30. Spain

30.1. Objective and design of the national control programme:

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

- The Sub-Directorate-General for Foreign 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 Program', a Guidance on programming have been developed and approved in Spain. This document is aimed to support the Autonomous Control Units and the Foreign 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.

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.

30.1.1. 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.

30.1.2. 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.
- 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 2021, 2022 and 2023, 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.

30.2. 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, has been influenced mainly by two aspects:

- The lockdowns and movement restrictions caused by COVID-19.
- The use of the national application for data collection, GEDA, based on Commission and EFSA's requisites, which improve the quality of the data by reducing the possibility of entering erroneous and false data, only allowing related to the full residue definition and the residues defined in the Commissions legal limits database.

30.2.1. Key findings:

In 2021 a total of 1905 samples were analysed for pesticide residues. 95.64% of the samples were objective samples and 4.36% were suspect sampling.

Regarding results, the analysis of the 1905 samples lead to 273292 results.

The 2.52% of the analysed samples shown pesticide residues levels exceeding the EC-MRL. In particular, there have been 48 non-compliant samples that correspond to 50 non-compliant results, since there are samples that have tested positive for more than one substance (e.g. a sample from Rice, was positive to *Acetamiprid* and *Tricyclazole)*.

None of the baby food samples were non-compliant, although a sample presented some detection (compliant with LMR). The group of "Fruits and other vegetables" shows the higher number of non-compliant results, but this is the group that comprehends 86.77% of the sample tested. The

parameter that has been confirmed in more samples within this group was *Imazalil (any ratio of constituent isomers)* with 16 positive results, followed by *Chlorpyrifos*, with 6 positive results. The biggest number of samples and analysed substances belong to this group, and 46 of the 50 pesticides detected, appeared within the group.

Regarding the groups "Products of animal origin", only one sample presented residues: "Honey-comb". The residues detected were *Fluvalinate (sum of isomers) and Coumaphos*.

The main results are detailed in Table 190 and Table 191

Table 190: General summary – part 1

Matrix	Total number of samples	Total number of results	Compliant samples	Samples with residues >MRL	% NC
Products of animal origin	118	5762	117	1	0.85%
Baby foods	37	4829	37	0	0%
Cereals	97	14157	96	1	1.03%
Fruits and other vegetables	1653	248544	1607	47	2.84%
Total	**1905**	**273292**	**1857**	**49**	**2.57%**

Table 191: General summary – part 2

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	114	4	2	3.39%	96.61%
Baby foods	36	1	0	2.70%	97.30%
Cereals	79	18	0	18.56%	81.44%
Fruits and other vegetables	907	746	27	45.13%	54.87%
Total	**1136**	**769**	**29**	**40.37%**	**59.63%**

30.2.2. Interpretation of the results

Although the number of samples is slightly higher than 2020, it doesn't reach the volume of samples collected in 2018. 2021 had been a year marked by lockdowns and movement restriction due to covid-19; this could be one of the reasons of the amount collected.

The residues have been set according to the Commission definitions, which may have led to a decrease of results, but it has improved 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/12682/2019 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 192.

Table 192: NC results. Summary

Matrix	Samples	Results	Pesticide	Frequency
Animal products	1	2	Coumaphos.	1
			Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate.	1
Baby foods	0	0	--	0
Cereals	1	2	Acetamiprid	1
			Tricyclazole	1
Fruits and other vegetables	47	47		3
			Chlorfenapyr	6
			Chlorpyrifos	1
			Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram)	2
			Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil)	1
			Fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)	1
			Flutriafol	2
			Formetanate: Sum of formetanate and its salts expressed as formetanate(hydrochloride)	1
			Hexaconazole	1
			Imazalil (any ratio of constituent isomers)	16
			Iprodione	3
			Methiocarb (sum of methiocarb and methiocarb sulfoxide and sulfone, expressed as methiocarb)	1
			Oxamyl	1
			Profenofos	1
			Propiconazole (sum of isomers)	4
			Proquinazid	1
			Tetraconazole	1
			Triflumizole Triflumizole and metabolite FM-6-1(N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetamidine), expressed as Triflumizole	1
Total	49	50		50

30.2.3. Comparability with the previous year results:

In 2021, a total of 1905 samples were analysed for pesticide residues compared to a total of 1543 samples analysed in 2020, and the 2314 samples analysed in 2019.

This year, the number of analyses has increased slightly comparing with the amount taken in 2020 (pandemic year).

Table 193: Comparability samples/results by year

Year	Total number of samples	Total number of results
2018	2,711	467,443
2019	2,314	299,811
2020	1,543	206,179
2021	1,905	273,292

The number of samples with ***Chlorpyrifos*** detected has slightly increased compared with the previous year, as seen in Table 194.

Table 194: Frequency of residue ***chlorpyrifos*** by year

Year	Residue non-compliant more common	Number of samples analysed	Number of non-compliant	%	Product more common
2019	Chlorpyrifos	1,176	1	0.08	Fruits and other vegetables (1 Artichoke)
2020	Chlorpyrifos	2,006	4	0.2	Fruits and other vegetables (2 Coffe beans/ 2 sweet peppers)
2021	Chlorpyrifos	3,057	6	0.2	Fruits and other vegetables (1 Coffe beans/ 5 oranges)

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

30.3.1. Possible reasons for non-compliant samples

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 received this information from some data providers.

This is the reason for being high the number of 'unknown'.

Table 195: Possible reasons for MRL non-compliance

Reasons for MRL non-compliance	Pesticide/food product[(a)]	Frequency[(b)]
Environmental contamination	Oranges / ***Chlorpyrifos***	1
Natural occurrence	Bananas / ***Imazalil (any ratio of constituent isomers)***	1
Cross contamination: spray drift or other accidental contamination	Cauliflower/ ***Fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)***	1
Good Agricultural Practice (GAP) not respected: use of an approved pesticide not authorised on the specific crop	Apple / ***Iprodione***	1
Good Agricultural Practice (GAP) not respected: use of	Oranges / ***Chlorpyrifos***	3

an approved pesticide, but application rate, number of treatments, application method or PHI not respected		
Residues resulting from other sources than plant protection product (e.g. biocides, veterinary drugs, bio fuel)	Honey comb / ***Coumaphos***	1
	Honey comb / ***Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate***	1
Use of a pesticide on food imported from third countries for which no import tolerance was set	Grapefruit / ***Tetraconazole***	1
Other	Bananas / ***Imazalil (any ratio of constituent isomers)***	15
	Organic Aubergines / ***Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil)***	1
	Melon / ***Iprodione***	1
	Sweet Pepper/ ***Hexaconazole***	1
	Sweet Pepper/ ***Proquinazid***	1
	Table Grapes / ***Methiocarb (sum of methiocarb and methiocarb sulfoxide and sulfone, expressed as methiocarb)***	1
Unknown	Organic Rice/ ***Tricyclazole***	1
	Organic Rice/ ***Acetamiprid***	1
	Chives/ ***Formetanate: Sum of formetanate and its salts expressed as formetanate(hydrochloride)***	2
	Coffe beans/ ***Chlorpyrifos***	1
	Lemons/ ***Propiconazole (sum of isomers)***	3
	Mandarines/ ***Propiconazole (sum of isomers)***	1
	Oranges/ ***Chlorpyrifos***	1
	Oranges/ ***Profenofos***	1
	Potatoes/ ***Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil)***	1
	Cucumbers/ ***Oxamyl***	1
	Sweet Pepper/ ***Chlorfenapyr***	1
	Pitahaya/ ***Iprodione***	1
	Tomatoes / ***Chlorfenapyr***	2
	Table grapes / ***Triflumizole Triflumizole and metabolite FM-6-1(N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetamidine), expressed as Triflumizole***	1
	Table grapes / ***Flutriafol***	1

30.3.2. Actions taken:

Table 196: Actions taken

Action taken	No. of non-compliant samples concerned	Residue/Product
Administrative consequences	2	Proquinazid***/ Sweet pepper*** Triflumizole Triflumizole and metabolite FM-6-1(N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetamidine), expressed as Triflumizole / ***Table grapes***
Follow-up action due to a residue of a pesticide detected in a EU sample, which is not approved for use in the EU territory	1	Tetraconazole/ ***Pomegrate***
Follow-up (suspect) sampling	1	Methiocarb (sum of methiocarb and methiocarb sulfoxide and sulfone, expressed as methiocarb)/ ***Table grapes***
Follow-up investigation	13	Acetamiprid/ ***Organic rice*** Fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)/ ***Cauliflowers*** Propiconazole (sum of isomers) / ***Lemons*** Propiconazole (sum of isomers) / ***Mandarins*** Iprodione / ***Apples*** Chlorpyrifos / ***Oranges*** Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / ***Potatoes*** Hexaconazole / ***Sweet Peppers*** Imazalil (any ratio of constituent isomers) / ***Bananas*** Flutriafol / ***Table grapes***
Lot not released on the market	3	Tricyclazole / ***Organic Rice*** Chlorpyrifos / ***Coffee beans*** Profenofos / ***Oranges***
Other	18	Imazalil (any ratio of constituent isomers) / ***Bananas*** Fipronil (sum Fipronil and sulfone metabolite (MB46136) expressed as Fipronil) / **Organic Aubergines** Oxamyl / ***Cucumbers*** Chlorfenapyr / ***Tomatoes***
Rapid Alert Notification	6	Chlorpyrifos / ***Oranges*** Coumaphos / ***Honey comb*** Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate / ***Honey comb***

		Chlorfenapyr / ***Sweet Peppers*** Iprodione / ***Pitahaya (dragon fruit)*** Dithiocarbamates (Dithiocarbamates expressed as CS2, including Maneb, Mancozeb, Metiram, Propineb, Thiram and Ziram) / ***Cultivated funghi*** Chlorfenapyr / ***Tomatoes***
Lot recalled from the market	2	Chlorpyrifos / ***Oranges***
Movement restriction	2	Formetanate: Sum of formetanate and its salts expressed as formetanate(hydrochloride) / ***Spring onions and chives.***
Warnings	1	Iprodione / ***Melon***

30.4. Quality assurance

Table 197: Laboratories participation in the national control program

Country	**Laboratory**	**Accreditation**		**Participation in proficiency tests or inter-laboratory tests**
	Name	**Date**	**Body**	
Spain	AINIA. ASOCIACIÓN DE INVESTIGACIÓN DE LA INDUSTRIA AGROALIMENTARIA	20/12/1996	ENAC	FAPAS, EUPT, Test-Qual
Spain	CENTRO NACIONAL DE TECNOLOGÍA Y SEGURIDAD ALIMENTARIA- CNTA	12/06/1997	ENAC	
Spain	LABORATORIO DE SAÚDE PÚBLICA DE GALICIA. Laboratorio de Lugo	10/07/1998	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO REGIONAL DEL GOBIERNO DE LA RIOJA	28/05/1999	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIOS AGROALIMENTARIO Y ENOLÓGICO DE LA GENERALITAT VALENCIANA.	22/10/1999	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO DE SALUD PÚBLICA DE BIZKAIA	04/02/2000	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO REGIONAL DE SALUD PÚBLICA DE MADRID	18/02/2000	ENAC	FAPAS
Spain	LABORATORIO DE SALUD PÚBLICA (MADRID SALUD). AYUNTAMIENTO DE MADRID	02/06/2000	ENAC	EUPT
Spain	ASOCIACIÓN EMPRESARIAL DE INVESTIGACIÓN. CENTRO TECNOLÓGICO NACIONAL DE LA CONSERVA (C.T.C.)	29/06/2000	ENAC	
Spain	LABORATORIO DE LA AGENCIA DE SALUD PÚBLICA DE BARCELONA	21/07/2000	ENAC	FAPAS, EUPT, Test-Qual
Spain	Laboratorio KUDAM S.L.U.	24/05/2002	ENAC	FAPAS, EUPT, Test-Qual
Spain	FItosoil Laboratorios S.L	03/10/2003	ENAC	

Spain	LABORATORIO DE SALUD PÚBLICA DE ALMERÍA	08/09/2005	ENAC	FAPAS, EUPT
Spain	LABORATORIO QUÍMICO MICROBIOLÓGICO. MURCIA	14/07/2006	ENAC	EUPT, Test-Qual
Spain	Laboratorio Regional: AGQ LABS: Labs & Technological Services AGQ, S.L. (Sevilla)	19/01/2007	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO AGROALIMENTARIO Y DE SANIDAD ANIMAL DE MURCIA	16/10/2009	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO AGROAMBIENTAL DE ARAGON	18/12/2009	ENAC	FAPAS, EUPT, Test-Qual
Spain	INSTITUTO TECNOLÓGICO DE CANARIAS	21/10/2011	ENAC	FAPAS, EUPT, Test-Qual
Spain	LABORATORIO DE SALUD PÚBLICA DE CUENCA	02/12/2011	ENAC	FAPAS, EUPT
Spain	LABORATORIOS APINEVADA, S.L.	06/07/2012	ENAC	
Spain	LABORATORIO DE SALUD PÚBLICA DE BADAJOZ	24/05/2013	ENAC	FAPAS, EUPT
Spain	LABORATORIO AGRARIO REGIONAL DE LA CONSEJERÍA DE AGRICULTURA Y GANADERÍA DE LA JUNTA DE CASTILLA Y LEÓN	28/11/2014	ENAC	FAPAS, EUPT
Spain	ANALYTICA ALIMENTARIA GMBH	15.02.2021	DAKKS	FAPAS, EUPT

30.5. 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 198: 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

30.6. Notified residues vs Accepted residues. Pesticides excluded from the EU report.

AESAN have received the analysis carried out in 1905 samples, and only 1898 samples will be included in the European report.

Pesticides samples reported	1.905
Pesticides samples reported included in report	**1.898**

Those 7 samples not included in the report are related with fish and seafood products, which are not in the scope of this report.

Regarding the residues notified, AESAN have received and forwarded to EFSA 273.292 residues, from which only 270.113 had been included in the European report in the first instance.

Pesticide results reported	**273.292**
Pesticides results reported included in report	**270.113**

There are 3179 residues analysed and notified that had been excluded from the report. None of the residues excluded were positive or non-compliant. The analysis of the reason for rejection showed that:

Reason for exclusion	**Number of residues**
Only the components of the Residue Definition are reported	1144
Wrong code selected to report the residue in the national application used to collect samples	1965
Residues related to Fish and seafood products	70
Total	**3179**

Out of the 1965 with the wrong code selected in the application where all the Spanish data providers, record their samples, the residues with the wrong code selected where:

Residue reported	***Total samples***
Boscalid	**1**
Carboxin	**2**
Chlorpyrifos-methyl	**58**
De-ethyl-bupirimate	**375**
Diclofop-Methyl	**138**
Gibberellic acid	**16**
Imazalil	**95**
Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)	**2**
Pencycuron	**1254**
Procymidone	**2**
Propyzamide	**2**
Sum of diclofop-methyl, diclofop acid and its salts, expressed as diclofop-methyl (sum of isomers)	**19**
Thiabendazole	**1**
Total general	**1965**