Part VII - Summary

Request for Authorization of genetically modified herbicide tolerant

RF3 Canola Quality *Brassica juncea*

for food and feed uses, and import and processing, in accordance with articles 9(2) and 21(2) of Regulation (EC)

No 1829/2003

EFSA-GMO-NL-2019-XXX

Version CC1

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PART VII – SUMMARY

EFSA-GMO-NL-2019-XXX (RF3 CANOLA QUALITY *BRASSICA JUNCEA*)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Netherlands

(b) Application number

EFSA-GMO-NL-2019-XXX

(c) Name of the product (commercial and any other names)

The RF3 event, with unique identifier: ACS-BNØØ3-6

(d) Date of acknowledgement of valid application

Not applicable at the time of submission

1.2. Applicant

(a) Name of applicant

BASF Agricultural Solutions Seed US LLC

(b) Address of applicant

BASF Agricultural Solutions
Seed US LLC
100 Park Avenue
Florham Park, NJ 07932
USA

Represented by:
BASF SE
Carl-Bosch-Str. 38
D-67063 Ludwigshafen
Germany

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany Agricultural Solutions Seed US LLC acts as representative of the applicant and has appointed BASF Agricultural Solutions Belgium NV as its contact for this submission and all correspondence should be directed to:

BASF Agricultural Solutions Belgium NV,
Rue Marie de Bourgogne 58,
1000 Brussel,
Belgium

1.3. Scope of the application

(a) Genetically modified food

☑ Food containing or consisting of genetically modified plants
☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

☑ Feed containing or consisting of genetically modified plants
☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation within the Union?

No ☐

Yes ☑ (in that case, specify)

The RF3 event, with unique identifier: ACS-BNØØ3-6, has been authorized in the EU under Commission Implementing Decision 2007/232/EC of March 26, 2007 and Commission Implementing Decision 2013/327/EU of June 25, 2013. At the time of submission, an amendment to Commission Implementing Decision 2013/327/EU is in preparation, pursuant to an application by Bayer CropScience AG, the predecessor of BASF with respect to these authorizations, to renew the authorization under Commission Implementing Decision 2007/232/EC and to consolidate both authorizations into a single authorization.

Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

This application requests authorization for food and feed uses, and import and processing and does not include cultivation in the EU. Risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC is provided in the application.

1.5. Has the genetically modified plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

No ☐

Yes☑ (in that case, specify)

The RF3 event, with unique identifier: ACS-BNØØ3-6, has been authorized in the EU under Commission Implementing Decision 2007/232/EC of March 26, 2007.

1.6. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☑ in that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

The RF3 event has been authorized to cover its initial commercialization in *Brassica napus* species.

Further authorizations specifically covering the presence of the RF3 event in CQ *Brassica juncea (B. juncea)* for cultivation have been issued in:

-We have not received official confirmation yet.

USA

- United States Department of Agriculture – March 22, 1999 (falls under RF3 *B. napus* authorization)
- Food and Drug Administration –

Australia

- Food Standards Australia New Zealand – May 9, 2002 (falls under RF3 *B. napus* authorization)

China

- Ministry of Agriculture and Rural Affairs – December 20, 2018 (falls under RF3 *B. napus* authorization)

1.7. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification.

RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *Brassica napus (B. napus)*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. RF3 contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyl transferase (PAT/*bar*) protein which confers tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant. RF3 also contains the *barstar* gene (origin *Bacillus amyloliquefaciens*), coding for the Barstar protein, which is an inhibitor of the Barnase protein. The *barstar* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for.

The purpose of the current application is to modify the terms of the existing authorisation in order to cover the presence of RF3 in Canola Quality *B. juncea* and its derived products for import, processing and all uses as any other oilseed rape in the EU, according to Art 9(2) and 21(2) of Regulation (EC) No 1829/2003, with the exception of cultivation. The

range of uses of this oilseed rape will be identical to the full range of equivalent uses of conventional oilseed rape.

(c) Intended use of the product and types of users.

RF3 CQ *B. juncea* will be traded and used in the EU in the same manner as current conventional commercial oilseed rape and by the same operators currently involved in the trade and use of oilseed rape.

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for.

With the exception of the herbicide tolerance, which only has agronomic relevance, the characteristics of RF3 CQ *B. juncea* oilseed rape and products derived from it are comparable to those of RF3 *B. napus* being on the EU market for more than 10 years without any adverse effects being reported. Therefore, RF3 CQ *B. juncea* and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial oilseed rape products. No specific instructions and/or recommendations are warranted or required for the placing on the market of RF3 CQ *B. juncea* for import, processing and all uses, excluding cultivation, in the EU.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for.

RF3 CQ *B. juncea* is suitable for use throughout the EU as any other oilseed rape. The scope of this application covers the import, processing and all uses of RF3 CQ *B. juncea*, excluding cultivation.

(f) Any type of environment to which the product is unsuited.

RF3 CQ *B. juncea* is suitable for use throughout the EU as any other oilseed rape. The scope of this application covers the import, processing and all uses of RF3 CQ *B. juncea*, excluding cultivation.

(g) Any proposed packaging requirements.

With the exception of the herbicide tolerance, which only has agronomic relevance, the characteristics of RF3 CQ *B. juncea*, similar to what is the case for RF3 *B. napus*, are not different from those of the conventional counterpart. Therefore, RF3 CQ *B. juncea* and derived products will be used in the same manner as other oilseed rape and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation then (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9% is applied for the placing on the market of RF3 CQ *B. juncea* and derived products.

Operators shall be required to label products containing or consisting of RF3 CQ *B. juncea* with the words “genetically modified oilseed rape” or “contains genetically modified oilseed rape” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from RF3 CQ *B. juncea* with the words “produced from genetically modified oilseed rape”. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using RF3 CQ *B. juncea* and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for RF3 CQ *B. juncea*. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the demand as a result of the introduction of RF3 CQ *B. juncea* into the oilseed rape as the changes have only an agronomic benefit. It is anticipated that the introduction of RF3 CQ *B. juncea* will replace some of the oilseed rape in existing food and feed products.

(ii) In EU export markets

There are no anticipated changes to the extent of oilseed rape production in export markets as a result of the introduction of RF3 CQ *B. juncea* oilseed rape. It is anticipated that the introduction of RF3 CQ *B. juncea* will replace some of the oilseed rape products.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The OECD unique identifier for the RF3 event in CQ *B. juncea* is identical to that of the RF3 event in B. *napus* as it concerns the same transformation event: ACS-BNØØ3-6.

1.8. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for its disposal and treatment

Because this application is for consent to import, process and all uses of RF3 CQ *B. juncea* as any other oilseed rape, not including the cultivation of varieties of RF3 CQ *B. juncea* in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of RF3 CQ *B. juncea*. However, modern methods of oilseed rape handling minimize losses of seed, so there is little chance of germination of spilled oilseed rape resulting in the development of mature RF3 CQ *B. juncea* plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since RF3 CQ *B. juncea*, like any other oilseed rape, is unlikely to effectively compete with perennial vegetation outside agricultural fields. The likelihood for spilled seed to survive and establish is negligible. Oilseed rape plants outside agricultural fields can produce seed but this is often prevented because most plants do not survive to reach maturity. This is due to competition from other vegetation, management operations such as roadside mowing, the use of broadleaf herbicides, animal predation, diseases and environmental conditions.

RF3 CQ *B. juncea* is not different in composition, nutritional and agronomic characteristics relative to conventional oilseed rape, except for the introduced tolerance to glufosinate, and therefore, it is unlikely to pose any threat to the EU environment or to require special

measures for its containment. Furthermore, oilseed rape volunteers can be easily controlled using currently available selective herbicides (other than glufosinate) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

2.1. Complete name

(a) Family name
Cruciferae

(b) Genus
Brassica

(c) Species
juncea

(d) Subspecies
oleifera

(e) Cultivar/breeding line
various

(f) Common name
brown, Indian, or oriental mustard*
* CQ B. juncea - Mustard qualities have been removed (through conventional breeding).

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

There are few areas of the world where members of the family *Brassicaceae* are totally absent. The exceptions are part of the tropics, where the family is thinly represented, and where some introduced cosmopolitan weeds have become established.

B. juncea is primarily a crop plant grown in China, the Russian Federation, and on the Indian sub-continent as a major source of edible oil. In Canada and a few other countries, *B. juncea* is grown as a condiment crop.

B. juncea breeders endeavor to make simultaneous improvements in agronomic performance, disease resistance, and quality traits. Agronomic traits include yield, lodging resistance, maturity, herbicide tolerance, drought tolerance, shattering resistance, and seed size. Disease resistance breeding efforts may include blackleg, white rust, *Alternaria* blackspot and *Fusarium* wilt resistance.

Improvements in *B. juncea* quality traits depend on whether the goal is to develop Canola-quality or mustard-quality *B. juncea* varieties. For Canola-quality varieties, high oil content, low glucosinolate content, high protein content, and a fatty acid profile with low erucic acid and low saturated fatty acid content are desired. For conventional mustard varieties, low oil content, high glucosinolate content and a fatty acid profile with a moderate level of erucic acid are desired. To the best of our knowledge, currently no CQ *B. juncea* is grown in the EU.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Under natural conditions, oilseed rape reproduction is through seeds. Oilseed rape flowers are bisexual and contain six stamens, a pistil of two carpels and a superior ovary. Oilseed rape has the capability of both self- and cross- pollination via both insect and wind. However, the majority of fertilization occurs by self-pollination as the large amounts of pollen produced from each flower out competes the pollen from adjacent flowers. Oilseed rape produces a large amount of pollen which can remain viable for four to five days under field conditions.

(b) Specific factors affecting reproduction

The optimum temperature for vegetative growth of oilseed rape is about 20°C. Reproduction of spring oilseed rape is favoured by dry weather conditions, which favours the activity of insect pollinators, and shorter growing seasons. Winter varieties take advantage of longer growing seasons. Water availability is also of importance, particularly during the period of seed ripening.

(c) Generation time

The generation time in agronomic ecosystems is normally about 4 - 5 months for spring sown crops or 10 - 11 months for autumn sown crops.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

Successful hybrid formation depends not only on the sexual compatibility between the plants (whether the same or related species) but the two plants must flower simultaneously, share the same insect pollinator (if insect pollinated) and be sufficiently nearby for the transfer of viable pollen. The consequences of successful transfer will depend on the sexual fertility of the hybrid progeny, vigour and the fertility of subsequent generations or their ability to propagate vegetatively. Finally, the fitness of the interspecific hybrids is generally reduced compared to the parents and the stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Oilseed rape is an annual plant that survives through seed formation. If seeds are buried due to e.g. cultivation, they may persist for periods of up to ten years under ideal conditions.

(b) Specific factors affecting survivability

Optimal germination conditions for oilseed rape are 20°C, high water availability (*e.g.* -0.2 MPa water pressure) and exposure to light. Consequently, the greatest proportion of oilseed rape plants that germinates after harvest (‘volunteers’) emerges in response to tillage. As most of the oilseed rape seeds that fall on the ground after harvesting will still germinate before the winter season, these seedlings will be destroyed by winter conditions. Seeds that get buried deeper can be lost from the seed bank by predation and decay.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Pollen dissemination is mainly affected by wind and insects. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* spp.) play a major role in *Brassica napus* pollination. The dynamics of bee-mediated pollen movement depend on the quantity of pollen available (size and density of donor population) and the size and location of the receiving populations, as well as environmental conditions and insect activity.

(b) Specific factors affecting dissemination

There is no specific factor affecting seed dissemination (oilseed rape seeds have no special adaptations to encourage transport). The seeds are small and birds and small mammals usually eat them on the spot rather than carrying them away.

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

Improvements in *B. juncea* quality traits depend on whether the goal is to develop Canola-quality or mustard-quality *B. juncea* varieties. For Canola-quality varieties, high oil content, low glucosinolate content, high protein content, and a fatty acid profile with low erucic acid and low saturated fatty acid content are desired. For conventional mustard varieties, low oil content, high glucosinolate content and a fatty acid profile with a moderate level of erucic acid are desired. To the best of our knowledge, currently no CQ *B. juncea* is grown in the EU.

The frequency of gene flow from oilseed rape to these wild relatives under natural conditions is considered very low and the fitness of the interspecific hybrids is generally reduced compared to the parents. Therefore, stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

2.8. In the case of plant species not normally grown in the Union, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Not relevant as oilseed rape is normally cultivated as a crop in the EU.

2.9. Other potential interactions, relevant to the genetically modified plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

The scope of this application does not include cultivation of RF3 CQ *B. juncea* seeds in the EU and therefore no potential interactions with organisms in the ecosystem in the EU are expected. However (and in regions where RF3 CQ *B. juncea* seed products will be cultivated) (e.g. North America), numerous insects, fungi, mycoplasmas and viruses are pathogenic to *B. juncea* and attack the crop during the growing season.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses.

(b) Nature and source of the vector used

For RF3, the plasmid vector used was pTHW118, derived from pGSC1700.

(c) Source of donor nucleic acid(s) used for the transformation, size and intended function of each constituent fragment of the region intended for insertion

Size, source and intended function of each constituent component of the inserted DNA fragment inherited from RF3 *B. napus*

Definition	Source	Size (bp)	Function
Right border sequence	*A. tumefaciens*	25	T-DNA integration
Polylinker sequence	Synthetic	28	Plasmid cloning
TL-DNA sequence	*A. tumefaciens*	37	None
Polylinker sequence	Synthetic	7	Plasmid cloning
Terminating signal from TL-DNA gene 7	*A. tumefaciens*	212	Stop signal
Polylinker sequence	Synthetic	21	Plasmid cloning
Glufosinate tolerance gene	*S. hygroscopicus*	552	Selectable marker and herbicide tolerance
Promoter	*A. thaliana*	1726	Constitutive promoter targeting expression mainly to green tissue
Polylinker sequence	Synthetic	50	Plasmid cloning
Polyadenylation region of nopaline synthase gene	*A. tumefaciens*	261	Stop signal
Polylinker sequence	Synthetic	21	Plasmid cloning
Terminating signal of *barstar* gene	*B. amyloliquefaciens*	40	Stop signal
Ribonuclease inhibitor gene	*B. amyloliquefaciens*	273	Fertility Restoration
Promoter	*N. tabacum*	1510	Expression only in anthers
Polylinker sequence	Synthetic	45	Plasmid cloning
Left border sequence	*A. tumefaciens*	25	T-DNA integration

3.2. Information relating to the genetically modified plant

RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. RF3 *B. napus* was produced by means of *Agrobacterium*-mediated transformation using vector pTHW118. RF3 *B. napus* contains the *barstar* gene (origin *Bacillus amyloliquefaciens*), coding for the Barstar protein, which is an inhibitor of the

Barnase protein. The *barstar* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development. Expression of the Barstar protein in the tapetum cells leads to restoration of fertility after crossing to a MS *B. napus* line. RF3 *B. napus* also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyl transferase (PAT/*bar*) conferring tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

3.2.1. Description of the trait(s) and characteristics which have been introduced or modified

The *barstar* gene

RF3 CQ *B. juncea* contains the *barstar* gene, coding for the Barstar protein, which is an inhibitor of the Barnase protein. The *barstar* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development.

The *bar* gene and tolerance to glufosinate-ammonium

RF3 CQ *B. juncea* contains the *bar* gene coding for phosphinothricin acetyltransferase (PAT/*bar*) conferring tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant. The *bar* gene has been isolated from *Streptomyces hygroscopicus*, a microorganism that produces bialaphos. Bialaphos or its synthetically produced component glufosinate-ammonium is classified as herbicide with phosphinothricin as the active ingredient. Phosphinothricin acts by the inhibition of a specific amino acid biosynthesis pathway in plants. It is a potent inhibitor of glutamine synthetase (GS), an enzyme that plays a central role in the assimilation of ammonia and in the regulation of the nitrogen metabolism in the plant. Phosphinothricin based herbicides are highly effective against plants, but are safe to humans and animals and are rapidly biodegraded in the environment. The *bar* gene product, PAT, metabolizes phosphinothricin to an inactive, acetylated derivative.

Glufosinate ammonium is defined as a non-selective and partially systemic contact herbicide. After application, the active ingredient phosphinothricin acts via the leaf. No action via the roots could be detected in plants after emergence and no damage is caused to seedlings before emergence. Shortly after the uptake, the herbicide will disturb the ammonium metabolism of the treated plants. The systemic transport from treated leaves to other parts of the plant is nevertheless limited. Ammonia is an important link between catabolic and anabolic processes in the plant metabolism and it is released and re-assimilated in large amounts at different processes. Regardless of the origin, however, it is essential that the ammonia is rapidly converted into a form that is not toxic to the organism. This detoxifying reaction is guided by the glutamine synthetase enzyme.

3.2.2. Information on the nucleic acid(s) sequences actually inserted or deleted

(a) The copy number of all detectable inserts, both complete and partial

The RF3 CQ *B. juncea* transgenic locus sequence was found to be identical to the corresponding sequence of RF3 *B. napus*.

The Southern blot results demonstrating the presence of one complete T-DNA insert containing the *barstar* and the *bar* gene cassettes in RF3 *B. napus* have been previously provided.

(b) In case of deletion(s), size and function of the deleted region(s)

Not applicable. RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses.

(c) Subcellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The transgenic DNA was integrated into a single genetic locus in the *B. napus* nuclear genome (chromosome). RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. No new genetic modification was used.

(d) The organisation of the inserted genetic material at the insertion site

Since the RF3 CQ *B. juncea* transgenic locus sequence was found to be identical to the corresponding sequence of RF3 *B. napus*, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in RF3 CQ *B. juncea*.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification

Not applicable

3.2.3. Information on the expression of the insert

(a) Information on developmental expression of the insert during the life cycle of the plant

RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. No new genetic modification was used. The determined RF3 CQ *B. juncea* transgenic locus sequence was found to be identical to the corresponding sequence of RF3 *B. napus*. The structural stability of the RF3 CQ *B. juncea* transgenic locus was demonstrated in five breeding generations. There is no evidence that the expression of the insert in the RF3 CQ *B. juncea* compared to the RF3 *B. napus* could be impacted. Therefore, no additional information and/or data is deemed to be necessary in this regards and the previous EFSA conclusions that "*The stability of inheritance of the introduced traits has been demonstrated, as has the expression of the transgenes*" (EFSA opinion, 2005) remain being applicable to the RF3 CQ. *B. juncea*.

(b) Parts of the plant where the insert is expressed

Not applicable. More details on parts of the plant where the insert is expressed in the RF3 *B. napus* have been previously provided.

3.2.4. Genetic stability of the insert and phenotypic stability of the genetically modified plant

The results of the Southern blot analysis of RF3 CQ *B. juncea* demonstrated the structural stability of the inserted sequences across different breeding generations.

3.2.5. Information (for environmental safety aspects) on how the genetically modified plant differs from the recipient plant in

(a) Mode(s) and /or rate of reproduction

No unexpected biologically relevant changes in the agronomic and phenotypic characteristics of RF3 CQ *B. juncea* compared to RF3 *B. napus* and, consequently, the conventional counterpart, taking into account natural variation, are expected based on available literature sources. On the basis of the references, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in RF3 CQ *B. juncea* and that RF3 CQ *B. juncea* is not different in its phenotypic and agronomic behaviour relative to conventional oilseed rape, except for the introduced trait.

(b) Dissemination

No differences in the dissemination compared to RF3 *B. napus* and, consequently, the conventional counterpart are expected in agronomic and phenotypic assessments.

(c) Survivability

No differences in the survivability compared to RF3 *B. napus* and, consequently, the conventional counterpart are expected in agronomic assessments.

(d) Other differences

Except for the introduced trait that is of agronomic interest, no biologically relevant differences are expected.

3.2.6. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms (for environmental safety aspects)

(a) Plant to bacteria gene transfer

RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. None of the genetic elements in RF3 *B. napus* have a genetic transfer function. Therefore, no changes are expected in the ability of RF3 CQ *B. juncea* to transfer genetic material to bacteria and the likelihood that plant to bacteria gene transfer occurs is highly unlikely.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in RF3 CQ *B. juncea* is unchanged compared to conventional oilseed rape, the out-crossing frequency to other oilseed rape varieties or to wild relatives would be unlikely to be different for RF3 CQ *B. juncea*, when compared to conventional oilseed rape varieties. Furthermore, the scope of the current application does not include the cultivation of RF3 CQ *B. juncea* varieties in the EU. As a consequence exposure to the environment will be very limited.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

Not applicable. The composition of CQ *B. juncea* is not expected to be different from *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. Therefore, it can be concluded that a new comparative assessment of CQ RF3 *B. juncea* is not deemed to be necessary.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

Not applicable. The composition of CQ *B. juncea* is not expected to be different from *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. Therefore, it can be concluded that a new comparative assessment of CQ RF3 *B. juncea* is not deemed to be necessary.

4.3. Selection of material and compounds for analysis

Not applicable. The composition of CQ *B. juncea* is not expected to be different from *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. Therefore, it can be concluded that a new comparative assessment of CQ RF3 *B. juncea* is not deemed to be necessary.

4.4. Comparative analysis of agronomic and phenotypic characteristics

Not applicable. The composition of CQ *B. juncea* is not expected to be different from *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. Therefore, it can be concluded that a new comparative assessment of CQ RF3 *B. juncea* is not deemed to be necessary.

4.5. Effect of processing

The methods for production and manufacturing applied to oilseed rape are well known and have long history of safe use. No new production or manufacturing processes are envisaged for CQ RF3 *B. juncea* compared to *B. napus*. The same production processes applied to traditional *B. napus* grain will be used for RF3 CQ *B. juncea* grain. Therefore, there is no need for new risk assessment of effects of processing rather than the data already provided in frame of previous application(s) for the RF3 *B. napus*. RF3 CQ *B. juncea* will be grown using the agronomic practices of the region of production and the grain will be harvested, transported, stored and processed using the same processes as any other *B. napus* currently in commerce.

5. TOXICOLOGY

(a) Toxicological testing of the newly expressed proteins

RF3 CQ *B. juncea* expresses the proteins Barstar and PAT/*bar*.

The available information for the assessment of the newly expressed proteins present in RF3 CQ *B. juncea* indicates that no adverse effects on human or animal health are expected. Furthermore, in absence of indications of potential interactions between the two newly-expressed proteins, as suggested in the molecular analysis and comparative assessment, the conclusions of the safety assessment for the individual Barstar and PAT/*bar* proteins are not changed when their expression in RF3 CQ *B. juncea* is considered.

(b) Testing of new constituents other than proteins

Not applicable as the genetic modification in RF3 *B. napus* does not give rise to the expression of any new constituents other than the Barstar and PAT/*bar* proteins. No new genetic modification was used to develop RF3 CQ *B. juncea*.

(c) Information on natural food and feed constituents

No relevant changes in the composition of RF3 *B. napus* were identified, therefore the levels of food and feed constituents in RF3 *B. napus* have not been altered and there is no need for further assessment. No new genetic modification was used to develop RF3 CQ *B. juncea*.

(d) Testing of the whole genetically modified food and feed

From the results of the 90-day feeding study in rats conducted with RF3 *B. napus,* it was concluded that the RF3 *B. napus* meal incorporated up to 15% (w/w) in the diet had no adverse effects on the growth or health of Sprague Dawley rats. A new 90-day feeding study with RF3 CQ *B. juncea* is not scientifically necessary owing to the similar nature of the products, and is not provided by the applicant in line with Article 5 of the Implementing Regulation (EU) No 503/2013.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The data provided lead to the conclusion that the Barstar and PAT/*bar* proteins are unlikely to be allergenic. In addition, there is no evidence that there could be interactions between these two proteins that would lead to additive, synergistic or antagonistic activities.

(b) Assessment of allergenicity of the whole genetically modified plant

The comparative analysis of RF3 CQ *B. juncea* demonstrated that composition of CQ *B. juncea* falls within the ranges of *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. The Barstar and PAT/*bar* proteins expressed in RF3 *B. napus* are unlikely to be allergenic. Therefore, no increased allergenicity is anticipated for RF3 CQ *B. juncea*.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

The genetic modifications in RF3 *B. napus* are not intended to change nutritional characteristics of RF3 *B. napus* compared to conventional *B. napus*. No new genetic modification was used to develop RF3 CQ *B. juncea*. Therefore, RF3 CQ *B. juncea* is not expected to be more or less attractive for use as food, so anticipated dietary intake of rapeseed-derived foods is not expected to be changed upon commercialization of RF3 CQ *B. juncea*.

Compositional evaluation showed that RF3 CQ *B. juncea* is not expected to be different from RF3 *B. napus* and, consequently, the conventional counterpart, except for the introduced trait taking into account natural variation. Therefore, there is no need to carry out further nutritional studies with food derived from RF3 CQ *B. juncea*.

(b) Nutritional assessment of the genetically modified feed

The genetic modifications in RF3 *B. napus* are not intended to change nutritional characteristics of RF3 *B. napus* compared to conventional *B. napus*. No new genetic modification was used to develop RF3 CQ *B. juncea*. Therefore, RF3 CQ *B. juncea* is not expected to be more or less attractive for use as feed.

Compositional evaluation showed that RF3 CQ *B. juncea* is not expected to be different from RF3 *B. napus* and, consequently, the conventional counterpart, except for the introduced trait taking into account natural variation. Therefore, there is no need to carry out further nutritional studies with feed derived from RF3 CQ *B. juncea*.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

Since no compositional differences are expected between RF3 CQ *B. juncea* and RF3 *B. napus*, taking into account natural variation, similar chronic dietary exposure estimates are expected for the RF3 CQ *B. juncea*.

9. RISK CHARACTERISATION

A comprehensive risk characterization of RF3 CQ *B. juncea* has been carried out by considering all available evidence from the analyses discussed through this application. The following conclusions from molecular characterization, phenotypic and agronomic analyses, compositional analyses, toxicology assessment, allergenicity assessment and exposure assessment have been considered:

- RF3 CQ *B. juncea* was produced by using conventional breeding to cross a *B. juncea* line with RF3 *B. napus*. The RF3 trait was incorporated into an elite CQ *B. juncea* line through a series of backcrosses. No new genetic modification was used.

  The obtained transgenic locus sequence was subsequently compared to the corresponding sequence of RF3 *B. napus* and found to be identical to the corresponding sequence of RF3 *B. napus*. The absence of vector backbone sequences in the RF3 CQ *B. juncea* was confirmed. The structural stability of the RF3 CQ *B. juncea* in five generations was demonstrated. The molecular characterization of the RF3 *B. napus* showed no evidence that the genetic modification of RF3 *B. napus* resulted in unintended changes or raises any safety concerns. Based on the aforementioned conclusions and the fact that no new genetic modification was used to create the RF3 CQ *B. juncea*, it can be concluded that the molecular characterization of the RF3 CQ *B. juncea* raises no safety concerns..

- Composition of CQ *B. juncea* is not expected to be different from *B. napus*, previously assessed by the EFSA GMO Panel. Therefore, it can be concluded that a new comparative assessment of CQ RF3 *B. juncea* would not bring an additional value to the previous EFSA conclusions of RF3 canola.

  Since no new production or manufacturing processes are envisaged for CQ RF3 *B. juncea* compared to *B. napus*, there is no need for new risk assessment of effects of processing other than the data already provided in frame of previous applications for the RF3 *B. napus*.

- The available information for the previous assessment of the newly expressed proteins present in RF3 CQ *B. juncea* indicates that no adverse effects on human or animal health are expected. The outcome of heat stability studies and data concerning stability to proteolytic enzymes previously provided to EFSA demonstrate that the Barstar and PAT/*bar* proteins are quickly degraded under heat treatment and have extremely short structural and functional stabilities under simulated gastric and intestinal conditions. These results indicate a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system and consequently that the newly expressed Barstar and PAT/*bar* is unlikely to be toxic.

  Since composition of the RF3 CQ *B. juncea* is not expected to be different to RF3 *B. napus*, there are no indications of any potential adverse effect that could arise from natural constituents' changes.

  Overall, the results of the toxicological assessment indicate that consumption of RF3 CQ *B. juncea* food and feed products will be as safe as consumption of equivalent products from RF3 *B. napus* and, consequently, conventional oilseed rape, regardless of the anticipated intake level.

- Bioinformatics analysis demonstrated that there are no biologically relevant sequence similarities to allergens when Barstar and PAT/*bar* protein sequences were used as query sequences for a FASTA search against the allergen database. There is also no evidence of possible adjuvanticity of both individual proteins.

  Based on the weight of evidence approach it can be concluded that the newly expressed Barstar and PAT/*bar* are unlikely to be allergenic.

  The comparative analysis of RF3 CQ *B. juncea* provides no evidence that composition of CQ *B. juncea* would be different from *B. napus*, previously assessed and considered safe by the EFSA GMO Panel. The newly expressed proteins are unlikely to be allergenic. Therefore, no increased allergenicity is anticipated for RF3 CQ *B. juncea* or for the food derived from RF3 CQ *B. juncea* in comparison to the food derived from the conventional *B. napus* varieties.

- Compositional assessment provided no evidence that RF3 CQ *B. juncea* would be different from RF3 *B. napus* and, consequently, the conventional counterpart, except for the introduced traits taking into account natural variation. In addition, the outcome of the 90-day feeding study revealed no toxicological findings associated with the consumption of the whole food derived from RF3 *B. napus* and, consequently, RF3 CQ *B. juncea*, in comparison with the conventional counterpart. Therefore, there is no need to carry out further nutritional studies with feed derived from RF3 CQ *B. juncea*.

  In summary, the food and feed derived from RF3 CQ *B. juncea* is assumed to be nutritionally equivalent to food and feed derived from RF3 *B. napus* and, consequently, conventional *B. napus* varieties.

The evidences presented throughout this application and summarized above demonstrate that:

- The food and feed derived from RF3 CQ *B. juncea* has no adverse effects on human and animal health;
- The food derived from RF3 CQ *B. juncea* does not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer compared to conventionally produced food;
- The food derived from RF3 CQ *B. juncea* does not mislead the consumer;

- The feed derived from RF3 CQ *B. juncea* does not differ from the feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans compared to conventionally produced feed;
- The feed derived from RF3 CQ *B. juncea* does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

The assumptions made during the risk assessment are very conservative and include the following:

- All CQ *B. juncea* grain consumed in the EU would be from RF3 CQ *B. juncea* plants.
- No loss or degradation of protein would occur during processing and food preparation of CQ *B. juncea* seed products.

The labelling requirements specified in Articles 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003 are not applicable because the characteristics of the food and feed products from RF3 CQ *B. juncea* are not different from the characteristics of RF3 *B. napus*, and, consequently, conventional counterpart taking into account natural variation.

10. POST-MARKET MONITORING ON GENETICALLY MODIFIED FOOD/FEED

The risk characterization of RF3 CQ *B. juncea* has shown that the risk for potential adverse effects on human and animal health is negligible in the context of the intended uses of RF3 CQ *B. juncea*. It is therefore considered that there is no need for post marketing monitoring of food and feed derived from RF3 CQ *B. juncea*.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the genetically modified plant and target organisms

In this area of assessment, the main environmental concern, according to the EFSA ERA Guidance, is that target organisms develop resistance to the insect or pathogen tolerance traits expressed by the GM plant.

RF3 CQ *B. juncea* has been developed to confer herbicide tolerance. The scope of this application covers the import, processing and food and feed use of RF3 CQ *B. juncea* in the EU. According to the EFSA ERA Guidance: "*resistance development is only relevant for applications with scope cultivation of GM plants and not for applications restricted to import and processing of GM plants and their products*". Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of RF3 CQ *B. juncea* is not relevant for this application. Even considering a scenario where accidental spillage of viable material of RF3 CQ *B. juncea* occurred and some plants grew in the EU, the levels of exposure would be low and limited temporally and spatially. The likelihood of target organisms developing resistance under this scenario would be "highly unlikely" and any consequences on target organism populations would be "marginal", therefore the risk would be "negligible".

11.2. Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification

The scope of the application is for food and feed uses, import and processing and excludes cultivation. The environmental exposure is limited to accidental release of RF3 CQ *B. juncea* during transportation and processing for food and feed.

(a) Persistence and invasiveness

The conclusions from the comparative safety assessment conducted confirmed that no biologically relevant differences (i.e. consistent differences or differences outside the ranges for conventional varieties) in agronomic or phenotypic characteristics were observed between RF3 CQ *B. juncea* and a conventional counterpart, apart from the intended traits.

The potential that the introduced traits confer a selective advantage or disadvantage to the GM crop or to sexually compatible wild relatives has also been assessed. The main limiting factors preventing the spread of the crop outside agro-ecosystems are human dependence and frost tolerance; therefore, the herbicide tolerance trait is unlikely to confer selective advantage or disadvantage to CQ *B. juncea*. Since no sexually compatible wild relatives of CQ *B. juncea* are found in the EU, cross-hybridisation and introgression is highly unlikely.

The conclusion is that risk that the import, processing or food and feed use of RF3 CQ *B. juncea* in the EU will result in harm to sustainable agricultural production or biodiversity is negligible.

(b) Selective advantage or disadvantage

Compared with conventional oilseed rape, the introduced herbicide tolerance trait in RF3 CQ *B. juncea* confer a selective advantage only under specific conditions (i.e. following treatment with trait-specific herbicide). The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments. Given the scope of this application, the likelihood is negligible for the inherited traits in RF3 CQ *B. juncea* to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

The scope of this application covers the import, processing and all uses of RF3 CQ *B. juncea* as any other oilseed rape in the EU, excluding cultivation. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of RF3 CQ *B. juncea* with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of RF3 CQ *B. juncea* in the EU is not likely to pose any risk to human and animal health or the environmental.

Considering the low exposure and lack of hazard from horizontal gene transfer of the *barstar* and *bar* genes from RF3 CQ *B. juncea* to micro-organisms resulting from the import, processing and all uses of RF3 CQ *B. juncea*, the risk that this would result in adverse effects on human or animal health or the environment is negligible.

(d) Interactions between the genetically modified plant and target organisms

RF3 CQ *B. juncea* has been developed to confer tolerance to glufosinate-ammonium, no target organisms are associated with this product, and therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of RF3 CQ *B. juncea* is not relevant for this application.

(e) Interactions of the genetically modified plant with non-target organisms

The scope of this application covers the import, processing and food and feed use of RF3 CQ *B. juncea* in the EU, no deliberate release of viable plant material in the EU environment is expected. Therefore, an assessment of potential direct effects of RF3 CQ *B. juncea* on NTO populations is not relevant for this application. However, the assessment considers potential indirect adverse effects on NTO populations due to exposure through faeces of animals fed with RF3 CQ *B. juncea*.

Exposure to faeces of animals fed with RF3 CQ *B. juncea* would lead to very low levels of environmental exposure. The newly expressed proteins are expressed at low levels in seed and they are readily degraded by enzymatic activity in the gastro-intestinal tract of animals. Only minimal amounts of these proteins will be present in animal faeces. There would subsequently be further degradation of these proteins due to microbial processes. Exposure of soil and water environments to these proteins from disposal of animal wastes is likely to be very low and localized. Thus, exposure of potentially sensitive NTOs (e.g. coprophagous Coleoptera species) to the RF3 CQ *B. juncea* is likely to be very low and of no ecological relevance.

(f) Effects on human health

See point 9.

(g) Effects on animal health

See point 9.

(h) Effects on biogeochemical processes

Cultivation of RF3 CQ *B. juncea* in the EU is not included in the scope of this application. Although environmental exposure could occur through the accidental spillage of RF3 CQ *B. juncea*, or through manure or faeces of animals fed on RF3 CQ *B. juncea* through organic matter or by-products from RF3 CQ *B. juncea*, these routes of exposure would represent very low levels of exposure that would be limited spatially and temporally. It is highly unlikely that adverse effects on biogeochemical processes could occur. Therefore, an assessment of the impacts of RF3 CQ *B. juncea* on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

(i) Impacts of the specific cultivation, management and harvesting techniques

Cultivation of RF3 CQ *B. juncea* in the EU is not included in the scope of this application. Therefore, an assessment of the impacts of specific cultivation, management and harvesting techniques of RF3 CQ *B. juncea* is not relevant given the scope of this application.

11.3. Potential interactions with the abiotic environment

Overall results of the comparative analysis of RF3 CQ *B. juncea* with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics fell within the range of natural variability for oilseed rape with a history of safe use. Therefore, there is no evidence that this oilseed rape would be any different from conventional oilseed rape with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other oilseed rape in the EU, but excluding cultivation, interactions of RF3 CQ *B. juncea* with the environment will be limited.

11.4. Risk characterisation

The ERA has been conducted following the requirements and methodology described in the EFSA Guidance documents. The baseline considered for this risk assessment is the use of conventional oilseed rape in the EU, applying the concept of "familiarity", where the fact that oilseed rape is a common crop in the EU, previously used as food and feed for centuries and considered safe for human and animal health and the environment.

A comparative safety assessment has been conducted using a weight-of-evidence approach, considering molecular characterization data as well as expression, compositional and agronomic comparisons between the product and its conventional counterpart. This assessment has been used to establish whether unintended changes in the GM plant have occurred. The results of this comparative safety assessment demonstrated that the only differences of biological relevance identified between RF3 CQ *B. juncea* and the conventional counterpart are the intended traits. Despite the large number of parameters compared, no unintended differences of biological relevance were found. Thus the exposure and hazard assessment has been used to support the ERA of RF3 CQ *B. juncea*.

An assessment whether RF3 CQ *B. juncea* will be more persistent than the conventional crop in agricultural habitats or more invasive in natural habitats has been conducted. The results of this assessment allowed the conclusion that the risk that the import, processing or food and feed use of RF3 CQ *B. juncea* in the EU will not result in harm to sustainable agricultural production or biodiversity as a result of changes in persistence or invasiveness compared with the conventional crop.

An assessment whether the new genes present in RF3 CQ *B. juncea* could be transferred into micro-organisms and become integrated into their genome leading to adverse effects in human and animal health or the environment has been performed. The conclusion from this assessment was that it is very unlikely that these genes would become established in the genome of micro-organisms in the environment or human and animal digestive tract. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health or the environment are expected.

Potential interactions with target and non-target organisms that could lead to harmful environmental effects have also been assessed. The conclusion from these assessments is that adverse effects on sustainable agricultural production or biodiversity due to adverse effects on populations of NTOs as resulting from the import, processing or food and feed use RF3 CQ *B. juncea* will be negligible.

No assessment of adverse environmental effects due to changes in management practices or effects on biogeochemical processes has been performed since cultivation of RF3 CQ *B. juncea* is not within the scope of this application.

Finally, risks associated with the import, processing and food and feed use of RF3 CQ *B. juncea* in the EU on human and animal health have been assessed. The conclusion from this assessment was that food and feed derived from RF3 CQ *B. juncea* is as safe for humans and animal consumption as food and feed derived from the conventional crop.

In summary the import, processing and food and feed use of RF3 CQ *B. juncea* in the EU will pose negligible risk to human and animal health or the environment. The uncertainties associated with this risk characterisation are very low and no long-term adverse environmental effects are expected.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for RF3 CQ *B. juncea* has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants

(b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for RF3 CQ *B. juncea* according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of RF3 CQ *B. juncea* in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of RF3 CQ *B. juncea*.

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

The scientific evaluation of the characteristics of RF3 CQ *B. juncea* in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of RF3 CQ *B. juncea*. It is therefore considered that there is no need for case-specific monitoring.

(d) General surveillance of the impact of the genetically modified plant (approach, strategy, method and analysis)

In accordance with Council Decision 2002/811/EC, general surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable Genetically Modified Organism (GMO) or its use for human and animal health or the environment that were not predicted in the ERA.

The scope of this application is the authorisation of RF3 CQ *B. juncea* for food and feed uses, import and processing. The scope of the application does not include authorisation for the cultivation of RF3 CQ *B. juncea* seed products. Therefore, exposure to the environment will be limited to unintended release of RF3 CQ *B. juncea*, which could occur for example via substantial losses during loading/unloading of the viable commodity including RF3 CQ *B. juncea* destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious oilseed rape plants, such as manual or mechanical removal and the application of herbicides (with the exception of glufosinate-ammonium herbicide).

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on RF3 CQ *B. juncea* will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of RF3 CQ *B. juncea* and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable RF3 CQ *B. juncea*. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable RF3 CQ *B. juncea*.

(e) Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of RF3 CQ *B. juncea* and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the confirmed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on unanticipated adverse effects, if any, that have arisen from handling and use of viable RF3 CQ *B. juncea*.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of RF3 CQ *B. juncea* and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

The detection method for RF3 CQ *B. juncea* will be sent to the Community Reference Laboratory (CRL) of the Joint Research Centre of the European Commission (EC-JRC) for the purposes of experimental testing and validation in the frame of the food and feed application of RF3 CQ *B. juncea*. Appropriate control samples will also become available to the JRC-CRL.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. History of previous releases of the genetically modified plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number

There is no history of field release of RF3 CQ *B. juncea* in the EU.

(b) Conclusions of post-release monitoring

Not applicable.

(c) Results of the release in respect to any risk to human health and the environment, submitted to the Competent Authority in accordance with Article 10 of Directive 2001/18/EC)

Not applicable.

14.2. History of previous releases of the genetically modified plant carried out outside the Union by the same notifier

(a) Release country

RF3 CQ *B. juncea* has been tested in Canada and the United States.

(b) Authority overseeing the release

Canada: Canadian Food Inspection Agency

USA: United States Department of Agriculture

(c) Release site

Multiple major canola-growing provinces (Manitoba, Saskatchewan, Alberta), states and regions (Idaho, North and South Dakota, Minnesota, Montana) respectively.

(d) Aim of the release

Regulatory trials, testing of efficacy, yield and product development.

(e) Duration of the release

RF3 CQ *B. juncea* has been tested in Canada for 12 years, starting in 2007.

(f) Aim of post-releases monitoring

Volunteer assessment.

(g) Duration of post-releases monitoring

The CFIA confined permits require 5 years of post-trial monitoring.

(h) Conclusions of post-release monitoring

Oilseed rape volunteers are sometimes observed since oilseed rape has secondary dormancy. If volunteers occur, the practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

(i) Results of the release in respect to any risk to human health and the environment

Field-testing provided no evidence that RF3 CQ *B. juncea* would be the cause of any adverse effects to human health or to the environment.