MRL PROGRAM IN PARAGUAY

Laura Vera, MSc

Department of Quality and Safety of Plant Products

SENAVE Paraguay

MRL Harmonization Workshop
May 24, 2023
San Diego, CA

Outline

1. About SENAVE
2. MRLs regulations in Paraguay
3. Problems with MRLs in international trade
4. Next actions and steps

Regulatory Agency for pesticide management and MRLs

SENAVE

(National Service for Quality and Health of Vegetables and Seeds)

autonomous organization

financial and admin. autarchy

Depends on the agricultural policy of the MAG

MAG System

YVY HA TYMBA ÑANGAREKO MOTENONDEHA
MINISTERIO DE AGRICULTURA Y GANADERÍA

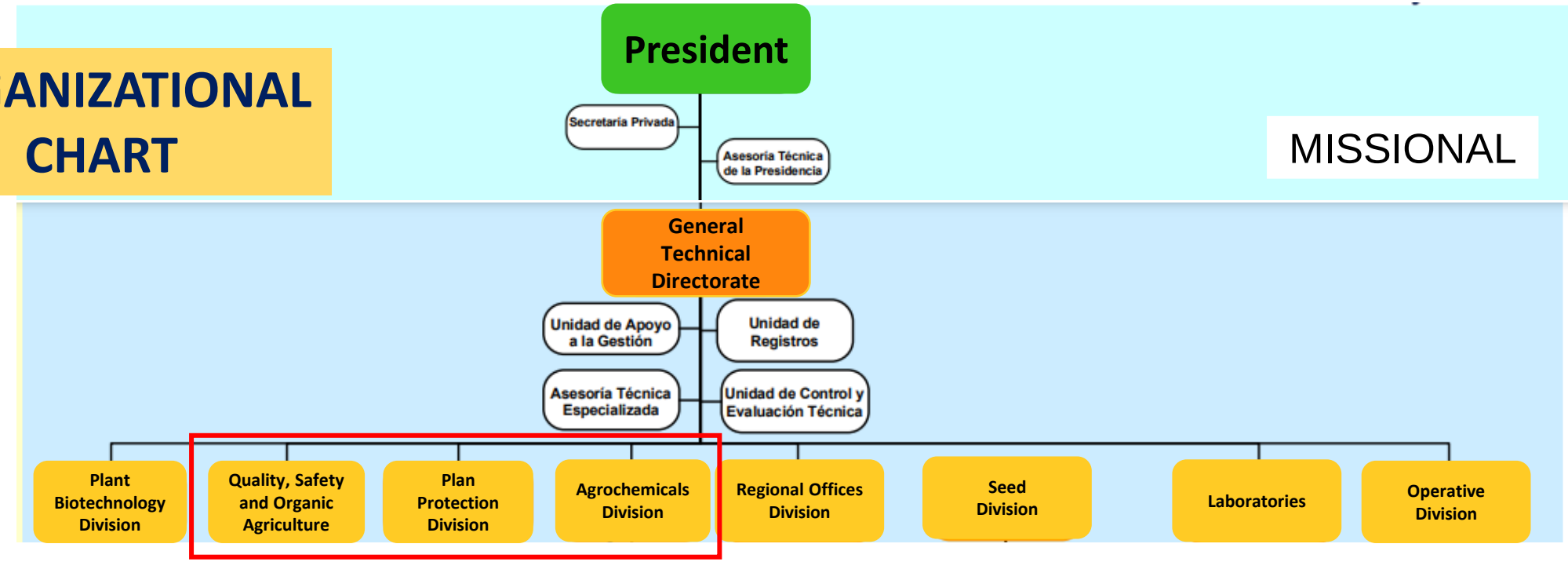
MISSION

To support the State's agricultural production policy, contributing to increasing the levels of competitiveness, sustainability, and equity of the agricultural sector by improving the situation of productive resources in terms of quality, phytosanitary conditions, genetic purity and the prevention of harm to humans, animals, plants and the environment, ensuring their safety.

MAIN RESPONSIBILITIES

- Protect agriculture from pest and diseases.
- Preserve a phytosanitary status that allows national agricultural products access to international markets.
- Ensure the quality and safety of plant origin products.
- Regulate use, sale and distribution of pesticides.
- Ensure that pesticide residue levels in commodities of plant origin comply with maximum residue limits.
- Ensure the identity and quality of seeds as well as protect the rights of breeders of new cultivars.
- Regulate plant biotechnology/GMO.

ORGANIZATIONAL CHART



MISSIONAL

Plant Protection Division

Pest, disease, quarantine

Agrochemicals Division

Pesticides registration and control

Quality, safety and Organic Agriculture Division

Sets food safety standards for plant origin products

Tests local and imported food of plant origin for compliance with MRLs

MRLs in Paraguay

No national list of MRLs

- Codex Alimentarius

- MERCOSUR

Southern Common Market

Regional integration process

Food Comission – SGT N°3

Develops regulations for food trade between member states

MRLs in Paraguay

Food Comission – SGT N°3

Regulation with list of MRLs -- repealed

2015- Criteria for the recognition of MRLs for pesticides in primary products of plant origin

MERCOSUR/GMC/RES. Nº 15/16

CRITERIOS PARA EL RECONOCIMENTO DE LÍMITES MÁXIMOS DE RESIDUOS DE PLAGUICIDAS EN PRODUCTOS VEGETALES *IN NATURA* (DEROGACIÓN DE LA RES. GMC Nº 14/95)

http://www.puntofocal.gov.ar/doc/r_gmc_15-16.pdf

RESOLUCIÓN N° 043.-

"POR LA CUAL SE DISPONE LA VIGENCIA EN LA REPÚBLICA DEL PARAGUAY DE LA RESOLUCIÓN MERCOSUR/GMC/RES N° 15/16 *"CRITERIOS PARA EL RECONOCIMIENTO DE LÍMITES MÁXIMOS DE RESIDUOS DE PLAGUICIDAS EN PRODUCTOS VEGETALES IN NATURA (DEROGACIÓN DE LA RES. GMC N° 14/95)"*, ACTUALIZADA Y APROBADA POR EL GRUPO MERCADO COMÚN DEL MERCOSUR, EN MATERIA FITOSANITARIA".

-1-

Asunción, 19 de enero del 2018.

RESOLUCIÓN N° 550.-

"POR LA CUAL SE ESTABLECE EL REGLAMENTO TÉCNICO PARA EL MUESTREO DE CULTIVOS Y/O PRODUCTOS VEGETALES CON FINES ANALÍTICOS DE RESIDUOS DE PLAGUICIDAS Y OTROS CONTAMINANTES".

-1-

Asunción, 21 de julio de 2011.-

Technical Regulation on sampling with analytical purposes – pesticides residue and other contaminants in plant origin products

Now under revision

Participation in international groups where MRLs are addressed

Paraguay participates in:

- Codex Alimentarius

  CCPR – Codex Committee on Pesticide Residues

- World Trade Organization (WTO)

  SPS – Committee on Sanitary and Phytosanitary Measures

  → Specific trade concerns on MRL measures

The impact of MRLs on Agriculture in Paraguay

A market economy highly dependent on agricultural products

20-30% GDP

35-40% of country's exports

MRLs sometimes become a trade barrier

most problems with minor crops

- 1st largest organic sugar exporter
- 3rd largest soybean exporter
- 6th largest cassava starch exporter
- 13th largest corn exporter
- 16th largest sesame exporter

Source: SENAVE & FAOSTAT, 2021

Sesame crop

Sesame *(Sesamum indicum* L.*)* is one of the oldest oilseed crop cultivated worldwide.

Origin: Asia and East Africa

The plant grows best in warm conditions

> 27°C / 80.6°F

Drought-tolerance nature

It thrives in tropical and subtropical countries.

Sesame seed is in hot demand globally

Good taste and quality

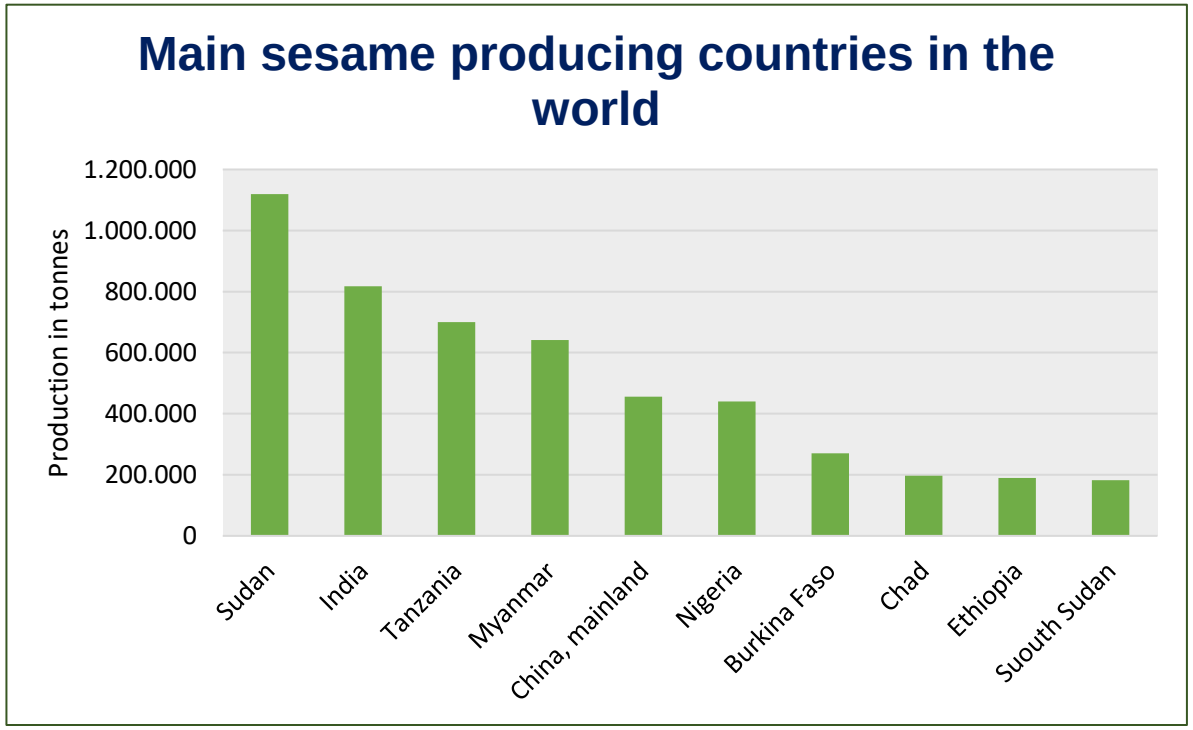
Very nutritious

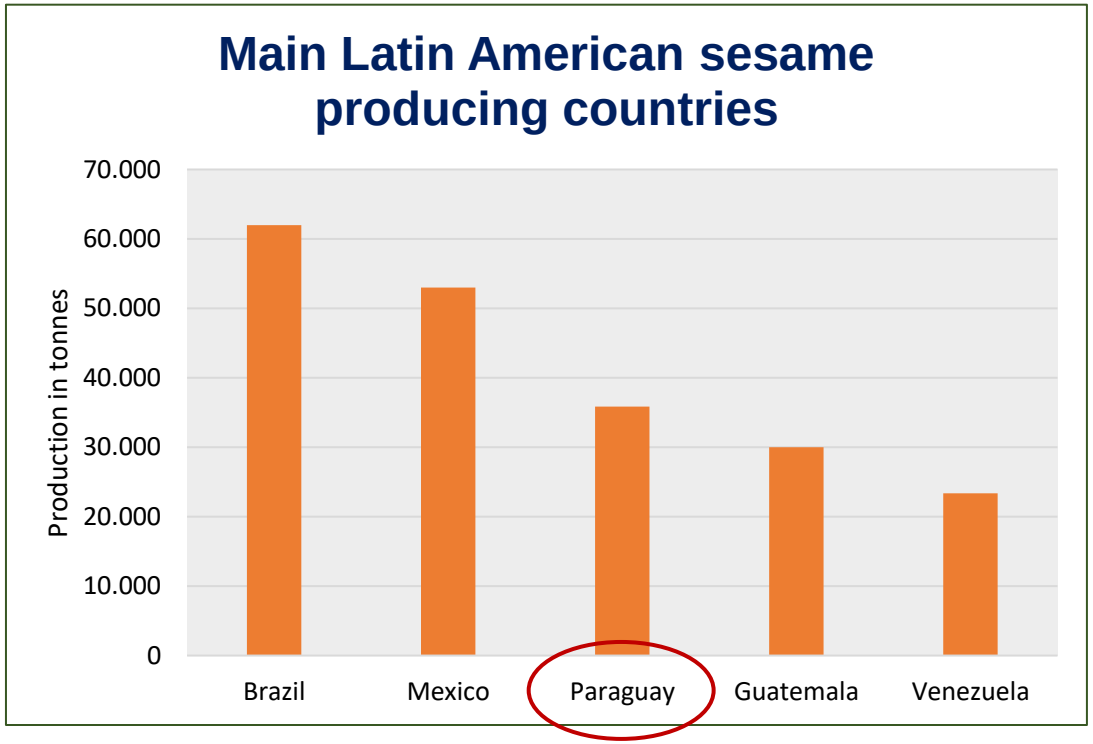
One of the highest oil content

- High unsaturated essential fatty acids
- Source of fiber, vitamins B, high biological value proteins
- Rich in antioxidants

Versatile ingredient: its usage has spread beyond bread and confectionary to a variety of food preparations.

Worldwide sesame production





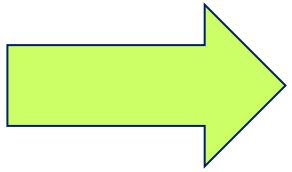
World production: > 6 million tons

Source: FAOSTAT, 2021

Sesame crop in Paraguay

Introduced in the mid-19th century

Commercial cultivation started at end of the 90’s as an alternative to cotton



A valuable cash crop for smallholder farmers

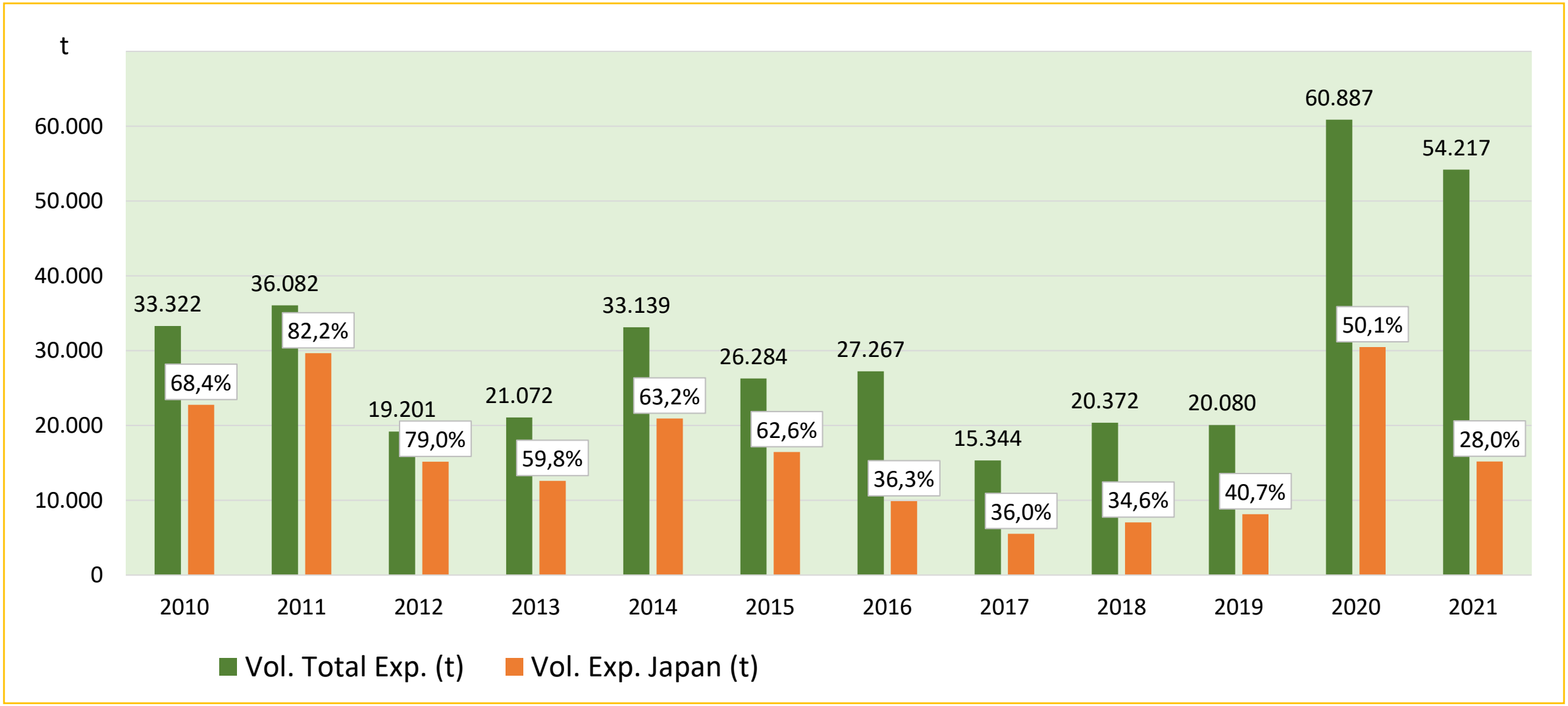
Cultivation started in San Pedro, and expanded rapidly to other regions, reaching 100,000 ha (247,105 acres) cultivated in the 2008/2009 season

Most of the sesame is produced by very small-scale producers ---> 2 Ha or less *(1 Ha = 2,47 acres)*

Source of income for more than 40,000 family farmers

manual production

Export volume of Paraguayan sesame (tons)



Source: Ministry of Trade & Industry

Problem – MRL violations

Numerous pesticide residue violations were detected during import inspections in Japan of sesame exported from Paraguay.

Imidacloprid

Nov. 2008 - Oct. 2010 Number of violations: 6

Carbaryl

Oct. 2009 - Jan. 2017 Number of violations:10

This had a profound impact on the hitherto thriving sesame exports.

Some likely reasons

Export rejection for exceeding Japan MRLs

→ No internationally established MRLs
No CODEX MRLs for sesame

→ Many default MRLs in Japan
(0.01 ppm)

→ Few plant protection products authorized.
No directions for use on the label.

↓

Huge problem

No pesticides registered in Paraguay with instructions for use on sesame

First measures taken

- **2015** – Ban on the use of carbaryl-based phytosanitary products in all stages of sesame cultivation

- **2016** – Improved pre-inspections (sampling of each container by SENAVE, analysis at SENAVE's Lab)


RESOLUCIÓN N° 554.-

"POR LA CUAL SE PROHIBE EL USO DE PRODUCTOS FITOSANITARIOS A BASE DE CARBARIL, EN TODAS LAS ETAPAS DE LA PRODUCCIÓN Y MANEJO POST COSECHA DEL SÉSAMO (*Sesamum indicum*)".

-1-

Asunción, 30 de julio de 2015.-

Que, por Memorando DICAO N° 113 del 04 de noviembre de 2014, la Dirección de Calidad, Inocuidad y Agrícola Orgánica presenta la justificación técnica y solicita la prohibición del uso de productos fitosanitarios a base de Carbaril en el cultivo de Sésamo (*Sesamum indicum*), a fin de controlar la calidad e inocuidad de los mismos.

RESOLUCIÓN N° 554.-

"POR LA CUAL SE APRUEBA EL PROTOCOLO DE BUENAS PRÁCTICAS AGRÍCOLAS PARA LA PRODUCCIÓN DE SÉSAMO (*Sesamum indicum*), DEL SERVICIO NACIONAL DE CALIDAD Y SANIDAD VEGETAL Y DE SEMILLAS (SENAVE)".

-1-

Asunción, 14 de agosto de 2017.

derivados de la contaminación de residuos de agroquímicos y contaminación que deriven de las fincas vecinas".

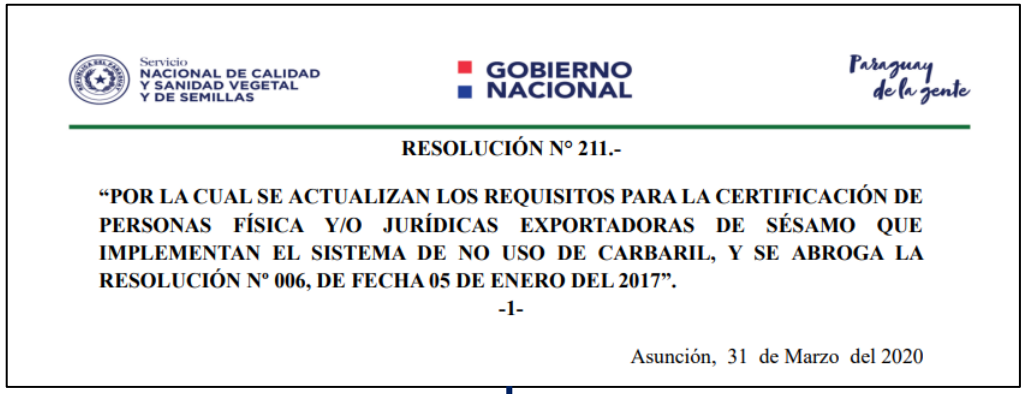
Humaitá 145 entre Independencia Nacional y Nuestra Señora de la Asunción
Edificio Planeta 1 – Piso 15
Telef. 445 769 / 441 54

- **2017** - Good Agricultural Practices (GAP) for sesame: general guideline

- **2017**- Company certification based on carbaryl non-use rule (2020 last updated)

  - Farmers registration
  - Collectors registration
  - Grower's commitment not to use carbaryl

  } Traceability



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RESOLUCIÓN N° 211.-

"POR LA CUAL SE ACTUALIZAN LOS REQUISITOS PARA LA CERTIFICACIÓN DE PERSONAS FÍSICA Y/O JURÍDICAS EXPORTADORAS DE SÉSAMO QUE IMPLEMENTAN EL SISTEMA DE NO USO DE CARBARIL, Y SE ABROGA LA RESOLUCIÓN N° 006, DE FECHA 05 DE ENERO DEL 2017".

-1-

Asunción, 31 de Marzo del 2020

Certified companies have been returned to the regular inspection regime in Japan

First achievement

- **2017**- INOPAR Project

INOPAR

Dec. 2017 – Aug. 2023

IMPROVING THE SAFETY OF AGRICULTURAL EXPORT PRODUCTS FROM SMALL-SCALE FARMERS

Objective: to prevent the recurrence of pesticide residue problems and improve the production of export crops by small-scale farmers that meet safety standards

- Dispatch of an expert from the Ministry of Health, Labor and Welfare of Japan
- Establishment of a working group – coordination and cooperation at all levels

Dec. 2017 – Aug. 2023

SPECIFIC GOALS

- Strengthening and expanding the laboratory's analytical capabilities.
- Providing training to growers.
- Implementing traceability.
- Conducting crop field trials / Establishing standard for use and MRLs

Crop field trials

To determine pesticide residue levels in or on raw agricultural commodities and are designed to reflect pesticide use patterns that lead to the highest possible residues[1].

Goal within the framework of the project

Define instructions for use of pesticides on sesame and establish maximum residue limits (MRLs) in accordance with Good Agricultural Practices in the use of pesticides, in order to apply for import tolerance (IT).

[1]*Organization for Economic Co-operation and Development (OECD), 2016*

Procedure for setting standard of use and MRLs in minor crops (1)

Prioritization of pesticides based on a study of their use situation.

- Verify the MRLs of the importing countries and make considerations about the probability of occurrence of problems.

Set the conditions for the crop field trials and carry out the trials.

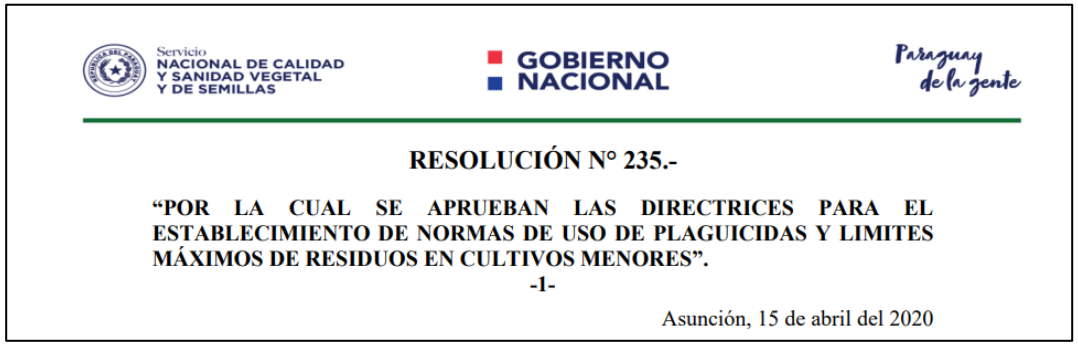
Calculate the highest residual concentration (HRC)

- Perform calculations with the OECD Calculator

Verify the compatibility of the HRC with the MRL of the importing country.

Approved by SENAVE regulation

Res. N° 235/2020



Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas

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Paraguay de la gente

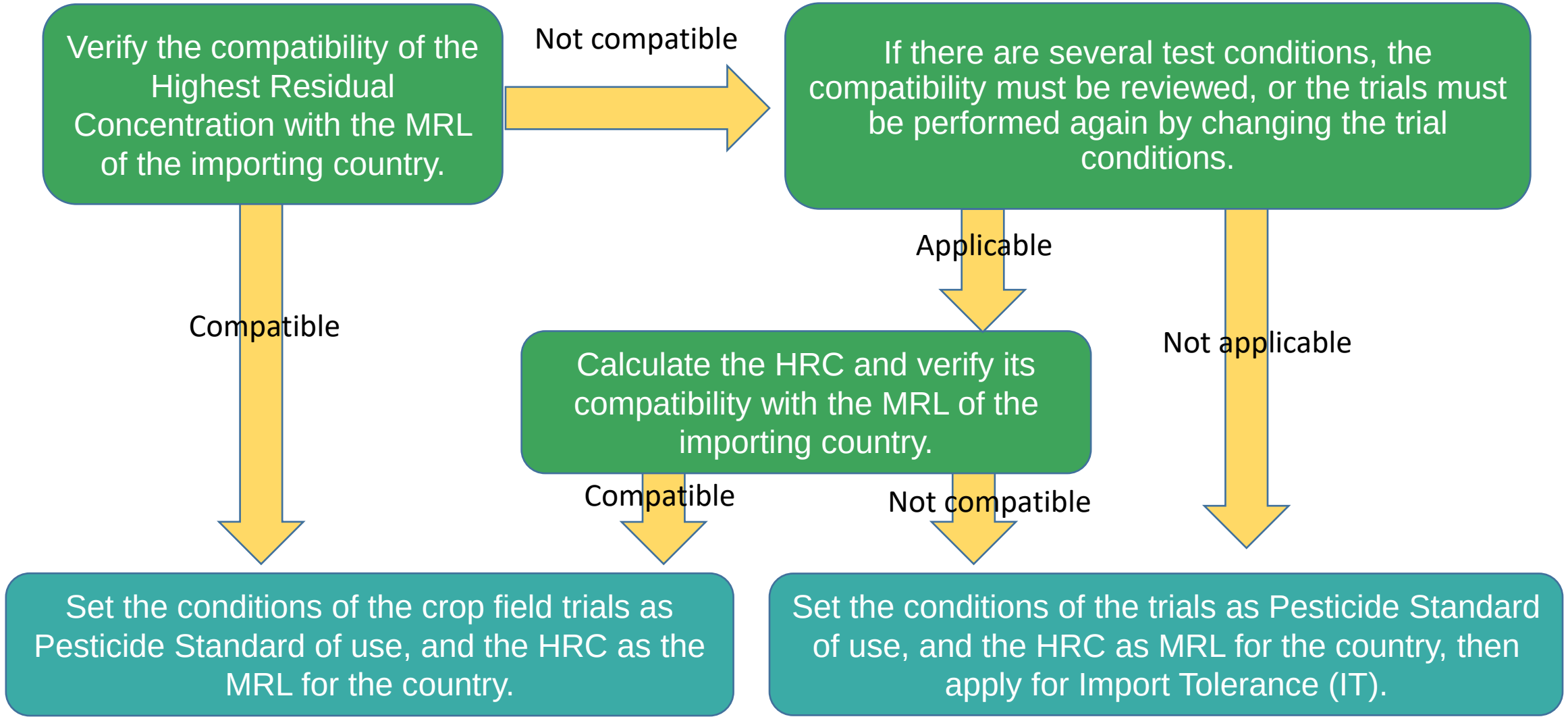
RESOLUCIÓN N° 235.-

"POR LA CUAL SE APRUEBAN LAS DIRECTRICES PARA EL ESTABLECIMIENTO DE NORMAS DE USO DE PLAGUICIDAS Y LIMITES MÁXIMOS DE RESIDUOS EN CULTIVOS MENORES".

-1-

Asunción, 15 de abril del 2020

Procedure for setting standard of use and MRLs in minor crops (2)



Pesticides used on Paraguayan sesame and their MRLs in Japan and the European Union (EU)

Surveys to
1800 farmers

Active ingredient	Type of agrochemical	Frequency of use (%)	EU MRL	Japan MRL
Glyphosate	Herbicide	54.4	0.1	40
Haloxyfop metil	Herbicide	47.6	0.01	0.01*
Clethodim	Herbicide	38.9	0.1	0.01*
Cypermethrin	Insecticide	20.9	0.2	0.1
Fipronil	Insecticide	20.1	0.005	0.01*
Emamectin benzoate	Insecticide	11.1	0.005	0.01*
Diuron	Insecticide	9.6	0.02	0.05
Thiamethoxam	Insecticide	9.6	0.02	0.02
Imidacloprid	Insecticide	8.8	0.01	0.05
Chlorpyrifos	Insecticide	8.7	0.01	0.05
Paraquat	Herbicide	7.4	0.02	0.05
Lufenuron	Insecticide	7.4	0.01	0.01*
Lambda-cyhalothrin	Insecticide	6.7	0.2	0.5
Tebuconazole	Fungicide	5.2	0.02	0.01*
Acetamiprid	Insecticide	4.5	0.01	0.01*
Methoxyfenozide	Insecticide	4.5	0.01	0.01*
Acephate	Insecticide	4.2	0.02	0.01*
Bifenthrin	Insecticide	3.0	0.02	0.01
Carbendazim	Fungicide	2.4	0.1	3
Azoxystrobin	Fungicide	2.2	0.01	0.01*
Teflubenzuron	Insecticide	2.2	0.02	0.01*
Thiodicarb	Insecticide	2.2	0.01	1
Carbaryl	Insecticide	0.3	0.05	0.01*

Pesticides included in the crop field trials

*default limit

Pesticides included in the trial

Prioritization of pesticides based on a study of their use situation.

Herbicides

- Haloxyfop-metil
- Clethodim

②

Insecticides

- Fipronil
- Carbaryl
- Emamectin benzoate
- Thiamethoxam
- Imidacloprid
- Chlorpyrifos
- Acetamiprid
- Novaluron

⑧

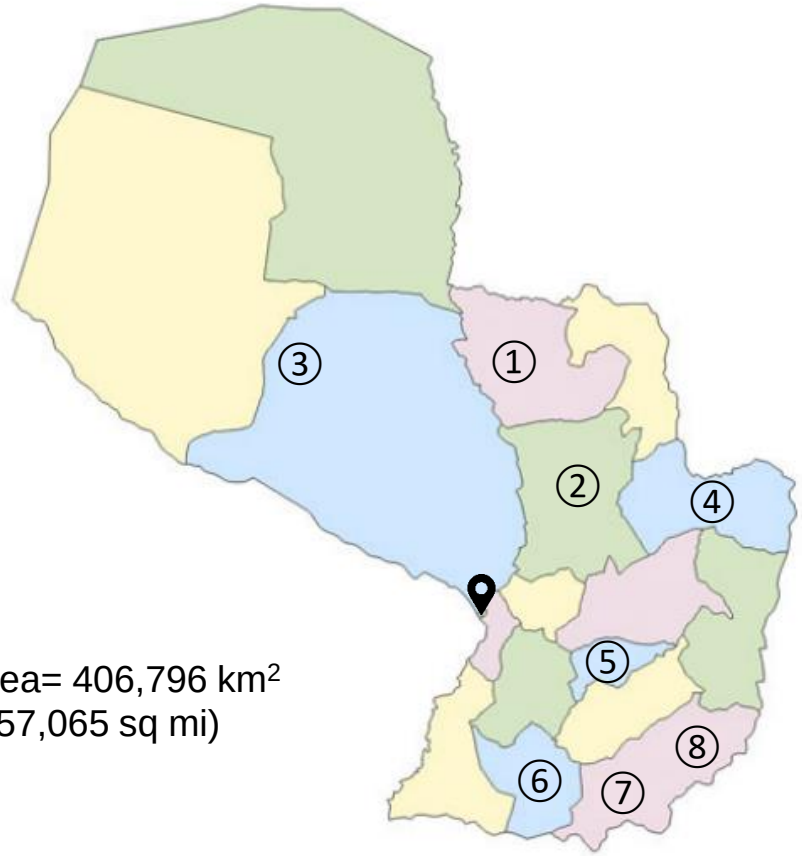
Fungicides

- Tebuconazole
- Azoxystrobin

②

Test sites: 8 different locations

Set the conditions for the crop field trials and carry out the trials.



Area= 406,796 km^2
(157,065 sq mi)

Name of experimental field	Department
1. Concepción	Concepción
2. Choré	San Pedro
3. Chaco	Pte. Hayes
4. Yhovy	Canindeyú
5. Natalicio Talavera	Guaira
6. San Juan Misiones	Misiones
7. Capitán Miranda	Itapúa
8. Tomas R. Pereira	Itapúa

Treatment

Three different treatments were established with application at two moments.

- 21 and 28 days before the cut
- 14 and 21 days before the cut
- 7 and 14 days before the cut

Preharvest interval

Analysis

At SENAVE's laboratory.

Determination of multi-residue in oilseeds by LC MS-MS

MRL Calculation/Data evaluation

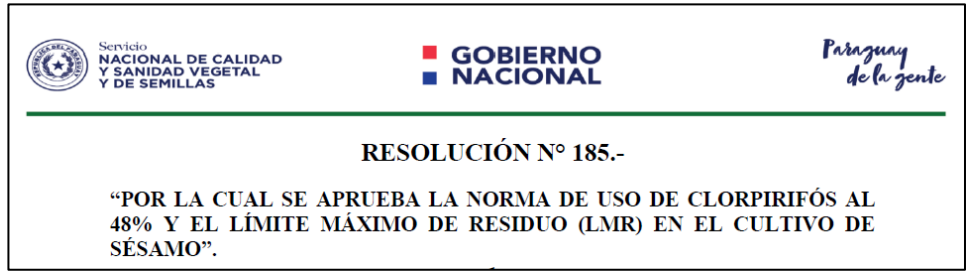
OECD MRL Calculator

Available data

Results

STANDARD OF USE FOR CHLORPYRIFOS 48% AND MRL IN SESAME CULTIVATION (RES. N° 185/21)

Product type:	**Concentrated emulsion 48%**
Dose rate:	**600 ml/ha**
Number of applications:	**2**
Preharvest intervals:	**7 days**
Time between applications:	**7 days**
Application method:	**Spray**
MRL:	**0.05 ppm**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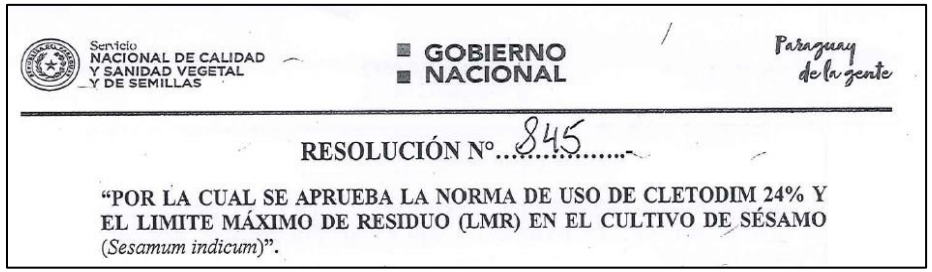
RESOLUCIÓN N° 185.-

"POR LA CUAL SE APRUEBA LA NORMA DE USO DE CLORPIRIFÓS AL 48% Y EL LÍMITE MÁXIMO DE RESIDUO (LMR) EN EL CULTIVO DE SÉSAMO".

CLETHODIM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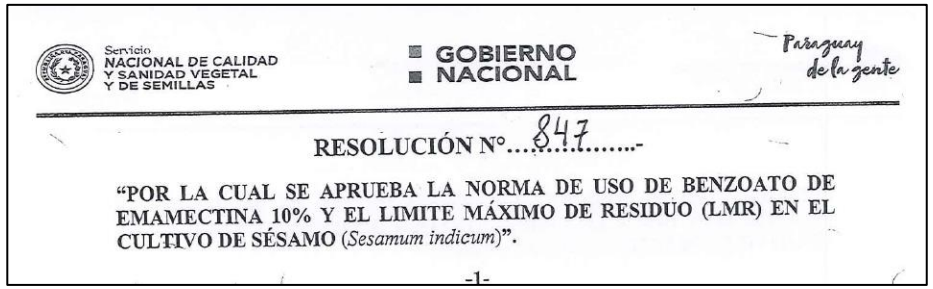
RESOLUCIÓN N°...845.....-

"POR LA CUAL SE APRUEBA LA NORMA DE USO DE CLETODIM 24% Y EL LIMITE MÁXIMO DE RESIDUO (LMR) EN EL CULTIVO DE SÉSAMO (*Sesamum indicum*)".

EMAMECTIN BENZOATE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GOBIERNO NACIONAL
Paraguay de la gente

RESOLUCIÓN N°...847.....-

"POR LA CUAL SE APRUEBA LA NORMA DE USO DE BENZOATO DE EMAMECTINA 10% Y EL LIMITE MÁXIMO DE RESIDUO (LMR) EN EL CULTIVO DE SÉSAMO (*Sesamum indicum*)".

-1-

WTO/SPS notifications

Notifying Member	Symbol and title	Distribution/Comments	Products covered	
Paraguay	G/SPS/N/PRY/33 Resolución "Por la cual se aprueba la norma de uso de cletodim 24% y el límite máximo de residuo (LMR) en el cultivo de sésamo (Sesamum... Notified document (1)	26/10/2022	HS code: 1207.40 - Sesamum seeds and other minor crops	
Paraguay	G/SPS/N/PRY/32 Resolución "Por la cual se aprueba la norma de uso de benzoato de emamectina 10% y el límite máximo de residuo (LMR) en el cultivo de... Notified document (1)	26/10/2022	HS code: 1207.40 - Sesamum seeds and other minor crops	
Paraguay	G/SPS/N/PRY/31 Resolución "Por la cual se aprueba la norma de uso de clorpirifós al 48% y el límite máximo de residuo (LMR) en el cultivo de sésamo"... Notified document (1)	15/12/2020	HS code: 1207.40 - Sesamum	
Paraguay	G/SPS/N/PRY/30 Directrices para el establecimiento de normas de uso de plaguicidas y límites máximos de residuos en cultivos menores (Guidelines for... Notified document (1)	22/01/2020	HS code 1207.40: Sesamum seeds and other minor crops	

WORLD TRADE ORGANIZATION

G/SPS/N/PRY/33

26 October 2022

(22-8032) Page: 1/2

Committee on Sanitary and Phytosanitary Measures Original: Spanish

NOTIFICATION

1.	**Notifying Member:** PARAGUAY **If applicable, name of local government involved:**
2.	**Agency responsible:** *Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas*, SENAVE (National Plant and Seed Quality and Health Service)
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** HS code: 1207.40 - Sesamum seeds and other minor crops
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** **[X] All trading partners** **[ ] Specific regions or countries:**
5.	**Title of the notified document:** *Resolución "Por la cual se aprueba la norma de uso de cletodim 24% y el límite máximo de residuo (LMR) en el cultivo de sésamo (Sesamum indicum)"* (Resolution approving the guidelines for the use of cletodim 24% and the maximum residue level (MRL) in sesamum (*Sesamum indicum*) crops) **Language(s):** Spanish **Number of pages:** 5 https://members.wto.org/crnattachments/2020/SPS/PRY/20_0496_00_s.pdf
6.	**Description of content:** The notified draft Resolution approves the guidelines for the use on sesamum crops of phytosanitary products formulated as cletodim 24%, which must be included on the labels of such products marketed in Paraguay. It also establishes the maximum residue level (MRL) for cletodim in sesamum.
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests.**
8.	**Is there a relevant international standard? If so, identify the standard:** **[X] Codex Alimentarius Commission (*e.g. title or serial number of Codex standard or related text*):** Codex Alimentarius Commission - Maximum Residue Limits (CAC/MRL) **[ ] World Organisation for Animal Health (OIE) (*e.g. Terrestrial or Aquatic Animal Health Code, chapter number*):** **[ ] International Plant Protection Convention (*e.g. ISPM No.*):** **[ ] None** **Does this proposed regulation conform to the relevant international standard?** **[X] Yes [ ] No**

	If no, describe, whenever possible, how and why it deviates from the international standard:
9.	**Other relevant documents and language(s) in which these are available:** Not applicable
10.	**Proposed date of adoption *(dd/mm/yy)*:** 45 days from the date of publication for public consultation on the official SENAVE website. **Proposed date of publication *(dd/mm/yy)*:** 45 days from the date of publication for public consultation on the official SENAVE website.
11.	**Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:** Immediately following adoption of the Resolution. **[X] Trade facilitating measure**
12.	**Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 15 November 2022 **Agency or authority designated to handle comments: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and email address (if available) of other body:** Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas (SENAVE) Address: Humaitá Nº 145 c/Ntra. Sra. de la Asunción, Asunción - Paraguay Fax: (+595 21) 445769/441549 Email: leticia.soria@senave.gov.py; maria.vera@senave.gov.py
13.	**Text(s) available from: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and email address (if available) of other body:** SENAVE website: https://www.senave.gov.py/proyectos-de-normativas-en-consulta

Next steps

STANDARD OF USE FOR AZOXYSTROBIN 20% AND TEBUCONAZOLE 25% AND MRLS

Request of Import Tolerance (IT)

If the MRL of the exporting country (Paraguay) is higher than that applied in Japan, the country can request to the MHLW to newly set MRLs or set MRLs higher than the corresponding Japan's MRLs.

Request CODEX to evaluate the study

There are no standards or MRLs for sesame. If there were, it could drastically prevent pesticide residue problems affecting trade between countries.

THANK YOU!

Laura Vera, MSc
Quality, Safety and Organic Agriculture Directorate (DICAO)
maria.vera@senave.gov.py

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