

Fact-sheet

LibertyLink® **Oilseed rape T45** Unique Identifier ACS-BNØØ8-2

July 2019

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported oilseed rape grains which may contain T45 oilseed rape (ACS-BNØØ8-2)

The information set out in this document is principally directed to all operators handling and processing bulk mixtures of imported oilseed rape grains.

A. Authorisation

On 10 March 2009, Commission Decision 2009/184/EC authorised the placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:

- a) foods and food ingredients containing or produced from T45 oilseed rape;
- b) feed containing or produced from T45 oilseed rape;
- c) products other than food and feed containing T45 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

On 10 July 2019, Commission implementing Decision (EU) 2019/1195 amending Decision 2009/184/EC as regards the authorisation holder and the representative for the placing on the market of genetically modified oilseed rape has adopted the transfer of authorisation from Bayer CropScience AG to BASF Agricultural Solutions Seed US LLC.

The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission Implementing Decision 2019/2081 of 28 November 2019.

For more information, please visit the Community Register of GM Food and Feed using the following link: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

B. General Product Information

The introduced trait in T45 oilseed rape is herbicide tolerance, based on the expression of the *pat* gene. The *pat* gene is isolated from the soil microorganism, *Streptomyces viridochromogenes*, and when expressed, enables the production of the phosphinotricin acetyl-transferase (PAT) protein. The expression of the PAT protein confers plant tolerance to the herbicide active ingredient, glufosinate ammonium.

C. Food, Feed and Environmental Safety

The Scientific Panel on Genetically Modified Organisms (“the GMO Panel”) of the European Food Safety Authority (EFSA) has considered information related to 1) the molecular characterization and expression of the inserted DNA in T45 oilseed rape, 2) the comparative assessment of T45 oilseed rape and its non-transgenic comparator, 3) the safety of the PAT protein expressed in T45 oilseed rape and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of T45 oilseed rape.

The GMO Panel concluded that: “oilseed rape T45 is unlikely to have any adverse effect on human



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or animal health or on the environment in the context of its intended uses.” The GMO Panel’s opinion is that: “GM oilseed rape T45 is as safe as its non genetically modified counterpart with respect to potential effects on human and animal health or the environment.” The GMO Panel also agrees with the

conclusions of the environmental risk assessment of the authorisation holder that: *“the likelihood of the establishment and spread of oilseed rape T45 is very low and that unintended environmental effects due to this GM oilseed rape will be no different from that of conventional oilseed rape varieties.”*

Further information can be retrieved from EFSA website at:
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2008.635>

An event-specific quantitative detection method for T45 oilseed rape was validated by the Community Reference Laboratory (CRL) of the Joint Research Centre (JRC) and is publicly available on the JRC-CRL website: http://gmo-crl.jrc.ec.europa.eu/summaries/T45_validated_RTPCR_method.pdf

Certified reference material of T45 oilseed rape is available from the American Oil Chemists Society (AOCS): <https://www.aocs.org/store/shop-aocs/shop-aocs?productId=81070651>

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM oilseed rape shall comply with the requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, handling the labelling and traceability of genetically modified organisms and the conditions for labeling and traceability outlined in Commission Decision 2009/184/EC on T45 oilseed rape. The words “Not for cultivation” shall appear either on the label or in a document accompanying the product. The Unique Identifier Code assigned to T45 oilseed rape is **ACS-BNØØ8-2**.

In addition, the operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of the viable T45 oilseed rape or its use for human and animal health or the environment that were not predicted in the e.r.a. (see point F). In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable oilseed rape and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM oilseed rape it is essential to develop an industry wide approach because the shipments entering the European harbours may be co-mingled.

EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers.

EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio will transfer the messages to the relevant GMO industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to EuropaBio at: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information>.

In addition, a complete list of national contact points for operators to directly address local questions or remarks is included in a separate document, named ‘List of national contacts’.

If required, additional comments or questions relative to T45 oilseed rape can also be addressed at gent.info.operators@basf.com

F. General surveillance

F1. Monitoring and General Surveillance

In the authorisation procedure for a GMO, an environmental risk assessment is included to identify and evaluate on a case by case basis potential adverse effects either direct or indirect, immediate or delayed of the GMO, on human health and the environment which the deliberate release or the placing on the market of GMOs may have.

To evaluate the conclusions reached in the environmental risk assessment, monitoring is required. The objective of the monitoring is:

1. To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. This is referred to as case-specific monitoring, and;
2. To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. This is referred to as general surveillance.

In the case of T45 oilseed rape, the EFSA GMO panel concluded that “*no potential risks requiring the establishment of a case-specific monitoring plan were identified in the environmental risk assessment.*”

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., a general surveillance plan for T45 oilseed rape is in place. The EFSA GMO Panel concluded that: “*the scope of the monitoring plan provided by the applicant is in line with the intended uses of oilseed rape T45 since this does not include cultivation.*”

The general surveillance system for T45 oilseed rape will involve the authorisation holder and operators handling and using viable T45 oilseed rape. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable T45 oilseed rape.

The authorisation holder will report the results of the general surveillance for T45 oilseed rape to the European Commission on an annual basis.

F2. Awareness of accidental spillage

Accidental or unintentional loss and spillage of imported oilseed rape grains in ports and crushing facilities should be minimized. In the event that grain containing T45 oilseed rape is lost during handling this may result in the germination and possible establishment of volunteer plants, including T45 oilseed rape.

Volunteers are plants emerging from grain losses. The likelihood of spillage or loss of viable grain is highest in ports and crushing or processing facilities during storage and handling prior to processing into derived, non-viable products. It is essential that good practices are followed to manage the accidental spillage of viable grains at those locations.

However, and in the case of accidental spillage of imported oilseed rape grains, it is very unlikely it would establish a feral population or that it would outcross to commercial oilseed rape. Furthermore,

unintended environmental effects due to the unintended release of T45 oilseed rape will be no different than that of other commercial oilseed rape. The only difference, tolerance to the herbicide glufosinate ammonium, would not provide a survival advantage as long as the herbicide glufosinate ammonium is not used.

In any case, environmental exposure from accidental spillage is highly unlikely to give rise to an adverse effect and can be easily 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 (see Point F.3.).

F3. Eradication of volunteer T45 oilseed rape plants

In the event that volunteer plants include T45 oilseed rape, these plants should be eradicated to minimize the potential for unanticipated adverse effects arising from the GM plant. In that perspective it is essential that good practices are followed to control the establishment of volunteer plants. In order to assist operators importing oilseed rape grain in the EU, the authorisation holder in collaboration with Bayer Agriculture BVBA has made available appropriate technical advice how to eradicate oilseed rape volunteers which may include T45 and/or MS8/RF3 and/or GT73 oilseed rape. Please refer to the Guideline for the Management of Oilseed Rape Volunteers.

In the event that herbicides are used to eliminate volunteer oilseed rape plants it is essential not to use products based on glyphosate or glufosinate ammonium only but to apply other broad-leaf herbicides. In the case of doubt it is advised to seek technical advice and support with the local supplier of pesticides regarding the appropriate product to use in areas such as harbours and/or crushing facilities or other non-agricultural environments.