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## **ASSESSMENT REPORT OF THE DUTCH COMPETENT AUTHORITY IN ACCORDANCE WITH DIRECTIVE 2001/18/EC**

### **NOTIFICATION C/NL/13/01**

#### **1. THE NOTIFICATION**

The notification, submitted by Suntory Holdings Limited, Osaka, Japan, concerns placing on the market of imported cut flowers derived from genetically modified carnation (*Dianthus caryophyllus*) line SHD-27531-4 in accordance with Directive 2001/18/EC. The flowers of the carnation line have been modified with the *dfc* gene from petunia (*Petunia x hybrida*) and the *f3'5'h* gene from *Viola* sp., resulting in a modified flower colour (purple/red). Line SHD-27531-4 also contains a herbicide resistance gene (*suRB*) from *Nicotiana tabacum*, used to facilitate selection *in vitro*.

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#### **2. SCOPE OF THE NOTIFICATION**

This notification concerns import, distribution and retailing of line SHD-27531-4 in the cut flower market in the same way as any other carnation. This notification does not include cultivation, the use as feed or as food of line SHD-27531-4.

#### **3. HISTORY**

Carnation line SHD-27531-4 is commercially grown in Columbia. In the USA and Canada the import of carnation line SHD-27531-4 is already approved. Two similar transgenic varieties which were modified with the same vector (pCGP1991), FLORIGENE Moonshadow™ (C/NL/97/13-1363A) and FLORIGENE Moonaqua™ (C/NL/06/01), have been approved for import and/or cultivation in the USA, Canada, Japan and Australia since 1997. Furthermore, the carnation lines FLORIGENE Moonaqua™ and FLORIGENE Moonlite™ (C/NL/04/02) have already been approved in the EU for import, distribution and retailing.

#### **4. PROCEDURE**

The Dutch competent authority (CA) received this dossier on March 13, 2013 under Directive 2001/18/EC. The dossier has been assessed with reference to Article 13 of this Directive.

#### **Additional information**

During the assessment period further information was requested on April 14 and May 28, 2013.

### Scientific advice

Based on the notification of March 4, 2013 and the corrected version of the dossier of May 7, 2013 the Dutch scientific advisory committee (COGEM) gave its advice on May 28, 2013 (CGM/130528-02). COGEM concluded that the molecular characterization as presented by the applicant does not meet their guidelines. The bioinformatic analysis of the putative proteins encoded by the fusion ORFs spanning the junctions between genomic carnation DNA and integrated T-DNA in transgenic carnation line SHD-27531-4 was analyzed from start codon to stop codon, while COGEM deems it necessary that the bioinformatics analysis is performed from stop codon to stop codon. On June 25, 2013 the applicant provided the requested additional information. COGEM concluded on July 11, 2013 that the risks for human health and the environment associated with import of cut flowers of line SHD-27531-4 are negligible (CGM/130711-01).

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### Public comments

The Summary Notification Information Format (SNIF) was published on the website of the Joint Research Center (JRC) on April 8 (2013). Public comments were received during 30 days and originated from the Netherlands and other member states. Only comments originating from the Netherlands (in Dutch and English) were addressed.

### Public comments on the notification C/NL/13/01 and reaction of the Dutch CA

Public comments which were addressed by the Dutch CA were:

1. A member of the public has sent in a copy of an open letter to mr. Barroso of the European Commission, dated April, 2013, in which is - among other- referred to GMOs, the Universal Declaration of Human Rights and the declaration of western principles on the conduct of journalists. This letter contains a section with comments on carnation SHD-27531-4 (C/NL/13/01). In this section of the letter it is stated that tetracycline is a regular used antibiotic and should not be used for this kind of useless purpose.  
**Answer:** Tetracycline is not used as an antibiotic on the flowers. However, the tetracycline resistance gene is used during the process of genetic modification. This gene was part of the vector used to genetically modify the carnation, but is not inserted in the carnation itself. The absence of the tetracycline resistance gene in the GM carnation is experimentally demonstrated.
2. In the section of the letter as mentioned above (see 1.), the person also states that GM carnation is not the same as natural carnation. They have different colours, and significantly fewer filaments and viable anthers than the recipient, and significantly shorter filaments. Moreover, the pollen is less viable.  
**Answer:** It was the purpose of the genetic modification to obtain a different flower colour. As a result of the process of genetic modification, the flowers can also develop other phenotypic differences, such as the observed changes in filaments, anthers and viability of pollen. These changes are not uncommon in breeding of flowers. More important, these changes will not result in a selective advantage of the modified carnation in comparison to its parental variety.
3. A member of the public states that profit seeking biotech companies must ensure a clean water supply, without any toxins. According to this person. biotech companies pose a worldwide danger and should be forced to build water treatment plants.  
**Answer:** It is not clear what the relation is between the import of genetically modified carnations and its effect on a clean water supply. The carnations will

not be cultivated in Europe, nor will they be treated with herbicides. Therefore, this comment cannot be further addressed.

4. A member of the public states that the GM carnation exhibits several phenotypic differences in comparison to the parental line with respect to filaments (number and length), anthers and pollen viability. This person also refers to the use of tetracycline.

**Answer:** See the reaction on comment 1 and 2.

5. A member of the public asks what would happen if bees are attracted to the genetically modified carnation flowers and would transport pollen. It is known that a German beekeeper could not sell its biological honey because of the presence of genetically engineered ingredients in the honey.

**Answer:** The scope of the notification is for import of cut flowers for ornamental use, and excludes cultivation. The imported flowers will mainly be used for ornamental use inside houses. Therefore, bees will not come in contact with the flowers. Even if they would come in contact with flowers, potential spread of pollen will be negligible since domesticated carnations, like the GM carnation, produce only a few anthers and little pollen.

6. The person asks what would happen with butterflies that are mainly attracted to purple flowers. Purple seems to be a popular colour for butterflies, according to this person. In addition, purple flowers seem to carry much nectar.

**Answer:** See also the reaction on question 5.

Butterflies that are mostly attracted to purple flowers will not be affected by the ornamental use of the carnations, since there will be no direct contact. The flowers will mainly be kept on display inside houses. Even in case a butterfly will come in contact with a few purple carnations, this will have no effect on populations of butterflies since the change in flower colour in carnation line SHD-27531-4 has been demonstrated not to result in toxic effects.

7. The person asks if bees, butterflies and other useful insects still recognize the colour, after the change in flower color. What do we know about the function of flower colour anyway? According to this person a certain colour represents a certain property or functionality, which is unknown.

**Answer:** See also the reaction on comment 6. The scope of the notification is for import of cut flowers for ornamental use, and excludes cultivation. Therefore bees or butterflies will not come in contact with the flowers. The question whether insects still recognize the colour of the flower or the question what the function is of flower colour is therefore not of relevance for this notification.

8. This member of the public notes that carnation flowers may form roots or may be otherwise propagated. Therefore it cannot be ruled out that the material will be propagated by third parties.

**Answer:** The Committee on Genetic Modification (COGEM) has reviewed this aspect in her advices CGM/130528-02 and CGM/130711-01. Carnation is not able to spread vegetatively and cut flowers are not able to form roots. It cannot be completely ruled out that buyers will propagate material to plant in their gardens. However, carnation has no weedy characteristics. Although carnation has been cultivated for decades, it has never been found outside the cultivation areas. The introduced traits (modified flower colour and herbicide tolerance) do not introduce a potential for weediness. It is therefore highly unlikely that the genetically modified carnation line SHD-27531-4 will spread in the environment after potential propagation by third parties.

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9. This person asks what will happen to the function of the aromatic substances, flavorings and toxic substances when the flower colour is changed?

**Answer:** Potential effects of colour changed carnation lines on incidental human consumption, allergenicity and (soil) toxicity were assessed using several assays. The results of these assays did not indicate any differences in comparison with the parental strains and are sufficient to conclude on the environmental safety of the product (cut flowers). Potential effects on other aspects like aromatic substances and flavorings of these flowers are not considered to be of importance for the safety assessment since the notification only covers import of cut flowers and no cultivation.

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10. This member of the public asks if the applicant used human embryonic intestinal cells to determine the toxicity of the flower for humans, as was performed for C/NL/04/02.

**Answer:** An Ames/Salmonella test was not performed for carnation line SHD-27531-4. The carnation is not meant for consumption and relevant data are supplied on the lack of toxicity for humans in case of incidental consumption, such as petals as garnishment of food. The data as contained in the dossier are therefore sufficient to conclude on the safety of cut flowers of this carnation line for human health and the environment.

11. This person objects to this market approval for ethical reasons and requests to take into account ethical considerations of European consumers. According to this person, Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.

**Answer:** According to Annex VI of Directive 2001/18/EC a notification has to be assessed on potential risks for human health and the environment only. Therefore comments not related to the environmental safety of the product are not taken into account in the assessment of this notification on genetically modified carnation.

### **Confidentiality**

The notification does not contain any information which the applicant regards as Confidential Business Information.

## **5. LIST OF DOCUMENTS**

The dossier consists of:

- Technical information required according to Annex III B of Directive 2001/18/EC;
- Environmental risk assessment according to Annex II of Directive 2001/18/EC;
- Additional information according to Annex IV of Directive 2001/18/EC;
- Monitoring plan according to Annex VII of Directive 2001/18/EC;
- Summary notification format;
- Information about previous releases of the genetically modified plant;
- Seventeen attachments (A1-A11, B1-B5 and C1).

## **6. PARENTAL OR RECIPIENT CROP**

Carnation (*Dianthus caryophyllus*) has a long history of safe use. Carnation does not have any weedy characteristics and despite hundreds of years of cultivation and plantings in parks and gardens, it has not become a weed or escaped from cultivation anywhere in the world.

Cultivation of carnation in the field is mainly conducted in Italy and Spain. In northern European countries such as Germany, France and the Netherlands, carnation is grown in greenhouses, due to a less favourable climate.

Within Europe, wild *Dianthus* species are mainly found in mountainous areas in the alpine region, the Balkan and the Mediterranean area.

Carnation is an annual plant. Carnation is semi-winter hardy and cannot survive in areas where temperatures occur below - 5 °C. Carnations are sold as cut flowers, cuttings or plants. Cultivated carnation is not propagated by seed but is propagated vegetatively by cuttings and tissue culture. In horticulture, propagation involves the use of mother plants. Cuttings of these mother plants are used for the production of flowers for a period of two years.

Carnation does not form vegetative reproductive structures such as bulbs, stolons or rhizomes. The genetic material of carnation can be disseminated via seed and by pollen. Seed dispersal can theoretically occur from plants, but seed formation is impossible for cut flowers. Carnation pollen can only be dispersed by lepidopteran insects as moths. Pollen is not wind dispersed. Carnation is highly domesticated by generations of breeding aimed at improvement of flower size and colour variation. As result of domestication, dissemination through pollination is much less effective in carnation than in wild *Dianthus* species. In general, production of viable pollen by carnation is much lower than that of wild *Dianthus* species.

Wild relatives which can give viable progeny after hybridisation with carnation are absent in large areas of Europe. The only possible hybridization partners are other cultivated carnations and wild *Dianthus* species. However, there has never been any evidence of spontaneous hybridization between cultivated carnation and wild *Dianthus* species, despite decades of cultivation in gardens and parks.

In summary, carnation does not have any characteristic which might pose a risk to human health and the environment.

## 7. DESCRIPTION OF THE PRODUCT

The genetically modified carnation (*Dianthus caryophyllus* L.) line SHD-27531-4 exhibits a modified flower colour (purple/red) resulting from expression of the *dfR* and *f3'5'h* genes. Gene expression enables the biosynthesis of delphinine pigment in the petals. Line SHD-27531-4 also contains the herbicide tolerance gene *suRB* (also known as ALS) used to facilitate selection *in vitro*. Expression of this gene confers tolerance to sulfonylurea herbicides.

## 8. MOLECULAR CHARACTERISATION

The Dutch CA is of the opinion that the provided information regarding the molecular characterization of line SHD-27531-4 is sufficient to assess potential hazards for human health and the environment.

### Modification

Carnation line SHD-27531-4 was obtained by *Agrobacterium tumefaciens* mediated transformation, by co-cultivating cells with strain AGL0 that contains vector pCGP1991. The transformation vector is completely sequenced and the sequence is part of the notification.

Plasmid pCGP1991 contains the following elements in the T-DNA:

Genetic element	Size (kbp)	Origin and function in plant
LB	0.8	Left T-DNA border from <i>A. tumefaciens</i>
35S promoter	0.2	Constitutive promoter from <i>Cauliflower mosaic virus</i> (CaMV)

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<i>Cab 5'utr</i>	0.1	5'untranslated region (UTR) from the chlorophyll a/b binding protein gene, derived from <i>Petunia x hybrida</i>
<i>suRB</i>	4.0	Encodes acetolactate synthase (ALS) from <i>Nicotiana tabacum</i> , resulting in resistance against chlorsulfuron. Contains its own terminator
<i>dfr</i> genomic clone	5.0	Encodes a key enzyme from the anthocyanin biosynthesis pathway, dihydroflavonol-4-reductase hydroxylase, from <i>Petunia x hybrida</i> , and containing its own promoter and terminator
CHS promoter	1.2	Petal specific promoter of chalcone synthase gene from <i>Antirrhinum majus</i>
<i>f3'5'h</i>	1.8	Encodes the key enzyme of the anthocyanin biosynthesis pathway, flavonoid 3'5'-hydroxylase, from <i>Viola</i>
D8 terminator	0.8	Terminator from <i>Petunia x hybrida</i>
RB	1.8	Right T-DNA border from <i>A. tumefaciens</i>

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Plasmid pCGP1991 contains the antibiotic resistance marker tetracycline on the vector backbone.

#### *f3'5'h* and *dfr*

The genes *f3'5'h* encoding flavonoid 3'5'hydrolase and *dfr* encoding dihydroflavonol 4-reductase are derived from *Viola* and *Petunia* (*Petunia x hybrida*), respectively. Simultaneous expression of both genes in carnation results in a modified flavonoid synthesis in flowers, and subsequent formation of the blue pigment delphinine. Carnation lacks part of the anthocyanin biosynthetic pathway involved in the production of delphinine, *i.e.* carnation lacks the flavonoid 3'5' hydrolase enzyme activities. Expression of both inserted genes, in combination with endogenous genes, results in a modified flower colour (purple/red instead of pink).

#### *SuRB*

The *suRB* gene from *Nicotiana tabacum* encodes a mutated acetolactate synthase. Expression of this mutated enzyme confers tolerance to sulfonylurea herbicides. According to the applicant, this tolerance was only included to allow selection *in vitro*.

### **Molecular characterization**

#### *Inserts*

Genomic DNA isolated from the transgenic line SHD-27531-4 and the non-transformed line Cinderella were compared using Southern analysis and sequencing to identify integrated sequences and copy number of the introduced genes. Southern analysis with *EcoRI* and *BglII* digested DNA indicates that a single integration of the T-DNA has occurred at a single locus in the carnation nuclear genome. A schematic of the arrangement of the inserted T-DNA is provided in Attachment A6. The sequence of the locus, including flanking regions, is provided in Attachment A7.

#### *Flanking sequences*

The flanking sequences of both ends of the locus are sequenced (150 bp). The flanking sequences were analysed for putative open reading frames (ORFs). All ORFs were included (no minimal size, from stop to stop codon). Eleven new ORFs in the junctions insert/plant were identified. None of the ORFs showed biologically significant homology to known toxins or allergens.

#### *Absence of tetracycline resistance gene (tetA)*

Southern analysis was conducted to demonstrate the absence of backbone vector sequences. The results prove the absence of any backbone vector sequences,

including *tetA* sequences encoding a resistance gene to the antibiotic tetracycline. In addition, PCR analysis with primers directed against the *tetA* gene confirmed the absence of this gene.

### Gene expression

Northern analysis conducted on RNA isolated from petal leaves showed that all three newly introduced genes are expressed in SHD-27531-4, whereas no signals could be detected in parental line Cinderella.

Except for flowers, delphinine production has not been observed in other tissues of the transgenic plant, such as stems, nodes, leaves and roots. Due to the petal specific promoter (CHS), production of delphinine is confined to the petals. Moreover, the biochemical pathway leading to anthocyanin biosynthesis is induced to coincide with flower development.

The concentration of delphinine was determined in flower samples of line SHD-27531-4 and of the non-transformed recipient strain by TLC and HPLC. The delphinine concentration amounts 1.18 mg/g fresh weight petal. Due to the genetic modification also cyanidine is produced in petal leaves with a concentration of 0.51 mg/g fresh weight.

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## 9. ENVIRONMENTAL RISK ASSESSMENT

The Dutch CA is of the opinion that the provided information regarding the environmental safety of line SHD-27531-4 is sufficient to assess potential hazards for human health and the environment.

The environmental risk assessment of the carnation with a modified flower colour was restricted to issues that are relevant within the scope of the notification: import, distribution and retailing of cut flowers.

### ***Selective advantage and potential for increased weediness or persistence***

#### *f3'5'h and dfr genes*

There is no reason to assume that carnation plants from spilled or discarded carnation exhibit an increased potential to survive, as a result of the modified colour of flowers resulting from expression of the *f3'5'h* and *dfr* genes. The gene products of *f3'5'h* and *dfr* are involved in the biosynthesis of the pigment delphinine in petals. Accumulation of these pigments in petals results in a purple/red flower colour and does not alter the biological characteristics of carnation. Therefore it is highly unlikely that the genetically modified carnation line SHD-27531-4 exhibits a selective advantage over non-modified carnation, based on the presence of the *f3'5'h* and *dfr* genes.

#### *suRB gene*

Carnation is not considered to be a weed in Europe. Carnation plants resistant to sulfonylurea herbicides can only exhibit a selective advantage after application of such herbicide. However, sulfonylurea herbicides are not designed/registered for use with ornamentals. Sulfonylureas are not effective against grasses, the major weeds of concern in the flower industry. The notifier prohibits use of sulfonylureas on their crops by their contract growers. The herbicide is not generally used for wide scale control of weeds outside agriculture.

### ***Effects on non-target organisms***

The environment in which the imported flowers will be used, the relatively small number of flowers imported, their dispersal across Europe, and the short longevity of the flowers are all factors that preclude any direct or indirect interaction between the genetically modified carnation and non-target organism.

Therefore it is highly unlikely that non-target organisms will be affected as a result of import of cut flowers of line SHD-27531-4.

### **Effects on the soil ecosystem**

Because the products are to be imported as cut flowers, no cultivation takes place. As the genetically modified carnation plants have similar production requirements as other carnations, any impact is no different to that of conventional carnation. Flowers imported to the EU will eventually be discarded in domestic and commercial waste, but the volume of the flowers and the fact that the products will be widely dispersed mean the organic mass is negligible. In addition, the compounds responsible for the colouration of the flowers are natural compounds which are widely present in the environment.

Therefore it is highly unlikely that any adverse effect on the soil ecosystem will occur as a result of imported or discarded genetically modified carnation.

### **Toxicity and allergenicity**

#### *Delphinine*

Carnation has been used safely by humans for ornamental purposes for centuries. The modification in line SHD-27531-4 (production of delphinine) is novel for carnation, but there are many flowers and other ornamental species that produce delphinine, such as *Gentiana*, *Petunia*, *Centaurea* and *Delphinium*. Delphinine is also present in many common foods, such as red grapes, black currants, eggplant and blueberry. Toxicity studies of delphinidins indicate very low levels of toxicity. Humans are commonly exposed to and ingest delphinidins in fruits and vegetables at similar or greater concentrations than are found in genetically modified carnation, without adverse effects.

#### *f3'5'h and dfr proteins*

Possible negative effects on human and animal health as a result of incidental consumption of petal leaves of carnation, for example as garnishing for food, were considered. The proteins for modified flower colour expressed in genetically modified carnation (f3'5'h and dfr) are similar to those found in purple-coloured fruits and vegetables that are commonly consumed, and in ornamental flowers. No significant homology was found between the inserted genes and known toxins or allergens. Reports of allergenicity to carnations are rare and there are no reports of allergenicity to genetically modified carnation.

#### *SuRB protein*

ALS enzymes are widely distributed among bacteria, yeast and higher plants. The *suRB* gene codes for an alternative form of the acetolactate synthase enzyme. This enzyme is not a known toxin or allergen and related enzymes are expressed in a variety of edible plants (e.g. soybean and rice).

No homology was found between the *suRB* gene and known toxins or allergens.

Based on the nature of the inserted genes and the history of safe use of similar genetically modified carnation lines, it is concluded that it is highly unlikely that the genetically modification in carnation line SHD-27531-4 will cause an adverse effect on the human health with respect to incidental human consumption or allergenicity, as compared to conventionally bred carnation.

### **Change in agricultural practice**

Since the notification covers only import, distribution and retailing of the genetically modified carnation, possible adverse environmental effects by changes in agricultural practice are not considered of importance for the risk analysis.

### **Conclusion**

The Dutch CA concludes that the provided information is sufficient and is of the opinion that in the context of its intended use, carnation line SHD-27531-4 is unlikely to have adverse effects on human and animal health or the environment.

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## 10. DETECTION METHOD

The applicant has provided a detection method that is specific for line SHD-27531-4, as is obligatory under the 2001/18/EC (Attachment C1). The Dutch CA considers the detection method as being sufficient. The detection method is not yet verified by the Community Reference Laboratory.

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## 11. UNIQUE IDENTIFIER

The unique identifier for the carnation line is SHD-27531-4.

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## 12. TRACEABILITY AND LABELLING

The notifier proposes to label flowers of the transgenic carnation line SHD-27531-4 similar to other GM carnation varieties, like Moonshadow (C/NL/97/13-1363A), Moondust (C/NL/96/14-11) and Moonlite (C/NL/04/02) which are (or have been) imported and sold in the EU. The flowers will be imported in cardboard boxes, within which 10-25 bunches of flowers will be packed and sleeved in plastic flower sleeves for protection. The notifier states that Florigene will place a label on the sleeves. The proposed wording of the label is as follows: "This product is a genetically modified carnation and is not for human or animal consumption nor for cultivation".

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## 13. MONITORING AND GENERAL SURVEILLANCE

### ***Specific monitoring***

Since the environmental risk analysis does not identify any potential risks, the notifier has not included a specific monitoring plan. The Dutch CA accepts this reasoning.

### ***General surveillance***

The intended use of the placing on the market of this product is import, distribution and retailing. Therefore the general surveillance plan addresses escapes of the genetically modified carnation (or its traits) to the environment, and unforeseen effects on human health by handling the product. Amongst others, the following monitoring activities will be undertaken:

1. Suntory will maintain exact records of all imports into Europe;
2. The importers will be asked in a questionnaire format for feedback on unexpected effects or illegal growth, on a yearly basis;
3. The Florigene website will provide a link at which European consumers will be invited to comment on Suntory products with all Suntory contact details;
4. After release, breeders and botanists with interest in *Dianthus* biology will be asked to alert Suntory in case of any unusual hybrids that they might find during survey work.
5. Each year the scientific literature is reviewed for new reports on *Dianthus* taxonomy, botany and vegetation;
6. Suntory will report the results of monitoring to the Dutch CA and the European Commission on an annual basis.

The Netherlands considers this general surveillance plan as sufficient.

## 14. ADVICE OF THE DUTCH COMPETENT AUTHORITY FOR DIRECTIVE 2001/18/EC

Based on the notification and the above mentioned considerations, the Dutch competent authority concludes that no reasons have emerged on the basis of which consent to the proposed placing on the market should be withheld.

The Dutch competent authority therefore proposes to consent to the placing on the market of the product as described below, for which a notification has been submitted on March 13, 2013, registered under number C/NL/13/01 under explicit specification of:

- a) The consent will be granted to Suntory Holdings Limited, Osaka, Japan and concerns the placing on the market under part C of 2001/18/EC of the product consisting of cut flowers of carnation (*Dianthus caryophyllus* L.) genetically modified with the *f3'5'h*, *dfr* and *suRB* genes for the purpose of import, distribution and retailing. The consent includes line SHD-27531-4.
- b) The product may be put to ornamental use only. This consent excludes cultivation and excludes the use as feed or as food of line SHD-27531-4.
- c) The unique identification code of the product will be SHD-27531-4.
- d) The period of validity of the consent shall be 10 years starting from the date on which the consent is issued.
- e) The words 'This product is a genetically modified organism' or 'This product is a genetically modified carnation', and the words 'not for human or animal consumption nor for cultivation' shall appear either on a label or in a document accompanying the product.
- f) The consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and to inspection services of Member States as well as the Community control laboratories.
- g) Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan to check for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented.
- h) The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management to be taken in case of accidental cultivation.
- i) The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.
- j) The decision shall apply from the date on which the detection method specific to carnation line SHD-27531-4 is verified by the Community Reference Laboratory.

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Den Haag, 23 juli 2013

DE STAATSSECRETARIS VAN INFRASTRUCTUUR EN MILIEU,  
namens deze,  
de directeur Veiligheid en Risico's,



drs. ing. Peter Torbijn