#### 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 (ASP)

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 ASP. AESAN is responsible for the coordination of control programme. The annual plans developed by the ASP 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.
- o 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 2020, 2021 and 2022, 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.

The 2020 data collection, is conditioned mainly by two important aspects:

- The pandemic cause by COVID-19 and the consequent issues in different social and economic sectors (lockdowns, market paralysis, etc.)
- The development of an application for data collection based on Commission and EFSA's premises, which would improve the quality of the data, reducing the possibility of entering erroneous and false data, introducing data mainly related to the full residue definition and the legal limits database.

The number of samples collected doesn't cover the schedule set for the EUCP programme, mainly due to the to the pandemic and the difficulty for providing information.

#### 1.2.1. Key findings

In 2020 a total of 1543 samples were analysed for pesticide residues. 97.9% of the samples were objective samples; 1.49% were selective samples and 0.58% were suspect sampling.

Regarding results, the analysis of the 1543 samples lead to 206179 results.

The 1.75% of the analysed samples shown pesticide residues levels exceeding the EC-MRL. In particular, there have been 27 non-compliant samples that correspond to 36 non-compliant results, since there are samples that have tested positive for more than one substance (e.g.: a sample from the group "Solanacea", was positive to *Chlorpyrifos, Spiroxamine (sum of isomers) and Triadimefon)* 

None of the baby food samples were non-compliant. The group of "Fruits and other vegetables" shows the higher number of Non-compliant results, but it's this is the group that comprehends 77% of the sample tested. The parameter that has been confirmed in more samples within this group was *Chlorpyriphos*, with 4 positive results, followed by *Iprodione*, with 3 positive results. The greatest number of samples and analysed substances belong to this group, and 33 of the 36 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 1 seafood samples, and it's related to "environmental contamination".

The main results are detailed in the tables below:

**Table SP.01**: General summary

Matrix	Total number of samples	Total number of results	Compliant samples	Samples with residues >MRL	% NC
Products of animal origin	177	8753	176	1	0.06%
Baby foods	62	7259	62	0	0%
Cereals	109	14013	107	2	0.13%
Fruits and other vegetables	1195	176154	1171	24	1.56%
Total	1543	206179	1516	27	1.75%

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	160	17	7	9.6%	90.4%
Baby foods	62	0	0	0%	100%
Cereals	83	26	3	23.85%	76.15%
Fruits and other vegetables	701	494	30	41.34%	58.66%
Total	1006	537	40	34.8%	65.2%

#### 1.3. Interpretation of the results

As mentioned previously, the pandemic situation has decreased the number of expected samples. Also, the residues has been set according to the Commision definitions, which may have led to a decrease of results, but it has improve the quality of the data reported considerably.

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

**Table SP.02**: NC results. Summary

Matrix	Samples	Results	Pesticide	Frequency
Animal products	1	1	DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'- TDE (DDD) expressed as DDT)	1
Baby foods	0	0	-	0
Cereals	2	2	Etofenprox Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)	1 1
Fruits and other vegetables	24	33	Chlorpyrifos Iprodione Acetamiprid Chlorfenapyr Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) Linuron Profenofos Imazalil (any ratio of constituent isomers) Boscalid Buprofezin Chlorpropham Diphenylamine Ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) Fenthion (fenthion and its oxigen analogue, their sulfoxides and sulfone expressed as parent) Pirimicarb Propamocarb (Sum of propamocarb and its salt expressed as propamocarb) Pymetrozine Pyraclostrobin Pyriproxyfen Spiroxamine (sum of isomers) Triadimefon Tolfenpyrad Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum	4 3 2 2 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Total	27	36	of R,S and S,R isomers)	36

#### 1.4. Comparability with the previous year results

In 2020 a total of 1543 samples were analysed for pesticide residues compared to a total of 2314 samples analysed in 2019, and 2711 samples analysed in 2018.

This year, the number of analysis dropped down.

The number of samples with Chlorpyrifos detected has been slightly increased compared with the previous year, as seen in Table SP 04.

Table SP.03: Comparability samples/results by year

Year	Total number of samples	Total number of results
2018	2711	467443
2019	2314	299811
2020	1543	206179

**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
2018	Chlorpyrifos	2346	18	0.77	Animal products
2019	Chlorpyrifos	1176	1	0.08	Fruits and other vegetables (1 Artichoke)
2020	Chlorpyrifos	2006	4	0.2	Fruits and other vegetables (2 Coffe beans/ 2 sweet peppers)

## 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 <sup>(a)</sup>	Frequency <sup>(b)</sup>
Accidental	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) / (Rice)	1
Environmental contamination	Etofenprox / <b>(Rye)</b> DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / <b>(Tuna)</b>	1 1
Other	Imazalil (any ratio of constituent isomers) / (Bananas)	1
Unknown	Acetamiprid (Tea/ Pomegrates) Boscalid / (Watercresses)	2 1 1
	Buprofezin / (Sweet peppers) Chlorfenapyr / (Dill seeds/Coriander leaves) Chlorpropham / (Oranges)	2
	Chlorpyrifos / (Coffee beans and Sweet peppers)	4
		1

Reasons for MRL non-compliance	Pesticide/food product <sup>(a)</sup>	Frequency <sup>(b)</sup>
	Ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide) / (Sesame seeds) Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / (Sweet)	1
	peppers) Iprodione / (Pumpkins)	1
	Lambda-cyhalothrin (includes gamma- cyhalothrin) (sum of R,S and S,R isomers) /	1
	(Tea)	1
	Pirimicarb / (Watercresses)	2
	Profenofos / (Oranges and Sweet Peppers) Propamocarb (Sum of propamocarb and its salt expressed as propamocarb) / (Globe	1
	Artichokes)	1
	Pymetrozine / (Coliflower)	1
	Pyraclostrobin / (Watercresses)	1
	Spiroxamine (sum of isomers) / (Sweet	
	peppers)	1
	Tolfenpyrad / <b>(Tea)</b> Triadimefon/ <b>(Tea)</b>	1

### 1.5.2. Actions taken

Table SP.06: Actions taken

Action taken	No. of non- compliant samples concerned	Comments	Residue/Product
Destruction of animals and/or products.	1		Chlorpyrifos / Sweet peppers
Follow-up (suspect) sampling	3		Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) / Rice Chlorpropham / Oranges Pymetrozine / Coliflower
Follow-up investigation	9		Boscalid / Watercresses DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) / Tuna Etofenprox / Rye Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / Potatoes Iprodione / Pumpkins Pirimicarb / Watercresses Propamocarb (Sum of propamocarb and its salt expressed as propamocarb) / Globe artichokes Pyraclostrobin / Watercresses

Action taken	No. of non- compliant samples concerned	Comments	Residue/Product
Other	17		Imazalil (any ratio of constituent isomers) / Bananas Acetamiprid / Pomegrates / Tea Buprofezin / Sweet Peppers Chlorfenapyr / Coriander leaves and Dill seeds Chlorpyrifos / Coffe beans, Sweet peppers. Ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide) / Sesame seeds Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / Sweet peppers Profenofos / Oranges, Sweet Peppers Spiroxamine (sum of isomers) / Sweet peppers Triadimefon / Sweet peppers Tolfenpyrad / Tea Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) / Tea
Unknown /	6		Diphenylamine / Pears Fenthion (fenthion and its oxigen analogue, their sulfoxides and sulfone expressed as parent) / Olives Iprodione / Pears Linuron / Spinaches and Chards Pyriproxyfen / Olives

## 1.6. Quality assurance

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

Country	Laboratory	Accredita	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

Country	Laboratory	Accredita	tion	Participation in	
_	Name	Date	Body	proficiency tests or inter-laboratory tests	
Spain	Laboratorio KUDAM S.L	20.07.18	ENAC	FAPAS, EUPT, Test-Qual	
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 Cordoba	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