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Ruimtelijke Ordening en Milieubeheer

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Directorate-General Environmental
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Directorate for Chemicals, Safety and Radiation
Protection

Florigene Europe B.V.
Waardlaan 4A
2231 NA RIJNSBURG

Uw kenmerk

Uw brief

June 3, 1997

Kenmerk

C/NL/97/13.con

Datum

October 20, 1998

Onderwerp

Consent to
placing on the Market
Notification C/NL/97/13

Dear Sir,

In response to your notification, forwarded to the European Commission by letter of July 29, 1998, for placing on the market of the genetically modified carnation lines 959A, 988A, 1226A, 1351A, 1363A and 1400A registered under number C/NL/97/13;

Having regard to the Council Directive 90/220/EEC of 23 april 1990 on the deliberate release into the environment of genetically modified organisms as amended by Commission directive 97/35/EEC and in particular Article 13 thereof;

Whereas the specificity of the product is an ornamental plant sold as cutflower, cuttings, plants or offspring of the plants when used for breeding purposes;

Whereas the notifier, will add a sentence to the proposed labelling leaflet that will accompany the flowers throughout the chain indicating that the flowers are genetically modified to alter the flower colour and are only produced for use as ornamental product;

Whereas the sulphonyl urea resistance is to be used as a marker trait only;

Whereas Florigene Europe B.V. has submitted additional information with respect to the molecular characterisation and the possibilities of hybridization with wild relatives, confirming the statements as made in the notification;

Whereas the competent authorities of other member states have not raised objections to the said notification;

Bijlagen
Whereas based on the above notification, the appendices, the additional information and the above considerations, The Netherlands Competent Authority concludes that no reasons have emerged on the basis of which a consent to the proposed placing on the market should be withheld;



Kenmerk

Datum

Bladnummer

I hereby give consent, also on behalf of the Minister of Agriculture, Nature Management and Fisheries, for the placing on the market of the product for which a notification is submitted, as forwarded to the European Commission by letter of July 29, 1998, registered under number C/NL/97/13.

The product consists of carnation plants (*Dianthus caryophyllus* L.) derived from genetically modified carnation lines 959A, 988A, 1226A, 1351A, 1363A and 1400A in which the following genes are introduced:

- the *dfp*-gene, coding for dihydroflavonol reductase, derived from *Petunia hybrida*, under its own promoter and terminator;
- the *bp40*-gene, coding for flavonoid 3', 5' hydroxylase, derived from *Viola* sp., under control of the petal specific CHS promoter derived from *Petunia hybrida* and the D8 terminator derived from *Petunia hybrida*;
- the *surB*-gene, coding for acetolactate synthase protein, derived from *Nicotiana tabacum*, under control of the constitutive 35S promoter derived from cauliflower mosaic virus and the *surB* terminator derived from *Nicotiana tabacum*.

The product includes progeny derived through vegetative reproduction as well as progeny derived through crosses of the genetically modified carnation lines 959A, 988A, 1226A, 1351A, 1363A and 1400A with any traditionally bred non-genetically modified carnation plant.

The above mentioned genetically modified carnation plants derived from the different lines are registered under the following separate consent registration numbers:

- carnation line 959A is registered under number C/NL/97/13-959A;
- carnation line 988A is registered under number C/NL/97/13-988A;
- carnation line 1226A is registered under number C/NL/97/13-1226A;
- carnation line 1351A is registered under number C/NL/97/13-1351A;
- carnation line 1363A is registered under number C/NL/97/13-1363A;
- carnation line 1400A is registered under number C/NL/97/13-1400A.

The Hague,

The Minister of Housing, Spatial Planning and the Environment,
p.p. the Director for Chemicals, External Safety and Radiation Protection



dr. C.M. Plug

Kopie f. Bendick
Kopie f. 51

TELEFAX

Im - Honiger

DATE: 24 december 1997 PAGE(S): 3	TO: The Competent Authorities for 90/220/EEC and the European Commission	
From: P.J. van der Meer Ministry of Housing, Spatial Planning and Environment VROM/DGM/SVS/SNB P.O. Box 30945 2500 GX The Hague The Netherlands Tel: +31 70 339 4893 Fax: +31 70 339 1314 E-mail: P.J.VanDerMeer@DSVS.DGM.minvrom.nl	Mr. A. Haslinger, AT	Dr. H. Marquard, GB
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	Dr. W. Moens, BE	Mr. G. Alvanopoulos, GR
	Dr. H.J. Buhk, DE	Ms. Th. Kelaidi, GR
	Dr. G. Schubert, DE	Dr. T.J. McLoughlin, IE
	Mr. A.S. Welinder, DK	Ms. A. Magnusdottir, IS
	Ms. E. Barahona, ES	Dr. G. Battaglini, IT
	Ms. H. Leiwo, FI	Ms. Backes-Lies, LU
	Ms. M. Ruohonen-Lehto, FI	Mr. I.A. Baste, NO
	Dr. S. Beranger, FR	Mr. J. Nascimento, PT
	Dr. H. Reverbori, FR	Mr. E. Jonsson, SE
	Ms. C. Pierce, EC	
REGARDS: Consent - notification nr. CNL/96/14		

Dear colleagues,

In accordance with Article 13.4 of Council Directive 90/220/EEC of 23 April 1990, I herewith send you a copy of a consent to market genetically modified organisms.

Sincerely yours,

P.J. van der Meer
P.J. van der Meer

Robert Koch-Institut	FR 5
24.12.97	51
97105257	525

29/12/97

*Sch. R. z.w.V.
Koch, S. & volder, par
Kochung an Koch*