SRL BIOLINE-PRODUCT

Republica Moldova
Anenii-Noi
c/f 1015600008915
c/d MD72VI022243000000032MDL
TVA 3001029
BC "Victoriabank"SA
VICBMD2X500

Mob: 060054430

Республика Молдова
Новые-Анены
ф/к 1015600008915
p/c MD72VI022243000000032MDL
НДС 3001029
МРФ КБ "Victoriabanc"
МФО VICBMD2X500

Catre
Ministerul Agriculturii Dezvoltarii
Regionale si Mediului al Republicii Moldova

Nr.114 dd 11.05.2018

Cerere

Solicitam permisul de efectuare a importului a srotului de soia produs din organisme modificate genetic cu unmatoarele coduri de identificare a liniei genelor modificate, conform specificatiilor tehnice : MON 40-3-2 (MONQ4Q32-6), MON 87701 (MON877Q1-2), MON 89788 (MON89788-1), in cantitate de 4000 tone pe an.

Produsul dat urmeaza a fi importat pe piata interna, utilizat in hrana pentru animale, pentru necesitati proprii, cu transport rutier , in vrag , la depozitul autorizat ce se afla pe adresa or. Anenii Noi str. Concelierii Nationale 43 (nr. Autorizatiei : AS1*VF*0012525 VF din data de 30.07.2015).

La comercializarea srotului ne obligam sa mentionam in actele confirmative de comercializare ca produsul dat este genetic modificat . Prealabil transportul este supus dezinfectarii la unitatile specializate si certificate si dupa expedierea acestuia la locul de pastrare, autovehicolul iarasi este supus dezinfectarii.

Director SRL Bioline-Product
Barbuta Tatiana P.

L.Ş.

MINISTERUL AGRICULTURII, DEZVOLTĂRII REGIONALE ŞI MEDIULUI AL REPUBLICII MOLDOVA
Intrare Nr. 4365
10 - 07 2018

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Catre
Ministerul Agriculturii Dezvoltarii
Regionale si Mediului al Republicii Moldova

Notificare la Cerere nr. 114 dd 11.05.2018 Privind intentia de efectuare a importului a srotului de soia produs din boabe genetic modificate (OMG)

Notificăm intentia de efectuare a importului a srotului de soia produs din organisme modificate genetic cu unmatoarele coduri de identificare a liniei genelor modificate, conform specificatiilor tehnice : MON 40-3-2 (MONQ4Q32-6), MON 87701 (MON877Q1-2), MON 89788 (MON89788-1), in cantitate de 4000 tone pe an.

Produsul dat urmeaza a fi importat pe piata interna, utilizat in hrana pentru animale, pentru necesitati proprii, cu transport rutier , in vrag , la depozitul autorizat ce se afla pe adresa or. Anenii Noi str. Concelierii Nationale 43 (nr. Autorizatiei : AS1*VF*0012525 VF din data de 30.07.2015).

La comercializarea srotului ne obligam sa mentionam in actele confirmative de comercializare ca produsul dat este genetic modificat . Prealabil transportul este supus dezinfectarii la unitatile specializate si certificate si dupa expedierea acestuia la locul de pastrare, autovehicolul iarasi este supus dezinfectarii.

Director SRL Bioline-Product
Barbuta Tatiana P.

L.Ş.

Anexa 4

AGENŢIA NAŢIONALĂ PENTRU SIGURANŢA ALIMENTELOR

Subdiviziunea teritorială pentru siguranţa alimentelor

AUTORIZAŢIE SANITARĂ VETERINARĂ DE FUNCŢIONARE

Seria ASVF

"30" iulie 2015

Nr. AS1 * VF * 0012525 VF

Valabilă pînă "____" _____ 201__

1. Eliberată **SRL „ BIOLINE-PRODUCT "**
denumirea agentului economic, adresa, telefon

or. Anenii Noi. str. Concelierii Naţionale 43. tel: 026523270

pentru funcţionarea **DEPOZIT DE CEREALE**
denumirea obiectului, adresa, telefon

or. Anenii Noi. str. Concelierii Naţionale 43. tel: 026523270

2. Profilul activităţii Achiziţionarea şi recepţionarea de culturi cereale, oleaginoase şi produselor lor, depozitarea, prelucrarea, ambalarea şi comercializarea furajelor cu operaţiuni de import, conform cerinţelor şi normelor sanitare veterinare în vigoare a R. Moldova
abataj, achiziţionare, păstrare, preluare; fabricare, distribuire, transportare, comercializare a animalelor vii, materiei prime, produselor alimentare de origine animală, furajelor şi produselor care conţin componenţi de origine animală, alte specificări de activitate

3. Baza de emitere a autorizaţiei Documentaţia prezentată la DRSA Anenii Noi şi referatul tehnic nr. **103** din 29-07-2015.

Agentul economic, posesor al prezentei autorizaţii este obligat:
- să respecte necondiţionat prescripţiile actului de emitere a prezentei autorizaţii;
- la expirarea valabilităţii autorizaţiei să organizeze înnoirea ei în modul stabilit;
- să asigure respectarea cerinţelor sanitar-veterinare prin prisma actelor normative şi legislative în vigoare.

Nerespectarea condiţiilor în baza cărora a fost emisă prezenta autorizaţie, schimbae profilul sau au fost efectuate alte activităţi atrag, după caz, suspendarea autorizaţiei.

Şef al Subdiviziunii teritoriale pentru siguranţa alimentelor Anenii Noi

(semnătura) P. Andronic (nume, prenume)

L.Ş.

Reclamaţii şi sugestii la telefonul: 0-265-2-29-57

Falsificarea prezentei autorizaţii se pedepseşte conform legislaţiei în vigoare.

Certificate N°: 18012506BD

GMO OR NON-GMO CERTIFICATE

Pursuant to an order received from Bunge S/A, requesting us to carry out instruction summarized as:
SAMPLING AND ANALYSIS FOR DETECTION OF PRESENCE/ABSENCE OF GENETICALLY MODIFIED ORGANISMS (GMO)
On a consignment described as follows:

Description of goods	: Brazil Soybean meal GMO in bulk
Packing	: IN BULK
Name of Vessel	: MV ODYSSEAS
Quantity	: 29,594.785 MT
Shipper	BUNGE ALIMENTOS S/A RUA MANOEL BONIFACIO, Nº 2315 PORTO - PARANAGUÁ - PR CEP: 83.203-150
Consignee	: TO ORDER
Notify	SC BUNGE ROMANIA SRL ALEEA INDUSTRIILOR NR. 5-7, : BUZAU, ROMANIA Reg. Companies Registry under No. J10/75/22.01.2009 Fiscal Code of Registration RO16791351
Origin	: BRAZIL
Loading port	: PARANAGUA, BRAZIL
Port of discharge	: CONSTANTA, ROMANIA
Bill of lading date	: PARANAGUA, BRAZIL, JANUARY 04TH, 2018
Stowage	: STOWED INTO HOLDS NUMBER: 1, 2, 3, 4 and 5

We certify as follows:

1. SAMPLING:

Increment samples were drawn uniformly and systematically, concurrently with loading, at the nearest and best practicable point to the vessel in accordance with the method laid down by GAFTA 124. The sample material so obtained was well mixed and reduced to constitute composite samples of each partial loaded.

2. QUALITY/ANALYSIS:

As per instructions received from our Principal, one representative composite sealed with SGS seal number 1347396 sample was forwarded to **SGS Santos laboratory** for analysis purposes and as report no. ST1800219.001 dated on January 17th, 2018, which reported the following results:

GMO Analysis by PCR methodology

GMO Content	Test Result	LOD
GTS40-3-2 (MON-Ø4Ø32-6)	: Detected	: 0.01%
A2704-12 (ACS-GMØØ5-3)	: Not detected	: 0.01%
MON89788 (MON-89788-1)	: Detected	: 0.01%
A5547-127 (ACS-GMØØ6-4)	: Not detected	: 0.01%
MON87701 (MON-877Ø1-2)	: Detected	: 0.01%
FG72 (MST-FGØ72-2)	: Not detected	: 0.01%
CV127-9 (BPS-CV127-9)	: Not detected	: 0.01%
		LOQ
GTS40-3-2 (MON-Ø4Ø32-6)	: 43 %	: 0.10%
MON89788 (MON-89788-1)	: 33 %	: 0.10%
MON87701 (MON-877Ø1-2)	: 46 %	: 0.10%

As per instructions received from our Principal, one representative composite sealed with SGS seal number 1347269 sample was forwarded to **Analitus laboratory** for analysis purposes and as report no. 18025-1 dated on January 23rd, 2018, which reported

SGS DO BRASIL LTDA
Avenida Andrômeda, 832 – Alphaville
CEP: 06473 000 – Barueri – São Paulo
t : 55 11 3883 8800
f : 55 11 3883 8900

Certificate N°: 18012506BD

the following results:

GMO Analysis by PCR methodology		
GMO Content	**Test Result**	**LOD**
DP305423 (DP-3Ø5423-1)	: Not detected	: 0.01%
DP356043 (DP-356Ø43-5)	: Not detected	: 0.01%
MON87705 (MON-877Ø5-6)	: Not detected	: 0.01%
MON87769 (MON-87769-7)	: Not detected	: 0.01%
MON87708 (MON-877Ø8-9)	: Not detected	: 0.01%

"The meal is produced from Soybeans registered with GMOs Unique Identifiers GTS40-3-2, MON89788 and MON87701 and they have been approved into the EEC under directive 1829/2003/EC and EC 1830/2003."

3. PLACE AND DATE OF INTERVENTION:
At Shed 206 Bunge Terminal, PARANAGUA, BRAZIL from December 23rd, 2017 to January 04th, 2018
Santos, JANUARY 10TH, 2018
AGRI.5991.17 – MM

"As per IFIA Agricultural Bulletin 11-2 of November 2011, <> statements on certificates are issued subject to the limitations of (i) the degree of uncertainty inherent in the sampling process, and (ii) the testing methodology applied as per current methods commonly used for the detection of the item in question or those stipulated in the contract".
"This certificate reflects our findings at time and place of our intervention only and does not relieve the parties from their contractual responsibilities"
(This does not relieve the Master and the owner of the MV ODYSSEAS of their obligations and duties in any all respects.)

SGS DO BRASIL LTDA
Avenida Andrômeda, 832 – Alphaville
CEP: 06473 000 – Barueri – São Paulo
t : 55 11 3883 8800
f : 55 11 3883 8900

Certificate N°: 180206070E

CERTIFICATE OF QUALITY

19 AFL / 019 - B

In pursuance to an order received from:

BUNGE ROMANIASRL

to carry out instructions summarized as:

QUALITY SUPERVISION AT TIME OF DISCHARGING

of a consignment described as follows:

Name of vessel	ODYSSEAS
Description of goods	BRAZIL SOYBEAN MEAL GMO IN BULK
Consignee	TO ORDER
Notify address	SC BUNGE ROMANIA SRL ALEEA INDUSTRIILOR NR, 5-7, BUZAU, ROMANIA REG. COMPANIES REGISTRY UNDER NO. J10/75/22.01.2009 FISCAL CODE OF REGISTRATION RO16791351
Port of loading	PARANAGUA, BRAZIL
Port of discharge	CONSTANTA, ROMANIA
Quantity discharged	29,589.720 MT, as per D/S

This is to certify that upon instructions received from our Principal Messrs. BUNGE ROMANIA SRL, our inspectors have supervised the discharging of a parcel described as "BRAZIL SOYBEAN MEAL GMO IN BULK" ex M/V ODYSSEAS into warehouse and trucks by shore crane, bunkers and conveyor belts system at the port of Constanta between 29.01.2018 and 04.02.2018.

Sampling:

Representative sampling of the cargo was performed at regular intervals throughout discharging as per GAFTA 124. A composite was submitted for analysis in SGS Romania SA laboratory (test report no. 475 / 2018) and we certify the actual analysis results as follows:

Analyses	Method	Actual Results
Moisture	ISO 771 / 77	11.44 %
Crude protein, Nx6.25	SR EN ISO 5983-1 / 06	46.02 %
Fat	ISO 734-1 / 07	0.98 %
Fiber	SR EN ISO 6865 / 02	5.88 %

Signed and dated in Constanta
On 06th of January, 2018

For and on behalf of
SGS Romania SA

SGS Romania SA
38, Calea Serban Voda,
040212 Bucharest 4, Romania.
t : +40 21 335 46 83 - 85
f : +40 21 335 46 20
e : sgs_romania@sgs.com

УКРАЇНА
ГОЛОВНЕ УПРАВЛІННЯ ДЕРЖАВНОЇ СЛУЖБИ УКРАЇНИ З ПИТАНЬ БЕЗПЕЧНОСТІ ХАРЧОВИХ ПРОДУКТІВ ТА ЗАХИСТУ СПОЖИВАЧІВ В ПОЛТАВСЬКІЙ ОБЛАСТІ
РЕГІОНАЛЬНА ДЕРЖАВНА ЛАБОРАТОРІЯ ДЕРЖПРОДСПОЖИВСЛУЖБИ В ПОЛТАВСЬКІЙ ОБЛАСТІ

38751 Полтавська обл., Полтавський район, с. Горбанівка, вул. Миру, 2
тел. (0532) 63-13-38, E-mail:poltavalab@pvl.gov.ua, www.pvl.gov.ua

РДЛВМ в Полтавській області акредитована Національним агенством з акредитації України на відповідність вимогам ДСТУ ISO/IEC 17025:2006

РДЛВМ в Полтавській області атестована ДНДІЛДВСЕ на проведення робіт у сфері поширення державного метрологічного нагляду
Свідоцтво про атестацію № 45-137/2014

ЕКСПЕРТНИЙ ВИСНОВОК № 000984 е/18
« 11 » квітня 2018 р.

Об'єкт(и) випробувань та ідентифікаційний(і) номер(и): 000984 е/1/18 - шрот соєвий кормовий тостований гранульований; 000984 е/2/18 - шрот соєвий кормовий тостований гранульований; 000984 е/3/18 - шрот соєвий кормовий тостований гранульований; 000984 е/4/18 - шрот соєвий кормовий тостований гранульований; 000984 е/5/18 - шрот соєвий кормовий тостований гранульований; 000984 е/6/18 - шрот соєвий кормовий тостований гранульований.

Дата та місце відбору: 05.04.2018 р., ТОВ "Глобинський переробний завод", м.Глобине, Глобинського району, Полтавської області. Відібрано комісією у складі: лікаря ветеринарної медицини Глобинської районної державної лікарні ветеринарної медицини Удод І.І., начальника Глобинської районної державної лікарні ветеринарної медицини Гармаш М.В.

Температура в товщі продукції на час відбору: для зразків 000984 е/1/18, 000984 е/2/18, 000984 е/3/18, 000984 е/4/18, 000984 е/5/18, 000984 е/6/18 - не визначалась.

Акт відбору зразків № 5 від 05.04.2018 р.

Дата надходження зразка: 05.04.2018 р. о 13 год. 50 хв

Відбір зразків згідно: Постанови Кабінету Міністрів України від 14 червня 2002 р. № 833 «Про затвердження Порядку відбору зразків продукції тваринного, рослинного і біотехнологічного походження для проведення досліджень».

Виробник: 000984 е/1/18, 000984 е/2/18, 000984 е/3/18, 000984 е/4/18, 000984 е/5/18, 000984 е/6/18 - ТОВ "Глобинський переробний завод", м. Глобине, Глобинського району, Полтавської області, Україна.

Дата виготовлення: 000984 е/1/18 - 30.03.2018 р.; 000984 е/2/18 - 31.03.2018 р.; 000984 е/3/18 - 01.04.2018 р.; 000984 е/4/18 - 02.04.2018 р.; 000984 е/5/18 - 03.04.2018 р.; 000984 е/6/18 - 04.04.2018 р. Відповідно термін реалізації згідно нормативної документації 000984 е/1/18, 000984 е/2/18, 000984 е/3/18, 000984 е/4/18, 000984 е/5/18, 000984 е/6/18 - 4 місяці від дати виготовлення.

Маса (об'єм) партії, з якої відібрано зразки: 000984 е/1/18 - 500.0 т.; 000984 е/2/18 - 500.0 т.; 000984 е/3/18 - 500.0 т.; 000984 е/4/18 - 500.0 т.; 000984 е/5/18 - 500.0 т.; 000984 е/6/18 - 500.0 т..

Назва та адреса замовника: ТОВ "Глобинський переробний завод", вул. Володимирівська, 203, м. Глобине, Полтавської області.

Посвідчення про якість на продукцію: № 1819 від 30.03.2018 р.; № 1820 від 31.03.2018 р.; № 1821 від 01.04.2018 р.; № 1822 від 02.04.2018 р.; № 1823 від 03.04.2018 р.; № 1824 від 04.04.2018 р.

Мета випробувань: Перевірка відповідності зразків 000984 е/1/18 - шрот соєвий кормовий тостований гранульований; 000984 е/2/18 - шрот соєвий кормовий тостований гранульований; 000984 е/3/18 - шрот соєвий кормовий тостований гранульований; 000984 е/4/18 - шрот соєвий кормовий тостований гранульований; 000984 е/5/18 - шрот соєвий кормовий тостований гранульований; 000984 е/6/18 - шрот соєвий кормовий тостований гранульований за радіологічними показниками, токсико-мікологічними показниками, токсикологічними показниками, фізико-хімічними показниками, за вмістом мікотоксинів, пестицидів, токсичних елементів відповідно з ДСТУ 4230:2003.

Термін проведення випробувань: 05.04.2018 р. - 11.04.2018 р.

000984 е/1/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність

Україна * ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ * ГЛОБИНСЬКИЙ ПЕРЕРОБНИЙ ЗАВОД * м. Глобине Полтавська область * ДЛЯ ДОКУМЕНТІВ №1 * ІДЕНТ.КОД 30547403

Питома активність цезію-137, Бк/кг, не більше	600	3,24	(N) Методика измерения активности радионуклидов в счетных образцах на сцинтилляционном гамма – спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±3,97	Відповідає
Питома активність стронцію-90, Бк/кг, не більше	100	0	(N) Методика измерения активности бета - излучающих радионуклидов в счетных образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±5,46	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка ртуті, не більше, мг/кг	0,02	*<0,0009	(N) ПВ-62 (Редакция 01)	-	Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакция 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,01	(N) ПВ-44 (Редакция 02)	±0,8	Відповідає
Масова частка олова, не більше, мг/кг	50,0	30,65	(N) ПВ-44 (Редакция 02)	±3,07	Відповідає
Масова частка свинцю, не більше, мг/кг	1,0	*<0,12	(N) ПВ-44 (Редакция 02)	-	Відповідає
Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакция 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакция 02)	Не визначалась	Відповідає

Пестициди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
ГХЦГ (його ізомери), мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДЕ, ДДД), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клейковини, %	Не більше 7,0	3,42	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Об'ємна енергія, МДж	Не менше 1,18	1,24	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,11	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в перерахунку на сухі речовини, %	Не більше 2,5	1,29	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну в перерахунку на абсолютно сухі речовини, %	Не менше 45,0	50,99	(N) ДСТУ 7169:2010	Не визначалась	Відповідає
Масова частка вологи та летких речовин, %	8,5-12,0	11,07	(N) ДСТУ 7621:2014	Не визначалась	Відповідає
Масова частка жиру, нерозчинного в 10% розчині кислоти в перерахунку на абсолютно сухі речовини, %	Не більше 1,5	1,19	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН/г	Не більше 30,0	13,37	(N) МВ 15-15-39 від 13.09.1993р.	Не визначалась	Відповідає
Масова частка кислотних солей в перерахунку на абсолютно сухі речовини, %	Не більше 6,0	1,19	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	(N) ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці, скло, земля)	Не допускається	Не виявлено	(N) ДСТУ 4638:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром більше 2 мм, з гострим краями	Не допускається	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Колір	Від світло-жовтого до світло-коричневого	Світло-жовтий	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Запах	Характерний соєвому шроту без стороннього запаху (затхлості, плісняви, горілості тощо)	Специфічний, властивий шроту соєвому кормовому тостованому гранульоваванному, без затхлості, плісняви, горілості	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Діаметр гранул, мм	6,0-20,0	8,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Довжина однієї гранули, мм.	10,0-26,0	11,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Масова частка проходу через сито (вічко - 2 мм), не більше, %	5,0	Не виявлено	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Зеараленон, мг/кг	Не більше 1,0	*<0,12	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає
Т-2 токсин, мг/кг	Не більше 0,1	*<0,05	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає

Токсикологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	51,9	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

000984 е/2/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Питома активність цезію-137, Бк/кг, не більше	600	0	(N) Методика измерения активности радионуклидов в счетных образцах на сцинтилляционном гамма – спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±6,28	Відповідає
Питома активність стронцію-90, Бк/кг, не більше	100	0,03	(N) Методика измерения активности бета - излучающих радионуклидов в счетных образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±5,29	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність

Масова частка ртуті, не більше, мг/кг	0,02	*<0,0009	(N) ПВ-62 (Редакція 01)		Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,56	(N) ПВ-44 (Редакція 02)	±0,86	Відповідає
Масова частка цинку, не більше, мг/кг	50,0	32,15	(N) ПВ-44 (Редакція 02)	±3,22	Відповідає
Масова частка свинцю, не більше, мг/кг	1,0	*<0,12	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакція 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакція 02)	Не визначалась	Відповідає

Пестициди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
ГХЦГ (його ізомери), мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДД, ДДЕ), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клітковини, %	Не більше 7,0	3,24	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Обмінна енергія, МДж	Не менше 1,18	1,24	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,09	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в перерахунку на суху речовину, %	Не більше 2,5	1,18	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну в перерахунку на абсолютно суху речовину, %	Не менше 45,0	50,25	(N) ДСТУ 7169:2010	Не визначалась	Відповідає
Масова частка вологи та летких речовин, %	8,5-12,0	11,02	(N) ДСТУ 7621:2014	Не визначалась	Відповідає
Масова частка золи, нерозчинної в 10% соляної кислоти в перерахунку на абсолютно суху речовину, %	Не більше 1,5	1,27	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН	Не більше 30,0	12,44	(N) МВ 15-15/39 від 13.09.1993р	Не визначалась	Відповідає
Масова частка загальної золи в перерахунку на абсолютно суху речовину, %	Не більше 6,0	5,87	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	(N) ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці, скло, земля)	Не допускається	Не виявлено	(N) ДСТУ 4638:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром більше 2 мм, з гострими краями	Не допускається	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
	Від світло-жовтого до	Світло-жовтий	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Запах	Характерний соєвому шроту без стороннього запаху (затхлості, плісняви, горілості тощо)	Специфічний, властивий шроту соєвому кормовому тостованому гранульоваввному, без затхлості, плісняви, горілості	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Діаметр гранул, мм.	6,0-20,0	8,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Довжина однієї гранули, мм.	10,0-26,0	13,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Масова частка проходу через сито (вічко - 2 мм), не більше, %	5,0	Не виявлено	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Зеараленон, мг/кг	Не більше 1,0	*<0,12	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає
Т-2 токсин, мг/кг	Не більше 0,1	*<0,05	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає

Токсикологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	47,35	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

000984 е/3/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Питома активність цезію-137, Бк/кг, не більше	600	1,52	(N) Методика измерения активности радионуклидов в счетных образцах на сцинтилляционном гамма – спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±5,35	Відповідає
Питома активність стронцію-90, Бк/кг, не більше	100	4,09	(N) Методика измерения активности бета - излучающих радионуклидов в счетных образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±5,81	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка ртуті, не більше, мг/кг	0,02	*<0,0009	(N) ПВ-62 (Редакція 01)	-	Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,88	(N) ПВ-44 (Редакція 02)	±0,89	Відповідає
Масова частка цинку, не більше, мг/кг	50,0	30,54	(N) ПВ-44 (Редакція 02)	±3,05	Відповідає
Масова частка свинцю, не більше, мг/кг	1,0	*<0,12	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакція 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакція 02)	Не визначалась	Відповідає

Пестициди

Найменування показника та	МДР за нормативними	Результати	Позначення НД на метод	Похибка або	Відмітка про

				вимірювання**	
ГХЦГ (його ізомери), мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДД, ДДЕ), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначались	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клітковини, %	Не більше 7,0	3,35	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Обмінна енергія, МДж	Не менше 1,18	1,24	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,10	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в перерахунку на суху речовину, %	Не більше 2,5	1,28	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну в перерахунку на абсолютно суху речовину, %	Не менше 45,0	50,19	(N) ДСТУ 7169:2010	Не визначалась	Відповідає
Масова частка вологи та летких речовин, %	8,5-12,0	11,00	(N) ДСТУ 7621:2014	Не визначалась	Відповідає
Масова частка золи, нерозчинної в 10% соляної кислоти в перерахунку на абсолютно суху речовину, %	Не більше 1,5	1,16	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН/г	Не більше 30,0	12,93	(N) МВ 15-15/39 від 13.09.1993р	Не визначалась	Відповідає
Масова частка чистої золи в перерахунку на абсолютно суху речовину, %	Не більше 6,0	5,78	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	(N) ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці, скло, земля)	Не допускається	Не виявлено	(N) ДСТУ 4638:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, % частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, % частинки розміром більше 2 мм, з гострими краями	Не допускається	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Колір	Від світло-жовтого до світло-коричневого	Світло-жовтий	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Запах	Характерний соєвому шроту без стороннього запаху (затхлості, плісняви, горілості тощо)	Специфічний, властивий шроту соєвому кормовому тостованому гранульованому, без затхлості, плісняви, горілості	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Діаметр гранул, мм	6,0-20,0	8,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Довжина однієї гранули, мм	10,0-26,0	15,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Масова частка проходу через сито (отвір ~2 мм), не більше, %	5,0	Не виявлено	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка пр відповідніст
Зеараленон, мг/кг	Не більше 1,0	<0,1*	(N) МВ № 115 від 07.10.2003	Не визначалась	Відповідає
Т-2 токсин	Не більше 0,1	<0,05	(N) МВ № 115 від 07.10.2009	Не визначалась	Відповідає

Токсикологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	43,6	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

000984 е/4/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Питома активність цезію-137, Бк/кг, не більше	600	2,97	(N) Методика измерения активности радионуклидов в счетных образцах на сцинтилляционном гамма – спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±4,51	Відповідає
Питома активність стронцію-90, Бк/кг, не більше	100	8,07	(N) Методика измерения активности бета - излучающих радионуклидов в счетных образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±7,37	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка ртуті, не більше, мг/кг	0,02	0,001	(N) ПВ-62 (Редакція 01)	±0,0003	Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,04	(N) ПВ-44 (Редакція 02)	±0,8	Відповідає
Масова частка цинку, не більше, мг/кг	50,0	31,47	(N) ПВ-44 (Редакція 02)	±3,15	Відповідає
Масова частка свинцю, не більше, мг/кг	1,0	*<0,12	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакція 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакція 02)	Не визначалась	Відповідає

Пестициди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
ГХЦГ і його ізомери, мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДД, ДДЕ), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клітковини, %	Не більше 7,0	3,20	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Обмінна енергія, МДж	Не менше 1,18	1,24	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,11	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в *перерахунку на суху речовину*, %	Не більше 2,5	1,12	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну	Не менше 45,0	50,45	ДСТУ 7169:2010	Не визначалась	Відповідає

Україна
ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ "ГЛОБИНСЬКИЙ ПЕРЕРОБНИЙ ЗАВОД"
ДЛЯ ДОКУМЕНТІВ
№1
ЦЕНТ КОД 30547403

Масова частка вологи та летких речовин, %	8,5-12,0	11,05	(N) ДСТУ 7621 2014	Не визначалась	Відповідає
Масова частка золи нерозчинної в 10% соляній кислоті в перерахунку на абсолютну суху речовину, %	Не більше 1,5	1,24	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН/г	Не більше 30,0	11,90	(N) МВ 15-15/39 від 13.09.1993р	Не визначалась	Відповідає
Масова частка загальної золи в перерахунку на абсолютно суху речовину, %	Не більше 6,0	5,86	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	(N) ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці, скло, земля)	Не допускається	Не виявлено	(N) ДСТУ 4638 2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, % частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600 2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, % частинки розміром більше 2 мм, з гострими краями	Не допускається	Не виявлено	(N) ДСТУ 4600 2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230 2003	Не визначалась	Відповідає
Колір	Від світло-жовтого до світло-коричневого	Світло-жовтий	(N) ДСТУ 4230 2003	Не визначалась	Відповідає
Запах	Характерний соєвому шроту без стороннього запаху (затхлості, плісняви, гіркості тощо)	Специфічний, властивий шроту соєвому кормовому тостованому гранульованому, без затхлості, плісняви, гіркості	(N) ДСТУ 4230 2003	Не визначалась	Відповідає
Діаметр гранул, мм	6,0-20,0	8,0	(N) ДСТУ 4230 2003	Не визначалась	Відповідає
Довжина однієї гранули, мм	10,0-26,0	19,0	(N) ДСТУ 4230 2003	Не визначалась	Відповідає
Масова частка проходу через сито (вічка - 2 мм), не більше, %	5,0	Не виявлено	(N) ДСТУ 4230 2003	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Зеараленон, мг/кг	Не більше 1,0	*<0,12	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає
Т-2 токсин, мг/кг	Не більше 0,1	*<0,05	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає

Токсикологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	50,65	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

000984 с/5/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Питома активність цезію-137, Бк/кг, не більше	600	4,51	(N) Методика измерения активности радионуклидов в счетных образцах на сцинтилляционном гамма спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	[illegible]	Відповідає

Питома активність стронцію-90, Бк/кг, не більше	100	3,17	(N) Методика измерения активности бета - излучающих радионуклидов в счетных образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	±5,46	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка ртуті, не більше, мг/кг	0,02	*<0,0009	(N) ПВ-62 (Редакція 01)	-	Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,61	(N) ПВ-44 (Редакція 02)	±0,86	Відповідає
Масова частка цинку, не більше, мг/кг	50,0	29,52	(N) ПВ-44 (Редакція 02)	±2,95	Відповідає
Масова частка свинцю, не більше, мг/кг	1,0	*<0,12	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакція 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакція 02)	Не визначалась	Відповідає

Пестициди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
ГХЦГ і його ізомери, мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДД, ДДЕ), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клітковини, %	Не більше 7,0	3,17	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Обмінна енергія, МДж	Не менше 1,18	1,24	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,09	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в перерахунку на суху речовину, %	Не більше 2,5	1,05	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну в перерахунку на абсолютну суху речовину, %	Не менше 45,0	50,88	(N) ДСТУ 7169:2010	Не визначалась	Відповідає
Масова частка вологи та летких речовин, %	8,5-12,0	11,01	(N) ДСТУ 7621:2014	Не визначалась	Відповідає
Масова частка золи, нерозчинної в 10% соляної кислоти в перерахунку на абсолютну суху речовину, %	Не більше 1,5	1,29	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН/г	Не більше 30,0	13,03	(N) МВ 15-15/39 від 13.09.1993р.	Не визначалась	Відповідає
Масова частка загальної золи в перерахунку на абсолютну суху речовину, %	Не більше 6,0	5,90	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	[illegible] ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці [illegible]	Не допускається	Не виявлено	[illegible]08:2006	Не визначалась	Відповідає

Масова частка металомагнітних домішок, %, частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром більше 2 мм, з гострими краями	Не допускається	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Колір	Від світло-жовтого до світло-коричневого	Світло-жовтий	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Запах	Характерний соєвому шроту без стороннього запаху (затхлості, плісняви, горілості тощо)	Специфічний, властивий шроту соєвому кормовому тостованому гранульованому, без затхлості, плісняви, горілості	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Діаметр гранул, мм	6,0-26,0	8,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Довжина однієї гранули, мм	10,0-26,0	17,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Масова частка проходу через сито (отвір) 2 мм, не більше, %	5,0	Не виявлено	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Токенкологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	56,2	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Зеараленон, мг/кг	Не більше 1,0	*<0,12	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає
Т-2 токсин, мг/кг	Не більше 0,1	*<0,05	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає

000984 е/6/18 - шрот соєвий кормовий тостований гранульований

Радіонукліди

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Питома активність цезію-137 (Cs-137), не більше	600	1,54	(N) Методика измерения активности радионуклидов цезия в сыпучих образцах на сцинтилляционном гамма-спектрометре с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	+/-25%	Відповідає
Питома активність стронцію-90, Бк/кг, не більше	100	2,77	(N) Методика измерения активности бета-излучающих радионуклидов в сыпучих образцах с использованием программного обеспечения Прогресс (ГП «ВНИИФТРИ», 1996)	+/-25%	Відповідає

Токсичні елементи

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка ртуті, не більше, мг/кг	0,02	*<0,0009	(N) ПВ-62 (Редакція 01)	-	Відповідає
Масова частка кадмію, не більше, мг/кг	0,1	*<0,03	(N) ПВ-44 (Редакція 02)	-	Відповідає
Масова частка міді, не більше, мг/кг	10,0	8,32	(N) ПВ-44 (Редакція 02)	±0,83	Відповідає
Масова частка цинку, не більше, мг/кг	50,0	33,22	(N) ПВ-44 (Редакція 02)	±3,32	Відповідає
Масова частка свинцю, не	1,0	*<0,12	(N) ПВ-44 (Редакція 02)	-	Відповідає

ДЛЯ ДОКУМЕНТІВ №1

Масова частка миш'яку, не більше, мг/кг	0,3	*<0,08	(N) ПВ-48 (Редакція 02)	-	Відповідає

Мікотоксини (ВЕРХ)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Афлатоксин В1, мг/кг	Не більше 0,005	*<0,00005	(N) ПВ-43 (Редакція 02)	Не визначалась	Відповідає

Пестициди

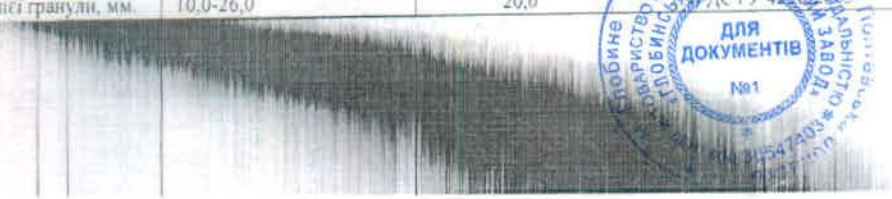
Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
ГХЦГ і його ізомери, мг/кг	Не більше 0,2	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
ДДТ і метаболіти (ДДД, ДДЕ), мг/кг	Не більше 0,05	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає
Гептахлор, мг/кг	Не допускається	*<0,05	(N) МВ № 2142-80	Не визначалась	Відповідає

Фізико-хімічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Масова частка сирої клітковини, %	Не більше 7,0	3,09	(N) ГОСТ 13496.2-91	Не визначалась	Відповідає
Обмінна енергія, МДж	Не менше 1,18	1,25	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Активність уреази, од. pH	Не більше 0,1-0,2	0,08	ДСТУ 8365:2015	Не визначалась	Відповідає
Масова частка сирого жиру в перерахунку на суху речовину, %	Не більше 2,5	1,28	(N) ГОСТ 13496.15-97	Не визначалась	Відповідає
Масова частка сирого протеїну в перерахунку на абсолютну суху речовину, %	Не менше 45,0	52,30	(N) ДСТУ 7169:2010	Не визначалась	Відповідає
Масова частка вологи та летких речовин, %	8,5-12,0	11,0	(N) ДСТУ 7621:2014	Не визначалась	Відповідає
Масова частка золи, нерозчинної в 10% соляної кислоти в перерахунку на абсолютну суху речовину, %	Не більше 1,5	1,33	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає
Кислотне число жиру, мг КОН/г	Не більше 30,0	12,47	(N) МВ 15-15/39 від 13.09.1993р.	Не визначалась	Відповідає
Масова частка загальної золи в перерахунку на абсолютну суху речовину, %	Не більше 6,0	5,95	(N) ГОСТ 13979.6-69	Не визначалась	Відповідає

Токсико-мікологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Токсичність	Не допускається	Не токсичний	(N) ДСТУ 3570-97 (ГОСТ 13496.7-97)	Не визначалась	Відповідає
Зараженість шкідниками або наявність слідів зараження	Не допускається	Не виявлено	(N) ГОСТ 13496.13-75	Не визначалась	Відповідає
Сторонні домішки (камінці, скло, земля)	Не допускається	Не виявлено	(N) ДСТУ 4638:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром до 2 мм включно	Не більше 0,01	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Масова частка металомагнітних домішок, %, частинки розміром більше 2 мм, з гострими краями	Не допускається	Не виявлено	(N) ДСТУ 4600:2006	Не визначалась	Відповідає
Зовнішній вигляд	Гранули циліндричної форми	Гранули циліндричної форми	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Колір	Від світло-жовтого до світло-коричневого	Світло-жовтий	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Запах	Характерний сосовому шроту без стороннього запаху (затхлості, плісняви, горілості тощо)	Специфічний, властивий шроту сосновому кормовому тостованому гранульованому, без затхлості, плісняви, горілості	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Діаметр гранул, мм.	6,0-20,0	8,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає
Довжина однієї гранули, мм.	10,0-26,0	20,0	(N) ДСТУ 4230:2003	Не визначалась	Відповідає



Масова частка проходу через сито (вічко - 2 мм), не більше %	5,0	Не виявлено	(N) ДСТУ 4230:2003	Не визначалась	Відповідає

Мікотоксини (ІФА)

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Зеараленон, мг/кг	Не більше 1,0	*<0,12	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає
Т-2 токсин, мг/кг	Не більше 0,1	*<0,05	(N) МВ № 115 від 07.10.2004	Не визначалась	Відповідає

Токсикологічні показники

Найменування показника та одиниці вимірювання	МДР за нормативними документами	Результати випробувань	Позначення НД на метод випробувань	Похибка або невизначеність вимірювання**	Відмітка про відповідність
Нітрити, мг/кг	Не більше 10	<2,0	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає
Нітрати, мг/кг	Не більше 450	47,8	(N) ГОСТ 13496.19-93	Не визначалась	Відповідає

Висновок: Надіслані зразки 000984 е/1/18 - шрот соєвий кормовий тостований гранульований, 000984 е/2/18 - шрот соєвий кормовий тостований гранульований, 000984 е/3/18 - шрот соєвий кормовий тостований гранульований, 000984 е/4/18 - шрот соєвий кормовий тостований гранульований, 000984 е/5/18 - шрот соєвий кормовий тостований гранульований, 000984 е/6/18 - шрот соєвий кормовий тостований гранульований за радіологічними показниками, токсико-мікологічними показниками, токсикологічними показниками, фізико-хімічними показниками, за вмістом мікотоксинів, рестрикторів, пестицидів, ГМО відповідають ДСТУ 4230:2003

Рекомендації щодо реалізації: Діяти згідно чинного законодавства України.

Примітка:
експертний висновок стосується тільки зразків, відданих випробуванням.
Цей експертний висновок не може бути повністю або частково відтворений, тиражований та розповсюджений як офіційний документ без дозволу Регіональної державної лабораторії Держпродспоживслужби в Полтавській області.
* "<" – менше межі виявлення методу;
** – оцінювання невизначеності вимірювань проводиться відповідно до операційної процедури ПЯ 5.4-02. Розрахунок похибки вимірювання проводиться відповідно до вимог на метод дослідження.
(N) – методика знаходиться в галузі акредитації НААУ.
Термін дії експертного висновку: 1 місяць

В.о. директора Ісаєва О.О.

Відповідальні виконавці:

Лікар ветеринарної медицини відділу відбору, реєстрації зразків продукції Любченко Т.С.

Завідувач бактеріологічного відділу Семенко М.А

European Food Safety Authority EFSA Journal 2010;8(12):1908

SCIENTIFIC OPINION

Scientific Opinion on applications (EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$, EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) for renewal of authorisation for the continued marketing of (1) food containing, consisting of, or produced from genetically modified soybean 40-3-2; (2) feed containing, consisting of, or produced from soybean 40-3-2; (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation, all under Regulation (EC) No 1829/2003 from Monsanto[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion is an evaluation of a risk assessment for the renewal of authorisations for continued marketing of the genetically modified herbicide tolerant soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6) for (1) food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2; (2) feed containing, consisting of, or produced from soybean 40-3-2; and (3) of other products containing or consisting of soybean 40-3-2 with the exception of cultivation. Soybean 40-3-2 has been developed for tolerance to glyphosate herbicides by the introduction, via particle gun acceleration technology, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 EPSPS). Molecular analyses indicated that soybean 40-3-2 contains one functional insert expressing CP4 EPSPS and a non-functional insert consisting of a fragment of the CP4 EPSPS coding sequence. Updated bioinformatic analyses of the flanking sequences and the open reading frames spanning the insert-plant DNA junctions and the levels of the newly expressed protein in soybean 40-3-2 did not raise any safety concern. The stability of the inserted DNA was confirmed over several generations. Available compositional and agronomic data show that soybean 40-3-2 is compositionally and agronomically equivalent to its conventional counterpart and to other commercial soybean varieties, except for expressing the CP4 EPSPS protein.

[1] On request from the European Commission on applications (EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) submitted by Monsanto, Questions No EFSA-Q-2007-142, EFSA-Q-2007-141 adopted on 10 November 2010.

[2] Panel members: Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Gerhard Flachowsky, Lieve Herman, Huw Jones, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper, Antoine Messéan, Kaare Magne Nielsen, Joe Perry, Annette Pöting, Jeremy Sweet, Christoph Tebbe, Atte Johannes von Wright, and Jean-Michel Wal. Correspondence: gmo@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Molecular Characterisation, Food and Feed and Environment for the preparatory work on this scientific opinion, Boet Glandorf, Niels Hendriksen as external experts and EFSA's staff members Zoltán Divéki (MC), Karine Lheureux (ENV) and Claudia Paoletti (FF) for the support provided to this EFSA scientific opinion.

Suggested citation: EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-RX-40-3-2) for the renewal of authorisation for the continued marketing of (1) food containing, consisting of, or produced from genetically modified soybean 40-3-2; (2) feed containing, consisting of, or produced from soybean 40-3-2; (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2010;8(12):1908, [1-38]. doi: 10.2903/j.efsa.2010.1908.

Available online: www.efsa.europa.eu/efsajournal.htm

It is estimated that the European consumers have been exposed to soybean 40-3-2 mainly via soybean oil Processed meal of soybean 40-3-2 has been given to farm animals in the EU at an estimated maximum dietary inclusion levels around 21% for broiler chickens, 18% for pigs, and 12% for dairy cattle. No adverse effects have been linked to these exposures. The safety assessment of the CP4 EPSPS protein expressed in soybean 40-3-2 and the whole soybean plant identified no concerns regarding potential toxicity and allergenicity of soybean 40-3-2. Considering the intended uses of soybean 40-3-2, which excludes cultivation within the European Union, no scientific assessment of potential environmental effects associated with cultivation of GM soybean 40-3-2 was required. In case of accidental release of viable grains produced by soybean 40-3-2 into the environment during transportation and processing, there are no indications of an increased likelihood of establishment and spread of feral soybean plants, except in the presence of the glyphosate herbicides. The EFSA GMO Panel considers unlikely that the recombinant DNA in soybean 40-3-2 transfers to bacteria and other micro-organisms and that the risk caused by a rare but theoretically possible transfer of the recombinant epsps gene from soybean 40-3-2 to environmental microorganisms is regarded to be negligible due to the lack of a selective advantage in the context of its intended use that would be conferred. Taking into account the scope of the application, the rare occurrence of feral soybean plants and the low levels of exposure through other routes, indicate that the risk to non-target organisms is extremely low. The scope of the monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean 40-3-2 since cultivation is excluded.
In conclusion, on the basis of the information considered in the original application, updated studies in the present applications, and other peer-reviewed scientific data on soybean 40-3-2, the EFSA GMO Panel confirms that soybean 40-3-2 is as safe and nutritious as the conventional counterpart and other commercial soybean varieties.

KEY WORDS

GMO, soybean, 40-3-2, glyphosate tolerance, risk assessment, food and feed safety, environment, import and processing, Regulation (EC) No 1829/2003, renewal.

SUMMARY

This document provides a scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on two applications (References EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) submitted by Monsanto under Regulation (EC) No 1829/2003 for renewal of the authorisation for continued marketing of (1) food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6); (2) feed containing, consisting of, or produced from soybean 40-3-2; and (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation.

The scopes of the two renewal applications cover the continued marketing of:

- existing food containing, consisting of, or produced from soybean 40-3-2 (including food additives) (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EC before the entry into force of Regulation (EC) No 258/97 and under Directive 89/107/EEC (Commission Decision 96/281/EC);
- existing feed containing, consisting of, or produced from soybean 40-3-2 (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EEC (Commission Decision 96/281/EC) and as feed materials and feed additives subject to Directive 70/524/EEC;
- other products containing or consisting of soybean 40-3-2 with the exception of cultivation (Commission Decision 96/281/EC).

After the date of entry into force of the Regulation (EC) No 1829/2003, the products mentioned above were notified to the European Commission according to Articles 8 or 20 of this Regulation and subsequently included in the Community Register of GM food and feed.

Soybean 40-3-2 has been developed for tolerance to glyphosate herbicides by the introduction, via particle gun acceleration technology, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium tumefaciens* (renamed *Rhizobium radiobacter*) strain CP4 (CP4 EPSPS). In delivering its scientific opinion, the EFSA GMO Panel considered the renewal applications (EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$, EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$); a consolidated application on the cultivation of soybean 40-3-2 (application EFSA-GMO-NL-2005-24); additional information submitted by the applicant on request of the EFSA GMO Panel; the scientific comments submitted by Member States; and relevant scientific publications. In accordance with the Guidance Document for renewal of authorisations of existing GMO products, the EFSA GMO Panel has taken into account the new information, experience and data on soybean 40-3-2, which have become available during the authorisation period.

The EFSA GMO Panel assessed soybean 40-3-2 with reference to the intended uses and appropriate principles described in the Guidance Documents of the EFSA GMO Panel for the Risk Assessment of Genetically Modified Organisms and Derived Food and Feed and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market. The scientific assessment included molecular characterisation of the inserted DNA and expression of the target proteins. A comparative analysis of agronomic traits and composition was undertaken and the safety of the new protein and the whole food/feed were evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plans were undertaken.

The molecular characterisation data establish that the genetically modified soybean 40-3-2 contains one functional insert expressing CP4 EPSPS and a non-functional insert consisting of a 72 bp

fragment of the CP4 EPSPS coding sequence. No other parts of the plasmid used for transformation are present in the transformed plant. Updated bioinformatic analyses of the flanking sequences and the open reading frames spanning the insert-plant DNA junctions and the levels of the newly expressed protein in soybean 40-3-2 did not raise any safety concern. The stability of the inserted DNA was confirmed over several generations and a Mendelian inheritance pattern was demonstrated.

The EFSA GMO Panel compared the composition and agronomic characteristics of soybean 40-3-2 and its conventional counterpart, assessed all statistical differences identified, and came to the conclusion that soybean 40-3-2 is compositionally and agronomically equivalent to its conventional counterpart and other commercial soybean varieties, except for the expressing the glyphosate tolerance trait. The risk assessment of the newly expressed protein and the whole crop included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The EFSA GMO Panel concluded that the soybean 40-3-2 is as safe as its conventional counterpart and that the overall allergenicity of the whole plant is not changed.

According to the information provided by the applicant, food and feed products produced from soybean 40-3-2 have been consumed without reports of adverse effects since they were approved in the EU in 1996. Scientific publications which have become available since the previous evaluation of soybean 40-3-2 by the Advisory Committee of the Competent Authority of the United Kingdom (UK-ACNFP, 1995) did not raise safety issues. In addition, bioinformatics studies comparing the amino acid sequences of the newly expressed CP4 EPSPS protein in soybean 40-3-2 with amino acid sequences in updated databases of toxic or allergenic proteins confirmed the results of the older studies which identified no relevant similarities to known toxic or allergenic proteins.

The applications EFSA-GMO-RX-40-3-2 concern food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6); feed containing, consisting of, or produced from soybean 40-3-2; and other products containing or consisting of soybean 40-3-2 with the exception of cultivation. Therefore, there is no requirement for scientific assessment of possible environmental effects associated with the cultivation of soybean 40-3-2. There are no indications of an increased likelihood of establishment and spread of feral soybean plants in case of accidental release into the environment of viable grains produced by soybean 40-3-2 during transportation and processing, except in the presence of glyphosate herbicides. Taking into account the scope of the applications, the rare occurrence of feral soybean plants and the low levels of exposure through other routes, the risk to non-target organisms is extremely low. The EFSA GMO Panel considers unlikely that the recombinant DNA in soybean 40-3-2 transfers to bacteria and other microorganisms and that the risk caused by a rare but theoretically possible transfer of the recombinant epsps gene from soybean 40-3-2 to environmental microorganisms is regarded to be negligible due to the lack of a selective advantage in the context of its intended use that would be conferred. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan. The EFSA GMO Panel recommends that appropriate management systems should be in place to restrict seeds of soybean 40-3-2 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

In conclusion, the EFSA GMO Panel considers that the information available for soybean 40-3-2 addresses the scientific comments raised by the Member States and that the soybean 40-3-2, as described in these applications, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that soybean event 40-3-2 is unlikely to have any adverse effect on human and animal health and the environment, in the context of its intended uses.

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BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission two applications submitted under Regulation (EC) No 1829/2003 for renewal of the authorisation of (1) food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6); (2) feed containing, consisting of, or produced from soybean 40-3-2; and (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation, developed by Monsanto to provide tolerance to glyphosate herbicides.

The scopes of the two renewal applications cover the continued marketing of:

- existing food containing, consisting of, or produced from soybean 40-3-2 (including food additives) (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EC before the entry into force of Regulation (EC) No 258/97 and under Directive 89/107/EEC (Commission Decision 96/281/EC);

- existing feed containing, consisting of, or produced from soybean 40-3-2 (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EEC (Commission Decision 96/281/EC) and as feed materials and feed additives subject to Directive 70/524/EEC;

- other products containing or consisting of soybean 40-3-2 with the exception of cultivation (Commission Decision 96/281/EC).

After the date of entry into force of the Regulation (EC) No 1829/2003, the products mentioned above were notified to the European Commission according to Articles 8 or 20 of this Regulation and subsequently included in the Community Register of GM food and feed.

Soybean 40-3-2 was the subject of an earlier safety assessment (UK-ACNFP, 1995) and has been authorised (EC, 1996) under Directive 90/220/EEC. In addition, national approvals for the food and feed use of soybean 40-3-2 and its derivatives were received from the United Kingdom, The Netherlands and Denmark prior to the entry into force of Regulation (EC) No 258/97.

After receiving the renewal applications (EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed Member States as well as the European Commission and made the summary of these applications publicly available on the EFSA website[4]. EFSA initiated a formal review of the renewal applications to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 03 March 2008, EFSA received additional information requested under completeness check (requested on 14 January 2008) and on 12 March 2008, EFSA declared the applications as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003.

EFSA made the valid applications available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC (EC, 2001) following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. The Member State bodies had 3 months after the date of receipt of the valid applications (until 13 June 2008) within which to make their opinion known.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-141 and http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-142

The EFSA GMO Panel carried out the safety evaluation of the renewal applications of the soybean 40-3-2 in accordance with the appropriate principles described in the EFSA GMO Panel Guidance Documents for the risk assessment of GM plants and derived food and fed (EFSA, 2006b) and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market (EFSA, 2006a). In addition, the scientific comments of Member States, the additional information provided by the applicant; the information provided in the context of application EFSA-GMO-NL-2005-24 and relevant scientific publications were taken into consideration.

The EFSA GMO Panel requested additional information from the applicant on (1) 15 July 2008, 12 September 2008, 11 December 2008 and 16 March 2010 for application EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$; (2) 12 September 2008, 11 December 2008 and 16 March 2010 for application EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$. The applicant provided the requested information on (1) 01 December 2008, 23 December 2008, 20 August 2009 and 15 July 2010 for application EFSA-EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$; (2) 23 December 2008, 20 August 2009 and 15 July 2010 for application EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$. Moreover, the EFSA GMO Panel considered the application and additional information submitted in the context of application EFSA-GMO-NL-2005-24 (soybean 40-3-2 for cultivation).

In giving its scientific opinion on soybean 40-3-2 to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the acknowledgement of the valid applications. As additional information was requested by the EFSA GMO Panel, the time-limit of six months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the overall opinions in accordance with Articles 6(5) and 18(5).

TERMS OF REFERENCE

The EFSA GMO Panel was requested to carry out a scientific assessment of soybean 40-3-2 for the renewal of authorisation of (1) existing food containing, consisting of, or produced from soybean 40-3-2 (including food additives) (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EC before the entry into force of Regulation (EC) No 258/97 and under Directive 89/107/EEC (Commission Decision 96/281/EC); (2) feed containing, consisting of, or produced from soybean 40-3-2 (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) that have been placed on the market in accordance with Part C to the Directive 90/220/EEC (Commission Decision 96/281/EC) and as feed materials and feed additives subject to Directive 70/524/EEC; and (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation (Commission Decision 96/281/EC). Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environments and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)e of Regulation (EC) No 1829/2003.

The EFSA GMO Panel was not requested to give a scientific opinion on information required under Annex II of the Cartagena Protocol. Furthermore, the EFSA GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

ASSESSMENT

1. Introduction

The initial safety assessment of soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6) was conducted according to Directive 90/220/EEC. During this process, the Advisory Committee on Releases to the Environment (ACRE), acting as the scientific authority of the UK Competent Authority, its sister organisations within the UK, as well as the Competent Authorities of the other Member States, concluded that this product did not pose safety concerns and that no risk management measures such as specific monitoring were required. This led to the Commission giving consent under Directive 90/220/EEC in 1996 (EC, 1996). In addition, national approvals for the food and feed use of soybean 40-3-2 and its derivatives were received from the United Kingdom, The Netherlands and Denmark prior to the entry into force of Regulation (EC) No 258/97. Switzerland also granted approval for import and use in 1996.

In addition to the renewal applications EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$, the applicant submitted to EFSA an application under Regulation EC No 1829/2003 (EFSA-GMO-NL-2005-24) for cultivation of soybean 40-3-2, which gather all the data supporting the safety of soybean 40-3-2 and complement the renewal applications. The scientific assessment in the cultivation application included the transformation process, the vectors used and the transgenic constructs in the GM plants. A comparative analysis of agronomic traits and composition was undertaken and the safety of the new proteins and the whole food/feed was evaluated with respect to toxicology and allergenicity. Although it also contained an extensive environmental risk assessment, this information was not necessary for the renewals concerned in the present opinion.

The assessment presented here is based on the information provided by the applicant in the renewal applications EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$ for continued marketing of food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2; feed containing, consisting of, or produced from soybean 40-3-2; and other products containing or consisting of soybean 40-3-2 with the exception of cultivation, appropriate sections of the application EFSA-GMO-NL-2005-24 for cultivation of soybean 40-3-2, additional information submitted by the applicant in response to questions requested from the EFSA GMO Panel, as well as comments from Member States and relevant scientific publications. The assessment has taken into account the appropriate principles described in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006b), and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003 (EFSA, 2006a).

Information in the applications include 1) updated information on the comparative compositional analysis; 2) an estimation of the human and live-stock exposure in Europe to soybean 40-3-2; 3) an update on peer-reviewed scientific data on soybean 40-3-2, and 4) updated information on potential for allergenicity and toxicity, including updated homology searches between the newly expressed proteins and known toxic and allergenic proteins.

2. Issues raised by the Member States

The comments raised by the Member States are addressed in Annex G of the EFSA overall opinions[5] and have been considered in this scientific opinion.

3. Molecular characterisation

3.1. Evaluation of relevant scientific data

3.1.1. Transformation process and vector constructs[6]

Soybean tissue, derived from cultivar A5403 was transformed with plasmid PV-GMGT04 using particle acceleration. The plasmid PV-GMGT04 contains two CP4 *epsps* expression cassettes conferring resistance to glyphosate herbicides, the marker gene *uidA* coding for β-D-glucuronidase (GUS) derived from *Escherichia coli* and the neomycin phosphotransferase (*npt*II) gene conferring resistance to kanamycin and neomycin for selection in *E. coli* and the *E. coli* origin of replication ColE1.

The first CP4 epsps expression cassette consists of the following elements: an enhanced 35S promoter derived from *Cauliflower mosaic virus*, the CTP4 N-terminal chloroplast transit peptide sequence from the *epsps* gene of *Petunia hybrida*, the coding sequence of CP4 *epsps* from *Agrobacterium tumefaciens* (renamed *Rhizobium radiobacter*) and the 3' *nos* terminator from *A. tumefaciens*. The second CP4 *epsps* expression cassette contains the same elements as the first cassette except for the *fmv* promoter from the *Figwort mosaic virus* which replaces the 35S promoter. The *uidA* gene is under control of the mannopine synthase (*mas*) promoter from *A. tumefaciens* and the 3' terminator from soybean 7S globulin gene.

3.1.2. Transgene constructs in the genetically modified plant[7]

Southern analysis of genomic DNA isolated from leaves of soybean 40-3-2 digested with three different restriction enzymes was performed using the complete vector PV-GMGT04 as a probe. This analysis demonstrated the presence of two inserts: a functional and a non-functional one. Southern analysis also demonstrated the absence of the *fmv* promoter and the *uidA* gene in soybean 40-3-2. The ColE1 origin of replication and the *npt*II gene were not detected by PCR analysis.

Sequencing of the functional insert in soybean 40-3-2 demonstrated that in the 5' region of the insert the first 354 bp of the 35S promoter are absent, thereby removing a duplicate portion of the 35S enhancer region. An additional 250 bp of CP4 *epsps* was found adjacent to the 3' *nos* terminator. With these exceptions, the nucleotide sequence of the insert is identical to the corresponding sequence of PV-GMGT04.

Sequencing demonstrated that the non-functional insert consists of 72 bp of the CP4 *epsps* coding sequence.

[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-141 and http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-142

[6] Technical Dossier / Section C1

[7] Technical Dossier / Section D2

Nucleotide sequences of the flanking regions have been determined. This includes 186 bp (at the 5') and 534 bp (at the 3') flanking the functional insert and 505 bp (at the 5') and 502 bp (at the 3') flanking the non-functional insert. The 3' flanking sequence of the functional insert has been shown to be rearranged soybean genomic DNA. The results of BLASTn and BLASTx analyses of the flanking sequences of both inserts do not indicate the disruption of known coding or regulatory sequences in 40-3-2 of soybean.

Updated bioinformatic analyses (2010)[8] of the DNA sequences of the functional and non-functional inserts and their flanks have been provided. The results indicate that in the unlikely event that any of the ORFs spanning the junctions were to be transcribed and translated, the translation products would not share significant similarity to known allergens, toxins, or other bioactive peptides.

3.1.3. Information on the expression of the insert[9]

Analysis of CP4 EPSPS protein levels was carried out by ELISA using seed and leaf samples from plants grown in 1992 and 1993 in the USA (at seven and four locations, respectively) and in 1998 at seven European locations in France and Italy. Mean protein levels in leaves of unsprayed plants in 1998 ranged from 0.32 to 0.62 µg/mg fresh weight (fw), and from 0.31-0.86 µg/mg fw in 1993. CP4 EPSPS protein levels were not determined in leaves in 1992. In seed samples of unsprayed plants mean protein levels were 0.09 to 0.27 µg/mg fw in 1998, 0.26 to 0.38 µg/mg fw in 1992 and 0.17 to 0.29 µg/mg fw in 1993. No significant differences in CP4 EPSPS protein levels were observed between glyphosate treated and non-treated samples in the European or USA studies. The levels of the newly expressed protein do not pose a safety concern (see also section 4.2.3. and 5.).

Northern analysis indicates that soybean 40-3-2 produces read-through transcripts initiated by the 35S promoter and which extend through the nos terminator into soybean genomic sequences flanking the 3' end of the functional insert (Rang et al., 2005). These transcripts are produced at very low levels (estimated to be 75 times lower than the intended transcript). However, no fusion proteins that might result from these read-through transcripts were detected by Western analysis (Rogan et al., 1999). If a fusion protein were to be produced at a level below the detection limit, bioinformatic analysis indicates that such a protein would not show similarity to known allergens or toxins.

3.1.4. Inheritance and stability of inserted DNA[10]

The inheritance of the introduced trait in soybean 40-3-2 follows a Mendelian pattern. Phenotypic stability was determined by application of glyphosate herbicides over multiple generations in two breeding lines. In addition, phenotypic stability was demonstrated in trials over four generations of soybean 40-3-2 in different genetic backgrounds at multiple geographical locations in the USA. Genetic stability of soybean 40-3-2 was demonstrated over four generations by Southern analysis.

3.2. Conclusion

The molecular characterisation data establish that the GM soybean 40-3-2 contains one functional insert expressing CP4 EPSPS and a non-functional insert consisting of a 72 bp fragment of the CP4 EPSPS coding sequence. No other parts of the plasmid used for transformation are present in the transformed plant. Updated bioinformatic analyses of the flanking sequences and the open reading

8 Additional information, July 2010
9 Technical Dossier / Section D3
10 Technical Dossier / Section D5

frames spanning the insert-plant DNA junctions and the levels of the newly expressed protein in soybean 40-3-2 did not raise any safety concern. The stability of the inserted DNA was confirmed over several generations and a Mendelian inheritance pattern was demonstrated. The EFSA GMO Panel considers that the molecular characterisation does not indicate a safety concern.

4. Comparative analysis

4.1. Comparative compositional and agronomic/phenotypic assessment

The original food safety assessment of soybean 40-3-2 within the European Union was performed by the Advisory Committee on Novel Foods and Processes in the UK(UK-ACNFP, 1995). Similarly, the Advisory Committee on Release to the Environment (ACRE) to the Secretary of State for the Environment, Transport and the Regions and Minister of Agriculture, Fisheries and Food of the UK advised on the importation storage and use of soybean 40-3-2 for processing to non-viable soybean fractions suitable for use in animal feeds, foods and any other products in which soybean fractions are used. On that occasion ACRE concluded that the risk of marketing this product would be no different from that of other soybeans marketed for the same purposes[11].

4.1.1. Choice of comparator and production of material for the compositional assessment

The original field trials giving comparative data on agronomic and phenotypic characteristics, and materials for investigation of the chemical composition on soybean 40-3-2 and an appropriate non-GM soybean conventional counterpart were performed in Puerto Rico (1991-1992) and the USA (1992 and 1993), and were subsequently extended with compositional data of seed material collected in field trials in France (1998) and Italy (1998). The design of these field trials with respect to choice of comparator, replication, herbicide spraying regime, materials collected for compositional analysis, and compounds analysed, varied considerably, and were not in accordance with the current EFSA Guidance document (EFSA, 2006b). Following a request for a comprehensive assessment of these field trial data during an ongoing assessment of an application to cultivate soybean 40-3-2 within the EU (EFSA-GMO-NL-2005-24), the applicant provided compositional data on soybean forage and seeds from an additional field trial in Romania in 2005. This field trial, which was designed essentially according to the EFSA Guidance document, compared the composition of soybean 40-3-2 with a conventional soybean variety having a comparable genetic background. The EFSA GMO Panel made a comprehensive comparative assessment of the compositional data in the application, but particularly focused on the data from the Romanian field trials.

In most compositional studies, the genetically modified (GM) soybean 40-3-2 was compared to the non-transgenic Asgrow variety A5403, which is the commercial soybean variety originally used when the soybean was transformed to establish transformation event 40-3-2. In cases where the GM event 40-3-2 had been bred into a soybean variety with another genetic background, the corresponding non-GM variety was used as conventional counterpart (Dekabig).

4.1.2. Compositional analysis

The Romanian field trials in 2005 were replicated and performed at five sites, and included soybean 40-3-2, the non-GM conventional counterpart (Dekabig), and a set of different conventional soybean varieties (Harrigan et al., 2007). The conventional soybeans were reference lines aimed to provide

11 http://tna.europarchive.org/20031224105948/http://www.defra.gov.uk/Environment/acre/annrep4/2.htm#2.4

data on the natural variation in composition of this food and feed plant. Whereas all varieties were treated with required conventional pesticides, soybean 40-3-2 was additionally treated with a glyphosate herbicide.

Soybean seeds were harvested and analysed for proximates (protein, fat, ash, and moisture), fibre fractions, amino acids, fatty acids, vitamin E, anti-nutrients (i.e. phytic acid, trypsin inhibitor, lectins, stachyose and raffinose) and other secondary metabolites (isoflavones). Forage was analysed for proximates, including fibre fractions. In total 63 different compounds were analysed in the materials from the Romanian field trials, fifty-six in seeds and seven in forage, essentially those recommended by OECD (2001). The early field studies were analysed for a lower number of constituents.

When the compositional data for forage and seed samples from the Romanian field trial were evaluated across sites, a statistically significant difference between soybean 40-3-2 and its conventional counterpart was found only for four of the 49 comparisons. These were acid detergent fibre in forage (31.93% vs. 30.26% dry weight (DW)), and isoleucine (1.69% vs. 1.73% DW), valine (1.80% vs. 1.84% DW), and genistein (1642 vs. 1717 µg/g DW) in seeds. However, when evaluated per site, the level of these constituents was significantly different at only one of the five field trial sites. Differences were small and levels fell within the normal variation of soybean constituents demonstrated by the reference soybeans included in the study and described in the ILSI (2006) and the USDA-ISO (2006) isoflavone databases. In addition to the differences mentioned above additional statistically significant differences were found for other constituents in the per site analysis. Twenty of these were found at one site only, and four at two of the five sites. Also in these cases differences were small, not consistent, and levels fell within the normal variation established by the reference lines.

The EFSA GMO Panel concludes that the data of the Romanian field trials confirmed the data from field trials in France and Italy in 1998, and the United States in 1992 and 1993. The studies from the United States have been published (Padgette et al., 1996; Taylor et al., 1999) and were considered by UK-ACNFP in their original safety assessment of soybean 40-3-2. Materials from the 1992 harvest were also used to analyse processed products. Defatted toasted meal was analysed for proximates, trypsin inhibitor, lectins, urease, isoflavones, staychose, raffinose and phytate; non-toasted meal for proximates, urease, trypsin inhibitor; protein isolate and protein concentrate for proximates; lecithin for phosphorylated compounds, and refined, bleached, deodorised soybean oil for fatty acids. It was concluded that the composition of processed products of soybean 40-3-2 were equivalent to those of the convention counterpart.

Further compositional comparisons (proximates, lectin, trypsin inhibitor, and isoflavones) between seeds of soybean event 40-3-2 crossed into soybeans of diverse genetic background and seeds of the corresponding conventional counterpart without the 40-3-2 event harvested in the 2000, 2001 and 2002 field seasons in the United States and Canada have been published by McCann et al. (2005). These additional studies found that the level of the measured analytes sometimes varied considerably across years but that the mean and range in soybean 40-3-2 is similar to the mean and range of conventional soybean varieties.

Since the original safety assessment of UK-ACNFP (1995), several investigators have confirmed the compositional equivalence of soybean 40-3-2 and commercial soybean varieties with regard to the content of isoflavone isomers, saponins, phospholipids, trypsin inhibitors, and lectins (List et al., 1999; Novak and Haslberger, 2000; Goda et al., 2002; Wei et al., 2004). One report claims soybean 40-3-2 to contain 12-14% less isoflavones (mainly genistin) than conventional non-GM soybeans (Lappé et al., 1998/1999). On the other hand, several investigators have reported that these compounds vary significantly in soybeans (Taylor et al., 1999; Wei et al., 2004). It has also been reported that various strategies for glyphosate herbicides applications to soybean 40-3-2 have no market influence on the isoflavone content (Duke et al., 2003). The EFSA GMO Panel concludes that

the data obtained since the original safety assessment of soybean 40-3-2 confirms that it is compositionally equivalent to its conventional counterpart and to other commercial soybean varieties.

4.1.3. Agronomic traits and GM phenotype, including ecological interaction

The applicant performed comparative assessments of the phenotypic and agronomic characteristics, and of the reproduction, dissemination, and survivability of soybean 40-3-2 and conventional soybeans based on field trials in the USA and Puerto Rico (1991-1994), Argentina (1993-1994), Canada (1993-1994), France (1994), and Italy (1994, 1996, and 1997). Parameters studied included date of emergence, % emergence, plant count, plant height, vigour and colour, morphological changes, date at 50% flowering, susceptibility to insects, nodes per plant, pods per plant, % lodging, % leaf drop, yield and % moisture, reproduction, dissemination and survivability. No meaningful difference between soybean 40-3-2 and its conventional counterpart were identified, except the expected difference in tolerance to glyphosate herbicides.

After commercial introduction of soybean 40-3-2 in North America, various research groups have published data on yield, height and glyphosate tolerance (Delannay et al., 1995; Elmore et al., 2001a, 2001b), as well as data on susceptibility of soybean 40-3-2 to insect pests (Morjan and Pedigo, 2002; McPherson et al., 2003), nematode damage (Koennig, 2002; Yang et al., 2002), and diseases, including resistance to fungal pathogens (Lee et al., 2000; Sanogo et al., 2000, 2001; Harikrishnan and Yang, 2002; Mueller et al., 2003; Njiti et al., 2003). These data contribute to the conclusion that the characteristics of soybean 40-3-2 do not differ from those of conventional soybean varieties, except for soybean 40-3-2 giving a slightly reduced yield (Elmore et al., 2001a), still within the range in yield of commercial soybean varieties, and being glyphosate tolerant as a consequence of the newly introduced trait. The EFSA GMO Panel accepted the applicants conclusion that soybean 40-3-2 is phenotypically and agronomically equivalent to traditional soybeans, except for the introduced glyphosate tolerance trait.

4.1.4. Conclusion

The EFSA GMO Panel considered the total set of compositional and agronomical data that have become available since the safety assessment of soybean 40-3-2 by the UK-ACNFP was published in 1995. Any statistically significant differences identified between soybean 40-3-2 and its conventional counterpart were assessed in the light of the field trial design, the level of the studied compounds in relation to identified biological variation, and agronomic and phenotypic characteristics in conventional soybean varieties. The EFSA GMO Panel concludes that soybean 40-3-2 is compositionally and agronomically equivalent to its conventional counterpart, and other conventional soybean varieties, except for the expression of the CP4 EPSPS protein. Furthermore, no unintended effects have appeared as a result of the genetic modification.

4.2. Food and feed safety assessment

In originally assessing the food safety of soybean 40-3-2 and products derived from them, the UK-ACNFP (1995) used a comparative approach to determine whether these soybeans are nutritionally, and with regard to safety, similar to conventional soybeans and products derived from them. Issues related to feeds were considered by the UK Inter-Departmental Group on New Feed Developments. The advisory committee noted that soybeans are not consumed or used in food (and feed) in an unprocessed form because they naturally contain anti-nutrients such as trypsin inhibitors which may give adverse effects if not destroyed by heating. The Committee was satisfied that the genetic

modification procedure had proceeded as intended and that the only complete novel gene present in soybean 40-3-2 is the CP4 *epsps* gene. The enzyme expressed from this gene is found only at very low levels in the GM soybeans (<0.1%) and is not detectable in oil derived from the GM beans. Soybeans are known to be allergenic. However, the levels of known allergenic proteins found in the modified beans were also similar to those found in conventional beans. The UK-ACNFP concluded that the GM soybeans and products derived from them are comparable to and as safe for human consumption as conventional, unmodified soybeans and products derived from them (UK-ACNFP, 1995). The Committee, therefore, recommended clearance for use in food of soybeans from the genetically modified soybean 40-3-2 and other glyphosate tolerant lines derived from subsequent crosses of this line with other commercial soybean cultivars.

In addition to the information available in the original applications, taken into account by the UK-ACNFP when giving its opinion on the food safety of soybean 40-3-2 (UK-ACNFP, 1995), the present renewal applications contain a few updated studies (bioinformatics comparison of amino acid sequence similarity of the newly expressed protein to known toxic or allergenic proteins), and a commentary on peer-reviewed publications on food and feed issues related to soybean 40-3-2 published after the approval to market these products were given in 1996. Issues specifically addressed in the update included information on areas where soybean 40-3-2 have been cultivated and the quantity produced, amounts imported into the EU, and the known and estimated human and animal exposure to soybean 40-3-2.

4.2.1. History of exposure to soybean 40-3-2 in Europe

Soybean 40-3-2 was first cultivated in the U.S.A. and Argentina in 1996, and subsequently commercialised in Canada, Uruguay, South Africa, Brazil, Romania and Paraguay. Thus, in Romania the bean was commercially produced between 1999 and 2006, prior to the accession to the EU in 2007. Production of soybean 40-3-2 was rapidly adopted in many markets, but most notably in the U.S.A. and Argentina, where current adoption rates exceed 90% of total soybean production area. When soybean 40-3-2 production was discontinued in Romania in 2006 it was cultivated on 84% of the area devoted to soybean cultivation.

Based on data on import of soybean seed, soybean meal and soybean oil into the 27 countries of the European Community from five 40-3-2 soybean producing countries (Argentina, Brazil, Canada, Paraguay and the USA) during the years 2003-2006, the applicant calculated that around 55% of soybean seed, 61% of soybean meal and 54% of soybean oil used in the EU might be based on soybean 40-3-2. It should be noted, however, that the calculations of these figures are based on several assumptions. Because operators in the food and feed chain in some Member States of the European Community have made efforts to preferentially source non-GM soybean products, the actual consumption of products derived from soybean 40-3-2 in food and feed may vary between Member States.

Based on FAO Statistics from 1997 to 2001, the human soybean oil consumption in Europe was calculated at 6.3-7.0 g/person/day. Assuming that 54% of the soybean oil was derived from soybean 40-3-2, an estimated average exposure of the European consumer to products of soybean 40-3-2 would be in the range of 3.4-3.7 g/person/day.

Animal feed is the major end use of soybean meal. The applicant calculated, based on data from 2006, that the maximum inclusion levels (% of the diet) of soybean 40-3-2 meal in the EU would be 21% for broiler chickens, 18% for pigs and 12% for dairy cattle.

Although no post-market monitoring for food and feed safety of soybean 40-3-2 has formally been performed, there is no evidence of any adverse effects being associated with the consumption of soybean 40-3-2 as food or feed within the European community.

4.2.2. Effects of processing

In the initial risk assessment the UK-ACNFP noted that the only protein present in soybean 40-3-2 as a result of the newly introduced DNA is the CP4 EPSPS enzyme. The enzyme is responsible for the soybean becoming tolerant to herbicides containing the active principle glyphosate. Soybean 40-3-2 will be used for production and manufacturing of food and feed products, as any other commercial soybean variety. Taking into account the compositional analysis providing no indication of relevant compositional changes, the EFSA GMO Panel has no reason to assume that the characteristics of soybean 40-3-2 and derived processed products would be different from those of the respective products derived from conventional soybean varieties. Intermediate temperatures (55°C) will reduce the activity of the CP4 EPSPS enzyme, whereas higher temperatures (65° and 75°C) will completely inactivate the enzyme. The pH will have less influence on the activity, only slightly lowering it at the low end of the pH range 4-11. Studies by Kim et al. (2006b) showed that the CP4 EPSPS enzyme is degraded during preparation of foods such as tofu and soybean paste.

Similarly, other investigators processed glyphosate tolerant soybeans by grinding, cooking, blending, homogenisation, sterilisation and spray-drying in order to study the fate of the soybean DNA in foods such as bean curd, soy milk and soy powder (Chen et al., 2005). In these studies an endogenous gene (*lectin*) present in all soybean varieties was compared with the CP4 *epsps* gene specific for soybean 40-3-2. Although both genes were degraded to various extents by the different processing procedures, the endogenous *lectin* gene was more stable than the introduced CP4 *epsps* gene. Large DNA fragments were affected more by processing than small ones. Thus, in processed foods and feeds mainly fragments of the CP4 *epsps* gene can be expected, and the size of the fragment would be dependent on the type of processing applied (Chen et al., 2005). Bauer et al. (2003) confirm that pH and temperature are important factors for DNA degradation when preparing foods from soybean 40-3-2.

4.2.3. Toxicological assessment of expressed novel protein in soybean 40-3-2

Submitted data indicated that CP4 EPSPS is unlikely to constitute a hazard to health. Thus, in an acute toxicity study in mice (Harrison et al., 1996), the CP4 EPSPS protein resulted in no adverse effects up to the highest dose administered (572 mg/kg body weight). Furthermore, the original data demonstrated a low expression of the CP4 EPSPS protein in soybean 40-3-2 (<0.1%). The protein was not detectable in soybean oil and showed no meaningful amino acid sequence homology to known toxic proteins (UK-ACNFP, 1995). Since the original submission of the soybean 40-3-2 application in 1994, the databases used to compare newly expressed proteins with known toxins (TOXIN database) have been updated several times and been published. Bioinformatics-supported studies with the updated databases, revealed no biologically relevant structural similarities between CP4 EPSPS and known toxic proteins.

Degradation in the gastrointestinal tract

UK-ACNFP also assessed *in vitro* digestion studies using simulated gastric fluid, which demonstrated that CP4 EPSPS is rapidly degraded at conditions mimicking the stomach (Harrison et al., 1996). Rapid digestion of microbially produced CP4 EPSPS, as well as of CP4 EPSPS extracted from soybean 40-3-2, has later been confirmed in studies using pepsin and pancreatin digestion assays

(Okunuki et al., 2002; Chang et al., 2003; Kim et al., 2006b). Pre-heating of soybean extracts containing the enzyme increased digestibility. No stable degradation fragments were formed. In the original risk assessment UK-ACNFP (1995) considered the potential for genetic transfer of the CP4 *epsps* gene from soybean 40-3-2 and derived products to human consumers, or their gut microflora, and concluded that the risk was negligible since the soybeans would not be consumed in a viable form and the processes used to derive the soybean products would destroy the DNA and protein. Subsequently, the fate of dietary CP4 *epsps* DNA and CP4 EPSPS protein as compared to plant DNA and proteins in general, have been studied both in laboratory animals and farm animals. Data are available from rats, broiler chickens, pigs, cows, salmon, rainbow trout and rabbits. There are also data from *in vitro* studies using tissues. These studies show that the CP4 EPSPS protein is easily degraded as levels are below the limit of detection in eggs, liver and faeces (Ash et al., 2003) as well as in muscle tissue (Jennings et al., 2003; Zhu et al., 2004) of hens, pigs and rats fed soybean 40-3-2. Thus, digestion seems to result in levels where no detectable protein is absorbed in the tissues investigated.

Data have been published about the fate of the CP4 *epsps* gene during digestion of various raw and processed dietary products of soybean 40-3-2. The results from a study employing an *in vitro* systems in which DNA was incubated subsequently with pepsin and ileal digesta in order to simulate the human digestive system have shown that less than 5% of the CP4 *epsps* transgenic DNA survive for three hours. It was considered that the DNA that survived, may be so fragmented that it is of limited biological significance, and thus may represent no apparent health risk (Martin-Orue et al., 2002). With detection methods sensitive enough, fragments of the CP4 *epsps* gene can easily be detected early in the digestive tract of broilers, but less easily further down in the tract and in the faeces (Deaville and Maddison, 2005). Fragments of the CP4 *epsps* gene were not detected in animal tissues (Deaville and Maddison, 2005; Jennings et al., 2003; Tudisco et al., 2006), or in blood (Chainark et al., 2008; Deaville and Madditon, 2005; Tudisco et al., 2006). Whereas some investigators found no CP4 *epsps* fragments in milk (and other tissues) of dairy cows (Phipps et al., 2002; 2003) and in the liver, muscle, and brain tissue of Atlantic salmon (Sanden et al., 2004), others reported that foreign DNA can be taken up by Atlantic salmon intestinal tissue and rainbow trout leukocytes, head kidney and muscle (Chainark et al., 2006, 2008; Sanden et al., 2007). The detection of transgenic DNA in fish tissue seems to be transient as it is no longer detectable in rainbow trout organs a couple of days after the intake of the 40-3-2 soybean meal (Chainark et al., 2006, 2008). It should be noted, however, that the multi-copy *rubisco* gene, common in plants, has been detected in several tissues of tested animals, such as in the blood and the milk (Deaville and Maddison, 2005; Phipps et al., 2003). It has been reported that CP4 *epsps* DNA has been detected in milk from the Italian market (Agodi et al., 2006), although in this case it is not known whether the molecules have a dietary origin or have contaminated the milk via air, animal feed or faeces.

Taken together, the studies investigating the digestive fate of the CP4 EPSPS protein and the CP4 *epsps* gene, indicate that no CP4 EPSPS protein accumulate in tissues of tested organisms, and that only fragments of DNA can be detected. Comparative studies on the digestive fate of endogenous and transgenic plant genes, show that these genes behave in a similar way.

4.2.4. Toxicological assessment of the whole soybean 40-3-2 food/feed

Although the chemical analysis provided showed soybean 40-3-2 to be compositionally equivalent to conventional soybean varieties (except for the newly expressed CP4 EPSPS protein), the applicant referred to four rat feeding studies with the GM soybean. Two of these were over four weeks with processed and unprocessed soybean 40-3-2, respectively. The other two were over thirteen and fifteen weeks with processed and heat-treated soybean 40-3-2, respectively.

In the first of the two 28-day studies, Charles River CD rats of both sexes (10 animals/sex) were fed *ad libitum* a diet with 24.8% processed (dehulled, defatted and toasted) soybean material from either event 40-3-2 or a conventional counterpart. An additional group of animals were fed a commercial rat diet containing dehulled soybean meal. Test animals survived and appeared healthy. The diet neither influenced feed consumption and body weights of the rats, nor had any significant influence on organ weights (only liver, testes, and kidneys measured). The few findings in the histopathological examinations at necropsy were randomly distributed among treatment groups and were commonly observed in control animals of this rat strain in the testing laboratory.

The second 28-day study had an experimental design very similar to the first study and also used CD rats of both sexes, but instead of feeding the animals processed soybean meal unprocessed meal was applied at inclusion rates of 5% and 10% of the diet. Such low inclusion rates might have been required as monogastric animals usually are not fed unprocessed soybeans due to the presence of anti-nutritive factors in the raw bean. Ruminants tolerate the raw material as the anti-nutrients are degraded by the rumen microflora. In this study test animals appeared healthy, and the diet neither influenced feed consumption, body weight and cumulative body weight gain, nor had any significant influence on absolute and relative organ weights (only liver, testes, and kidneys measured) in relation to the conventional counterpart. When soybean 40-3-2 fed rats were compared with rats fed the commercial rat feed, a slightly increased relative kidney weight was observed at a dose of 5% soybean 40-3-2 but not at the higher dose. As the influence on kidney weight was not dose-related, the finding was not considered relevant to the treatment. Animals that received the higher dose unprocessed soybean frequently showed darker livers, possibly related to the inclusion rate of unprocessed soybean and not to the genetic modification. The few findings in the histopathological examinations at necropsy were randomly distributed among all groups as in the first experiment. Since unprocessed soybean meal contains trypsin inhibitors that can cause hypertrophy of the pancreas when soybeans are the sole protein source (Liener and Kakade, 1980), this organ was examined histologically for all animals in the study. No pathological lesions, but minimal to mild microscopic changes were observed in the pancreas of animals of all groups. Thus, this characteristic was not related to the treatment with soybean 40-3-2.

The third study was a 90-day feeding study in Sprague-Dawley rats fed *ad libitum* diets with processed soybean 40-3-2 meal or meal from a conventional soybean (Zhu et al., 2004). The test diets contained 30%, 60% or 90% processed soybean 40-3-2 meal or 60% traditional/commercial soybean meal (conventional counterpart). The only deviation in feed intake and body weight was observed during the first week in rats of both sexes fed 90% soybean 40-3-2 meal, apparently due to the exposure to high protein levels and not to the exposure to soybean 40-3-2. Later on in the study, there was no influence on feed intake and body weight gain. No treatment-related adverse effects were observed in the study. There were also no meaningful differences in gross necropsy findings, haematology or urinalysis parameters between rats fed processed 40-3-2 and conventional soybean meal.

The final study was a 15-week rat feeding study with heat-treated soybean meal in female Brown Norway rats and female B10A mice, aiming to study potential effects on the immune system (Teshima et al., 2000). The heat-treated soybean meal was incorporated at a level of 30% in the rat and mice feed produced from soybean 40-3-2 in the test group and produced from a closely related conventional non-GM soybean in the control group. No treatment-related changes in growth, food consumption, liver and spleen weight between rats and mice fed 40-3-2 and animals fed the control soybean meal were observed. Based on the level of soybean-specific IgG and IgE in rodent sera and histological examination of immune-related organs, it was concluded that soybean 40-3-2 was not more antigenic or immunogenic than traditional soybeans.

A few additional rodent feeding studies with diet containing soybean 40-3-2 is available in the peer-reviewed literature. In two long-term studies over 52 and 104 weeks, respectively, Japanese

investigators fed F344 DuCrj rats diets that contained 30% either of a powder of processed soybean 40-3-2 or of the non-GM soybean conventional counterpart having a similar genetic background to soybean 40-3-2, or a basal diet (CE-2) (Sakamoto et al., 2007, 2008). When the three groups were compared, some statistically significant differences in animal growth, food intake, serum biochemical parameters and histological findings were noted, in particular between rats fed the two types of soybean diet (with GM and non-GM soybean) and the rats fed the basal diet. However, body weight and food intake were similar for the rats fed soybean 40-3-2 and conventional soybean. Gross necropsy findings, haematological and serum biochemical parameters, organ weights, and microscopic findings were comparable between rats fed soybean 40-3-2 and conventional soybean. In the 2-year study, the histopathological investigations did not reveal an increase in the incidence, nor in any specific type of non-neoplastic or neoplastic lesions in the GM soybean-exposed group of both sexes. The investigators concluded that the long-term effects of soybean 40-3-2 are not different than the long-term effects of non-GM soybeans.

Brake and Evenson (2004) fed pregnant C57Bl/6J mice transgenic (40-3-2) or non-transgenic soybean meal as 21.35% of the diet through gestation and lactation, and followed up by maintaining weanling young male mice on the respective diets until an age of 87 days. After different length of treatment, mice were killed, the testes surgically removed, and the cell populations measured by flow cytometry techniques. Multi-generational studies were conducted in a similar manner. The studies showed that soybean 40-3-2 had no different effect on macromolecular synthesis or cell growth and differentiation (as evidenced by no differences in the percentages of testicular cell populations) than conventional non-GM soybean. Furthermore, the different treatments resulted in no difference in litter size and body weights of mice. The investigators concluded that diets containing soybean 40-3-2 had no negative effect on foetal, postnatal, pubertal or adult testicular development.

Malatesta and co-workers in a series of publications summarised their result of studies in which histo-cytochemistry was performed on cells of specific organs, such as liver, pancreas, and testis, of progeny of Swiss mice fed during pregnancy and/or for 1, 2, 5, 8 or 24 months after weaning diets containing 14% soybean 40-3-2 or wild type soybean (Malatesta et al., 2002a, 2002b, 2003, 2005, 2008; Vecchio et al., 2004). In most studies only female mice were used. Although growth was comparable in animals receiving the two types of diets, and no macroscopic alterations or pathological lesions were found, the investigators reported to have identified differences in transcriptional activity, revealed as alterations in staining characteristics of chromatin-associated elements in cell nuclei. The investigators concluded from three animals per treatment only, and that no information was available on the natural variability in the specific histocytochemical endpoints analysed. The authors claimed that the altered staining characteristics indicate that feeding diets containing GM soybean may be associated with reversible changes in nucleic transcriptional activity, possibly as a consequence of exposure to residues of glyphosate, differences in phytoestrogen content between the diets, the genetic modification in soybean 40-3-2, or a combination of these. However, the experimental designs of the studies and their evaluation can be criticised. In particular the studies do not provide detailed account of the origin and characteristics of the control soybeans used, or whether the soybeans were processed or not. The levels of soybean bioactive constituents in the two diets were not stated. In addition, it is noted that in these studies particular biological phenomena were examined but not those parameters which are normally regarded as indicative for specific organ toxicity. Also the statistical evaluation of the data has been criticised. Therefore, the toxicological relevance of the findings, if any, is not clear.

More recently, the same research team reported on preliminary observations indicating that a diet containing soybean 40-3-2 neither affects fertility of female mice raised since weaning on a diet containing 14% GM soybean, nor parturition time or litter health (Cisterna et al., 2008). From a limited dataset, they concluded that a transient depression in pre-mRNA transcription and processing take place at the 2- to 8-cell stage of embryos, but that this transient episode does not affect foetal development. Also this study is weakened by a non-appropriate experimental design.

A transient mild histological alteration in the pancreas and a fast recovery has been reported in rats fed up to 30 days with a diet containing 18% soybean protein (Magaña-Gómez et al., 2008). Unfortunately, also in this study it is unclear whether the control diets used was based on soybean isogenic to soybean 40-3-2 or another type of commercially available non-GM soybean. It is also unclear whether the soybean products used have been appropriately processed before being included in the diet. Thus, it cannot be excluded that the transient alterations reported could have been the result of non-controlled levels of anti-nutrients in the diet.

The EFSA GMO Panel concludes that the feeding studies with laboratory animals to investigate potential toxicity demonstrate that soybean 40-3-2 and its derived products are as safe as conventional soybean varieties and their products.

4.2.5. Allergenicity

Assessment of allergenicity of the newly expressed protein

Theoretical assessment of the allergenic potential of the CP4 EPSPS protein by UK-ACNFP (1995) showed that it is unlikely to be an allergen since i) the CP4 *epsps* gene was taken from a source not known to be allergenic, and ii) the molecular weight of the protein and its glycosylation characteristics and acid lability are not indicative of an increased risk of allergenicity. In addition, a bioinformatics-supported comparison of the amino acid sequence of the CP4 EPSPS protein with the sequences of known allergens, gliadins, and glutenins (which included an updated analysis with published databases), identified no similarities which would cause concern.

European and Asian patients allergic to soybean and/or other foods do not express IgE that specifically bind the purified CP4 EPSPS protein (Chang et al., 2003; Batista et al., 2005; Kim et al., 2006a, 2006b; Hoff et al., 2007). The purified CP4 EPSPS enzyme also did not result in pronounced change in histamine release or cytokine production in sensitised peritoneal mast cells or unsensitised but antisera-labelled mast cells cultivated *in vitro* (Chang et al., 2003). The EFSA GMO Panel considers that these studies further confirm that the newly expressed CP4 EPSPS protein is unlikely to be allergenic.

Assessment of allergenicity of the whole GM plant

UK-ACNFP (1995) noted that soybeans are known to be allergenic for certain individuals. However, studies supplied in the original notification under Directive 90/220/EEC (Burks and Fuchs, 1995), allowed to conclude that the levels of known allergenic proteins in soybean 40-3-2 does not differ from the levels in non-GM soybeans. The results of these initial pre-marketing studies have recently been confirmed after the product has been on the market for some time. Using two-dimensional gel electrophoresis followed by peptide tandem mass spectrometry to identify soybean proteins, and Western analysis to evaluate the IgE response of soybean allergic individuals, Batista et al. (2007) were able to show that none of the five soybean-allergic individuals tested reacted differently to soybean 40-3-2 and its appropriate conventional counterpart. Similarly, several other investigations based on blood/sera of soybean allergic patients (from Denmark, Korea, Portugal) or on skin prick tests have found no difference in allergenic potential of extracts of soybean 40-3-2 and extracts of non-GM soybeans (Park et al., 2001; Sten et al., 2004; Batista et al., 2005; Kim et al., 2006a, 2006b; Hoff et al., 2007). Furthermore, another study (Hoff et al. 2007) did not observe cross-reactivity between CP4 EPSPS and known allergens including the mite allergen Der f 2 using sera of patients allergic to certain foods and mites.

Further support for unaltered allergenic potential for soybean 40-3-2 was presented by Gizzarelli et al. (2006), who developed and characterised a murine model (Balb/c mice) of IgE-mediated soybean

sensitisation induced by intragastric immunisation (in the presence of Cholera Toxin) with soybean extracts. Extracts of soybean 40-3-2 induced an immunological response that was comparable with that induced by non-GM soybean extracts. In other sensitisation studies, the purified CP4 EPSPS protein, homogenates of soybean 40-3-2 and control soybean were subcutaneously injected for three weeks (3 times/week) at various doses into male Sprague Dawley rats (Chang et al., 2001, 2003). A week after the last sensitisation antisera were recovered from individual animals and injected intradermally into unsensitised rats followed by a challenge with soybean homogenate. There were no signs of passive cutaneous anaphylaxis. Furthermore, sera of rats treated with both types of soybean homogenate resulted in comparable histamine release in cultured peritoneal mast cells. In addition, as already mentioned above, Teshima et al. (2000) were unable to identify effects on biomarkers for immunotoxicity and allergenicity in rodents fed a diet with 30% heat-treated soybean meal for 15 weeks, the test group receiving meal from soybean 40-3-2, the control group meal from a closely related conventional non-GM soybean.

The EFSA GMO Panel concludes that the information presented confirms that the overall allergenicity of the whole soybean 40-3-2 plant is not changed compared with that of its conventional counterpart.

4.2.6. Nutritional assessment of soybean 40-3-2

To substantiate that soybean 40-3-2 has equivalent nutritional quality to conventional soybeans, as indicated by equivalent chemical composition, the applicant originally supplied short-term feeding studies with soybean 40-3-2 on the target animals broiler chicken, quail, swine, dairy cow and catfish. The EFSA GMO Panel considered the feeding studies on broiler chickens, swine and catfish for the nutritional assessment of soybean 40-3-2 as compared to its conventional counterpart. The study with dairy cattle was not considered by the EFSA GMO Panel because the study had a short duration (3 weeks only) and additional weaknesses in experimental design (Flachowsky and Aulrich, 1999). The feeding study in quails was not considered due to its short duration, five days only.

Broiler chickens were fed starter diets containing 32.9% processed (dehulled, defatted and toasted) soybean meal (soybean 40-3-2 or an appropriate non-GM soybean) from day 0 to 21, and grower/finisher diets containing 26.6% soybean meal from day 22 to 42, when the study was terminated (Hammond et al., 1996). In these 42 days the broilers reached a market weight of approximately 2 kg. The experimental diets had no influence on feed intake, weight gain, feed conversion, and liveability (percent live birds; survival rate). There were also no significant difference in the performance parameters investigated (breast muscle weight and abdominal fat pad weight; in both cases total weight and percent of body weight) between broilers fed diets with soybean 40-3-2 and broilers fed its conventional counterpart. Additional information on broiler chickens is available from a small feeding study in which the birds were given a diet with 24-25% soybean meal (Deaville and Maddison, 2005). The broilers fed soybean 40-3-2 had as high feed intake, growth and feed conversion ratio as broilers fed control soybean.

One hundred cross-bred pigs of both sexes were fed for about 100 days with soybean meal diets containing about 14-24% (depending on age of animals) of dehulled soybean meal derived from either the GM event 40-3-2 or its conventional counterpart (Cromwell et al., 2002). During the feeding period the pigs grow in weight from about 24 kg to 111 kg. No difference between treatment groups were observed for feed intake, efficiency of feed utilisation and body weight gain, scanned backfat and longissimus area, and calculated carcass lean percentage. The sensory characteristics of the longissimus muscles were not influenced by treatment. The differences observed were not between pigs given the different feeds but those expected between sexes.

The fish feeding study was performed on 300 fingerling channel catfish (*Ictalurus punctatus*) of mixed sex. The study duration was over 10 weeks with diets containing processed meal (45-47% w/w) (Hammond et al., 1996). There was no statistically significant difference in survival, feed conversion ratio, and percentage weight gain between the groups receiving diets based on control soybean meal and glyphosate tolerant soybean meal. Although fish receiving the diet with soybean 40-3-2 meal consumed slightly less feed (2.85% of their body weight) than fish fed a diet with the control soybean meal (3.63%), this did not influence body composition data. There were no differences in moisture, protein, fat or ash among fish regardless of dietary treatment.

Feeding studies to investigate the nutritional wholesomeness of soybean 40-3-2 have also been performed. Norwegian investigators in a series of publications presented data on the nutritional adequacy of soybean 40-3-2 for the Atlantic salmon, *Salmo salar*, and concomitantly studied selected parameters of fish health. In one set of studies post-smolt salmon (average weight 104 g) were fed for 3 months with diets containing 17.2% soybean meal prepared either from genetically modified (GM) soybean event 40-3-2 or a non-appropriate non-GM soybean (Bakke-McKellep et al., 2007; Hemre et al., 2005; Sanden et al., 2004), and in another set of studies salmon parr (average weight 0.2 g) were fed for 8 months a diet in which 12.5% were soybean full-fat meal either from GM event 40-3-2 or from a non-appropriate non-GM soybean (Bakke-McKellep et al., 2008; Sanden et al., 2005, 2006). As the control materials in these studies were not suitable to assess the influence of the specific genetic modification in soybean 40-3-2, they were not used in the assessment of the nutritional wholesomeness of soybean 40-3-2.

Two later studies performed by the same research team, however, used an appropriate control material, and the studies give a valuable contribution to the assessment of the nutritional quality of soybean 40-3-2 as compared to a non-GM soybean with a comparable genetic background. In the first of these studies, farmed Atlantic salmon (weighing around 700g) were fed for four weeks a diet with 15% or 30% full-fat meal of soybean 40-3-2 or non-GM conventional soybean counterpart (Frøystad et al., 2008; Sagstad et al., 2008). Meal of soybean 40-3-2 neither affected growth, feed utilisation and proximate composition, nor organ weights and haematology. Spleen somatic index was higher in fish fed soybean 40-3-2 than in fish given non-GM soybean, while the plasma triacylglycerol (TAG) level was lower. The investigators subsequently concluded that this observation is unlikely to be related to the genetic modification per se (Sissener et al., 2009a). The investigators considered the possibility of whether the altered spleen somatic index could indicate a possible immune response (Sagstad et al., 2008), but experimental support for this speculation was not provided. In the same experiment, Frøystad et al. (2008) investigated gene expression in the distal intestine. Whereas most genes studied were equally expressed in fish fed diets with soybean 40-3-2 and fish fed diets with the non-GM soybean, expression of a lectine gene was down-regulated in salmon fed diets containing soybean 40-3-2. The investigators hypothesised, without supporting data, that this could have relevance for the local immunity in the distal gastrointestinal tract. In the second experiment, Sissener et al. (2009a) conducted a seven month feeding trial on Atlantic salmon (initial weight 40 g) going through the parr-smolt transformation and fed a full fat soybean meal derived from soybean 40-3-2 or its conventional counterpart at an inclusion rate of 25% of the diet. The two diets were compositionally similar in all analysed macro- and micro-nutrients. The parr-smolt transformation stage is a particular sensitive stage of Atlantic salmon as it enables the fish to migrate from freshwater to seawater, a process comprising a range of preparatory physiological adaptations that are dependent on nutritional status and energy turnover above a certain level. The performance and health of the fish were assessed by growth, body composition, organ development, haematological parameters, clinical plasma chemistry and lysozyme levels, with fish samples collected both in the freshwater and seawater stages. At the last sampling the average fish weight was around 190 g. In all parameters studied no diet-related differences were observed. The investigators concluded that soybean 40-3-2 can be used as an equivalent and safe substitute for conventional soybean varieties in feeds for Atlantic salmon. The wholesomeness of soybean 40-3-2 was further supported by histo-morphological analysis of these fish (Sissener, 2009), and proteomic profiling of their livers (Sissener et al., 2009b).

Similarly, Chainark et al. (2006) reported no difference in growth and feed performance of rainbow trout fed a fish diet with soybean 40-3-2 or non-GM soybean meal.

Tudisco et al. (2006) reported a 40 day feeding study in New Zealand rabbits given a diet with 20% soybean meal derived from soybean 40-3-2 or non-GM soybean. There was no differential influence of the two treatments on body weight, fresh organ weights, and serum and tissue enzyme levels in both males and females, with exception of a slight increase in lactic acid dehydrogenase 1 in the kidneys and heart of animals fed soybean 40-3-2. No difference was observed in the muscle.

Some additional studies have investigated the influence of diets containing soybean 40-3-2 as compared to diets with non-GM soybeans on the feed intake, growth rate, serum biochemistry, muscle composition and organ weights of the studied animals (Soares et al., 2005, de Silva Faria et al., 2009; Brasil et al., 2009), but as the diets have not been appropriately defined or chosen, these studies only marginally contribute to the safety assessment of soybean 40-3-2.

In conclusion, feeding studies with several target animal species (swine, broiler chickens, rabbits, catfish and salmon) have shown that soybean 40-3-2 is nutritionally equivalent to a non-GM soybean with a comparable genetic background. The risk assessment concluded that no data have emerged to indicate that soybean 40-3-2 is any less safe than its non-GM comparator. In addition, soybean 40-3-2 is, from a nutritional point of view, equivalent to conventional soybean. Thus, the EFSA GMO Panel, like previously the UK-ACNFP (1995), concludes that soybean 40-3-2 is nutritionally equivalent to the conventional counterpart and to other commercial soybean varieties, and in line with its Guidance document (EFSA, 2006b), the EFSA GMO Panel is of the opinion that post-market monitoring of the GM food/feed is not necessary.

4.2.7. Conclusion

The exposure assessment indicated an average exposure of the European consumer to products of soybean 40-3-2 (mainly soybean oil) in the region 3.4-3.7 g/person/day, and a maximum dietary inclusion levels of soybean 40-3-2 meal (% of diet) for farm animals in the EU being around 21% for broiler chickens, 18% for pigs, and 12% for dairy cattle. No adverse reactions have been reported upon exposure of humans and animals to products of soybean 40-3-2. Recombinant DNA and the CP4 EPSPS protein is to a large extent degraded during processing of food and feed. Furthermore, the CP4 EPSPS is quickly degraded in simulated gastric fluid. Bioinformatic studies demonstrated that the CP4 EPSPS protein shows no similarities to known toxic and allergenic proteins. The CP4 EPSPS protein induced no toxicity when administered orally to mice in an acute toxicity study. A number of feeding studies of various duration on laboratory rodents given processed and unprocessed soybean 40-3-2 in the diet indicated no toxicity related to the genetic modification. Whole-product testing with sera from soybean-allergic patients showed that the overall allergenicity of soybean 40-3-2 is not different from that of the conventional counterpart. Feeding studies on broiler chickens, rabbits, swine, catfish and salmon show that soybean 40-3-2 is nutritionally equivalent to the conventional counterpart. The EFSA GMO Panel is of the opinion that soybean 40-3-2 is as safe as the conventional counterpart and commercial varieties, and considers that no additional animal safety or nutritional wholesomeness studies are needed.

In conclusion, on the basis of the original information considered in the original application, updated studies in the present applications, and peer-reviewed scientific data on soybean 40-3-2, the EFSA GMO Panel confirms that soybean 40-3-2 is as safe and nutritious as the conventional counterpart and other commercial soybean varieties.

5. Environmental risk assessment and monitoring plan

5.1. Environmental risk assessment

The scope of applications EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) is for renewal of the authorisation of (1) food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6); (2) feed containing, consisting of, or produced from soybean 40-3-2; and (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation. Considering the intended uses of soybean 40-3-2, the environmental risk assessment is concerned with the exposure through manure and faeces from animals fed grain produced by soybean 40-3-2 and with the accidental release into the environment of viable grains produced by soybean 40-3-2 during transportation and processing.

As the scope of the present applications excludes cultivation, environmental concerns related to the use of glyphosate herbicides on soybean 40-3-2 apply only to imported and processed soybean products that may have been treated with those herbicides in countries of origin. The EFSA GMO Panel is aware that the risk assessment of active substances falls within the scope of Directive 91/414/EEC concerning the placing of plant protection products on the market.

5.1.1. Unintended effects on plant fitness due to the genetic modification[12]

Cultivated soybean (*Glycine max* (L.) *Merr.*) is a species in the subgenus *Soja* of the genus *Glycine*. The species originated from eastern Asia and is a highly domesticated crop (Liu and Agresti, 2005). The major worldwide soybean producers are the United States (USA), Brazil, Argentina, China, North Korea and South Korea. In the European Union, soybean is mainly cultivated in Italy, France and Romania (Dorokhov et al., 2004).

Cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year following cultivation (OECD, 2000). In soybean fields, seeds usually do not survive during the winter due to predation, rotting, germination resulting in death, or due to management practices prior to planting the subsequent crop (Owen, 2005).

Applicant's field trials have been conducted at several locations in USA, Puerto Rico, Argentina, Canada, France and Italy. Information on phenotypic and agronomic characteristics was provided to assess the agronomic performance of soybean 40-3-2 in comparison with its conventional counterpart. These field trial data did not show changes in plant characteristics that indicate altered fitness and invasiveness of GM soybean 40-3-2 compared to its conventional counterpart, except in the presence of glyphosate herbicides (according to field studies carried out in United States, Puerto Rico (1991-1994), Argentina (1993-1994), Canada (1993 and 1994) and field trials carried out in Europe in France and Italy (1994) and Italy (1996, 1997). In addition to the data presented by the applicant, the EFSA GMO Panel is not aware of any scientific report of increased spread and establishment of existing GM soybeans and any change in survival capacity, including overwintering (Dorokhov et al., 2004, Owen, 2005, Bagavathiannan and Van Acker, 2008, Lee et al., 2009).

Furthermore there is no evidence that the glyphosate tolerant trait introduced by genetic modification results in increased invasiveness of any crop species, except when glyphosate herbicides are applied. Thus, the accidental release of GM soybean 40-3-2 seeds would not result in the establishment of plants exhibiting dissemination capabilities different from existing conventional soybean varieties and would not create additional agronomic or environmental impacts. The GM soybean plants will only be

[12] Technical Dossier / section D9.1

fitter in the presence of glyphosate herbicides which are not currently used in most areas where the GM soybean might be spilled.

Survival of soybean plant outside cultivation or other areas is mainly limited by a combination of low competitiveness, absence of a dormancy phase, and susceptibility to plant pathogens and cold climate conditions. Since these general characteristics are unchanged in soybean 40-3-2, it can be considered that soybean 40-3-2 has no altered survival, multiplication or dissemination characteristics, except when glyphosate herbicides are applied. Therefore, the EFSA GMO Panel is of the opinion that the likelihood of unintended environmental effects of the soybean 40-3-2 in Europe will not be different from that of conventional soybean varieties.

5.1.2. Gene transfer[13]

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer of DNA, or vertical gene flow via seed dispersal and cross-pollination.

a) Plant to bacteria gene transfer

Genomic DNA is a component of many food and feed products derived from soybean. It is well documented that DNA present in food and feed becomes substantially degraded during digestion in the human or animal gastrointestinal tract. However, a low level of exposure of fragments of ingested DNA, including the recombinant fraction of such DNA, to micro-organisms in the digestive tract of humans, domesticated animals, and other animals feeding on soybean 40-3-2 is expected (see section 4 of the scientific opinion).

Current scientific knowledge of recombination processes in bacteria indicates that horizontal transfer of non-mobile, chromosomally-located DNA fragments between unrelated organisms (such as plants to microorganisms) is not expected to occur at detectable frequencies under natural conditions (see EFSA, 2009c for further details).

A successful horizontal transfer would require stable insertion of the transgene sequences into a bacterial genome enabling it to multiple at a higher rate than non-transformed cells. The only known mechanism that facilitates horizontal transfer of non-mobile, chromosomal DNA fragments into bacterial genomes is homologous recombination (HR). HR depends on the presence of stretches of similar DNA sequences between the recombining DNA molecules. In addition to substitutive recombination events, HR can also facilitate the insertion of non-homologous DNA sequences into bacterial genomes (additive recombination) if the flanking regions share sequence similarity.

The CP4 *epsps* gene originates from a bacterium and therefore the recombinant DNA contains sufficient sequence similarity for homologous recombination to take place in related bacterial species. However, such a hypothesised horizontal gene transfer event is not likely to be maintained in bacterial populations due constraints to efficient expression and a limited selective advantage for gene transfer recipients in the case of CP4 *epsps* expression. In addition to homology-based recombination processes, illegitimate recombination that does not require the presence of DNA similarity between the recombining DNA molecules is also theoretically possible. However, the transformation rates for illegitimate recombination were considered to be 10^{10}-fold lower than for homologous recombination (EFSA 2009c, Hülter and Wackernagel, 2008). Illegitimate recombination events have not been detected in studies that have exposed bacteria to high concentrations of GM-plant DNA (see EFSA 2009c). For these reasons, illegitimate recombination is not further considered here.

[13] Technical Dossier / section D9.2

The exposure of bacterial communities to the recombinant genes in soybean 40-3-2 must be seen in the context of the natural occurrence and level of exposure to alternative sources of similar genes to which bacterial communities are continually exposed. The protein encoded by CP4 EPSPS is an enzyme involved in the biosynthesis of chorismate, the common precursor of numerous aromatic compounds in bacteria, fungi and plants. Thus, it can be expected that both sequence-similar and divergent *epsps* genes are widely distributed in gut inhabiting and other environmental microorganisms.

In the context of its intended use as food and feed, there is no direct exposure of microorganisms to the herbicidal compound glyphosate. The selective advantage of glyphosate resistance in bacteria is therefore predicted to be limited. The hypothetical rare acquisition of the CP4 *epsps* from recombinant DNA plants is therefore not considered to confer a selective advantage to microorganisms that would allow them to enhance their viability or to alter their habitat range.

The EFSA GMO Panel concludes that the recombinant DNA in soybean 40-3-2 does not represent an environmental risk in relation to its potential for horizontal transfers to bacteria and other microorganisms.

(b) Plant to plant gene transfer

Considering the intended uses of soybean 40-3-2 and physical characteristics of soybean seeds, a possible pathway of gene dispersal is from seed spillage and pollen of occasional feral GM soybean plants originating from accidental seed spillage during transportation and/or processing.

The genus *Glycine* is divided into two distinct subgenera: *Glycine* and *Soja*. Soybean is in the subgenus *Soja*. The subgenus *Glycine* contains 16 perennial wild species, whilst the cultivated soybean, *Glycine max*, and its wild and semi-wild annual relatives, *Glycine soja* and *Glycine gracilis*, are classified in the subgenus *Soja* (OECD, 2000). Due to the low level of genomic similarity among species of the genus *Glycine*, *Glycine max* can only cross with other members of *Glycine* subgenus *Soja* (Hymowitz et al., 1998, Lu, 2005). Hence, the three species of *Soja* are capable of cross-pollination and the hybrid seed that is produced can germinate normally and produce plants with fertile pollen and seed (Abe et al., 1999, Nakayama and Yamaguchi, 2002). However, since *Glycine soja* and *Glycine gracilis* are indigenous to China, Taiwan, Korea, Japan, the Far East Region of Russia, Australia, the Philippines and South Pacific, and since they have not been reported in other parts of the world, where the cultivated soybean is grown (Dorokhov et al., 2004, Lu, 2005), the plant to plant gene transfer from soybean is restricted to cultivated areas and the occasional soybean plants resulting from seed spillage in the EU.

Soybean (*Glycine max*) is an annual almost completely self-pollinating crop in the field, which has a percentage of cross-pollination usually lower than 1% (Weber and Hanson, 1961, Caviness, 1966, Ray et al., 2003, Lu, 2005, Yoshimura et al., 2006, Abud et al., 2007). Soybean pollen dispersal is limited because the anthers mature in the bud and directly pollinate the stigma of the same flower (OECD, 2000). However, cross-pollination rates as high as 6.3% have been reported for closely spaced plants (Ray et al., 2003), suggesting the potential of some within-crop gene flow. These results indicate that natural cross-pollination rates can fluctuate significantly among different soybean varieties under particular environmental conditions, such as favourable climate for pollination and abundance of pollinators (Gumisiriza and Rubaihayo, 1978, Ahrent and Caviness, 1994, Ray et al., 2003, Lu, 2005).

Plant to plant gene transfer could therefore occur under the following scenario: imports of soybean 40-3-2 grains (while most soybean 40-3-2 grains will be processed in countries of production), processing outside of importing ports, transportation in regions of soybean production in Europe, spillage of GM grains during transportation, germination and development of spilled grains within

soybean fields or in very close vicinity of cultivated soybean fields, overlap of flowering periods and environmental conditions favouring cross-pollination. The overall likelihood of cross-pollination between GM soybean plants and cultivated soybean is therefore extremely low. Apart from seed production areas, GM plants and derived from out-crossing with this GM soybean will not persist overtime. Dispersal of soybean seeds by animals is not expected due to the characteristics of the seed, but accidental release into the environment of seeds may occur during transportation and processing for food, feed and industrial uses. However, cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year following cultivation (OECD, 2000). Even in soybean fields, seeds usually do not survive during the winter due to predation, rotting, germination resulting in death, or due to management practices prior to planting the subsequent crop (Owen, 2005).

The EFSA GMO Panel takes into account that these applications do not include cultivation of the soybean within the EU so that the likelihood of cross-pollination between cultivated soybean and occasional soybean plants resulting from grain spillage is considered extremely low. However, in countries cultivating this GM soybean and producing seed for export, there is a potential for admixture in seed production and thus the introduction of GM seeds through this route. Hence, it is important that appropriate management systems are in place to restrict seeds of soybean 40-3-2 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) 1829/2003.

In conclusion, since soybean 40-3-2 has no altered survival, multiplication or dissemination characteristics, the EFSA GMO Panel is of the opinion that the likelihood of unintended environmental effects as a consequence of spread of genes from soybean 40-3-2 in Europe will not differ from that of conventional soybean varieties.

5.1.3. Interactions of the GM plant with target organisms

Due to the intended uses of soybean 40-3-2, which exclude cultivation and due to the low level of exposure to the environment, potential interactions of the GM plant with target organisms were not considered an issue by the EFSA GMO Panel.

5.1.4. Interactions of the GM plant with non-target organisms

Due to the intended uses of soybean 40-3-2, which exclude cultivation and due to the low level of exposure to the environment, potential interactions of the GM plant with non-target organisms were not considered an issue by the EFSA GMO Panel.

5.1.5. Interactions with the abiotic environment and biochemical cycles

Due to the intended uses of soybean 40-3-2, which exclude cultivation and due to the low level of exposure to the environment, potential interactions of the GM plant with abiotic environment and biochemical cycles were not considered an issue by the EFSA GMO Panel.

5.2. Post-market environmental monitoring[14]

The objectives of a monitoring plan according to Annex VII of Directive 2001/18/EC are 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 are correct and 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.

Monitoring is related to risk management, and thus a final adoption of the monitoring plan falls outside the mandate of EFSA. However, the EFSA GMO Panel gives its opinion on the scientific quality of the monitoring plan provided by the applicant (EFSA, 2006). The potential exposure to the environment of soybean 40-3-2 would be through manure and faeces from animals fed with GM soybean or through accidental release into the environment of GM soybean grains during transportation and processing. The EFSA GMO Panel is aware that, due to physical characteristics of soybean seed and methods of transportation, accidental spillage cannot be excluded. Therefore, the EFSA GMO Panel recommends that appropriate management systems are introduced to actively monitor the occurrence of feral soybean plants in areas where soybean spillage and plant establishment are likely to occur as proposed in the EFSA Guidance Document (EFSA, 2006a) and the scientific opinion of the EFSA GMO Panel on post-market environmental monitoring (EFSA, 2006b).

The scope of the monitoring plan provided by the applicant is in line with the intended uses. Since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects, no case-specific monitoring is necessary.

The general surveillance plans proposed by the applicant includes (1) the description of an approach involving operators (federations involved in soybean import and processing) reporting to the applicants via a centralised system any observed adverse effect(s) of GMOs on human health and the environment, (2) a coordinating system established by EuropaBio for the collection of information recorded by the various operators (Lecoq et al., 2007, Windels et al., 2008), (3) the use of networks of existing surveillance systems. The applicant proposes to submit a general surveillance report on an annual basis and a final report at the end of the consent[15].

Issues relating to the practical implementation of general surveillance and the evaluation of monitoring results are currently outside the remit of the EFSA GMO Panel. Details of the specific plans and methods of monitoring in each country should be developed by the applicant after the applications have been accepted (EFSA 2006).

The EFSA GMO Panel is of the opinion that the scope of the monitoring plans proposed by the applicant are in line with the intended uses of soybean 40-3-2 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

5.3. Conclusion

The scope of the applications EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) is for renewal of the authorisation of (1) food containing, consisting of, or produced from genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6); (2) feed containing, consisting of, or produced from soybean 40-3-2; and (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation. Considering the intended uses, the environmental risk

[14] Additional information / December 2008
[15] Technical Dossier / section D11

assessment is concerned with indirect exposure mainly through manure and faeces from animals fed grains produced by soybean 40-3-2 and with the accidental release into the environment of viable grains by soybean 40-3-2 during transportation and processing.

In case of accidental release into the environment of viable grains of soybean 40-3-2 during transportation and processing, there are no indications of an increased likelihood of establishment and spread of feral soybean 40-3-2 plants, except in the presence of glyphosate herbicides. In addition, the low levels of environmental exposure of these GM soybean plants and the newly expressed protein through other routes indicate that the risk to non-target organisms is extremely low. The EFSA GMO Panel considers that it is unlikely that the recombinant DNA in soybean 40-3-2 transfers to bacteria and other microorganisms and that the risk caused by a rare but theoretically possible transfer of the recombinant epsps gene from soybean 40-3-2 to environmental microorganisms is regarded to be negligible due to the lack of a selective advantage in the context of its intended use that would be conferred. The scope of the post-market environmental monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean 40-3-2.

The EFSA GMO Panel is aware that, due to physical characteristics of soybean seed and methods of transportation, accidental spillage cannot be excluded. Therefore, the EFSA GMO Panel recommends that, within general surveillance, appropriate management systems are introduced to actively monitor the occurrence of feral soybean plants in areas where spillage and soybean plant establishment are likely to occur as proposed in the EFSA Guidance Document (EFSA, 2006a) and the scientific opinion of the EFSA GMO Panel on post-market environmental monitoring (EFSA, 2006b).

The EFSA GMO Panel also recommends that appropriate management systems should be in place to restrict seeds of soybean 40-3-2 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) 1829/2003.

Overall Conclusions and Recommendations

The EFSA GMO Panel was requested to deliver a scientific opinion for renewal of the authorisation for continued marketing of existing products from GM soybean 40-3-2 (references EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$ and EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$) under Regulation (EC) No 1829/2003. The scope of these applications cover the continued marketing of (1) existing food containing, consisting of, or produced from soybean 40-3-2 (including food additives) (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$); (2) existing feed containing, consisting of, or produced from soybean 40-3-2 (Reference EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$); (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation (Commission Decision 96/281/EC) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003 and included in the Community Register of genetically modified food and feed.

In delivering its scientific opinion, the EFSA GMO Panel considered the renewal applications (EFSA-GMO-RX-40-3-2$_{[8\text{-}1a/20\text{-}1a]}$, EFSA-GMO-RX-40-3-2$_{[8\text{-}1b/20\text{-}1b]}$); a consolidated application on the cultivation of soybean 40-3-2 (application EFSA-GMO-2005-NK-24); additional information submitted by the applicant on request of the EFSA GMO Panel; the scientific comments submitted by Member States; and relevant scientific publications. In accordance with the Guidance Document for renewal of authorisations of existing GMO products, the EFSA GMO Panel has taken into account the new information, experience and data on soybean 40-3-2, which have become available during the authorisation period.

The EFSA GMO Panel is of the opinion that the molecular characterisation data provided for soybean 40-3-2 are sufficient. The results of the bioinformatic analyses of the inserted DNA and the flanking

regions do not raise safety concern. The levels of CP4 EPSPS in soybean 40-3-2 have been sufficiently analysed and the stability of the genetic modification has been demonstrated. The EFSA GMO Panel considers that the molecular characterisation does not indicate a safety concern.

The new data from field trials confirms that soybean 40-3-2 is compositionally, agronomically and phenotypically equivalent to the conventional counterpart and to other commercial soybean varieties, except for being tolerant to glyphosate herbicides. The updated bioinformatics analysis of the newly expressed protein provided by the applicant and the safety assessment of the whole soybean plant identified no concerns regarding potential toxicity and allergenicity of soybean 40-3-2. Feeding studies on laboratory animals and several farm animals and fish confirmed the nutritional equivalence of soybean 40-3-2 to its conventional non-GM counterpart. New information available in peer-reviewed scientific literature and supplementary studies supplied by the applicant confirms that soybean 40-3-2 is as safe and as nutritious as the conventional counterpart and to other commercial soybean varieties. The European consumers have been exposed to soybean 40-3-2 mainly via soybean oil at levels around 3.4-3.7 g/person/day. Processed meal of soybean 40-3-2 has been given to farm animals within the EU at maximum dietary inclusion levels around 21% for broiler chickens, 18% for pigs, and 12% for dairy cattle. No adverse effects have been reported.

Considering the intended uses of soybean 40-3-2, which exclude cultivation, there is no requirement for scientific assessment on possible environmental effects associated with the cultivation of soybean 40-3-2. In case of accidental release into the environment of viable grains of soybean 40-3-2 during transportation and processing, there are no indications of an increased likelihood of establishment and spread of feral soybean 40-3-2 plants, except in the presence of glyphosate herbicides. In addition, the low levels of environmental exposure of these GM soybean plants and the newly expressed protein through other routes indicate that the risk to non-target organisms is extremely low. The EFSA GMO Panel considers that it is unlikely that the recombinant DNA in soybean 40-3-2 transfers to bacteria and other microorganisms and that the risk caused by a rare but theoretically possible transfer of the recombinant epsps gene from soybean 40-3-2 to environmental microorganisms is regarded to be negligible due to the lack of a selective advantage in the context of its intended use that would be conferred. The scope of the post-market environmental monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean 40-3-2. The EFSA GMO Panel is aware that, due to physical characteristics of soybean seed and methods of transportation, accidental spillage cannot be excluded. Therefore, the EFSA GMO Panel recommends that, within general surveillance, appropriate management systems are introduced to actively monitor the occurrence of feral soybean plants in areas where soybean spillage and plant establishment are likely to occur.

The EFSA GMO Panel recommends that appropriate management systems should be in place to restrict seeds of soybean 40-3-2 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

In conclusion, the EFSA GMO Panel considers that the information available for soybean 40-3-2 addresses the scientific comments raised by the Member States and that the soybean 40-3-2 assessed in these applications is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that soybean event 40-3-2 is unlikely to have any adverse effects on human and animal health and the environment, in the context of its intended uses.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the Competent Authority of the MS, received 15 May 2007, concerning a request for placing on the market of 40-3-2 (8-1a_20-1a and 8-1b_20-1b) Soybean by Monsanto in accordance with Regulation (EC) No 1829/2003.

2. Acknowledgement letter, dated 20 July 2007, from EFSA to the Competent Authority of the MS.

3. Letter from EFSA to applicant, dated 14 January 2008, requesting additional information under completeness check (Ref. SR/KL/shv (2008) 2619864).

4. Letter from applicant to EFSA, received 3 March 2008 providing additional information under completeness check.

5. Letter from EFSA to applicant, dated 12 March 2008, delivering the 'Statement of Validity' for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b) Soybean submitted by Monsanto under Regulation(EC) No 1829/2003 (Ref. SR/KL/md (2008) 2768971).

6. Letter from EFSA to applicant, dated 15 July 2007, requesting additional information and stopping the clock for application EFSA-GMO-RX-40-3-2 (8-1a_20-1a). (Ref. PB/KL/md (2008) 3172306).

7. Letter from EFSA to applicant, dated 12 September 2008, requesting additional information and maintaining the clock stopped for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).(Ref.PB/KL/md(2008) 3288577).

8. Letter from applicant to EFSA, received 1 December 2008 providing additional information for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).

9. Letter from EFSA to applicant, dated 11 December 2008, requesting additional information and maintaining the clock stopped for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).(Ref. PB/KL/md(2008) 3522843).

10. Letter from applicant to EFSA, received 23 December 2008 providing additional information for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).

11. Letter from applicant to EFSA, received 26 May 2009 providing additional information for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).

12. Letter from applicant to EFSA, received 20 August 2009 providing additional information for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).

13. Letter from EFSA to applicant, received 16 March 2010, requesting additional information and maintaining the clock stopped for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b) (Ref.PB/KL/ZD/shv (2010) 4722621).

14. Letter from applicant to EFSA, received 15 July 2010, providing additional information for applications EFSA-GMO-RX-40-3-2 (8-1a_20-1a and 8-1b_20-1b).

15. Letter from EFSA to applicant, dated 17 July 2010 restarting the clock (Ref.PB/KL/lg (2010) 5143985).

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European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on an application (EFSA-GMO-NL-2010-85) for the placing on the market of MON 87769 × MON 89788 soybean, genetically modified to contain stearidonic acid and be tolerant to glyphosate for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The EFSA GMO Panel previously assessed the two single events that are combined to produce soybean MON 87769 × MON 89788 and did not identify safety concerns. No new data on these single events, leading to a modification of the original conclusions on safety, were identified. The molecular, agronomic, phenotypic and compositional data on soybean MON 87769 × MON 89788 did not give rise to safety concerns. The Panel considers that there is no reason to expect interactions between the single events to impact on food and feed safety. There were no concerns regarding the potential toxicity or allergenicity of soybean MON 87769 × MON 89788, and no evidence that the genetic modification significantly changes the overall allergenicity. Because of the lack of data on dietary exposure to refined bleached deodorised oil from soybean MON 87769 × MON 89788, the EFSA GMO Panel could not complete the human health and nutrition assessment. There are no concerns regarding the use of feedingstuffs derived from defatted toasted MON 87769 × MON 89788 soybean meal. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Potential interactions of soybean MON 87769 × MON 89788 with biotic and abiotic environments were not considered relevant to this application. The unlikely, but theoretically possible, transfer of recombinant genes from soybean MON 87769 × MON 89788 to environmental bacteria is not of safety concern. The post-market environmental monitoring plan and reporting intervals conform with the scope of this application. In conclusion, the Panel could not complete the food and feed safety assessment of soybean MON 87769 × MON 89788 because of the lack of an appropriate nutritional assessment. The Panel concludes that soybean MON 87769 × MON 89788 is unlikely to have adverse effects on the environment in the context of application EFSA-GMO-NL-2010-85.

KEY WORDS

GMO, soybean (*Glycine max* (L.) Merr.), CP4 EPSPS, herbicide tolerant, production of stearidonic acid, stack

[1] On request from the Competent Authority of the Netherlands on an application (EFSA-GMO-NL-2010-85) submitted by Monsanto, Question No EFSA-Q-2010-01086, adopted on 17 September 2015.

[2] Panel members: Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal. Correspondence: gmo@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Groups on Molecular Characterisation, Food/Feed safety and Environment on GMO applications for the preparatory work on this scientific opinion, and EFSA staff: Hermann Broll, Sylvie Mestdagh and Matthew Ramon for the support provided to this scientific opinion.

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SUMMARY

Following the submission of application EFSA-GMO-NL-2010-85 under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of herbicide-tolerant, stearidonic acid (SDA)-producing genetically modified (GM) soybean MON 87769 × MON 89788 (Unique Identifier MON-87769-7 × MON-89788-1). The scope of application EFSA-GMO-NL-2010-85 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

Soybean containing the single events MON 87769 (expressing the Δ15 desaturase protein from *Neurospora crassa* (NcΔ15D) and the Δ6 desaturase protein from *Primula juliae* (PjΔ6D)) and MON 89788 (expressing the CP4 protein 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS)) were assessed previously and no concerns were identified for human and animal health or environmental safety. No safety concern was identified by updated bioinformatic analyses, or reported by the applicant with regard to the two single soybean events, since the publication of the corresponding scientific opinions. Consequently, the EFSA GMO Panel considers that its previous conclusions on the safety of the single soybean events remain valid.

The two-event stack soybean MON 87769 × MON 89788 was produced by conventional crossing of the soybean lines MON 87769 and MON 89788, combining the production of SDA and the tolerance to glyphosate-based herbicides. The EFSA GMO Panel evaluated soybean MON 87769 × MON 89788 with reference to the scope and appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed, the environmental risk assessment of GM plants and the post-market environmental monitoring (PMEM) of GM plants. The scientific evaluation of the risk assessment included molecular characterisation of the inserted DNA and analysis of the expression of the corresponding proteins. An evaluation of the comparative analyses of the compositional, agronomic and phenotypic characteristics was undertaken, and the safety of the newly expressed protein and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional wholesomeness. Evaluations of environmental impacts and the PMEM plan were also undertaken. In accordance with the EFSA GMO Panel guidance document applicable to this application (EFSA GMO Panel, 2011a), "*For GM plants containing a combination of transformation events (stacked events) the primary concern for risk assessment is to establish that the combination of events is stable and that no interactions between the stacked events, that may raise safety concerns compared to the single events, occur. The risk assessment of GM plants containing stacked events focuses on issues related to: a) stability of the inserts, b) expression of the introduced genes and their products and c) potential synergistic or antagonistic effects resulting from the combination of the events*".

The molecular data establish that the transformation events stacked in soybean MON 87769 × MON 89788 have the same molecular properties and characteristics as the single transformation events. Comparison of the levels of the NcΔ15D, PjΔ6D and CP4 EPSPS proteins between the stack and the corresponding single events did not reveal an interaction that would affect protein or trait expression levels in a way that would give rise to safety concerns. The biological functions of the newly expressed proteins did not suggest the possibility of interactions between the events at a functional level.

The EFSA GMO Panel considered the compositional, phenotypic and agronomic data supplied and the observed statistically significant differences between soybean MON 87769 × MON 89788 and its comparator, in the light of the field trial design, measured biological variation and the level of the studied compounds in commercial non-GM soybean varieties. No relevant differences were identified in the compositional characteristics of soybean MON 87769 × MON 89788 in comparison with its comparator, except for the altered fatty acid composition (of SDA, γ-linolenic acid and two trans-fatty acids) and a reduction in linoleic acid.

The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed PjΔ6D, NcΔ15D and CP4 EPSPS proteins, and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 × MON 89788. The EFSA GMO Panel could not complete a full assessment on the possible impact of MON 87769 × MON 89788 soybean oil on health and nutrition, because of the lack of data on dietary exposure to refined bleached deodorised (RBD) oil from MON 87769 × MON 89788 soybean. There are no concerns regarding the use of feeding stuffs derived from defatted toasted MON 87769 × MON 89788 soybean meal.

No safety concerns for the environment from the import and processing of soybean MON 87769 × MON 89788 were identified. There are no indications of an increased likelihood of establishment and spread of feral soybean MON 87769 × MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. The unlikely, but theoretically possible, transfer of the recombinant genes from soybean MON 87769 × MON 89788 to bacteria does not give rise to a safety concern for these bacteria owing to the lack of a selective advantage. Potential interactions of soybean MON 87769 × MON 89788 with the biotic and abiotic environment were not considered relevant by the EFSA GMO Panel. The PMEM plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2010-85.

In conclusion, the EFSA GMO Panel could not complete the food and feed safety assessment of soybean MON 87769 × MON 89788 because of the lack of an appropriate nutritional assessment. The EFSA GMO Panel concludes that soybean MON 87769 × MON 89788 is unlikely to have any adverse effects on the environment, considering the scope of application EFSA-GMO-NL-2010-85.

As a full assessment on the possible health and nutritional impact of MON 87769 × MON 89788 soybean oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling provided by the applicant, in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

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BACKGROUND

On 30 July 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands application EFSA-GMO-NL-2010-85, for authorisation of genetically modified (GM) soybean MON 87769 × MON 89788 submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 for food and feed uses, import and processing[4].

After receiving the application EFSA-GMO-NL-2010-85 and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and the European Commission, and made the summary of the application available to the public on the EFSA website[5]. EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 5 November 2010, EFSA received additional information (requested on 9 September 2010). On 26 November 2010, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003.

EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC[6] following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had three months after the date of receipt of the valid application (from 21 May 2014 to 21 August 2014)[7] to make their opinion known.

The EFSA GMO Panel carried out an evaluation of the scientific risk assessment of soybean MON 87769 × MON 89788 for food and feed uses, import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel took into account the appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed (EFSA GMO Panel, 2006), the environmental risk assessment of GM plants (EFSA GMO Panel, 2010) and on the post-market environmental monitoring of GM plants (EFSA GMO Panel, 2011b). Furthermore, the EFSA GMO Panel also took into consideration the scientific comments of Member States, the additional information provided by the applicant and the relevant scientific publications.

On 14 July 2014, 25 July 2014, 10 November 2014 and 30 March 2015, the EFSA GMO Panel requested additional information from the applicant. The applicant provided the requested information on 12 September 2014, 15 September 2014, 28 January 2015, 1 June 2015 and 10 July 2015. The applicant also spontaneously provided additional information on 14 October 2013.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the acknowledgement of the valid application. As additional information was requested by the EFSA GMO Panel, the time limit of six months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003 (EC, 2003), this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

[4] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

[5] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-01086

[6] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

[7] Upon validation, application EFSA-GMO-NL-2010-85 was stopped pending the finalisation of application EFSA-GMO-NL-2008-76 (soybean MON 87769). The scientific opinion on application EFSA-GMO-NL-2008-76 was adopted on 10 April 2014.

TERMS OF REFERENCE

The EFSA GMO Panel was requested to carry out a scientific assessment of soybean MON 87769 × MON 89788 for food and feed uses, import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

Since the EFSA GMO Panel was not in the position to make a full assessment on possible health and nutritional impact of soybean MON 87769 × MON 89788, the need for a specific labelling in accordance with Articles 13(2) (a) and 25(2)(c) of Regulation (EC) No 1829/2003 was not considered. Neither did the EFSA GMO Panel consider methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

ASSESSMENT

1. Introduction

Application EFSA-GMO-NL-2010-85 covers the two-event stack soybean MON 87769 × MON 89788 produced by conventional crossing. The scope of this application is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

The European Food Safety Authority (EFSA) guidance applicable to this application establishes that "*Where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to a) stability, b) expression of the events and c) potential interactions between the events*" (EFSA, 2006, 2007). Additional information, received after May 2011, was assessed in accordance with the EFSA 2011 guidance (EFSA GMO Panel, 2011a).

Soybean MON 87769 × MON 89788 was developed to produce stearidonic acid (SDA) and to confer tolerance to glyphosate (*N*-(phosphonomethyl)glycine)-based herbicides. The production of SDA is achieved by the expression of the Δ6 desaturase protein from *Primula juliae* (PjΔ6D) and the Δ15 desaturase protein from *Neurospora crassa* (NcΔ15D). Tolerance to glyphosate is achieved by expression of CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS).

The two single soybean events MON 87769 and MON 89788 have been previously assessed (see Table 1) on the basis of experimental data. No concerns for human and animal health or environmental safety were identified.

Table 1: Single soybean events already assessed by the EFSA Panel on Genetically Modified Organisms

Event	Application	EFSA scientific opinion
MON 87769	EFSA-GMO-NL-2008-76	EFSA GMO Panel (2014)
MON 89788	EFSA-GMO-NL-2005-36	EFSA (2008)

2. Issues raised by Member States

Issues raised by Member States on soybean MON 87769 × MON 89788 were considered in this scientific opinion and are addressed in detail in Annex G of the EFSA overall opinion[8].

3. Updated information on single events

Since the publication of the scientific opinions on the single soybean events by the EFSA Panel on Genetically Modified Organisms (GMO) (EFSA, 2008; EFSA GMO Panel, 2014), no safety issues pertaining to the two single events have been reported by the applicant.

Updated bioinformatic analyses on the junction regions for events MON 87769 and MON 89788 confirmed that no known endogenous genes were disrupted by any of the inserts[9]. Updated bioinformatic analyses of the amino acid sequences of the newly expressed proteins and of the open reading frames (ORFs) in the inserts and spanning the junction regions revealed no new significant similarities to known toxins or allergens[10]. The similarity to allergens search used a criterion of 35 % identity to the amino acid sequence of known allergens in a window of 80 amino acids. No matches of eight contiguous identical amino acid sequences between these proteins and known allergens were found, with the exception of one match of eight contiguous serine residues (SSSSSSSS) which was already assessed by the EFSA GMO Panel (see Section 5.1.4.1 of EFSA GMO Panel, 2014).

[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00551
[9] Additional information: 10/07/2015.
[10] Additional information: 10/07/2015.

Having assessed the updated information on soybean MON 87769 × MON 89788, the EFSA GMO Panel considers that its previous conclusions on the safety of the single soybean events remain valid.

4. Risk assessment of the two-event stack soybean MON 87769 × MON 89788

4.1. Molecular characterisation

The possible interactions between the known biological functions conferred by the individual inserts and interactions that would affect protein or trait expression level are considered.

4.1.1. Genetic elements and biological functions of the inserts[11]

Soybean MON 87769 and MON 89788 are combined by conventional crossing to produce soybean MON 87769 × MON 89788. The structure of the inserts introduced into soybean MON 87769 × MON 89788 is described in detail in previous EFSA scientific opinions (EFSA, 2008; EFSA GMO Panel, 2014), and no new genetic modifications were involved. The genetic elements in the expression cassettes of the single events are summarised in Table 2.

Table 2: Genetic elements in the expression cassettes of the events stacked in soybean MON 87769 × MON 89788

Event	Promoter	5′ UTR	Transit peptide	Coding region	Terminator
MON 87769	*7Sα'* from the *SphasI* gene (*Glycine max*)	*7Sα'* from the *SphasI* gene (*Glycine max*)	No	*Pj.D6D* (*Primula juliae*)	*Tml* (*Agrobacterium tumefaciens*)
	7Sα from the *Sphas2* gene (*Glycine max*)	*7Sα* from the *Sphas2* gene (*Glycine max*)	No	*Nc.Fad3* (*Neurospora crassa*)	*E9* (*Pisum sativum*)
MON 89788	*FMV/Tsf1* (*Arabidopsis thaliana*)	*Tsf1* (*Arabidopsis thaliana*)	*CTP2* (*Arabidopsis thaliana*)	*CP4 epsps* [a] (*Agrobacterium* sp. CP4)	*E9* (*Pisum sativum*)

a: Codon-optimised for expression in plants.
FMV, figwort mosaic virus; UTR, untranslated region.

There are three newly expressed proteins in soybean MON 87769 × MON 89788, all of which are enzymes. The biological functions conferred by these proteins are summarised in Table 3.

Table 3: Biological functions related to the events stacked in soybean MON 87769 × MON 89788

Event	Protein	Function in donor organism	Function in GM plant
MON 87769	NcΔ15D	Donor organism: *Neurospora crassa* Δ15 desaturase converts linoleic acid to α-linolenic acid (Stafford et al., 1998)	The Δ6 and Δ15 desaturases act together in the GM plant leading to the accumulation of stearidonic acid (Eckert et al., 2006; Vrinten et al., 2007; Haslam et al., 2013)
	PjΔ6D	Donor organism: *Primula juliae* Δ6 desaturase converts α-linolenic acid to stearidonic acid and can also convert linoleic acid to γ-linolenic acid (Sayannova et al., 2006; Ruiz-Lopez et al.,2009)	
MON 89788	CP4 EPSPS	Donor organism: *Agrobacterium* strain CP4. 5-Enolpyruvyl-shikimate-3-phosphate (EPSPS) synthase is an enzyme involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and microorganisms (Herrmann, 1995). Glyphosate is a competitive inhibitor of this enzyme	The bacterial CP4 EPSPS confers tolerance to glyphosate-based herbicides as it has a greatly reduced affinity towards glyphosate than the plant endogenous enzyme.

[11] Dossier: Part I—Section C.

4.1.2. Integrity of the events in the two-event stack soybean MON 87769 × MON 89788

The genetic stability of the inserted DNA over multiple generations in the single soybean events MON 87769 and MON 89788 was demonstrated previously (EFSA, 2008; EFSA GMO Panel, 2014). The integrity of these events in soybean MON 87769 × MON 89788 was demonstrated by Southern analyses[12] in the third self-pollinating generation after crossing the parental lines[13].

4.1.3. Information on the expression of the inserts[14]

Plants were grown at five locations (three replicate blocks) under field conditions in the USA in 2007. The levels of the PjΔ6D and NcΔ15D proteins in the two-event stack soybean and the single event MON 87769 were quantified by Western blot, while the levels of CP4 EPSPS were analysed by enzyme-linked immunosorbent assay (ELISA) in the two-event stack soybean and the single event MON 89788. Protein levels were determined in over season leaf (OSL1, OSL2, OSL3 and OSL4), forage, root, mature and immature seed. The data on mature seeds are reported and discussed below (Table 4). PjΔ6D, NcΔ15D and CP4 EPSPS protein levels in the two-event stack soybean were similar to the corresponding levels in the single-event soybean plants.

Table 4: Means, standard deviations and ranges (n = 15) of protein levels in mature seeds (µg/g dry weight) from soybean MON 87769, MON 89788 and the two-event stack soybean

Event / Protein	MON 87769 × MON 89788	MON 87769	MON 89788
PjΔ6D	3.4[a] ± 2.3[b] 0.76-10[c]	3.0 ± 3.3 0.69-9.2	---
NcΔ15D	9.6 ± 3.2 3.4-16	8.7 ± 3.8 3.4-17	---
CP4 EPSPS	120 ± 24 70-160	---	90 ± 31 33-140

a: mean
b: standard deviation
c: range
'---': not assayed

As the promoter used is a seed-specific promoter and, in the single events, the expression in immature seeds was shown to be markedly higher than in mature seeds, the PjΔ6D and NcΔ15D levels were also analysed in two-event stack immature soybean seeds. The mean levels of PjΔ6D were ca. 46 ± 32 µg/g dry weight (dw) with a range of 13–130 µg/g dw for immature seeds. The mean NcΔ15D levels were ca. 120 ± 60 µg/g dw with a range of 33–290 µg/g dw for immature seeds. As previously observed for the single events, the levels for the two proteins were shown to be higher in immature than in the mature seeds.

4.1.4. Conclusion with regard to the molecular characterisation

The molecular data establish that the transformation events stacked in soybean MON 87769 × MON 89788 have the same molecular properties and characteristics as the single transformation events. The comparison of the NcΔ15D, PjΔ6D and CP4 EPSPS protein levels between the two-event stack soybean and the single events did not reveal an interaction that would affect protein or trait expression level in a way that would require further assessment. The biological functions of the newly expressed proteins do not suggest the possibility of interactions between the events at the functional level (see Section 4.3.2.1).

[12] Dossier: Part I—Section D2(a).
[13] Dossier: Part I – Section D3.
[14] Dossier: Part I—Section D3.

4.2. Comparative analysis

4.2.1. Evaluation of relevant scientific data

4.2.1.1. Choice of comparator and production of material for the comparative analysis[15]

In application EFSA-GMO-NL-2010-85, the applicant supplied data on agronomic and phenotypic characteristics of soybean MON 87769 × MON 89788 from a set of field trials carried out at five locations in the major soybean growing regions of Argentina during the 2007/2008 season[16]. A maintenance regime based on conventional herbicides was applied to all materials. This experimental design allows a direct comparison between the double-event stack soybean and its comparator treated under the same management regimes (including conventional herbicides). The treatment of the genetically modified (GM) soybean with glyphosate-based herbicides, which would have allowed the assessment of herbicide effects, was not included.

The applicant supplied data on the composition of forage and seeds of soybean MON 87769 × MON 89788 and its comparator harvested from another set of field trials carried out at five locations in the major soybean growing regions of the USA in 2007[17]. While the comparator A3525 and the non-GM soybean varieties received only conventional herbicide treatment ("untreated"), soybean MON 87769 × MON 89788 received a single application of a glyphosate-based herbicide (between growth stage V2 to R1) in addition to the conventional herbicide treatment ("treated").

In both sets of field trials, the test materials were grown in a randomised complete block design with three replicates. Because the GM events in soybean MON 87769 × MON 89788 were introduced into the Asgrow A3525 genetic background, the comparator used was the Asgrow soybean variety A3525. Each block at each of the field trial sites included soybean MON 87769 × MON 89788, the comparator A3525, and three to four commercial non-GM soybean varieties[18]. In total, 12 non-GM soybean varieties, with similar maturity classifications, were included across field trial sites in Argentina[19], and 15 varieties were included across the field trial sites in the USA[20].

The test materials soybean MON 87769 × MON 89788 and A3525 soybean were characterised by event-specific polymerase chain reactions (PCRs) for the presence or absence of the MON 87769 and MON 89788 events. These studies confirmed an adequate quality of the test materials. The identity of the commercial non-GM soybean reference varieties were confirmed by chain-of-custody documentation.

Data on compositional, agronomic and phenotypic endpoints were statistically analysed for potential differences between soybean MON 87769 × MON 89788 and A3525 soybean using two analysis of variance (ANOVA) models: an across-site ANOVA (all trial sites combined) followed by an

[15] Technical dossier/Sections A3.1–3.2 and additional information received on 2/09/2013 and 20/06/2014.
[16] Alejo Ledesma, Córdoba; San Francisco, Santa Fe; Tacuari, Buenos Aires; Gahan, Buenos Aires; and Inès Indart, Buenos Aires.
[17] Jefferson County, Iowa (IA); Ottawa County, Michigan (MI); York County, Nebraska (NE); Berks County, Pennsylvania (PA); and Walworth County, Wisconsin (WI).
[18] Four commercial non-GM soybean reference varieties were included at each field trial site in Argentina in the season 2007/2008, and three at each field trial site in the USA in the season 2007.
[19] The commercial non-GM soybean reference varieties included in the field trials in Argentina were Asgrow A3244, Lewis 372, CB3461, Quality Plus, Hoegemeyer 333, Croplan 3596STS, NK 32Z3, Garst 3585N, Stine 3300-0, Stewart 3454 and Pioneer 93B52.
[20] The commercial non-GM soybean reference varieties included in the field trials in the USA were Asgrow A3244, A2869, ST 3870-0, CB 3461, CB 37002, NK32Z3, Garst 3585N, Stine 3300-0, Stine 2788, Stine 3608-0, Pioneer 93B52, QP 365C, HT 3596STS and MG-M3444.

individual-site analysis[21]. No statistical comparisons were made between soybean MON 87769 × MON 89788 and the set of non-GM soybean commercial varieties.

4.2.1.2. Agronomic and phenotypic characteristics[22]

The phenotypic and agronomic characteristics evaluated at the five field trial sites in Argentina were early stand count, seedling vigour, plant growth stages, days to 50 % flowering, flower colour, plant pubescence, plant height, final stand count, lodging, pod shattering, seed moisture, 100 seed weight, test weight, yield, plant response to abiotic stressors, and plant response to disease damage.

The ANOVA across field trial sites showed a significant difference between soybean MON 87769 × MON 89788 and its comparator in mean plant height (59.8 ± 2.74 cm in soybean MON 87769 × MON 89788 vs. 57.2 ± 2.32 cm in the comparator). If field trial sites were analysed separately, the difference was observed at only one site. The range of the mean plant height observed for the commercial non-GM soybean reference varieties was 45.2–67.8 cm. The observed mean for soybean MON 87769 × MON 89788 falls within the range of commercial varieties.

Three site-specific abiotic stressors[23] and three diseases were evaluated on a continuous 0–9 symptom scale by experienced field coordinators four times during the growing season. Observations were considered to be different between soybean MON 87769 × MON 89788 and its comparator at a particular day and site if the scores did not overlap. No differences in response to abiotic stress were noted in any of the 60 comparisons. There were also no differences in response to disease damage in 58 of 60 comparisons. A difference was observed for two diseases; one at each of two sites at one observation. Finally, there were three statistically significant differences in arthropod damage detected out of 85 comparisons between soybean MON 87769 × MON 89788 and its comparator in the individual-site analysis but there were no overall differences in arthropod damage in any of the 24 comparisons.

4.2.1.3. Compositional analysis[24]

Soybean forage and seeds of soybean MON 87769 × MON 89788, its comparator and the commercial non-GM varieties harvested from the field trials carried out in the USA during the 2007 growing season were analysed for 75 constituents (68 in seeds[25] and 7 in forage[26]), including the key constituents recommended by the Organisation for Economic Co-operation and Development (OECD, 2001). Twenty-six parameters that had 50 % or more sample values below the assay limit of

[21] In both models, the overall mean and the genotype effect were fixed factors. The random factors (apart from residual error) were the block effect for the individual-site analysis, the site effect, the block-within-site effect and the site-by-genotype interaction for the across-site analysis.

[22] Technical dossier/Section D4 and additional information received 28/01/2015 and 01/06/2015.

[23] Drought, flooding, hail, soil compaction, strong wind and temperature stress.

[24] Technical dossier/Section D7.1.

[25] Protein, total fat, ash, moisture, carbohydrate by calculation, acid detergent fibre (ADF), neutral detergent fibre (NDF), caprylic acid (C8:0), capric acid (C10:0), lauric acid (C12:0), myristic acid (C14:0), myristoleic acid (C14:1), pentadecanoic acid (C15:0), pentadecenoic acid (C15:1), palmitic acid (C16:0), palmitoleic acid (C16:1), heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), stearic acid (C18:0), oleic acid (C18:1), total trans C18:1, linoleic acid (C18:2), isolinoleic acid (C18:2), total trans C18:2, linolenic acid (C18:3), γ-linolenic acid (C18:3), trans-α-linolenic acid (C18:3), other trans C18:3, stearidonic acid (C18:4), trans-stearidonic acid (C18:4), arachidic acid (C20:0), eicosenoic acid (C20:1), eicosadienoic acid (C20:2), eicosatrienoic acid (C20:3), arachidonic acid (C20:4), EPA (eicosapentaenoic acid; C20:5), behenic acid (C22:0), erucic acid (C22:1), DPA (docosapentaenoic acid, C22:5), DHA (docosahexaenoic acid, C22:6), lignoceric acid (C24:0), methionine, cystine, tryptophan, threonine, isoleucine, histidine, valine, leucine, arginine, phenylalanine, lysine, glycine, alanine, aspartic acid, glutamic acid, proline, serine, tyrosine, daidzein, glycitein, genistein, stachyose, raffinose, lectin, phytic acid and trypsin inhibitor.

[26] Moisture, crude protein, crude fat, ash, crude fibre, acid detergent fiber (ADF), neutral detergent fiber (NDF) and total carbohydrate by calculation.

quantitation were excluded from the statistical analysis[27]. Four of these (γ-linolenic acid, SA, trans-α-linolenic acid (trans-ALA), trans-SA) occurred at quantifiable levels in seed of soybean MON 87769 × MON 89788, but at levels below the limit of quantitation in soybean A3525.

The across-site statistical analysis using a mixed model ANOVA of compositional data on soybean forage identified significant differences in only the level of moisture and total fat between soybean MON 87769 × MON 89788 and its comparator. As shown in Table 5, the identified levels for moisture content and total fat in soybean MON 87769 × MON 89788 were within the variation observed in commercial non-GM soybeans. The EFSA GMO Panel considered that none of the statistical differences in forage constituents was of relevance or needs further assessment.

Table 5: Constituents (least square mean) occurring at significantly different levels in forage and seeds of soybean MON 87769 × MON 89788 and its comparator A3525, harvested from field trials in the USA in 2007

Constituents	Estimated means across locations		
	MON 87769 × MON 89788 ("treated")	Comparator A3525 ("untreated")	Observed ranges of variation of non-GM soybean reference varieties ("untreated")
Forage			
Moisture (% fresh weight)	73.27	73.98	69.90–79.90
Total fat (% dw)	6.97	6.40	2.67–9.59
Seeds			
Palmitic acid (C16:0) (% total fatty acids)	12.32	11.80	9.91–12.15
Stearic acid (C18:0) (% total fatty acids)	4.22	4.12	3.61–4.93
Oleic acid (C18:1) (% total fatty acids)	18.10	20.37	19.17–26.06
Linoleic acid (C18:2) (% total fatty acids)	25.42	54.25	51.08–58.44
Linolenic acid (C18:3) (% total fatty acids)	10.70	8.68	7.24–8.50
Arachidic acid (C20:0) (% total fatty acids)	0.34	0.31	0.25–0.36
Eicosenoic acid (C20:1) (% total fatty acids)	0.18	0.16	0.15–0.19
Behenic acid (C22:0) (% total fatty acids)	0.28	0.30	0.29–0.38
Carbohydrates (% dw)	34.57	37.37	32.41–39.15
Protein (% dw)	41.84	40.70	38.01–43.18
Total fat (% dw)	17.95	16.38	16.79–21.92
Arginine (% total protein)	8.56	8.34	7.39–8.42
α-Tocopherol (mg/100 g dw)	2.15	1.94	1.05–2.75
Phytic acid (% dw)	1.34	1.24	0.92–1.69
Daidzein (μg/g dw)	1040.47	1477.34	540.83–1429.49
Genistein (μg/g dw)	705.74	991.32	637.53–1642.84
SDA (% total fatty acid)	21.62	–	–
Trans-SDA (% total fatty acid)	0.14	–	–
γ–Linolenic acid (% total fatty acid)	6.49	–	–
Trans-ALA (% total fatty acid)	0.20	–	–

–: Below the limit of quantification.

[27] The parameters excluded from the statistical analysis were caprylic acid (C8:0), capric acid (C10:0), lauric acid (C12:0), myristic acid (C14:0), myristoleic acid (C14:1), pentadecanoic acid (C15:0), pentadecenoic acid (C15:1), palmitoleic acid (C16:1), heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), total trans C18:1, isolinoleic acid (C18:2), total trans C18:2, γ-linolenic acid (C18:3), trans-α-linolenic acid (C18:3), other trans C18:3, stearidonic acid (C18:4), trans-stearidonic acid (C18:4), eicosadienoic acid (C20:2), eicosatrienoic acid (C20:3), arachidonic acid (C20:4), EPA (eicosapentaenoic acid; C20:5), erucic acid (C22:1), DPA (docosapentaenoic acid, C22:5), DHA (docosahexaenoic acid, C22:6) and lignoceric acid (C24:0).

As expected, owing to the genetic modification characterising the event MON 87769, significant differences in seed fatty acid composition were observed between soybean MON 87769 × MON 89788 and its comparator (Table 5). The altered fatty acid profile was accompanied by a slight increase in total fat content of the seed, but it remained within the range characterising the commercial non-GM soybean varieties analysed in the study.

The reductions in linoleic acid and in oleic acid were accompanied by the appearance of two metabolites: SDA (21.6%) and γ-linolenic acid (GLA) (6.5%). In addition, low amounts of two trans-fatty acids not occurring at measurable concentrations in commercial soybean oil were detected. These trans-fatty acids were 9c,12c,15t trans-ALA (18:3), at 0.20 % of total fatty acids, and 6c,9c,12c,15t trans-SDA (C18:4), at 0.14 % of total fatty acids. These major alterations in the fatty acid profile of the fat portion of seeds of soybean MON 87769 × MON 89788 were accompanied by altered levels of several other fatty acids (an increase in the proportion of palmitic acid, stearic acid, linolenic acid, arachidic acid and eicosenoic acid, and a decrease in the proportion of behenic acid and linoleic acid). Except for linoleic and linolenic acid, the levels observed in soybean MON 87769 × MON 89788 were within the variability of these constituents in conventional soybean varieties. The change in the levels of these fatty acids in the GM soybean would have no nutritional consequences and therefore are of no relevance for food and feed safety. The levels of linolenic acid observed in soybean MON 87769 × MON 89788 were within the range reported in the literature (Padgette et al., 1996) and the EFSA GMO Panel considered that the increase in linolenic acid did not need further assessment for food and feed safety.

The statistical analysis also revealed an increase in the protein content and a reduction in the carbohydrate content of seeds. As the carbohydrate content is calculated by taking the difference from the sum of the other proximate constituents, the apparent reduction of this parameter is likely to be a consequence of the altered protein and total fat content. The levels of both constituents of soybean MON 87769 × MON 89788 fell within the range established by the commercial non-GM soybean varieties analysed in the study. Although the arginine level in soybean MON 87769 × MON 89788 treated with the intended herbicide was outside the range of the non-GM soybean reference varieties, the EFSA GMO Panel concluded that no further assessment was needed as the reported differences would have no nutritional consequences and are not relevant to food and feed safety. A reduction in daidzein and genistein content of about 30 % was observed. However, because of the characteristic variability in isoflavone levels in soybean, the isoflavone levels were still within the range of the commercial non-GM soybean varieties included in the field trials.

4.2.2. Conclusion

The EFSA GMO Panel confirms that soybean MON 87769 × MON 89788 differs from its comparator and other non-GM soybean reference varieties by having an altered fatty acid profile and a higher level of SDA, as addressed in Section 4.3. None of the other differences identified in the composition of grain and forage obtained from soybean MON 87769 × MON 89788 requires further assessment with regard to food and feed safety.

The difference in plant height between soybean MON 87769 × MON 89788 and the comparator is further assessed for its potential environmental impact in Section 4.4.

4.3. Food and feed safety assessment

4.3.1. Effect of processing[28]

Soybean MON 87699 × MON 89788 will undergo the existing methods of production and processing used for commercial soybean. No novel method of production and processing is envisaged.

[28] Additional information: 03/06/2015.

Seeds of soybean MON 87769 × MON 89788 collected from the 2007 USA field trials were processed into refined bleached deodorised (RBD) oil and analysed for fatty acid composition. The applicant indicated that the intended effects of the genetic modification on the fatty acid pattern already seen in the analysis of unprocessed soybean seeds were also reflected in the composition of RBD oil obtained from soybean MON 87769 × MON 89788 (Table 6).

Table 6: Fatty acid composition of RBD oil and seeds of soybean MON 87769 × MON 89788 based on two composite samples analysed

Fatty acid	MON 87769 × MON 89788 RBD oil, mean (% total FA)	MON 87769 × MON 89788 Unprocessed seed, mean (% total FA)
16:0 Palmitic acid	12.36	12.32
18:0 Stearic acid	4.27	4.22
18:1 Oleic acid	18.10	18.10
18:2 Linoleic acid	25.28	25.42
18:3 GLA	6.45	6.49
18:3 Linolenic acid	10.56	10.70
18:3 trans-ALA	0.29	0.20
18:4 SDA	21.38	21.62
18:4 trans-SDA	0.24	0.14
20:0 Arachidic acid	0.35	0.34
20:1 Eicosenoic acid	0.23	0.18
22:0 Behenic acid	0.29	0.28

FA, fatty acid.

The influence of the modified fatty acid pattern seen in the unprocessed soybean seeds on the various products obtained after seed processing was described and assessed by the EFSA GMO Panel for soybean MON 87769 (EFSA GMO Panel, 2014). The products studied included RBD oil, isolated soy protein, toasted defatted meal and crude lecithin.

As observed for MON 87769, the modified fatty acid composition of soybean MON 87769 × MON 89788 seeds is also reflected in the composition of the RBD oil.

The oil of soybean MON 87769 × MON 89788 has a fatty acid profile that is more similar to other types of vegetable oil (e.g. olive oil) than oil from conventional soybean. Therefore, the production of food-quality oil from soybean MON 87769 × MON 89788 (as from MON 87769) is expected to be kept separate from the production of oil from conventional soybean varieties.

4.3.2. Toxicology

4.3.2.1. Toxicological assessment of newly expressed proteins

The newly expressed proteins in soybean MON 87769 × MON 89788 are the desaturases PjΔ6D and NcΔ15D, and the CP4 EPSPS protein.

All of these have been assessed in the context of the corresponding single events (PjΔ6D and NcΔ15D in MON 87769 (EFSA GMO Panel, 2014) and CP4 EPSPS in MON 89788 (EFSA, 2008)) and no safety concerns for humans and animals were identified. The EFSA GMO Panel is not aware of any new information that would change these conclusions. Updated bioinformatic studies[29] confirmed the absence of relevant similarities between these newly expressed proteins to known toxins. The potential for a functional interaction of the newly expressed desaturases and the CP4 EPSPS protein in the two-event stack soybean MON 87769 × MON 89788 has been assessed with regard to human and animal health. The two desaturase enzymes are intended to act in combination on plant fatty acid metabolism.

[29] Additional information: 10/07/2015.

The CP4 EPSPS enzyme catalyses a distinctly different biochemical reaction. No information was identified to suggest that the combination of the desaturases PjΔ6D and NcΔ15D with CP4 EPSPS would result in effects different from those observed in the single events. Since the individual proteins were considered safe for humans and animals, the same conclusion can be extended to their presence in the stacked soybean MON 87769 × MON 89788.

The EFSA GMO Panel concludes that there are no safety concerns for human and animal health related to the PjΔ6D, NcΔ15D and CP4 EPSPS proteins newly expressed in soybean MON 87769 × MON 89788.

4.3.2.2. Toxicological assessment of components other than newly expressed proteins

The compositional analysis of soybean MON 87769 × MON 89788 confirmed the expected altered fatty acid profile and a higher SDA level in seeds (see Table 5). All of these fatty acids occur naturally in the diet of humans and animals. The safety impact of the altered fatty acid profile is evaluated in Sections 4.3.4 and 4.3.5.

4.3.3. Animal studies with the food/feed derived from genetically modified plants

A 42-day feeding study with a total of 800 male and female (one-day-old Cobb 500) chickens for fattening was provided[30]. The birds were randomly allocated to eight dietary treatments with 100 chickens per treatment (five pens/treatment per gender, initially 12 birds per pen and reduced to 10 birds per pen at day seven). Birds were fed diets containing soybean MON 87769 × MON 89788 (verified by PCR in seeds), and compared with those fed diets containing the comparator (A3525) or any of the six non-GM commercial varieties (Anand, Ozark, NK S38-T8, H437, NC+2A86 and NK25-J5). The starter and grower/finisher diets consisted of 33 % and 30 % toasted meal, respectively. Other components were mainly maize and maize gluten meal (about 60 % and 63 % in the starter and grower/finisher diets, respectively). Before feed formulation, all soybean seeds were analysed for proximates, amino acids, minerals, vitamin E, antinutrients, mycotoxins and pesticides. The diets were isonitrogenous, isocaloric and balanced for limiting amino acids (confirmed by analysis). The starter diets (about 22 % crude protein (CP), 3 080 kcal metabolisable energy (ME) /kg) were given until day 21 and grower/finisher diets (about 20 % CP, 3 135 kcal ME/kg) were given from day 22 until the end. Feed (starter as crumbles and grower/finisher as pellets) and water were provided for *ad libitum* intake.

Chickens were observed twice daily for clinical signs; deaths were recorded and necropsy was performed on all birds found dead. Body weight per pen was measured at the start and the end of the trial. Feed intake was determined at day 21 and day 42 for each pen. At days 43 (males) and 44 (female) all surviving birds were taken for carcass evaluation (dressing percentage weight of thighs, breast, wings, drums, abdominal fat and whole liver). Data were analysed by a two-factor ANOVA (diet and sex) and pair-wise comparison was made by a Fischer's Least Significant Difference test. A mixed linear model was applied to compare soybean MON 87769 × MON 89788 with the mean of all non-GM varieties.

Overall mortality was low (< 3 %) with no significant difference between the groups. No significant treatment–sex interaction was detected for performance characteristics. Overall, no significant difference was seen in final body weight (about 2.6 kg), feed intake (about 3.9 kg), or feed to gain ratio (about 1.54) between soybean MON 87769 × MON 89788 and the comparator, or the comparator and the non-GM variety. No significant differences were observed in carcass characteristics.

No evidence of unintended effects introduced by the genetic modification was detected in the tested chickens. The Panel concluded that toasted soybean meal derived from MON 87769 × MON 89788 is as nutritious as the comparator and non-GM commercial varieties.

[30] Dossier: Part I— CQR-08-034 (2009) & RAR-10-168 (2010).

4.3.4. Allergenicity

For an allergenicity assessment, a weight-of-evidence approach is followed, taking into account all of the information obtained on the newly expressed proteins, since no single piece of information or experimental method yields sufficient evidence to predict allergenicity (EFSA, 2006a, 2011a; Codex Alimentarius, 2009). In addition, if known functional aspects of the newly expressed protein or structural similarity to known adjuvants may indicate an adjuvant activity, the possible role of these proteins as adjuvants is considered (EFSA, 2011a). If newly expressed proteins with a potential adjuvant activity are expressed together, possible interactions that might increase adjuvanticity and impact the allergenicity of the GM crop are assessed.

4.3.4.1. Assessment of allergenicity of the newly expressed proteins

With regard to allergenicity, the EFSA GMO Panel has previously evaluated the safety of the CP4 EPSPS, PjΔ6D and NcΔ15D proteins and no concerns were identified in the context of the applications assessed (e.g. EFSA, 2008, 2014). No new information on allergenicity of the newly expressed proteins that might change the previous conclusions of the EFSA GMO Panel has become available. Based on current knowledge, and since none of the newly expressed proteins showed allergenicity, no reasons for concern regarding the presence of these newly expressed proteins, in this stacked soybean, that affect allergenicity were identified.

As regards adjuvanticity, no information is available on the structure or function of the newly expressed CP4 EPSPS, PjΔ6D and NcΔ15D proteins that would suggest an adjuvant effect of the individual proteins or their presence in soybean MON 87769 × MON 89788 that would result in or increase an eventual IgE response to a bystander protein.

4.3.4.2. Assessment of allergenicity of the whole GM plant

Soybean is considered to be a common allergenic food[31] (OECD, 2012). Therefore, any potential change in the endogenous allergenicity of the GM plant when compared with that of its comparator(s) should be assessed (EFSA, 2011a). Such assessments were performed for the single-event soybeans MON 87769 and MON 89788, and no reasons for concern were identified by the EFSA GMO Panel (EFSA, 2008; EFSA GMO Panel, 2014).

At the request of the EFSA GMO Panel, the applicant provided an assessment of the endogenous allergenicity, comparing protein extracts of soybean MON 87769 × MON 89788 and its comparator by gel electrophoresis followed by mass spectrometry[32]. The intensities of the bands corresponding to specific allergens were analysed. No relevant changes in the allergen content between the protein extracts of soybean MON 87769 × MON 89788 and its comparator were identified.

The EFSA GMO Panel considers that there is no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 × MON 89788 when compared with that of its comparator.

4.3.5. Nutritional assessment of genetically modified food/feed

4.3.5.1. Human nutritional assessment

The main product for human consumption from soybean is the oil. The nutritional consequences of the modifications in the fatty acid profile were assessed in the context of the previous opinion on the single event MON 87769 (EFSA GMO Panel, 2014).

[31] Directive 2007/68/EC of the European Parliament and of the Council of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. OJ L 310, 27.11.2007, p. 11–14.
[32] Additional information: 11/09/2014.

In the context of this application, the applicant provided a dietary exposure and nutritional assessment based on data derived from the single event MON 87769, but not on soybean MON 87769 × MON 89788. Therefore, the applicant was asked to provide a dietary exposure assessment based on the compositional analysis of the RBD oil from soybean MON 87769 × MON 89788, taking into account different exposure scenarios, covering low and high consumer groups. However, the applicant did not provide this data[33]. The EFSA GMO Panel therefore cannot complete the assessment on the possible impact of soybean MON 87769 × MON 89788 oil on human health and nutrition.

Other soybean products for human consumption are not expected to differ in their composition, except for their fatty acid content. The contribution of fatty acids from such products to overall human exposure would be small and is not expected to affect the conclusion on human health and nutrition.

4.3.5.2. Animal nutritional assessment

Defatted toasted soybean meal represents the most common soybean by-product used in animal feed formulations, with around 90 % of the defatted soybean meal entering the feed chain in the EU for poultry, pigs and cattle. Presently, only small amounts of full-fat soybeans (1 % of the total soybean feed) are directly fed to food-producing animals. The use of soybean oil in animal feed is limited and only small amounts (0.5–3 %) are added to mixed feed (especially for poultry and pigs) in order to avoid dust, to improve the quality/stability of pellets and to add energy to the diets[34].

Compositional data indicates that the defatted soybean meal from soybean MON 87769 × MON 89788 would be expected to deliver the same nutrition as its comparator and other non-GM commercial varieties. This was confirmed by the results of a feeding study in chickens for fattening (see Section 4.3.3).

4.3.6. Post-market monitoring of genetically modified food/feed

As a full assessment on the possible health and nutritional impact of the soybean MON 87769 × MON 89788 oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling.

4.3.7. Conclusion

The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed PjΔ6D, NcΔ15D and CP4 EPSPS proteins, and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 × MON 89788. The EFSA GMO Panel could not complete a full assessment on the possible impact of the soybean MON 87769 × MON 89788 oil on human health and nutrition. There are no concerns regarding the use of feeding stuffs derived from defatted toasted MON 87769 × MON 89788 soybean meal.

4.4. Environmental risk assessment and monitoring plan

4.4.1. Evaluation of relevant scientific data

Considering the scope of application EFSA-GMO-NL-2010-85, the environmental risk assessment (ERA) of soybean MON 87769 × MON 89788 is concerned mainly with (1) the exposure of bacteria to recombinant DNA in the gastrointestinal tract of animals fed GM material and bacteria present in environments exposed to faecal material; and (2) the accidental release into the environment of viable seeds of soybean MON 87769 × MON 89788 during transportation and processing.

[33] Additional information: 03/06/2015.
[34] Personal communication from Deutscher Verband für Tiernahrung, 29/07/2011.

As the scope of the present application excludes cultivation, environmental concerns in the EU related to the use of glyphosate-based herbicides on the GM soybean do not apply.

4.4.2. Environmental risk assessment

4.4.2.1. Potential unintended effects on plant fitness due to the genetic modification[35]

Cultivated soybean (*Glycine max* (L.) Merr.) is a species in the subgenus *Soja* of the genus *Glycine*. The species originated from eastern Asia and is a highly domesticated crop (Lu, 2005). The major worldwide soybean producers are Argentina, Brazil, China, North Korea, South Korea and the USA. In the EU, soybean is mainly cultivated in Italy, Romania, France, Hungary, Austria, Slovakia and the Czech Republic (Dorokhov et al., 2004; Krumphuber, 2008). Cultivated soybean seeds rarely display any dormancy characteristics and grow as volunteers in the year after cultivation under only certain environmental conditions. If volunteers occur, they do not compete well with the succeeding crop, and can easily be controlled mechanically or chemically (OECD, 2000). In soybean fields, seeds usually do not survive during the winter owing to herbivory, rotting and germination, or owing to management practices prior to planting the subsequent crop (Owen, 2005). Also, survival of soybean plants outside cultivation areas is limited mainly by a combination of low competitiveness, absence of a dormancy phase, and susceptibility to plant pathogens and cold climatic conditions.

The expected changes in seed fatty acid composition in soybean MON 87769 × MON 89788 resulting from the newly inserted *Pj.D6D* gene (encoding the Δ6 desaturase protein from *Primula juliae*) and the *Nc.Fad3* gene (encoding the Δ15 desaturase protein from *Neurospora crassa*) are not known to provide a potential agronomic advantage. The CP4 *epsps* gene-encoded herbicide tolerance trait does provide a potential agronomic and selective advantage for this GM soybean plant if glyphosate-based herbicides are applied.

Considering the scope of application EFSA-GMO-NL-2010-85, special attention is paid to those agronomic and phenotypic characteristics (for further details see Section 4.2) which may be indicative of changes in the survival of soybean MON 87769 × MON 89788 grains which could be accidentally released into the environment, as well as in the establishment and fitness of GM soybean plants, such as early and final stand count, yield, seedling vigour and 100 seed weight. As described in Section 4.2, all of these agronomic and phenotypic characteristics, except plant height, of soybean MON 87769 × MON 89788 did not differ from those of its comparator. Soybean MON 87769 × MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic were within the natural range established using a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential.

Specific data on pollen viability and seed germination for soybean MON 87769 × MON 89788 were not provided by the applicant. The EFSA GMO Panel considered the data[36] provided on seed germination for the single soybean events MON 87769 and MON 89788, their comparators and non-GM reference varieties. No statistically significant difference was observed in seed germination of soybean MON 87769 and soybean MON 89788 compared with their conventional counterparts across all sites. In addition, the early stand count data on soybean MON 87769 × MON 89788 indicated that changes in seed germination are unlikely.

Because the general agronomic and phenotypic characteristics that might be indicative of changes in survival, establishment and fitness are unchanged in soybean MON 87769 × MON 89788, herbicide tolerance is not likely to provide a selective advantage outside cultivation. Even if glyphosate-based herbicides are applied to these plants, this will not change their ability to survive over seasons. Therefore, it is considered very unlikely that soybean MON 87769 × MON 89788 will differ from

[35] Dossier: Part II—Section E 3.1 and Appendix D.
[36] Section D.4 of EFSA-GMO-NL-2006-36 and Section D.4 of EFSA-GMO-UK-2009-76.

conventional soybean varieties in its ability to survive until subsequent seasons or to establish feral populations under European environmental conditions.

The EFSA GMO Panel is not aware of any scientific report of increased survival capacity, including overwintering, of existing GM soybeans varieties, (Dorokhov et al., 2004; Owen, 2005; Bagavathiannan and Van Acker, 2008; Lee et al., 2009).

Therefore, the EFSA GMO Panel is of the opinion that the likelihood of environmental effects of soybean MON 87769 × MON 89788 in Europe will not be different from that of conventional soybean varieties.

4.4.2.2. Potential for gene transfer[37]

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer of DNA or through vertical gene flow via seed dispersal and cross-pollination.

Plant-to-bacteria gene transfer

The potential for horizontal gene transfer of the single events was assessed in previous opinions (EFSA, 2008, 2014) and no concern for an unlikely, but theoretically possible, horizontal gene transfer of the recombinant genes to bacteria in the gut or other receiving environments was identified.

Synergistic effects of the recombinant genes, for instance because of combinations of recombinogenic sequences, which would cause an increase in the likelihood for horizontal gene transfer or a selective advantage were not identified.

Bioinformatic analysis of the inserted DNA and flanking regions (Section 3) did not identify sufficient sequence identity with bacterial DNA (including the modified CP4 *epsps* gene, which has been codon-optimised for expression in plants) that would facilitate homologous recombination-mediated gene transfer between plants and bacteria.

Therefore, the EFSA GMO Panel concludes that horizontal gene transfer from soybean MON 87769 × MON 89788 to bacteria is highly unlikely, theoretically possible but does not raise a safety concern.

Plant-to-plant gene transfer

Considering the scope of this application and the biology of soybean, a possible pathway of gene dispersal is through seed from accidental seed spillage during transportation and/or processing, and pollen from feral GM soybean plants.

The genus *Glycine* is divided into two distinct subgenera: *Glycine* and *Soja*. Soybean is in the subgenus *Soja*. The subgenus *Glycine* contains 16 perennial wild species, while the cultivated soybean, *Glycine max*, and its wild and semi-wild annual relatives, *G. soja* and *G. gracilis*, are classified in the subgenus *Soja* (OECD, 2000). Owing to the low level of genomic similarity among species of the genus *Glycine*, *G. max* can cross with only other members of the *Glycine* subgenus *Soja* under natural conditions (Singh et al., 1987; Hymowitz et al., 1998; Lu, 2005). Hence, the three species of the subgenus *Soja* are capable of cross-pollination and the hybrid seed that is produced can germinate normally and produce plants with fertile pollen and seed (Abe et al., 1999; Nakayama and Yamaguchi, 2002). Since *G. soja* and *G. gracilis* are indigenous to China, Taiwan, Korea, Japan, the far-east region of Russia, Australia, the Philippines and the South Pacific, and since they have not been reported in other parts of the world where the cultivated soybean is grown (Dorokhov et al., 2004; Lu, 2005), the plant-to-plant gene transfer from soybean is restricted to cultivated areas and occasional soybean plants resulting from seed spillage in the EU.

[37] Technical dossier/Part E/Section 3.2.

Soybean is an annual, almost completely self-pollinating crop with a percentage of cross-pollination usually lower than 1 % (OECD, 2000; Ray et al., 2003; Lu, 2005; Yoshimura et al., 2006; Abud et al., 2007). Soybean pollen dispersal is limited because the anthers mature in the bud and directly pollinate the stigma of the same flower (OECD, 2000).

However, cross-pollination rates as high as 6.3 % have been reported for closely spaced plants (Ray et al., 2003), suggesting the potential for some within-crop gene flow in soybean. These results indicate that natural cross-pollination rates can fluctuate significantly among different soybean varieties under particular environmental conditions, such as favourable climate for pollination and an abundance of pollinators (Gumisiriza and Rubaihayo, 1978; Kikuchi et al., 1993; Ahrent and Caviness, 1994; Ray et al., 2003; Lu, 2005).

For plant-to-plant gene transfer to occur, imported soybean MON 87769 × MON 89788 grains need to be processed outside the importing ports, transported into regions of soybean production in Europe, spilled during transportation, germinate and develop into plants in the very close vicinity of soybean fields, and there needs to be an overlap of flowering periods and environmental conditions favouring cross-pollination. It must be noted that most soybean MON 87769 × MON 89788 grains are processed in the countries of production or in ports of importation. The overall likelihood of cross-pollination between feral GM soybean plants and cultivated soybean is therefore extremely low.

In conclusion, as soybean MON 87769 × MON 89788 has no altered survival, multiplication or dissemination characteristics (see Section 4.4.2.1), the EFSA GMO Panel is of the opinion that the likelihood of environmental effects as a consequence of the spread of genes from this GM soybean in Europe will not differ from that of conventional soybean varieties.

4.4.2.3. Interactions of the GM plant with target organisms[38]

Considering the scope of application EFSA-GMO-NL-2010-85 and the absence of target organisms, potential interactions of the GM plant with target organisms were not considered a relevant issue by the EFSA GMO Panel.

4.4.2.4. Interactions of the GM plant with non-target organisms[39]

Considering the scope of application EFSA-GMO-NL-2010-85 and the low level of exposure to the environment, potential interactions of the GM plant with non-target organisms were not considered a relevant issue by the EFSA GMO Panel.

4.4.2.5. Interactions with the abiotic environment and biogeochemical cycles[40]

Considering the scope of application EFSA-GMO-NL-2010-85 and the low level of exposure to the environment, potential interactions with the abiotic environment and biogeochemical cycles were not considered a relevant issue by the EFSA GMO Panel.

4.4.3. Post-market environmental monitoring[41]

The objectives of a post-market environmental monitoring (PMEM) plan, according to Annex VII of Directive 2001/18/EC, are (1) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the genetically modified organism (GMO), or its use, in the ERA are correct and (2) to identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment that were not anticipated in the ERA.

Monitoring is related to risk management, and thus a final adoption of the PMEM plan falls outside the mandate of EFSA. However, the EFSA GMO Panel gives its opinion on the scientific content of

[38] Technical dossier/Part D/Section 9.4.
[39] Technical dossier/Part D/Section 9.5.
[40] Technical dossier/Part D/Section 9.8.
[41] Technical dossier/Part D/Section 11.

the PMEM plan provided by the applicant (EFSA, 2006, 2011b). The potential exposure of the environment to soybean MON 87769 × MON 89788 would be through faecal material from animals fed the GM soybean or through accidental release into the environment of GM soybean seeds during transportation and processing. The EFSA GMO Panel is aware that, owing to the physical characteristics of soybean seeds and the methods of transportation, accidental spillage cannot be excluded. Also, it is important that appropriate management systems are in place to restrict seeds of soybean MON 87769 × MON 89788 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

The PMEM plan proposed by the applicant includes (1) the description of a monitoring approach involving operators (federations involved in soybean import and processing), reporting to the applicants, via a centralised system, any observed adverse effect(s) of GMOs on human health and the environment; (2) a coordinating system established by EuropaBio for the collection of information recorded by the various operators (Lecoq et al., 2007; Windels et al., 2008); and (3) the use of networks of existing surveillance systems. The applicant proposes to submit a PMEM report on an annual basis and a final report at the end of the consent period.

The EFSA GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2010-85. As no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

4.5. Conclusion

No safety concerns with regard to the environment from the import and processing of soybean MON 87769 × MON 89788 were identified. There are no indications of an increased likelihood of the establishment and spread of feral soybean MON 87769 × MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. The unlikely, but theoretically possible, transfer of recombinant genes from soybean MON 87769 × MON 89788 to bacteria does not give rise to a safety concern for these bacteria owing to the lack of a selective advantage. Potential interactions of soybean MON 87769 × MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The PMEM plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2010-85.

CONCLUSIONS AND RECOMMENDATIONS

No new data on the single soybean events MON 87769 and MON 89788 that would lead to a modification of the original conclusions on their safety were identified.

The combination of the single soybean events MON 87769 and MON 89788 in the two-event stack soybean MON 87769 × MON 89788 did not give rise to issues, related to molecular, agronomic, phenotypic or compositional characteristics, regarding food and feed safety. The EFSA GMO Panel considers that there is no reason to expect interactions that could impact on the food and feed safety.

The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed PjΔ6D, NcΔ15D and CP4 EPSPS proteins, and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 × MON 89788. Because of the lack of data on dietary exposure, based on the compositional analysis of RBD oil from soybean MON 87769 × MON 89788, the EFSA GMO Panel could not complete an assessment on the possible impact of MON 87769 × MON 89788 soybean oil on human health and nutrition. Therefore, the EFSA GMO Panel is not in the position to conclude on the food safety of soybean MON 87769 × MON 89788. There are no concerns regarding the use of feeding stuffs derived from defatted toasted MON 87769 × MON 89788 soybean meal.

No safety concerns with regard to the environment from the import and processing of soybean MON 87769 × MON 89788 were identified. There are no indications of an increased likelihood of

establishment and spread of feral soybean MON 87769 × MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. The unlikely, but theoretically possible, transfer of recombinant genes from soybean MON 87769 × MON 89788 to bacteria does not give rise to a safety concern for these bacteria owing to the lack of a selective advantage. Potential interactions of soybean MON 87769 × MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The PMEM plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2010-85.

In conclusion, the EFSA GMO Panel could not complete the food and feed safety assessment of soybean MON 87769 × MON 89788 because of the lack of an appropriate nutritional assessment. The EFSA GMO Panel concludes that soybean MON 87769 × MON 89788 is unlikely to have any adverse effect on the environment in the context of the scope of application EFSA-GMO-NL-2010-85.

As a full assessment on possible health and nutritional impact of soybean MON 87769 × MON 89788 oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling provided by the applicant, in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from Competent Authority of the Netherlands received on 30 July 2010 concerning a request for authorisation for the placing on the market of MON 87769 × MON 89788 soybean (application EFSA-GMO-NL-2010-85) submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V.
2. Acknowledgement letter dated 9 September 2010 from EFSA to the Competent Authority of the Netherlands.
3. Letter from EFSA to applicant dated 9 September 2010 requesting additional information under completeness check.
4. Letter from applicant to EFSA received on 5 November 2010 providing additional information under completeness check.
5. Letter from EFSA to applicant dated 26 November 2010 delivering the "Statement of Validity" of application EFSA-GMO-NL-2010-85 (soybean MON 87769 × MON 89788) submitted by Monsanto Europe S.A./N.V under Regulation (EC) No 1829/2003.
6. Letter from EFSA to applicant dated 26 November 2010 stopping the clock because of single event.
7. Letter from applicant to EFSA received on 14 October 2013 spontaneously providing additional information.
8. Letter from EFSA to applicant dated 20 May 2014 re-starting the clock because of single event.
9. Letter from EFSA to applicant dated 14 July 2014 requesting additional information and stopping the clock.
10. Letter from EFSA to applicant dated 25 July 2014 requesting additional information and maintaining the clock stopped.
11. Letter from applicant to EFSA received on 12 September 2014 providing additional information.
12. Letter from applicant to EFSA received on 15 September 2014 providing additional information.

13. Letter from EFSA to applicant dated 10 November 2014 requesting additional information and maintaining the clock stopped.

14. Letter from applicant to EFSA received on 28 January 2015 providing additional information

15. Letter from EFSA to applicant dated 2 March 2015 re-starting the clock.

16. Letter from EFSA to applicant dated 30 March 2015 requesting additional information and stopping the clock.

17. Letter from applicant to EFSA received on 1 June 2015 providing additional information.

18. Letter from applicant to EFSA received on 10 July 2015 providing additional information.

19. Letter from EFSA to applicant dated 14 September 2015 re-starting the clock.

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