urgently needed.

Scope

The scope of the draft Commission Directive is limited to the plant species for which genetically modified varieties have currently been obtained and which are cultivated in the EU irrespective whether the seed was produced or harvested in the EU or in a third country : beet, maize, potato, swede rape, soya bean, cotton, chicory and tomato. If a new plant species has to be included later on, this can be done by Comitology by introducing new requirements for it in the annexes of the relevant seed marketing Directive.

Different requirements

The attached draft Commission Directive aims at achieving the objective for purity regarding the presence of genetically modified seeds in seed of non-genetically modified plant varieties, through the introduction of requirements in five different 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 (SCP) 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 non-genetically modified variety, the adventitious or technically unavoidable presence of genetically modified seed having received authorisation under part C of Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, should not exceed a specified threshold. The aim of this Directive is thus to introduce such a threshold.

In doing so, one has to take into account the threshold of 1% established for the adventitious presence of genetically modified material in food and food ingredients for labelling purposes under Commission Regulation (EC) N° 49/2000, which is in fact a derogation from labelling the food or food ingredient 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 presence 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 SCP.

In establishing such thresholds, the reproductive system of the plant as well as the probability of volunteers, as confirmed by the SCP, should be taken into account. Accordingly, the threshold should be :

- 0.3% for swede rape and cotton,
- 0.5% for tomato, beet, chicory, maize and potato,
- 0.7 % for soya bean.

Where the above thresholds are not fulfilled, the seed lot can be nevertheless marketed but with the conditions that any label or document, which accompanies the seed lot should state that the seed lot contains genetically modified seeds exceeding the established threshold. This approach is coherent with the approach followed under Commission Regulation (EC) N° 49/2000.

Where the above thresholds are respected, the seed lot can be marketed without special provisions in respect of labelling.

The above thresholds should however be without prejudice to the current standards for the minimum varietal purity, as established without specific reference to the presence of GM seed. They should normally be assessed in field inspections and refer to the presence of plants of the crop species which are recognisable as not being true to the variety. When such standards are not fulfilled, the seed lot must be rejected and can thus not be marketed.

b) Threshold for unauthorised GM seed

Directive 2001/18/EC requires that no genetically modified organism may be placed on the market, unless it has been authorised in accordance with that Directive. Compliance with this requirement should be ensured by applying defined seed sampling and testing conditions, as specified in a Commission Regulation on this topic described below.

It should be underlined that the envisaged Commission Directive amending the annexes of the seed Directives cannot modify Council Directive 2001/18/EC.

However, it is the intention of the Commission to propose to amend Directive 2001/18/EC to provide for the possibility of establishing thresholds for adventitious or technically unavoidable presence in seeds of non-genetically modified varieties, of minute amounts of genetically modified seeds not authorised in accordance with Community legislation, provided that certain conditions are fulfilled (positive opinion of a Scientific Committee or of the European Food Safety Agency).

Regulation on sampling and testing

In order to be able to monitor the requirements set out under a) and b) above in a harmonised way, a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seeds will be laid down in a Commission Regulation which should enter into force simultaneously with this Directive. In this Regulation, statistical parameters (level of quality – AQL and LQL- and confidence levels for consumer and producer) will be set. In particular, it will be defined that a lot can be accepted for certification

if no non-authorised genetically modified seeds are detected in 3000 seeds (Lower Quality Level of 0.1%, with a confidence level of 95% for the consumer).

c) Previous cropping

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 in order to limit the frequency of volunteer plants in the seed crop. In accordance with the SCP, which based its recommendation on current knowledge of seed longevity, 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 in

- the previous year in the case of maize and soya bean,
- the previous two years in the case of cotton, chicory and tomato,
- the previous five years in the case of beet, potato and swede rape.

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 by the SCP that current isolation distances are in general adequate if other measures to reduce out-crossing are implemented (in particular the use of physical or pollen barriers). As suggested in the opinion of the SCP, the normal distance should however be increased

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

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, as confirmed by the SCP.

Exemption from the examination of the satisfaction of the requirements

However, the various requirements related to the seed crop or to the seed lot, might not be carried out under given conditions, including the establishment and subsequent monitoring of areas for seed production for which it has officially been ensured that genetically modified plants of the same species or of a closely related species are not grown. Suitable arrangements should be taken at least by check inspection as regards compliance of the seed crop or seed lot with the requirements. The above conditions shall be established by the Commission by implementing measures.

This establishment of areas, at local level, based on criteria which will be harmonised, should avoid systematic control by the seed certifying agencies. Such controls are costly because of the technology used for the detection of GM. The establishment of areas will also have the indirect effect of facilitating the information between farmers and seed growers operating in this area and of fulfilling the requirements as regards isolation distances, previous cropping and thresholds. The control of such areas will be left to the national authorities.

It has to be mentioned that areas for seed production are already being set at national level (e.g.: in Italy for the production of beet seed, in UK for the production of seed of swede rape, beet and onion, to avoid cross-pollination affecting the production of seed), independently from the GM problematic, in order to facilitate seed production.

Revision clause

The provisions of this Directive will be reviewed by the Commission 4 years after its entry into force, in the light of new available information. In particular consideration will be taken of the extent of the cultivation of genetically modified varieties, of the status of the current food and food ingredient labelling threshold, or of the possible establishment of thresholds for the adventitious or technically unavoidable presence of genetically modified organisms in trace amounts in seeds of non-genetically modified varieties, for which an authorisation would not be required if certain conditions are fulfilled.

Delay of implementation of the requirements for seed crops

This Directive should enter into force as soon as possible (31 December 2002). However, the requirements as regards the obligations of means as described under c), d) and e) above of the seed crops, which were established before the date of publication of this Directive, cannot be imposed retroactively. They should thus be exempted for the initial implementation of this Directive.

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 information relating to the genetic modification itself.

4. Third Countries

Once this Directive will be adopted and before its entry into force, the Commission will adapt the current EU "seed equivalency regime" (Decisions 95/513/EEC and 95/514/EEC) according to which seed harvested in third countries may be marketed in the EU, to the conditions set out in this Commission Directive.

EN

SANCO/1542/02- January 2002

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



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29 January 2002

P:bn/doc2001/va/1542-jan2002

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

COMMISSION DIRECTIVE/EC

of [...]

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 and Decision 95/232/EC on the organisation of a temporary experiment in order to establish conditions to be satisfied by the seed of hybrids and varietal associations of swede rape and turnip rape

Draft

COMMISSION DIRECTIVE .../.../EC

of

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 and Decision 95/232/EC on the organisation of a temporary experiment in order to establish conditions to be satisfied by the seed of hybrids and varietal associations of swede rape and turnip rape

(Text with EEA relevance)

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, as last amended by Directive 98/96/EC² and in particular Article 21a thereof,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed³, as last amended by Directive 2001/64/EC⁴ and in particular Article 21a thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed⁵, as last amended by Directive 2001/64/EC and in particular Article 21a thereof,

Having regard to Council Directive 66/403/EEC of 14 June 1966 on the marketing of seed potatoes⁶, as last amended by Commission Decision 1999/742/EC⁷, and in particular Article 19a thereof,

Having regard to Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre plants⁸, as last amended by Directive 98/96/EC, and in particular Articles 2(1b), 12a and 20a thereof,

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- 1 OJ 125, 11.7.1966, p. 2290/66.
 - 2 OJ L 25, 1.2.1999, p. 27.
 - 3 OJ L 25, 11.7.1966, p. 2298/66.
 - 4 OJ L 234, 1.9.2001, p. 62.
 - 5 OJ 125, 11.7.1966, p. 2309/66.
 - 6 OJ 125, 11.7.1966, p. 2320/66.
 - 7 OJ L 297, 18.11.1999, p. 39.

Having regard to Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed⁸, as last amended by Council Directive 98/96/EC and in particular Article 40a thereof

Having regard to Commission Decision 95/232/EC of 27 June 1995 on the organisation of a temporary experiment under Council Directive 69/208/EEC in order to establish conditions to be satisfied by the seed of hybrids and varietal associations of swede rape and turnip rape¹⁰, as last amended by Decision 2001/18/EC¹¹,

Whereas:

- (1) Directives 66/400/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC as well as Commission Decision 95/232/EC in respect inter alia of hybrids of swede rape, lay down minimum conditions in respect of the crop and the seed, including those related to varietal purity. These conditions do not include specific growing conditions and other requirements regarding the presence of genetically modified seed, in particular in seed lots of non-genetically modified varieties. It is therefore appropriate to complement the minimum conditions in the seed marketing Directives with additional conditions and requirements concerning the presence of genetically modified seed, in particular in the case of adventitious or technically unavoidable presence of such seeds, in seed crops and in seed lots of non-genetically modified varieties.
- (2) Currently genetically modified varieties have been obtained for the following species cultivated in the EU : beet, maize, potato, swede rape, soya bean, cotton, chicory and tomato, and it is therefore appropriate to limit the scope of this Directive to such species.
- (3) It should be ensured that the level in seed lots of non-genetically modified varieties, of genetically modified seed having received authorisation in accordance with Community legislation for the placing on the market of genetically modified organisms, should be consistent with Community legislation for the adventitious presence of genetically modified organisms in food and food ingredients. Thresholds should be established in the case of adventitious or technically unavoidable presence

8 OJ L 169, 10.7.1969, p. 3.

9 OJ L 225, 12.10.1970, p. 7.

¹⁰ OJ L 154, 5.7.1995, p 22.

¹¹ OJ L 4, 9.1.2001, p.36.

of such seeds. In establishing such thresholds, the reproductive system of the plants concerned, as well as the probability of volunteers, as confirmed by the Scientific Committee on Plants (SCP) in its opinion on 7 March 2001 concerning the adventitious presence of GM seed in conventional seed, should be taken into account. Accordingly this threshold should be 0.3% for swede rape and cotton (cross-pollinated); 0.5% for tomato (self-pollinated), beet and chicory (cross-pollinated cultivated vegetatively), maize (cross-pollinated for which the probability of volunteers is very low) and potato (propagated and cultivated vegetatively); and 0.7% for soja bean (self-pollinated for which the probability of volunteers is very low). The above thresholds would contribute to achieve the current 1% threshold in food and food ingredients pursuant to Commission Regulation (EC) N° 49/2000¹², above which the indication of the presence of a genetic modification is compulsory. The impact of the inclusion of GM seed in the seed used to produce food and food ingredients on the target threshold of 1% has been confirmed by the SCP. Where the above thresholds are not fulfilled, any label or document which is affixed or accompanies the seeds should state that the seed lot contains genetically modified seeds exceeding the established threshold. The latter threshold should be without prejudice to the existing conditions to be satisfied by the seed in respect of the varietal purity.

- (4) Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC¹³ requires that no genetically modified organism may be placed on the market, unless it has been authorised in accordance with that Directive. Compliance with this requirement should be ensured by applying defined seed sampling and testing conditions. This requirement should be adapted following the adoption of a proposal which should amend Directive 2001/18/EC and foresee that the adventitious or technically unavoidable presence of genetically modified organisms in trace amounts in seeds should not require authorisation, if certain conditions are fulfilled.
- (5) Compliance with the above requirements should 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, as laid down in Commission Regulation (EC) N°/....

¹² OJ L 6, 11.1.2000, p. 13.

- (6) 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. As confirmed by the SCP, different break of rotation period based on the seed longevity should be followed.
- (7) 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. As confirmed by the SCP, higher isolation distances than the ones currently applicable to seed crops of the species concerned would not be needed, except in the case of beet and hybrids of swede rape for which the increased distances recommended by the SCP should be followed. As recommended by the SCP, other appropriate measures to reduce foreign pollination such as the use of physical or pollen barriers should be taken.
- (8) Furthermore, as recommended by the SCP, good practices for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling should be implemented.
- (9) The examination of the satisfaction of the various requirements related to the seed crop or seed lot, where appropriate, might not be carried out under given conditions, including the establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species or of a closely related species are not grown. Suitable arrangements should be taken at least by check inspection as regards the compliance of the seed crop and by check testing as regards the compliance of the seed lot. The above conditions shall be established by the Commission by implementing measures.
- (10) According to the seed marketing Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC, 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. It is 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 seed marketing Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC and Decision 95/232/EC should therefore be amended accordingly.
- (12) The provisions of this Directive will be reviewed in the light in particular of the extent of the cultivation of genetically modified varieties, of the status of the current food and food ingredient labelling threshold, or of the possible establishment of thresholds for the adventitious or technically unavoidable presence of genetically modified organisms in trace amounts in seeds of non-genetically modified varieties, for which an authorisation will not be required if certain conditions are fulfilled.
- (13) The requirements in respect of seed crops cannot apply retroactively to the seed crops established before the publication of this Directive and an exemption has thus to be foreseen in this Directive.
- (14) 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

Annexes I, III and IV to Directive 66/400/EEC are amended in accordance with Annex I to this Directive.

Article 2

Annexes IV and V to Directive 66/401/EEC are amended in accordance with Annex II to this Directive.

Article 3

Annexes I, II, IV and V to Directive 66/402/EEC are amended in accordance with Annex III to this Directive.

Article 4

Annexes I, II and III to Directive 66/403/EEC are amended in accordance with Annex IV to this Directive.

Article 5

Annexes I, II, IV and V to Directive 69/208/EEC are amended in accordance with Annex V to this Directive.

Article 6

Article 5 of Decision 95/232/EC is amended in accordance with Annex VI to this Directive.

Article 7

Annexes I, II, IV and V to Directive 70/458/EEC are amended in accordance with Annex VII to this Directive.

Article 8

The requirements specified in Annex I point 1, Annex III point 1, Annex IV point 1, Annex V point 1, Annex VI and Annex VII point 1 shall not apply to seed from seed crops which were established before the publication of this Directive.

Article 9

The Commission shall review the provisions of this Directive before 31 December 2006, on the basis of new available information.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2002. 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 9

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

Article 10

This Directive is addressed to the Member States.

Done at Brussels.

For the Commission

Member of the Commission

ANNEX I

Annexes I, III and IV to Directive 66/400/EEC are amended as follows:

(1) Annex I, Part A is amended as follows:

(a) In section 01 the following subparagraph is 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."

(b) The following sections 6, 7 and 8 are added:

"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 examination of the satisfaction of the conditions under sections 01, second subparagraph, and 6 above need not to be carried unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check inspection as regards the compliance of the seed crop with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 21. Such conditions shall include the establishment and subsequent monitoring of areas for seed production 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) In Annex I, part B the following section 1a is inserted after section 1:

"1a. Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I Part A and B section 1, in the case of seed of a non-genetically modified variety, the adventitious or technically unavoidable 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 0,5 %. In order to establish that the presence of this material is adventitious or technically unavoidable, the producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid genetically modified organisms.

Compliance with the above requirement and the requirement of Directive 2001/18/EC that no GMO be deliberately released or placed on the market unless it has been authorised in accordance with that Directive, 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 as laid down in Commission Regulation (EC) N° ...

The examination of the satisfaction of these requirements need not be carried unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 21. Such conditions shall include the establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

Notwithstanding the conditions laid down in the first subparagraph of this section, the Member States shall permit the marketing of such a seed of a non-genetically modified variety provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states :

- "the seeds contain genetically modified seeds exceeding 0.5%".

(3) Annex III is amended as follows:

(a) In part A I the following points 5a and 5 b are inserted:

"5a. For seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

5b. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(b) In part B the following points 7 a and 7 b are inserted:

"7a. For seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

7b. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(4) Annex IV is amended as follows:

(a) In part A the following indents are inserted after the fourth indent:

"- for seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1 a, first subparagraph :

"the seed lot contains genetically modified seeds exceeding 0.5%".

- in the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself. "

(b) In part C the following indents are inserted after the third indent:

"- for seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, first subparagraph :

"the seed lot contains genetically modified seeds exceeding 0.5%".

- in the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself. "

ANNEX II

Annexes IV and V to Directive 66/401/EEC are amended as follows :

(1) Annex IV is amended as follows:

(a) In part A(b)(a) the following point 5a is inserted:

“5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(b) In part A(1) (c) (4) the following subparagraph is added:

“In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(c) In part B (a) the following points 7a is inserted:

“7a. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(d) In part B (c)(11) the following subparagraph is added:

“In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(2) Annex V is amended as follows:

(a) In part A the following indent is inserted after the third indent:

“- in the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(b) In part C the following indent is inserted after the third indent:

“- in the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

ANNEX III

Annexes I, II, IV and V to Directive 66/402/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) In section 1 the following subparagraph is added:

"In the case of a crop of a non-genetically modified variety of maize, 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."

(b) The following section 2a is inserted after section 2:

"2a. In relation to any neighbouring sources of pollen of genetically modified plants of maize 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."

(c) The following sections 6 and 7 are added:

"6. In the case of maize, 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. In the case of maize, the examination of the satisfaction of the conditions under sections 1, second subparagraph, and 2a above need not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check inspection as regards the compliance of the seed crop with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 21. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production 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) In Annex II the following section 1a is inserted after section 1:

"1a. Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 3 and Annex II section 1, in the case of seed of a non-genetically modified variety of maize, the adventitious or technically unavoidable 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 0,5 %. In order to establish that the presence of this material is adventitious or technically unavoidable, the producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid genetically modified organisms.

Compliance with the above requirement and the requirement of Directive 2001/18/EC that no GMO be deliberately released or placed on the market unless it has been authorised in accordance with that Directive, 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 as laid down in Commission Regulation (EC) N° .../...

The examination of the satisfaction of these requirements needs not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 21. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

Notwithstanding the conditions laid down in the first subparagraph of this section, the Member States shall permit the marketing of such a seed of a non-genetically modified variety provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

(3) Annex IV is amended as follows:

(a) In part A (a) the following points 5a and 5 b are inserted:

"5a. For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

5b. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(b) In part A (b)(4) the following subparagraphs are added:

For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a first subparagraph :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(4) Annex V is amended as follows:

(a) In part A the following indents are inserted after the third indent:

- For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

“the seed lot contains genetically modified seeds exceeding 0.5%”.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(b) In part C the following indents are inserted after the third indent:

- For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

“the seed lot contains genetically modified seeds exceeding 0.5%”.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

ANNEX IV

Annexes I, II and III to Directive 66/403/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) the following section 01 is 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."

(b) The following sections 7, 8 and 9 are added:

"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 examination of the satisfaction of the condition under section 01, second sentence above needs not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check inspection as regards the compliance of the seed crop with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 21. Such conditions shall include the possible establishment and monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

9. Presence of genetically modified seed potatoes:

Without prejudice to the conditions to be satisfied by the seed potatoes in respect of varietal purity in accordance with Annex I sections 1b and 2b, in the case of seed potatoes of a non-genetically modified variety, the adventitious or technically unavoidable 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 0,5 %. In order to establish that the presence of this material is adventitious or technically unavoidable, the producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid genetically modified organisms.

Compliance with the above requirement and the requirement of Directive 2001/18/EC that no GMO be deliberately released or placed on the market unless it has been authorised in accordance with that Directive, 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 as laid down in Commission Regulation...

The examination of the satisfaction of these requirements need not be carried out unless there is doubt whether these requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 19. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

Notwithstanding the requirements laid down in the first subparagraph of this section, the Member States shall permit the marketing of such a seed of a non-genetically modified variety provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states :

- "the seed potato lot contains genetically modified seeds exceeding 0.5%".

(2) In Annex III, part A, the following points 4a and 4 b are inserted:

- For seed potatoes of non-genetically modified varieties which do not meet the condition laid down in Annex I point 9, first subparagraph :

"the seed potato lot contains genetically modified seed potatoes exceeding 0.5%".

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

ANNEX V

Annexes I, II, IV and V to Directive 69/208/EEC are amended as follows:

(1) Annex I is amended as follows.

(a) In section 1 the following subparagraph is 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 cotton,
- the previous five years in the case of swede rape."

(b) The following section 2a is inserted after section 2:

"2a. In relation to any neighbouring sources of pollen of genetically modified plants of swede rape or cotton, 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. "

(c) The following sections 6 and 7 are added:

"6. In the case of swede rape, soya bean or cotton, 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. In the case of swede rape, soya bean or cotton, the examination of the satisfaction of the conditions under sections 1, second subparagraph, and 2a above needs not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check inspection as regards compliance of the seed crop with the requirements. The conditions for the exemption shall be determined in accordance with the procedure laid down in Article 20. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production 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) Annex II is amended as follows:

In Part I the following section 1b is inserted after section 1a:

"1b. Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 3 and Annex II section 1 or in the case of hybrids of swede rape with points 2, 3 and 5 of the annex to Commission Directive 95/232/EEC, in the case of seed of a

non-genetically modified variety of swede rape, soya bean or cotton, the adventitious or technically unavoidable 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 0,3 % for swede rape and cotton, and 0,7 % for soya bean. In order to establish that the presence of this material is adventitious or technically unavoidable, the producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid genetically modified organisms.

Compliance with the above requirement and the requirement of Directive 2001/18/EC that no GMO be deliberately released or placed on the market unless it has been authorised in accordance with that Directive, 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 as laid down in Commission Regulation (EC) N°/....

The examination of the satisfaction of these requirements needs not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements. The conditions for the exemption shall be determined in accordance with the procedure laid down in Article 20. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

Notwithstanding the conditions laid down in the first subparagraph of this section, the Member States shall permit the marketing of such a seed of a non-genetically modified variety provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states :

- "the seed lot contains genetically modified seeds exceeding

0.3% for swede rape and cotton

0.7% for soya bean".

(3) In Annex IV, part A(a), the following points 6a and 6 b are inserted:

"6a. For seed of non-genetically modified varieties of swede rape, soya bean and cotton, which do not meet the conditions laid down in Annex II, Part I, section 1b, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding

0.3% for swede rape and cotton

0.7% for soya bean".

6b In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(4) In Annex IV, part A(b), the following point 6 b is inserted:

"6 b. For seed of non-genetically modified varieties of swede rape, soya bean and cotton, which do not meet the conditions laid down in Annex II, Part I, section 1b, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding

0.3% for swede rape and cotton

0.7% for soya bean".

(5) Annex V is amended as follows:

(a) In part A the following indents are inserted after the third indent:

- For seed of non-genetically modified varieties of swede rape, soya bean and cotton, which do not meet the conditions laid down in Annex II, Part I, section 1b, first subparagraph :

"the seed lot contains genetically modified seeds exceeding

0.3% for swede rape and cotton

0.7% for soya bean".

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(b) In part C the following indents are inserted after the third indent:

- For seed of non-genetically modified varieties of swede rape, soya bean and cotton, which do not meet the conditions laid down in Annex II, Part I, section 1b, first subparagraph :

"the seed lot contains genetically modified seeds exceeding

0.3% for swede rape and cotton

0.7% for soya bean".

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

ANNEX VI

Decision 95/232/EC is amended as follows :

(1) Article 3 is replaced by the following :

“ Seed of hybrids and varietal associations of swede rape and turnip rape may be marketed within the Community provided that the conditions and requirements in the Annex are satisfied, without prejudice to the conditions laid down in Council Directive 69/208/EEC in respect of the seed crops, the seed lots and the labels of non-genetically modified varieties of swede rape”.

(2) In point 1(c) of the Annex the following subparagraph is added :

“ For the production of seed of hybrids of swede rape the minimum distance shall be at least 5000 meters for the production of basic seed and 3000 meters for the production of certified seed”.

ANNEX VII

Annexes I, II, IV and V to Directive 70/458/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) The following section 01 is 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 of chicory or tomato, no genetically modified plants of the same species or of a closely related species shall have been grown in the field during the previous two years.

(b) The following sections 6, 7 and 8 are added:

"6. In the case of any neighbouring sources of pollen of a genetically modified plant of chicory 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."

7. In the case of chicory and tomato, 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. In the case of chicory and tomato, the examination of the satisfaction of the conditions under sections 01, second subparagraph, and 6 above needs not be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check inspection as regards the compliance of the seed crop with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 40. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production 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) In Annex II the following section 1a is inserted after section 1:

"1a. Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 1 where applicable and Annex II section 1, in the case of seed of a non-genetically modified variety of chicory or tomato, the adventitious or technically unavoidable 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 0,5 %. In order to establish that the presence of this material is adventitious or technically unavoidable, the producers must be in a

position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid genetically modified organisms.

Compliance with the above requirements and the requirement of Directive 2001/18/EC that no GMO be deliberately released or placed on the market unless it has been authorised in accordance with that Directive, 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 as laid down in Commission Regulation (EC) N° .../...

The examination of the satisfaction of these requirements needs not to be carried out unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements. The conditions for the application of this exemption shall be determined in accordance with the procedure laid down in Article 40. Such conditions shall include the possible establishment and subsequent monitoring of areas for seed production for which it has been officially ensured that genetically modified plants of the same species, or of a closely related species, are not grown.

Notwithstanding the conditions laid down in the first subparagraph of this section, the Member States shall permit the marketing of such a seed of a non-genetically modified variety provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

(3) Annex IV is amended as follows:

(a) In Part A (a) the following point 6a and 6 b are inserted:

"6a. For seed of non-genetically modified varieties of chicory or tomato which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

- "the seed lot contains genetically modified seeds exceeding 0.5%".

6b. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(b) In Part B (a) the following point 5a and 5 b are inserted:

"5a. For seed of non-genetically modified varieties of chicory or tomato which do not meet the condition laid down in Annex II, section 1a, first subparagraph:

- "the seed lot contains genetically modified seeds exceeding 0.5%".

5b. In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself."

(4) Annex V is amended as follows:

(a) In Part A the following indent is inserted after the third indent:

- For seed of non-genetically modified varieties of chicory or tomato which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

“the seed lot contains genetically modified seeds exceeding 0.5%”.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”

(b) In Part C the following indent is inserted after the third indent:

- For seed of non-genetically modified varieties of chicory or tomato which do not meet the condition laid down in Annex II, section 1a, first subparagraph :

“the seed lot contains genetically modified seeds exceeding 0.5%”.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information relating to the genetic modification itself.”