30. Spain

30.1. Objective and design of the national control programme:

Responsibilities:

The following areas participate in the preparation and execution of the national control program:

- The general sub directorate of foreign health of the Ministry of Health, consumer affairs and social welfare (*the Spanish acronyms is MSCBS*)
- The general sub directorate for official control and alerts of the Spanish Agency for Food Safety and Nutrition Autonomous Organization (*the Spanish acronyms is AESAN OA*).
- The control units of the regional competent authorities (*the Spanish acronyms is CCAA*).

Each unit has assigned coordination or execution functions within its scope.

The AESAN OA is an autonomous body attached to the ministry of consumer affairs and acts as a link between the European Commission, the European Food Safety Authority (EFSA) and the regional competent authorities (CCAA), which are the responsible for the execution of the programs at regional level.

For the development and implementation of the "Annual National Programme" based on risk, a Programming Guide has been developed and approved in Spain. This document aims to support the autonomous control units and the foreign health unit in their programming functions.

The national program is made up of two sub-programs, which are based on the point at which the samples are collected:

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

Official controls on pesticides:

The national pesticide residue control program include the controls carried out by the CCAA, acting the AESAN OA as coordinator. The annual plans developed by the CCAA and coordinated by AESAN OA include supervision of unauthorized products.

30.1.1. Objectives:

The objectives of the national control plan are:

- To ensure that official controls are carried out to avoid to place in market food products treated with unauthorized pesticides.
- To ensure that official controls are carried out in order to avoid to place in market food products with pesticide residue levels higher than those established by current regulations, which may pose a risk to the health of consumers.

30.1.2. Design of programmes:

Those responsible for sampling are the inspectors of the regional competent authorities.

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

The selection of samples is based on:

- Consumer data: Spanish diet model to determine exposure to chemical products; foods intended for populations at risk (baby foods).

- Production data.
- 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.

The combination of sample-pesticide residues is based on:

- 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 Implementing Regulation (EU) 2021/601 of the Commission, 13th of April 2021, concerning a concerning a coordinated multiannual control programme of the Union for 2022, 2023 and 2024 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

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

This report includes the pesticide residues analysed during the year 2022 within the framework of the monitoring and control program for pesticide residues in food. These data have been provided by the Health affairs and Public Health services of the regional competent authorities and by the General Sub-directorate of foreign affairs.

Within the multiannual national control program for pesticides residue, it had been analysed the phytosanitary residues that the different laboratory entities have been able to determine, based on legal requirements defined in the legislation and the available detection methodology.

Food matrices have been categorized in this report following the classification settled in Annex I, of Regulation (EC) 396/2005, (which is defined in Regulation (EC) 2018/62), as well as the standardized nomenclature for the classification and description of EFSA´s FOODEX2, following the standards established by said authority.

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

Pesticide residue control data for the year 2022 have been collected in two modalities:

- The main route, the application developed by the official control and alerts general sub-directorate which name is "GEDA". This application has been developed to standardize and facilitate the collection of data, thus generating a database that allows the management of information. 92.82% of the data received have been sent using this application.
- The second option, the tool provided by EFSA for manual data collection: "EFSA XML TOOL". This tool, in Excel format, allows the introduction of information by means of codes defined by EFSA, collected in different catalogues, and facilitates the creation of XMLs for direct submission to the EFSA platform. Through this system, 7.08% of the data were collected.

The data is received following the scheme designed by the European Security Authority Food (EFSA); the "Standard Sample Description 2" (SSD2). This scheme defines the structure in which the information must be described, which is introduced using a controlled terminology (catalogues that codify each possible definition, to harmonize criteria), and allows to follow validation rules to guarantee the quality of the data provided. This allows the harmonization of the data received by EFSA for subsequent analysis. This scheme is transmitted to EFSA in XML format to the Data Collection Framework (DCF).

30.2.1. Key findings:

In 2022 a total of 1743 samples were analysed for pesticide residues within the framework of the monitoring and control program for pesticide residues in food. The analysis of those **1743** samples lead to 292340 results.

The **0.75%** of the analysed samples shown pesticide residues levels exceeding the EC-MRL. In particular, there have been 13 non-compliant samples that correspond to 16 non-compliant results, since there are samples that have tested positive for more than one substance (e.g. a Honey sample, was positive to *Chlorfenvinphos, Coumaphos* and *Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate)*.

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 this is the group that comprehends 78.37% of the sample tested. The parameter that has been confirmed in more samples within this group was *Acetamiprid and Diflubenzuron* with 2 positive results each one. The biggest number of samples and analysed substances belong to this group, and 10 of the 16 pesticides detected, appeared within the group.

Regarding the groups "Products of animal origin", three samples presented residues; 2 fish products, and 1 honey product.

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	152	11940	149	3	1.97 %
Baby foods	26	3162	26	0	0 %
Cereals	117	20043	117	0	0 %
Fruits and other vegetables	1448	257195	1438	10	0.69 %
Total	**1743**	**292340**	**1730**	**13**	**0.75 %**

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	11940	4	0	2.63 %	97.37 %
Baby foods	3162	0	0	0 %	100 %
Cereals	20043	11	1	9.4 %	90.60 %
Fruits and other vegetables	257195	603	15	41.64 %	58.36 %
Total	**292340**	**618**	**16**	**35.46 %**	**64.54 %**

From the 1743 samples taken;

- **97.71%** of the samples were objective samples,
- **0.06%** of the samples were selective samples,
- **2.24%** were suspect sampling.

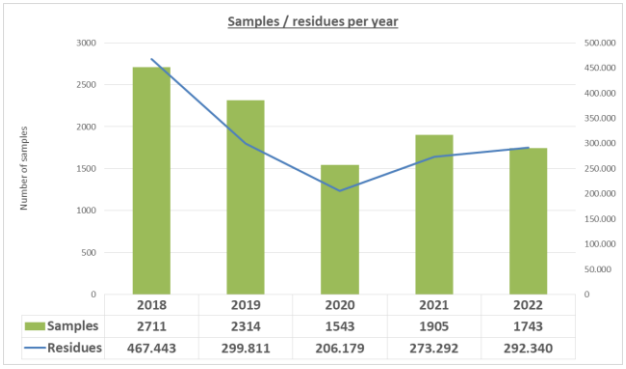
Samples, had been collected in the framework of the following legal references:

- Regulation (EC) No 396/2005 (amended) → **99.66%** of the samples;
- Commission Directive (EC) No 125/2006 and 2006/141/EC → **0.17%**
- Commission Implementing Regulation (EU) 2019/1793 → **0.17%**

Below, you can see how the samples sent had been scheduled and taken.

- Official (National and EU) programme → **20,54%**
- Official (EU) programme → **34,88%**
- Official (National) programme → **44,58%**

30.2.2. Interpretation of the results



The amount of samples received is slightly lower than previous years, as shown in the graphic.

But, in other hand, the amount of residues tested is slightly higher than previous years, which could be interpreted as an improvement of the analysis of the sample taken.

91.11% of the samples taken were of Spanish origin while the rest of the samples were from third countries and European countries. Related with the non-compliances, 12 out of 13 samples were Spanish, and just 1 from a third country.

The quality of the data sent to EFSA has improved because the AESAN OA application (called GEDA) has been adapted to the latest EFSA's requirements, that only allow the reporting of

substances that are part of the of the legal residue definitions described by the European Commission. Perhaps for this reason, some autonomous communities may not have been able to report all the substances analysed by their laboratories (part of the sum).

To decide on any compliance action, all laboratories have procedures for estimating analytical uncertainty. The SANTE/11312/2021 document is also considered.

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

The results are detailed in the Table shown below:

Table 192: NC results. Summary

Matrix	Samples	Results	Pesticide	Frequency
Animal products	3	6	Acrinathrin Chlorfenvinphos Coumaphos DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT) Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate	1 1 2 1 1
Baby foods	0	0	--	0
Cereals	0	0	--	0
Fruits and other vegetables	10	10	Acetamiprid Anthraquinone Bifenthrin (sum of isomers) Chlorfenapyr Diflubenzuron Ethirimol Lenacil Propyzamide	2 1 1 1 2 1 1 1
Total	13	16		16

30.2.3. Comparability with the previous year results:

In 2022, a total of 1743 samples were analysed for pesticide residues compared to a total of 1905 samples analysed in 2021, and the 1543 samples analysed in 2020.

This year, the number of analyses has decreased slightly comparing with the amount taken in 2021.

Table 193: Comparability samples/results by year

Year	Total number of samples	Total number of results
2019	2,314	299,811
2020	1,543	206,179
2021	1,905	273,292
2022	**1,743**	292,340

Chlorpyrifos has not been detected in the sample tested in 2022, as seen in Table 194. The residues checked were:

- Chlorpyrifos.
- Chlorpyrifos-methyl.
- Sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl.

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
2020	Chlorpyrifos	1,041	4	0.2	Fruits and other vegetables (2 Coffe beans/ 2 sweet peppers)
2021	Chlorpyrifos	1,720	6	0.2	Fruits and other vegetables (1 Coffe beans/ 5 oranges)
2022	Chlorpyrifos	1,632	0	0	--

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 the high number of 'unknown' conclusion.

Table 195: Possible reasons for MRL non-compliance

Reasons for MRL non-compliance	Pesticide/food product[a]	Frequency[b]
Environmental contamination	Acrinathrin/ **Honey** Chlorfenvinphos/ **Honey** Coumaphos/ **Honey** Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate/ **Honey**	2
Good Agricultural Practice (GAP) not respected: use of an approved pesticide not authorised on the specific crop	Diflubenzuron/ **Tigernuts** Ethirimol/ **Spinaches**	3
Unknown	Acetamiprid/ **Kaki/ Persimmon** Anthraquinone/ **Mate infusion material** Bifenthrin (sum of isomers)/ **Kaki/ Persimmon** Chlorfenapyr/ **Tomatoes** DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT)/ **Fish product** Lenacil/ **Spinaches**	7
Other	Propyzamide/ **Celery**	1

30.3.2. Actions taken:

Table 196: Actions taken

Action taken	No. of non-compliant samples concerned	Residue/Product
Administrative consequences	1	Lenacil/ **Spinaches**
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	10	Propyzamide/ **Celery** Acetamiprid/ **Kaki/ Persimmon** Bifenthrin (sum of isomers)/ **Kaki/ Persimmon** Diflubenzuron/ **Tigernuts** Ethirimol/ **Spinaches** Acrinathrin/ **Honey** Chlorfenvinphos/ **Honey** Coumaphos/ **Honey** Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate/ **Honey** Chlorfenapyr/ **Tomatoes** DDT (sum of p,p'-DDT, o,p'-DDT, p-p'-DDE and p,p'-TDE (DDD) expressed as DDT)/ **Fish product**
Follow-up (suspect) sampling	1	Diflubenzuron/ **Tigernuts**
Lot not released on the market	1	Anthraquinone/ **Mate infusion material**

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	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

30.5. Processing Factors (PF)

In the table below you can find 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	3
All pesticides	Olives for oil organic production	Organic extra virgin olive oil	3
All pesticides	Rye	Rye Flour	2,4

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

AESAN have received the analysis carried out in 1743 samples, and only 1737 samples will be included in the European report.

Pesticides samples reported	**1743**
Pesticides samples reported included in report	**1737**

Those 6 samples not included in the report corresponded 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 292340 residues, from which only 289043 had been included in the European report.

Pesticide results reported	**292340**
Pesticides results reported included in report	**289043**

Those 3297 residues rejected were excluded because they were part of a sum and didn't comply with the full definition of the residue, and those residues are excluded from the scope of the report.