Determination of the Safety of BASF’s

Oilseed Rape RF3

for Direct use as Food, Feed, or Processing

The product dossier of BASF Philippines’ oilseed rape RF3 was reviewed for safety and nutritional differences compared to the conventional oilseed rape. The focus of the food/feed safety assessment is based on the following issues: (a) the nature of the genetic modification; (b) novel protein expression; (c) in vitro digestibility; (d) toxicological assessment; (e) allergenic potential; and (f) compositional and nutritional assessment.

A biosafety permit for oilseed rape RF3 and all progenies derived from crosses of the product with any conventionally bred oilseed rape and oilseed rape containing approved-biotech events for direct use as food, feed or for processing, was issued to BASF Philippines Inc. on November 21, 2018. The permit is valid for five years and shall expire on November 20, 2023 subject to the terms and conditions set forth in DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 series of 2016. The said product was included in the Lists of Approval Registry being prepared by the Department of Agriculture – Bureau of Plant Industry.

This approval is for use as Food, Feed or Processing only. This does not include cultivation of RF3 in the Philippines. Food and Feed use of RF3 and its by-products is therefore authorized as of November 21, 2018. The biosafety permit (No. 18-029FFP) stated that RF3 is as safe for human food, livestock feed and for processing as its conventional counterparts.

1. Brief Identification of the Genetically Modified Organism (Living Modified Organism)

Designation: Oilseed Rape RF3

Applicant: **BASF PHILIPPINES, INC.**

11F HHIC Building, 1128 University Parkway,

Bonifacio Global City, Taguig

Plant Species:

Name: Oilseed rape (*Brassica napus*)

Parent Material: Oilseed rape RF3

Center of Origin: Canada

Toxic Factors/Allergen(s): Glucosinolates, eruric acid, phenolic compounds

Trait Description: Glufosinate herbicide tolerance, fertility restoration

Trait Introduction Method: Agrobacterium tumefaciens-mediated transformation

**Donor Organisms***:**Bacilllus amyloliquefaciens, Streptomyces hygroscopicus*

 Pathogenicity: *bar* eliminates herbicidal activity of glufosinate (phosphinothricin) herbicides by acetylation

*barstar* restores fertility by repressing the inhibitory effect of barnase on tapetum cells of the anther

Proposed Use: For direct use as food, feed or for processing

## Background Information

On November 22, 2016, Bayer CropScience Inc. submitted oilseed rape RF3 for direct use as food and feed, or for processing, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

Bayer CropScience Inc., on their letter last August 22, 2018, stated that in light of their acquisition of Monsanto, Bayer AG and its affiliates signed an agreement to sell selected CropScience Businesses to BASF SE. According to the said agreement, ownership of this transformation event needs to be transferred from Bayer CropScience Inc. to BASF Philippines Inc. by changing the applicant name in all pending applications and accordingly direct future correspondences relevant to events with valid biosafety permits.

After reviewing the Risk Assessment Report and attachments submitted by the applicant, the assessors namely: Scientific and Technical Review Panel (STRP), BPI Plant Products Safety Services Division (BPI-PPSSD) and Bureau of Animal Industry- Biotech Team (BAI-BT), concurred that oilseed rape RF3 is as safe for human food and animal feed as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the documents related to Environmental Risk along with the submitted sworn statement and accountability of the proponent, recommended the issuance of a biosafety permit for this regulated event provided the conditions set by DENR are complied.

Also, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that oilseed rape RF3 will not pose any significant risk to the health and environment and that any hazards could be managed by the measures set by the department. DOH-BC also recommended for the issuance of biosafety permit for oilseed rape RF3.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

The DA-Biosafety Committee evaluated the assessment of all agencies including the SEC experts and recommended for the approval of the said application.

Food and Feed Safety

## Description of Novel (Introduced) Traits

RF3 oilseed rape contains a fertility restorer gene barstar from Bacillus amyloliquefaciens which encodes for the ribonuclease inhibitor Barstar. Barstar can form a one-to-one complex with Barnase in a male sterile line so the hybrid progeny will develop normally and rendered male fertile. RF3 oilseed rape also contains the bar gene from Streptomyces hygroscopicus which encodes for phosphinothricin acetyltransferase (PAT) conferring tolerance to herbicides containing glufosinate-ammonium.

### Safety of the Expressed Proteins

Safety assessments conducted on RF3 oilseed rape demonstrate no potential effects on human and animal health and the environment. Barstar in RF3 is expressed selectively in the tapetum during anther development therefore no exposure is expected to the Barstar protein for animals or humans. The PAT protein has well understood activity, substrate specificity and share similar structural and functional properties with the class of acetyltransferase proteins that are widely distributed in nature. The PAT proteins share no sequence homology with known allergens and toxins and are not stable in digestive environments. An acute gavage study in mice found no adverse effects from exposure to a high oral dose of the PAT protein. The donor organisms, the introduced genes and the expressed proteins are widely distributed in nature and ubiquitous in the environment.

## Nutritional Composition (Compositional Analysis)

Proximate and fiber compounds in seeds from transgenic RF3 and non-transgenic counterpart plants ranges from commercial Canola hybrids and references ranges from literature are presented. Similarly, the table of micro-nutrients, anti-nutrients and amino acids in seeds is also presented.

Assessment of substantial equivalence conducted showed that glufosinate tolerant B. napus transformation Event RF3 is compositionally and nutritional equivalent to its non-transgenic counterpart in the same hybrid background and to commercial B. napus hybrids currently in the market. Based on statistical evaluation of results, it was concluded that there is no impact on the nutritional value of the B. napus seeds as a result of genetic modification.

## Anti-Nutritional Factors

Some anti-nutrients are present in low erucic acid rapeseed meal like glucosinolates, sinapine, tannins and phytic acid in very small amount, hence not considered a health concern for man and animals. Glucosinolates, considered toxicants, are low to zero. While these may be considered “toxicants” the bioactive compound may also be beneficial in cases of the Brassica species, e.g., cabbage, which is considered in phytomedicine as “anti-cancer.”

Allergy to plants of Brassica species have been seen to have a shared sensitivity to other food allergens and is likely to be from other food allergens than from Brassica. The overall risk is very low as an allergen.

Environmental Risk Assessment

After a thorough scientific review and evaluation of the documents provided by the Bureau of Plant Industry (BPI) to the DENR Biosafety Committee within the prescribed period pursuant to the Joint Department Circular (JDC) No. 1 S 2016 on the application of BASF Philippines Inc. for direct use for feed, food or processing of Genetically Modified oilseed rape with single-trait product RF3, along with the submitted sworn statement and accountability of the proponent, a biosafety permit may be issued to the proponent if the conditions set by DENR are followed.

Environmental Health Risk Assessment

After a thorough scientific review and evaluation of the documents, DOH find sufficient evidence that the regulated article applied for direct use will not pose any significant risk to health and environment and that any hazards could be managed by the measures set by DOH.

Socio-economic. Ethical and Cultural Impact Assessment

Patterns in utilization as food and feed, and for processing as well as patterns in trade are not expected to be drastically changed by the issuance of the biosafety permit. Based on Risk Assessment Form submitted by the applicant and a scientific opinion adopted on 15 October 2017 by the European Food and Safety Authority (EFSA), there is “no evidence ... for new hazards, modified exposure of scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape MS8, RF3 and MS8xRF3.

Therefore, the SEC Expert recommended for the approval and issuance of biosafety permit of the said GM product.

Regulatory Decision

Based on the results of the risk evaluation of the submitted scientific data and other information relevant to the application of BASF Philippines Inc., it is concluded that oilseed rape RF3, and all progenies derived from crosses of the product with any conventionally-bred oilseed rape, and oilseed rape containing approved-biotech events for direct use as food, feed or for processing, is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, feed or for processing. BASF Philippines Inc. shall duly inform the public of this approval by way of publishing in any one (1) of the top three (3) leading newspapers in the country that import of this product is covered by conditions for approval as provided in the Biosafety Permit.