PART 1 (COUNCIL DECISION 2002/813/EC)

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 11 OF DIRECTIVE 2001/18/EC

In order to tick one or several possibilities, please use crosses (meaning x or X) into the space provided as (.)

A. General information

1. Details of notification

(a) Member State of notification: SPAIN
(b) Notification number: B/ES/14/07
(c) Date of acknowledgement of notification: 25/09/14
(d) Title of the project: Reduction of the period for citrus flowering by the use of a viral vector based on Citrus leaf blotch virus:
(e) Proposed period of release October 2014

2. Notifier

Name of institution or company: Instituto Valenciano de Investigaciones Agrarias

3. GMO characterisation

(a) Indicate whether the GMO is a:

viroid		(.)	
RNA virus		(X.)	
DNA virus		(.)	
bacterium		(.)	
fungus		(.)	
animal			
-	mammals	(.)	
-	insect	(.)	
-	fish	(.)	
-	other animal	(.)	specify phylum, class

other, specify (kingdom, phylum and class)

(b) Identity of the GMO (genus and species) *Citrus leaf bloch virus*, genus *Citrivirus*

(c) Genetic stability – according to Annex IIIa, II, A(10)
It is stable

4. Is the same GMO release planned elsewhere in the Community (in conformity with Article 6(1)), by the same notifier?

Yes (.) No (x.)

If yes, insert the country code(s)

5. Has the same GMO been notified for release elsewhere in the Community by the same notifier?

Yes (.) No (.x)

If yes:

- Member State of notification
- Notification number

Please use the following country codes:
Austria AT; Belgium BE; Germany DE; Denmark DK; Spain ES; Finland FI; France FR; United Kingdom GB; Greece GR; Ireland IE; Iceland IS; Italy IT; Luxembourg LU; Netherlands NL; Norway NO; Portugal PT; Sweden SE

6. Has the same GMO been notified for release or placing on the market outside the Community by the same or other notifier?

Yes (.) No (.x)

If yes:

- Member State of notification
- Notification number

7. Summary of the potential environmental impact of the release of the GMOs.

Environmental impact null

B. Information relating to the recipient or parental organism from which the GMO is derived

1. Recipient or parental organism characterisation:

(a) Indicate whether the recipient or parental organism is a:

(select one only)

viroid (.)
RNA virus (.x)
DNA virus (.)
bacterium (.)
fungus (.)
animal
- mammals (.)
- insect (.)
- fish (.)
- other animal (.)
(specify phylum, class)

other, specify

2. Name
   (i) order and/or higher taxon (for animals)
   (ii) genus Citrivirus
   (iii) species Citrus leaf bloch virus (CLBV)
   (iv) subspecies
   (v) strain
   (vi) pathovar (biotype, ecotype, race, etc.)
   (vii) common name

3. Geographical distribution of the organism

   (a) Indigenous to, or otherwise established in, the country where the notification is made:
   Yes (.x) No (.) Not known (.)

   (b) Indigenous to, or otherwise established in, other EC countries:
   (xi) Yes (.)

   If yes, indicate the type of ecosystem in which it is found:

Atlantic	..
Mediteranean	..x
Boreal	..
Alpine	..
Continental	..
Macaronesian	..

   (ii) No (.)
   (iii) Not known (.)

   (c) Is it frequently used in the country where the notification is made?
   Yes (.) No (x.)

   (d) Is it frequently kept in the country where the notification is made?
   Yes (.) No (x.)

4. Natural habitat of the organism

   (a) If the organism is a microorganism

water	(.)
soil, free-living	(.)
soil in association with plant-root systems	(.)
in association with plant leaf/stem systems	(x.)
other, specify Citrus Plants	

   (b) If the organism is an animal: natural habitat or usual agroecosystem:

5. (a) Detection techniques .Molecular hybridization and RT_PCR

(b) Identification techniques. RT-PCR and sequencing

6. Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?

Yes (.) No (.x)

If yes, specify

…

7. Is the recipient organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?

Yes (.) No (.x) Not known (.)

If yes:

(a) to which of the following organisms:

humans	(.)
animals	(.)
plants	()
other	(.)

(b) give the relevant information specified under Annex III A, point II. (A)(11)(d) of Directive 2001/18/EC

8. Information concerning reproduction. The virus has not natural dispersion. The virus is only graft transmitted the citrus to citrus

(a) Generation time in natural ecosystems:

(b) Generation time in the ecosystem where the release will take place:

(c) Way of reproduction: Sexual .. Asexual ..

(c) Factors affecting reproduction:

9. Survivability

(a) ability to form structures enhancing survival or dormancy:

(i)	endospores	(.)
(ii)	cysts	(.)
(iii)	sclerotia	(.)
(iv)	asexual spores (fungi)	(.)

(v)	sexual spores (funghi)		(.)
(vi)	eggs		(.)
(vii)	pupae		(.)
(viii)	larvae		(.)
(ix)	other, specify	none	

(b) relevant factors affecting survivability:

none

10. (a) Ways of dissemination

it has not natural dissemination, only is transmitted by graft inoculation from a infected citrus plant to other

(b) Factors affecting dissemination; none

11. Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers) NO

C. **Information relating to the genetic modification**

1. Type of the genetic modification

(i)	insertion of genetic material	(x.)
(ii)	deletion of genetic material	(.)
(iii)	base substitution	(.)
(iv)	cell fusion	(.)
(v)	others, specify	

2. Intended outcome of the genetic modification

Reduction of the period for citrus flowering

3. (a) Has a vector been used in the process of modification?

Yes (.) No (.x)

If no, go straight to question 5.

(b) If yes, is the vector wholly or partially present in the modified organism?

Yes (.) No (x.)

If no, go straight to question 5.

4. If the answer to 3(b) is yes, supply the following information

(a) Type of vector

plasmid (.)

bacteriophage (.)
virus (.)
cosmid (.)
transposable element (.)
other, specify

(b) Identity of the vector

(c) Host range of the vector

(d) Presence in the vector of sequences giving a selectable or identifiable phenotype
Yes (.) No (.)

antibiotic resistance (.no)
other, specify

Indication of which antibiotic resistance gene is inserted no

(e) Constituent fragments of the vector

(f) Method for introducing the vector into the recipient organism

(i) transformation (.)
(ii) electroporation (.)
(iii) macroinjection (.)
(iv) microinjection (.)
(v) infection (.)
(vi) other, specify

5. If the answer to question B.3(a) and (b) is no, what was the method used in the process of modification?

(i) transformation (.)
(ii) microinjection (.)
(iii) microencapsulation (.)
(iv) macroinjection (.)
(v) other, specify (.) Cloning the full length cDNA of CLBV genome in a binary vector. Insertion of FT gen into CLBV genome .Agrioinoculation of N.benthamiana plants, semi purification of recombinant virions and mechanical inoculation in a citrus plats. **From here to infect another citrus plant we graft inoculate from the infected citrus plant to other plant**.

6. Composition of the insert

(a) Composition of the insert FLOWERING LOCUS T (FT) From A.thaliana (genBank AB027504

(b) Source of each constituent part of the insert Arabidobsis thaliana

(c) Intended function of each constituent part of the insert in the GMO
Reduction of the period for citrus flowering

(d) Location of the insert in the host organism

- on a free plasmid (.)
- integrated in the chromosome (.)
- other, specify CLBV genome

(e) Does the insert contain parts whose product or function are not known?
Yes (.) No (.x)
If yes, specify

D. Information on the organism(s) from which the insert is derived

1. Indicate whether it is a:

viroid (.)
RNA virus (.)
DNA virus (.)
bacterium (.)
fungus (.)
animal
- mammals (.)
- insect (.)
- fish (.)
- other animal (.)
(specify phylum, class)

other, specify Plant (A.thaliana)

2. Complete name

(i) order and/or higher taxon (for animals) …
(ii) family name for plants Brassicaceae …
(iii) genus Arabidobsis …
(iv) speciesthaliana …
(v) subspecies …
(vi) strain …
(vii) cultivar/breeding line …
(viii) pathovar …
(ix) common name …

3. Is the organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?
Yes (.) No (.x) Not known (.)

If yes, specify the following:

(b) to which of the following organisms:

humans (.)
animals (.)
plants (.)
other ..

(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism
Yes (.) No (x.) Not known (.)

If yes, give the relevant information under Annex III A, point II(A)(11)(d):
…

4. Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks to exposure to biological agents at work?
Yes (.) No (x.)
If yes, specify

5. Do the donor and recipient organism exchange genetic material naturally?
Yes (.) No (x.) Not known (.)

E. Information relating to the genetically modified organism

1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification

(a) is the GMO different from the recipient as far as survivability is concerned?
Yes (.) No (.x) Not known (.)
Specify

(b) is the GMO in any way different from the recipient as far as mode and/or rate of reproduction is concerned?
Yes (.) No (.x) Unknown (.)
Specify

(c) is the GMO in any way different from the recipient as far as dissemination is concerned?
Yes (.) No (.x) Not known (.)
Specify

(d) is the GMO in any way different from the recipient as far as pathogenicity is concerned?

Yes (.) No (x.) Not known (.)
Specify

2. Genetic stability of the genetically modified organism stable

3. Is the GMO significantly pathogenic or harmful in any way (including its extracellular products), either living or dead?
Yes (.) No (x.) Unknown (.)

(a) to which of the following organisms?

humans (.)
animals (.)
plants (.)
other (.)

(b) give the relevant information specified under Annex III A, point II(A)(11)(d) and II(C)(2)(i)

4. Description of identification and detection methods

(a) Techniques used to detect the GMO in the environment Molecular Hybridization and RT-PCR

(b) Techniques used to identify the GMO RT-PCR and sequencing

F. Information relating to the release

1. Purpose of the release (including any significant potential environmental benefits that may be expected)

Reduction of the period of citrus flowering

2. Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, kept or found?
Yes (.) No (.x)
If yes, specify

3. Information concerning the release and the surrounding area

(a) Geographical location (administrative region and where appropriate grid reference):
Instituto Valenciano de investigaciones Agrarias, Moncada Valencia.

(b) Size of the site (m^2):
(i) actual release site (m^2):150
(ii) wider release site (m^2):

(d) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected: No

(e) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO No

4. Method and amount of release

(a) Quantities of GMOs to be released: 62 citrus trees infected with clbv IN pr FT

(b) Duration of the operation:5 years

(c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release. It is not possible natural spread

5. Short description of average environmental conditions (weather, temperature, etc.) Mediterranean weather of Valencia (Spain)

6. Relevant data regarding previous releases carried out with the same GMO, if any, specially related to the potential environmental and human health impacts from the release.

No

G. Interactions of the GMO with the environment and potential impact on the environment, if significantly different from the recipient or parent organism

1. Name of target organism (if applicable)

(i)	order and/or higher taxon (for animals)	…
(ii)	family name for plants	…
(iii)	genus	...
(iv)	species	...
(v)	subspecies	…
(vi)	strain	…
(vii)	cultivar/breeding line	…
(viii)	pathovar	…
(ix)	common name	…

2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable) Reduction of the period for citrus flowering

3. Any other potentially significant interactions with other organisms in the environment.

No

4. Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur? No

Yes (.) No (.X) Not known (.)
Give details

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established

None

6. Complete name of non-target organisms which (taking into account the nature of the receiving environment) may be unintentionally significantly harmed by the release of the GMO

(i) order and/or higher taxon (for animals) …
(ii) family name for plants …
(iii) genus …
(iv) species …
(v) subspecies …
(vi) strain …
(vii) cultivar/breeding line …
(viii) pathovar …
(ix) common name …

7. Likelihood of genetic exchange in vivo

(a) from the GMO to other organisms in the release ecosystem: none

(b) from other organisms to the GMO: none

(c) likely consequences of gene transfer: none

None

8. Give references to relevant results (if available) from studies of the behaviour and characteristics of the GMO and its ecological impact carried out in stimulated natural environments (e.g. microcosms, etc.): None

9. Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism) none

H. Information relating to monitoring

1. Methods for monitoring the GMOs
Molecular hybridization and RT-PCR

2. Methods for monitoring ecosystem effects

Only infect citrus plants and natural dispersion it is not possible

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms It is impossible transfer genetic material to other organism.

4. Size of the monitoring area (m^2) 150

5. Duration of the monitoring 5 years

6. Frequency of the monitoring one time each year

I. Information on post-release and waste treatment

1. Post-release treatment of the site

The usual management for citrus plants

2. Post-release treatment of the GMOs

3. (a) Type and amount of waste generated

Pruning material, leaves and flowers

3. (b) Treatment of waste

None

J. Information on emergency response plans

1. Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread. The dissemination of GMO it is not possible

2. Methods for removal of the GMO(s) of the areas potentially affected

3. Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread

4. Plans for protecting human health and the environment in the event of an undesirable effect

There are not risk to human