1. Spain

1.1. Objective and design of the national control programme

Responsibilities:

The elaboration and implementation of the national control programme involves the following units:

- The Sub-Directorate-General for Foreing Health of the Ministry of Health.
- The Sub-Directorate-General for Coordination of Alerts and Programming Official Control of the Spanish Agency for Food Safety and Nutrition (in Spanish AESAN).
- Control Units of the Autonomous Spanish Regions

Each unit has assigned its duties about coordination or execution within its scope.

AESAN is an autonomous body under the Ministry of Consumer Affairs, and acts as liaison between the Commission and the European Food Safety Authority (EFSA), and the Autonomous Communities (AA CC) which are the Competent Authorities for the execution of programmes at regional level.

For the development and implementation of the risk based "Annual National Programm", a Guidance on programming have been developed and approved in Spain. This document is aimed to support the Autonomous Control Units and the Foreing Health Unit in its duties on programming.

The national programme is made up of two subprogrammes based on the point where the samples are collected:

- market subprogramme, coordinated by AESAN;
- imports subprogramme, coordinated by MSCBS.

Official Controls on residues:

The National Pesticide Residues Control programme integrates controls carried out by the AA CC. AESAN is responsible for the coordination of control programme. The annual plans developed by the AA CC and coordinated by AESAN include monitoring of unauthorised products.

1.1.1.Objectives

To ensure that official controls are carried out in order not to place on the market food products treated by unauthorized pesticides.

To ensure that official controls are carried out in order not to place on the market food products with pesticide residues levels above those established in regulations in force, so they can pose a health risk for consumers.

1.1.2. Design of programmes

Staffs responsible for sampling are inspectors from the Autonomous Communities.

Those samples taken at the border inspection posts/points of entry are taken by staff from the General Directorate of Public Health.

Sample selection

- Data from consumers.
- $_{\odot}$ $\,$ The Spanish diet model for determining exposure to chemicals.
- Food intended for populations at risk (baby food).
 - Data from production.
 - Products with a high consumption in each region.

- Information from import programme.
- Information from the Plant Health of the Ministry of Agriculture services on recent inspections, prohibited use of pesticide, etc.
- The pattern of use of plant protection products (commonly used, time of application).
- Toxicity of the active substances.
- Recent changes in the MRL or withdrawal of authorisations for use/approval of active substances.
- Scope of accreditation of the laboratory/analytical capacity/resources.
- Non-compliant results obtained in previous years.
- Pesticide residues selection: In the national risk-based programming work, the Working Document SANCO / 12745/2013 is also taken into consideration, as it includes the pesticides that should be considered for inclusion in the national control programs to guarantee compliance with the maximum levels of pesticide residues in food of plant and animal origin.

Sample-pesticide residues combination

- Frequency of findings of residues of active substances in food products in reporting plans (national and EU) official control from prior years.
- RASFF notifications.
- The products listed in the Regulation on a Coordinated Multiannual Control Programme of the European Union for 2019, 2020 and 2021, aimed at ensuring the enforcement of MRLs pesticides in food of animal or plant origin and on them, and to assess the degree of consumer exposure to these residues.

1.2. Key findings, interpretation of the results and comparability with the previous year results

In order to get a better understanding of the information regarding the number of samples taken by Spain by number of inhabitants, it should be taken into account that the results sent to EFSA from Spain do not include those samples taken in primary production. Due to the Spanish administrative organization, samples taken in primary production are considered to be excluded from the scope of Regulation (EC) No. 396/2005.

1.2.1. Key findings

All of the samples programmed in the Pesticide Residues Monitoring and Control Program in products of plant and animal origin and baby food in Spain for 2019 have been collected.

In 2019 a total of 2314 samples were analysed for pesticide residues. All of the 2314 samples were objective samples.

Regarding results, the analysis of the 2314 samples lead to 299811 results.

The 1,38% of the analysed samples shown pesticide residues levels exceeding the EC-MRL. In particular, there have been 32 non-compliant samples that correspond to 38 non-compliant results, since there are samples that have tested positive for more than one substance. (e.g.: a sample from the group "other stone fruits", was positive to Clorotalonil, Deltametrin, Lambda-cihalotrina, Piraclostrobina and Tebuconazol)

None of the baby food samples, nor the cereal group samples were non-compliant. It is remarkable that there has been any non-compliant result within the cereal group, considering the amount of parameters analysed (18161 results within 126 samples).

The group of "Fruits and other vegetables" shows the higher number of Non-compliant results. The parameter confirmed in more samples in this group was Oxamyl, with 6 positive results, followed by Dimethoate, with 5 positive results. The greatest number of samples and analysed substances belong to this group, and 20 of the 21 pesticides detected, appeared within the group.

Regarding the groups "Products of animal origin", only one pesticide was detected (DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT)). This parameter was detected in 6 seafood samples.

The main results are detailed in the tables below:

Matrix	Total number of samples	Total number of results	Compliant samples	Samples with residues >MRL	% NC
Products of animal origin	447	6929	441	6	1.34%
Baby foods	93	8280	93	0	0%
Cereals	126	18161	126	0	0%
Fruits and other vegetables	1648	266444	1622	26	1.58%
Total	2314	299811	2282	32	1.38%

 Table SP.01: General summary

Matrix	Samples without residues detected	Samples with residues detected	Samples compliant due to the analytical method uncertainty	% With presence	% Without residues
Products of animal origin	431	16	1	3.6%	96.4%
Baby foods	78	15	2	16.1%	83.9%
Cereals	108	18	0	14.3%	85.7%
Fruits and other vegetables	916	732	18	44.4%	55.6%
Total	1533	781	21	33.7%	66.3%

1.3. Interpretation of the results

The results gathered in 2019 are highly satisfactory, on the one hand the sample program has been carried out according to the plan, and on the other hand the analyzed results shows an accurate and responsible management of pesticides and complies the current legislation as shown on the Table SP.01.

Although the presence of some pesticides have been detected in some babyfood samples, they were below the limit of MRL and all of them were compliant.

It is especially remarkable that there has been none non-compliant sample in the cereals food group.

All the laboratories have procedures to estimate analytical uncertainty, which is taken into account to decide any enforcement action. Document SANTE/11945/2015 is also considered.

Some new confirmation methods were implemented in Spanish laboratories in order to increase the number of pesticide residues measured and to bring down detection limits of some of them.

The results are detailed in Table

Matrix	Samples	Results	Pesticide	Frequency
Animal products	6	6	DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT)	1 1 4
Baby foods	0	0	-	0
Cereals	0	0	-	0
Fruits and other vegetable s	26	32	Acephate Acetamiprid Acrinathrin and its enantiomer Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) Chlorpropham Chlorpyrifos Clorotalonil DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) Deltametrin Dimethoate Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) Fluazifop-P Imazalil Imidacloprid Iprodione Lambda-cihalotrina Omethoate Oxamyl Piraclostrobina Pyraclostrobin	2 1 1 2 2 1 1 1 1 5 1 1 1 1 1 1 1 1 1 1
Total	32	38		38

Table SP.02: NC results. Summary

1.4. Comparability with the previous year results

In 2019 a total of 2314 samples were analysed for pesticide residues compared to a total of 2711 samples analysed in 2018, and 2273 samples analysed in 2017.

This year, the number of analysis dropped down.

Table SP.03: Comparability samples/results by year

Year	Total number of samples	Total number of results
2017	2773	419596
2018	2711	467443
2019	2314	299811

Table SP.04: Frequency of residue Chlorpyrifos by year

Year	Residue non- compliant more common	Number of samples analysed	Number of non- compliant	%	Product more common
2017	Chlorpyrifos	2773	7	0.25	Fruits and other vegetables (3 Beets / beet leaves)
2018	Chlorpyrifos	2346	18	0.77	Animal products
2019	Chlorpyrifos	1176	1	0.08	Fruits and other vegetables (1 Artichoke)

1.5. Non-compliant samples: possible reasons, ARfD exceedances and actions taken

1.5.1. Possible reasons for non-compliant samples

Table SP.05: Possible reasons for MRL non-compliance

This year is the first data collection for Spain reporting their data in the new SSD2 EFSA system. In order to make it as easy as possible for our data providers, information on mandatory SSD2 elements was only requested.

As the data element N.06.01. Conclusion of follow-up investigation (evalInfo.conclusion) is considered "Optional" in the current SSD2 guidance, we have not receive this information from some data providers.

This is why the number of "Unknown" is high.

Reasons for MRL non-compliance	Pesticide/food product ^(a)	Frequency ^(b)
Bad Practices.	Chlorpropham	2
	Chlorpyrifos	1
	Dimethoate	2
	Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil)	1
	Iprodione	<u> </u>
Pesticide misuses	Acetamiprid	1
	Pyraclostrobin	1
	Imazalıl	1
Unknown	DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT)	6
	Oxamyl	6
	Dimethoate	3
	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)	2
	Acephate	2
	Omethoate	1
	Fluazifop-P	1
	Piraclostrobina	1
	Tebuconazol	1
	Lambda-cihalotrina	1
	Clorotalonil	1
	Deltametrin	1
	Acrinathrin and its enantiomer	1
	Imidacloprid	1

1.5.2. Actions taken

Table	SP.06:	Actions	taken
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	Action taken	No. of non- compliant samples concerned	Comments	Residue/Product
Rapid Alert Notification		1		DIMETHOATE/ Kiwi
Follow-up investigatio ns initiated when there is suspicion of an irregularity		9		Acetamiprid / Escaroles Pyraclostrobin / Escaroles Chlorpyrifos / Artichokes Chlormequat (sum of chlormequat and its salts, expressed as chlormequat- chloride) / Lettuces Dimethoate / Lemons Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / Potatoes Imazalil / Mandarins Iprodione / Table Grapes Chlormequat (sum of chlormequat and its salts, expressed as chlormequat- chloride) / Lettuces
Administrat ive consequen ces imposed when there is evidence of an irregularity		10		Dimethoate / Artichokes Omethoate / Artichokes Dimethoate / Artichokes Dimethoate / Cherries Piraclostrobina / Other stone fruits Tebuconazol / Other stone fruits Lambda-cihalotrina / Other stone fruits Clorotalonil / Other stone fruits Deltametrin / Other stone fruits Imidacloprid / Chards
Follow-up (suspect) sampling of similar products, samples of same producer or country of origin		4		Chlorpropham / Lemons Chlorpropham / Oranges Fluazifop-P / Broccoli Oxamyl / Lettuces
Warnings		2		Acephate / Apples Acephate / Apples

	Action taken	No. of non- compliant samples concerned	Comments	Residue/Product
No actions taken or described		12		Acrinathrin and its enantiomer Tomatoes Oxamyl / Tomatoes Oxamyl / White cabbage Oxamyl Tomatoes Oxamyl Tomatoes Oxamyl Tomatoes Oxamyl Tomatoes Oxamyl Tomatoes Oxamyl Tomatoes DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Crab, sea-spiders DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Crab, sea-spiders DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Crab, sea-spiders DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Crab, sea-spiders DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Squid DDT (sum of p,p'-DDT, o,p'- DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) /

1.6. Quality assurance

Table SP.07: Laboratories p	participation in the	national control	program

Country	Laboratory	Accreditat	tion	Participation in
-	Name	Date	Body	proficiency tests or inter-laboratory tests
Spain	Laboratorio de la Agencia de Salud Pública de Barcelona (LASPB)	03.06.19	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio Regional de Salud Pública de Madrid	14.10.16	ENAC	FAPAS
Spain	Laboratorio de Salud Pública de Badajoz	24.05.13	ENAC	FAPAS, EUPT
Spain	Laboratorio de Salud Pública de Valencia	24.03.17	ENAC	FAPAS, EUPT
Spain	Laboratorio Agroalimentario de Burjasot-Valencia (Comunidad Valenciana)	02.11.99	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio KUDAM S.L	20.07.18	ENAC	FAPAS, EUPT, Test-Qual

Country	Laboratory	aboratory Accreditation		Participation in
-	Name	Date	Body	proficiency tests or inter-laboratory tests
Spain	Laboratorio Químico Microbiológico S.A., de Mairena de Aljarafe, de Sevilla	16.12.05	ENAC	EUPT, EUPT, Test-Qual
Spain	Laboratorio de Salud Pública de Almería (Junta de Andalucía)	11.01.19	ENAC	FAPAS, EUPT
Spain	Laboratorio COEXPHAL de El Viso (Almería)	16.02.18	ENAC	FAPAS, Test-Qual
Spain	Laboratorio Oficial de Salud Pública de la Delegación de Salud y Bienestar Social de Cuenca	02.12.11	ENAC	FAPAS, EUPT
Spain	Laboratorio Tecnológico de las Palmas de Gran Canarias (Gobierno de Canarias)		ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio Agroalimentario y de Sanidad Animal (LAYSA) de Murcia	21.07.15	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio Agrario Regional de Burgos (Junta de Castilla León)	18.05.01	ENAC	FAPAS, EUPT
Spain	Laboratorio Normativo de Salud Pública de Bilbao	19.09.18	ENAC	FAPAS, EUPT
Spain	Laboratorios ECOSUR, S.A.L.	21.06.19	ENAC	FAPAS, EUPT, Test-Qual
Spain	AINIA	20.12.96	ENAC	FAPAS, EUPT, Test-Qual
Spain	Analytica Alimentaria GmbH Sucursal en España	11.07.16	DAKKS y IAS	FAPAS, EUPT
Spain	Químico microbiológico S.A. Murcia	14.07.06	ENAC	EUPT, Test-Qual
Spain	Laboratorio de Salud Pública (Madrid Salud) Ayto.M	04.01.06	ENAC	EUPT
Spain	Laboratorio analítico bioclínico S.L	25.11.05	ENAC	FAPAS, EUPT, Test-Qual
Spain	Labs & technological Services AGQ, S.L.	29.03.19	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio de Salud Pública de Galicia	27.07.18	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio de Salud Pública en Bizkaia	05.07.19	ENAC	FAPAS
Spain	Laboratorio Regional del Gobierno de La Rioja	10.07.19	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio Agroalimentario de Zaragoza	19.07.19	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio agroalimentario de Cordiba	21.09.01	ENAC	

1.7. Processing Factors (PF)

In the table below the processing factors that were used by national competent authorities to verify compliance of processed products with EU MRLs are compiled.

Table SP.08: Processing factors overview

Pesticide (report name)	Unprocessed product (RAC)	Processed product	Processing factor
All pesticides	Wine grapes	Wine	1
All pesticides	Olives for oil production	Olive oil	5
All pesticides	Olives for oil organic production	Organic extra virgin olive oil	5