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Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356Ø43-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2012) 702) (Only the Dutch, English and French texts are authentic) (Text with EEA relevance) (2012/84/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

(a)Applicant and Authorisation holder

Name : Pioneer Overseas Corporation

Address : Avenue des Arts/Kunstlaan 44, 1040 Bruxelles/Brussel, BELGIQUE/

BELGIË

On behalf of Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, UNITED STATES OF AMERICA.

(b) Designation and specification of the products

- (1) Foods and food ingredients containing, consisting of, or produced from DP-356Ø43-5 soybean.
- (2) Feed containing, consisting of, or produced from DP-356Ø43-5 soybean.
- Products other than food and feed containing or consisting of DP-356Ø43-5 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified DP-356Ø43-5 soybean, as described in the application, expresses the GAT protein which confers tolerance to glyphosate herbicides and GM-HRA protein which confers tolerance to ALS-inhibiting herbicides.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-356Ø43-5 soybean referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection

- Event-specific real-time PCR-based method for the quantification of DP-356Ø43-5 soybean,
- validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm
- reference material: ERM®-AD425 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue

(e) Unique identifier

DP-356Ø43-5.

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Biosafety Clearing House, Record ID: see [to be completed when notified].

(g) Conditions or restrictions on the placing on the market, use or handling of the products

Not required.

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(h) Monitoring plan

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/

[Link: plan published on the Internet]

Post-market monitoring requirements for the use of the food for human consumption

Not required.

Note: Links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the EU register of genetically modified food and feed.

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View outstanding changes

Changes and effects yet to be applied to:

- Annex point (a) substituted by S.S.I. 2023/59 reg. 5(4)
- Annex point (a) substituted by S.I. 2023/235 reg. 5(4)
- Annex point (a) substituted by S.I. 2023/379 reg. 5(4)
- Annex Note word omitted by S.I. 2019/705 reg. 176