NATIONAL INSTITUTE OF TOXICOLOGY
AND FORENSIC SCIENCES

GOBIERNO DE ESPAÑA
MINISTERIO DE JUSTICIA

INT CIENCIAS FORENSES

TOXICOLOGICAL INFORMATION SERVICE (SIT)

MADRID

Report 2019

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National Institute of Toxicology and Forensic Sciences

Toxicological Information Service

Report 2019

GOBIERNO DE ESPAÑA | MINISTERIO DE JUSTICIA

Madrid, 2021

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1. INTRODUCTION TO THE TOXICOLOGY INFORMATION SERVICE

The Toxicology Information Service (SIT, from spanish Servicio de Información Toxicológico) was created in February 1971, by Decree 1789/1967 of 13 July, as a technical and advisory body to the Ministry of Justice on toxicological matters and carries out its tasks as the Spanish Poison Centre.

It carries out the institutional and technical assistance functions for the Department of Justice at the request of courts, prosecutors, magistrates, judges, Institutes of forensic medicine, and medical examiners in matters within its competence. In addition, it performs, among others, the health role and better-known service of providing an immediate telephone response through its medical staff to queries about intoxication or exposure to toxic substances through initial advice and recommended treatment employing the medical staff.

It also aims to spread toxicology-related knowledge and contribute to preventing intoxications through pharmacological and toxicological precautionary measures, carried out in a health and social context.

As well as the medical service and the SIT medical staff, SIT includes a Documentation Section staffed by qualified professionals with education and training in health sciences. Its role includes the design, review, and updating of the database with information on the composition, toxicity, and hazard level of the products sold and marketed in Spain and previously reported to the National Institute of Toxicology and Forensic Sciences (INTCF from spanish Instituto Nacional de Toxicología y Ciencias Forenses) . As regulated in Law 8/2010, 31 March, the INTCF is the agency to which companies that sell market hazardous chemical mixtures must under the CLP Regulation, provide relevant information, including the composition of the mix, to provide the healthcare response in case of intoxication or ingestion of a toxic substance, as well as the chemical identity of the substances for which an alternative chemical name has been accepted under Art. 24 of the CLP Regulation.

Therefore, it is the national agency that receives the information of the chemical compositions through the documentation section, as well as provides the immediate healthcare response to users. The general public can consult its service, staffed by expert medical personnel any day, any day or night, without interruption. (24-hour public service)

The SIT is an easy to access public service, its phone number for Toxicology Emergencies is 915620420, which appears on all labels of product packages, on their safety data sheets, and the package inserts of all pharmaceutical products marketed as medicinal products. However, it is only regulated on bleaches and cleaning products. This widespread dissemination of the SIT phone number facilitates the direct and immediate contact of any person who has ingested or been exposed to a potentially toxic agent and

requires information about toxicology from the service´s medical staff, who are available to the general public, thus reducing the workload on health services.

This report sets out the activities carried out through 2019 by the SIT regarding the telephone enquiries received related to exposures to toxins involving both humans, animals and the training carried out by the Documentation Section of the registration of chemical mixtures.

2. ORGANIZATION AND ROLE OF THE TOXICOLOGY INFORMATION SERVICE

The SIT is a nationwide reference institution. It is the only one with these characteristics; continuous availability around the clock, universal accessibility, direct contact via telephone, and rapid response offering immediate health advice to the general public.

The medical staff perform different functions, which will be detailed in the relevant section. On the one hand, it is an agency at the disposal of the Department of Justice, providing toxicological advice at the request of magistrates, judges, prosecutors, courts, forensic doctors of Legal medicine Institutes; On the other hand, it provides a public health service based on the medical response to intoxicated patients or members of the public who have ingested or been exposed to toxins.

It must be stressed (because it is so established by law and relevant regulations) that companies must report the chemical compositions of the substances and the chemical identity present in the mixtures they sell and market that are classified as hazardous because of their possible effects on human health. The Documentation Section staff manages the notifications to include them in our databases and make them available to doctors to make the corresponding health response.

In the in-house database constructed and maintained by the SIT personal, through 2019, 37,238 new records were added to the INTCF database. Among these there are both active ingredients and chemical mixtures of new products marketed on the Spanish market or previously reported product formulas that have undergone modifications. The database contains the compositions, the hazard classification, the physical characteristics, the information on the packages, as well as other information which makes it possible to know the toxicity of the product and provide an immediate medical response to an enquiry due to potentially toxic exposure or intoxication with one of the products reported to the SIT.

In contrast to other poison centers, the medical personal are available 24/7, 365 days a year, giving permanent attention and a direct and immediate medical response. Furthermore, these staff are not associated with any emergency department, unlike other countries, although they can avail of information and disclose it because they have the specific acknowledgement of the registered product formulations that are sold in the market. Regarding this last point, personal are bound by the Institution´s duty to respect the commitment to confidentiality with regard to this information issued by the companies when they put their products in the market.

The SIT phone number (915620420) is available to the general public. The health services can contact the SIT by using a different phone number specifically set up for their personal (914112676). The latter phone number facilitates direct and

inter-professional communication, allowing an exchange of opinions about the treatment to be given to each patient depending on their own characteristics and intoxication. We also point out the important work carried out by other healthcare professionals such as pharmacists, nurses, and veterinarians. The European Association of Intoxication Centers and Clinical Toxicologists (EAPCCT) considers that one of the indicators which show the quality of a Poison Center is the accessibility and extent to which the people to whom it provides its services are aware of the Toxicology Emergencies phone number.

In addition, the SIT is interconnected through another direct telephone line with the National Centre for Civil Protection Emergencies (CENEM) to speed up their consultation in the event of toxicological accidents or toxic spills involving hazardous chemicals.

The queries received in the SIT are always handled by medical experts in Toxicology, who belong to the professional association of forensics scientists and physicians, who provide immediate guidance on the initial management of a patient who has been exposed to a potential toxic agent. Likewise and if required, they inform the caller about the toxic, kinetic, and dynamic characteristics of the active ingredients and commercial preparations and the analytic and therapeutic measures that may support the recommended treatment. Similarly, a foreseeable prognosis is interpreted as an estimate of the severity to the toxic exposure, among other contributions collected after the enriquiry is made.

These will be included and collected in each toxicological sheet filled in after each call, as well as the most relevant data from the epidemiological point of view collected from the person requesting the information, such as the province, age, sex, the product involved in the potential intoxication, the clinical effects, the recommended medical treatment, as well as any other information collected for the purpose of statistical data, with a view to carrying out epidemiological monitoring of toxic exposures or intoxications.

On rare occasions, it depends on the magnitude of the intoxication and its prognosis. A priori, the possibility of recommending the patient´s transfer to the health centre or their admission to a hospital is assessed, always considering the distance from the place where the person is located to the nearest and most appropriate healthcare facility. In these cases, the assessment of severity gravity estimation must be made in the first instance by the SIT medical staff as a moderate or severe case, after which a further assessment of the case will be carried out by healthcare professionals.

Table 2.1. Ways of contacting the SIT

Phone numbers	*91 562 04 20 – Attention to individuals* *91 411 26 76 – Attention to health personal* *Direct interconnection line with CENEM*
Emails	*intcf.sit@justicia.es (Toxicological Information Service)* *intcf.doc@justicia.es (Documentation Section)*
Portal web	https://www.mjusticia.gob.es/es/ministerio/organismos-entidades/instituto-nacional/servicios/servicio-informacion
Postal Address	*c/ José de Echegaray, 4. 28232 - Las Rozas - Madrid*

The SIT staff is formed by different professional categories which belong to forensic doctors, physicians, pharmaceutical and different administrative scales. We also have the Documentation Section with its head office.

Table 2.2. Toxicology Information Service staff

	Toxicology Information Service INTCF-MADRID
Head of the Service	1
Head of the Documentation Section	1
Pharmacists & Physicians	17
Forensic Doctors	7
Administratives	7

13 physicians and 7 forensic doctors with university degrees in medicine and surgery attend 24-hour via telephone. 5 experts in health sciences (including the head of the section) with university degrees in pharmacy, medicine, surgery, and biology sciences attend the documentation section.

Depending on the professional categories included inside the Service, different functions are carried out by the staff.

Medical Personal

- The elaboration of expert reports at the request of the Justice Administration
- Elaboration of toxicological reports to citizenship
- Attendance at trials as official experts
- Toxicological assessment to the Legal Medicine and Forensic Institutes

- Attention and management to toxicological consultations
- Approach and initial treatment to the consultations for intoxicated patients
- Dissemination and educational activity for the toxic requested information
- Management proposals for chemical accidents and toxic disasters
- Epidemiological toxicovigilance

Documentation Section Personal

- The elaboration of expert reports at the request of the Justice Administration
- Actualization of the databases already existing in the SIT
- Interconnection with official statements, associations, companies manufacturers, or marketers of chemical products
- Receipt of notifications from chemical companies
- Evaluation of the formulations by toxicokinetics and toxicodynamics
- Authorization of the SIT phone number on the chemical labels
- Inclusion of compounds and products through the toxic cards
- To participate actively in the European harmonization of the information that should be proportionate to the organisms designated in each member state
- Participation in the necessary technological development for the reception of the information emitted by the chemical companies to the INTCF
- Epidemiological toxicovigilance

Administrative Personal

- Receipt of notifications and documents from companies and manufacturers
- Management and administrative processing
- Referral of expert reports and opinions drawn up by staff

The resources that SIT works with consist fundamentally in:

- Database handling with 426,971 product data sheets up to 12/31/2019, which includes both active ingredients and products marketed in the Spanish market. A prior toxicological assessment has been carried out on each file to provide an immediate medical response in the event of consultation following a toxic exposure.
- Database prepared according to the characteristics of the consultations received by telephone, using data collection sheets including an applicant for information, intoxicated person, the product involved in the intoxication, symptomatology presented by

the intoxicated person, estimation of the seriousness of the case, and the treatment recommended by the SIT, and other parameters.

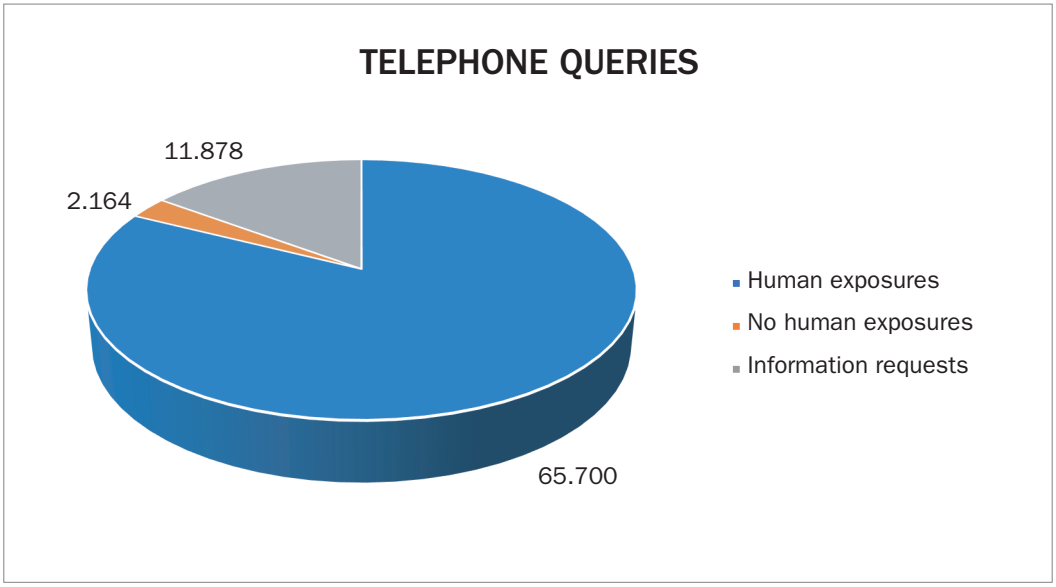
(Actually, the collected registers through the years and including 2019, they rise to 1.513.649 records).

- Drugs and new psychoactive substances database, recently elaborated by part of the health experts.
- Plants database, maintained and elaborated by part of the health experts.
- Different commercial databases, national and foreign, and toxicological interest related to chemical substances (synthesis and naturals).
- The library, with nearly 200 volumes, and treatises on toxicology found in the general library of the INTCF.

3. STATISTICAL AND EPIDEMIOLOGICAL DATA ON TELEPHONE ENQUIRIES RECEIVED ON SITE FOR EXPOSURE TO TOXIC SUBSTANCES DURING 2019

The activity realized during 2019 by the SIT with respect to telephone consultations are seen at figure 3.1.

Figure 3.1. Telephone consultations handled by the SIT during 2019



79,742 telephone consultations have been resolved by its medical staff in 2019. According to the information provided by the applicant, two main groups should be distinguished (figure 3.1):

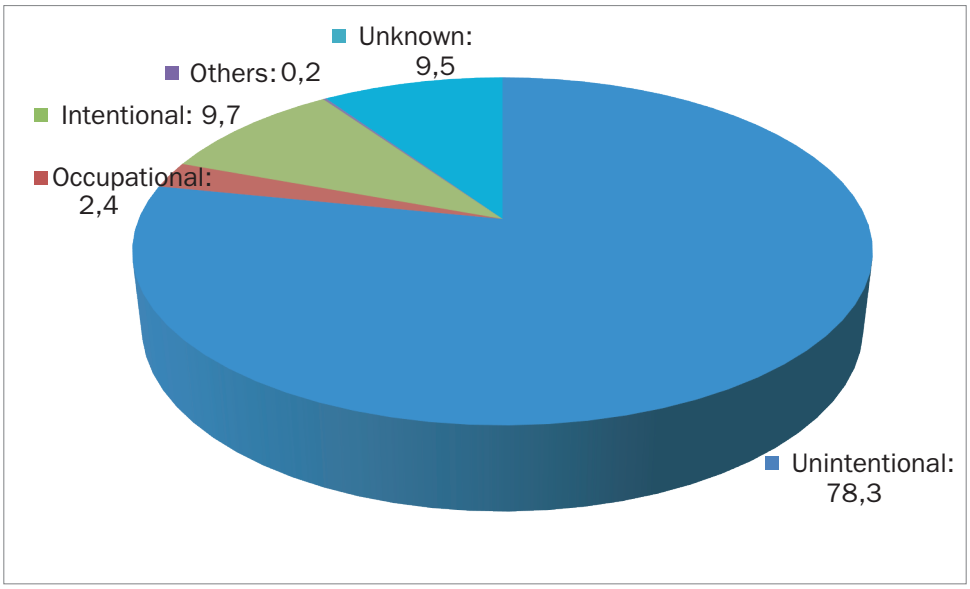
- The “toxicological consultations” by toxic exposures or intoxications to any substance or product potentially toxic. 67,864 poisonings were solved, of which 65,700 corresponded to humans and 2,164 to animals.
- The “informative consultations”, not related to toxic exposures nor intoxications. 11,878 consultations were attended.

3.1. TOXIC EXPOSURES IN HUMANS

During 2019, the SIT has attended 65,700 consultations by intoxications or by toxic exposures in humans. The following statistical figures are shown in general and according to the parameter studied.

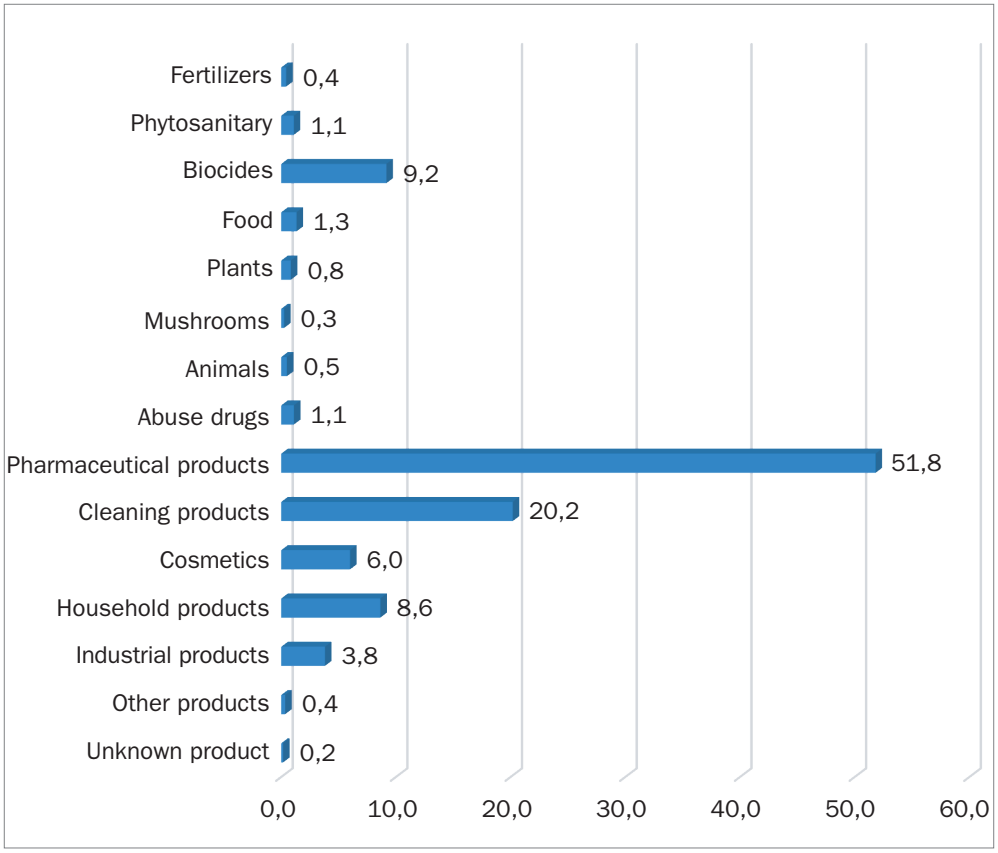
Figure 3.1.1 shows the distribution according to the etiology of the poisoning, in which it can be seen that the most frequent etiology was accidental.

Figure 3.1.1.Distribution of toxicology consultations by type of aetiology



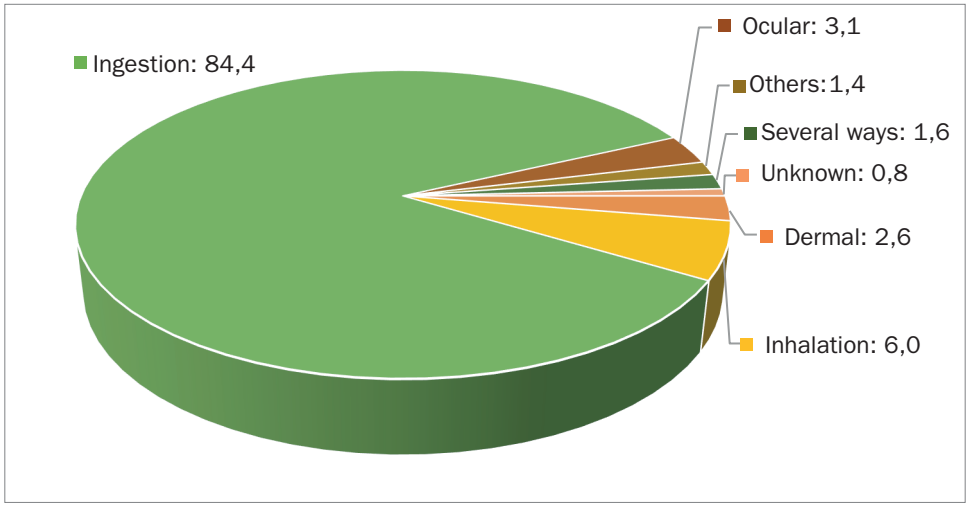
With regard to the type of product involved in toxic exposure, pharmaceutical products were the majority, followed by cleaning products, biocides, and household products.

Figure 3.1.2. Distribution of toxicological consultations by type of product



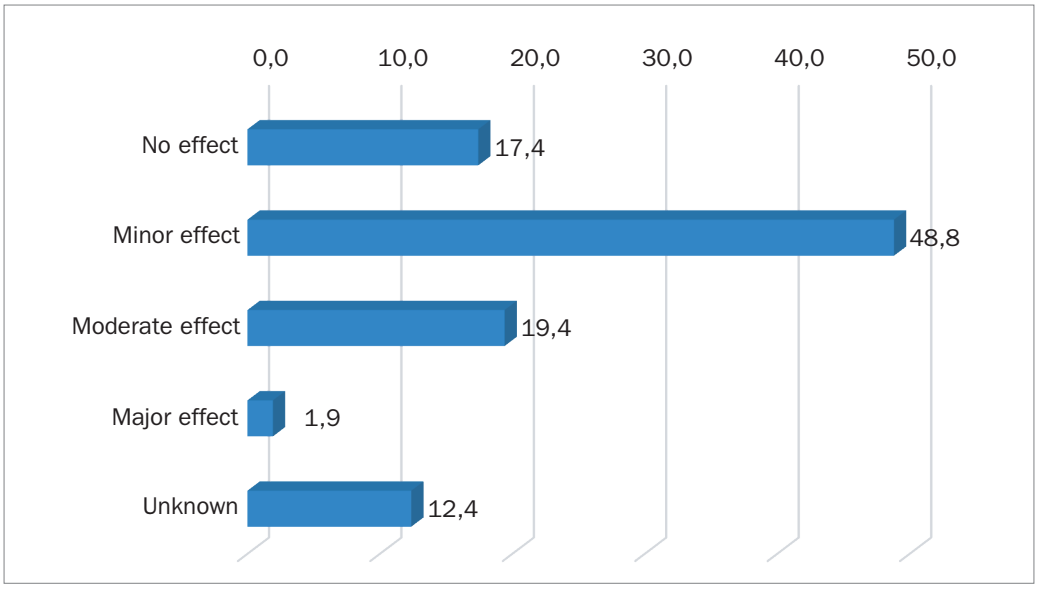
The most frequent way of administration was the ingestion route (84.4%) followed by inhalation (6%), ocular mucous (3.1%), and dermal (2.6%).

Figure 3.1.3. Distribution of toxicological consultations by the way of administration



With regard to the estimated severity of the poisoning, most of the exposures were minor (48.8%), moderate (19.4%) or asymptomatic (17.4%), and only in 1.9% of the cases was it considered a serious symptomatology.

Figure 3.1.4. Distribution of toxicological consultations by estimated severity of the intoxication



In the following figures and table we can see the distribution by sex, age, the month of the year, and hour of the day when the intoxication happened.

With respect to the sex and age (Figures 3.1.6), the major incidence of intoxications is observed in male children of 2 years old (11.1%, being female of that age a 9.2%). There's a slight percentage of male children of 3 years old (5.1% and 3.8% in female from that age). In the adult population, the major percentage corresponds to female with an age range of 40-49 (5.3% of all adult age groups).

According to the sex, female have more incidence (50.1%) while in male is slightly less (47.4%).

The joint age and sex distribution graph (Figure 3.1.6) highlights the striking change in the predominant percentage of males in minors compared to females in adults.

Figure 3.1.5. Age distribution of toxicological consultations

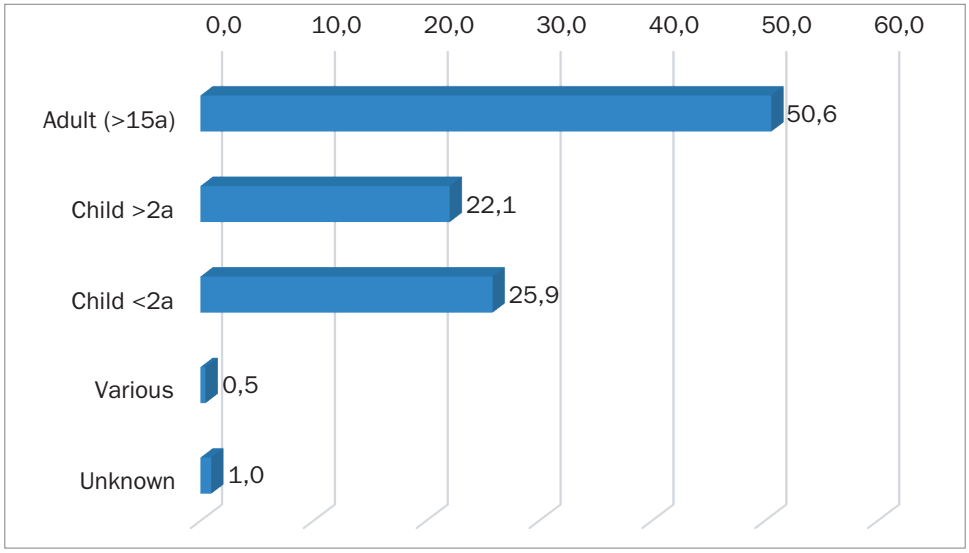
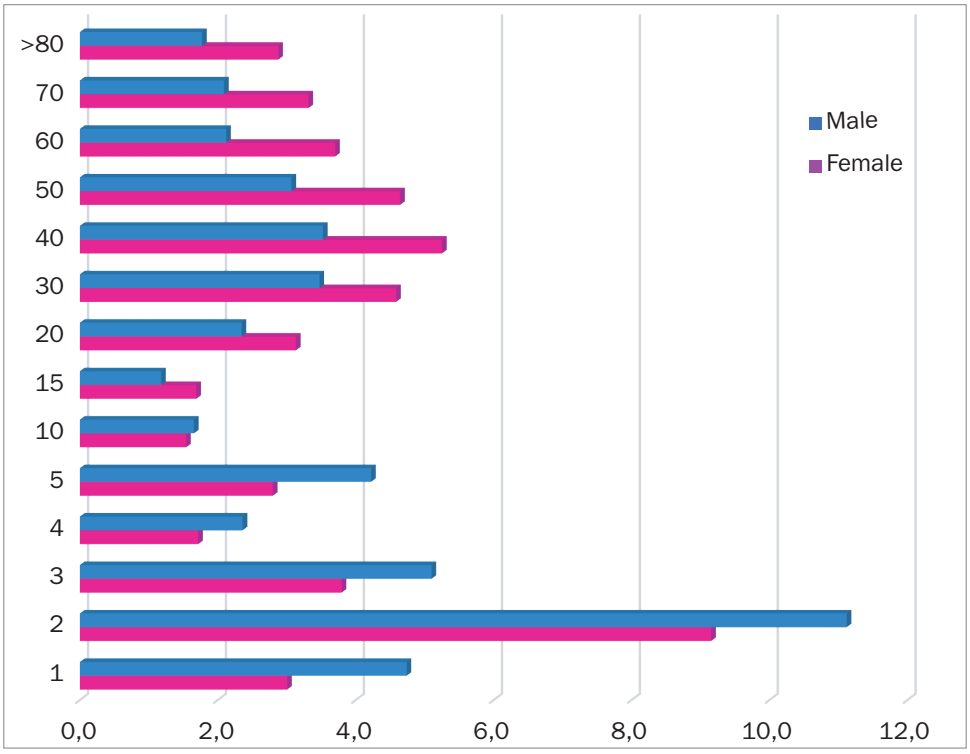
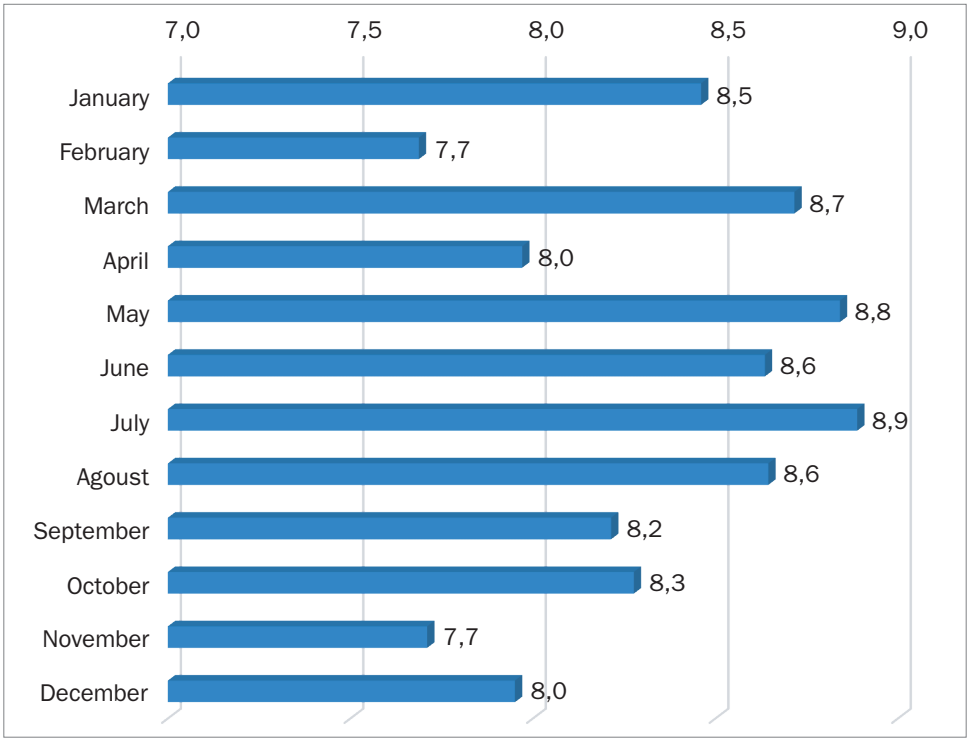


Figure 3.1.6. Age and gender distribution of toxicological consultations



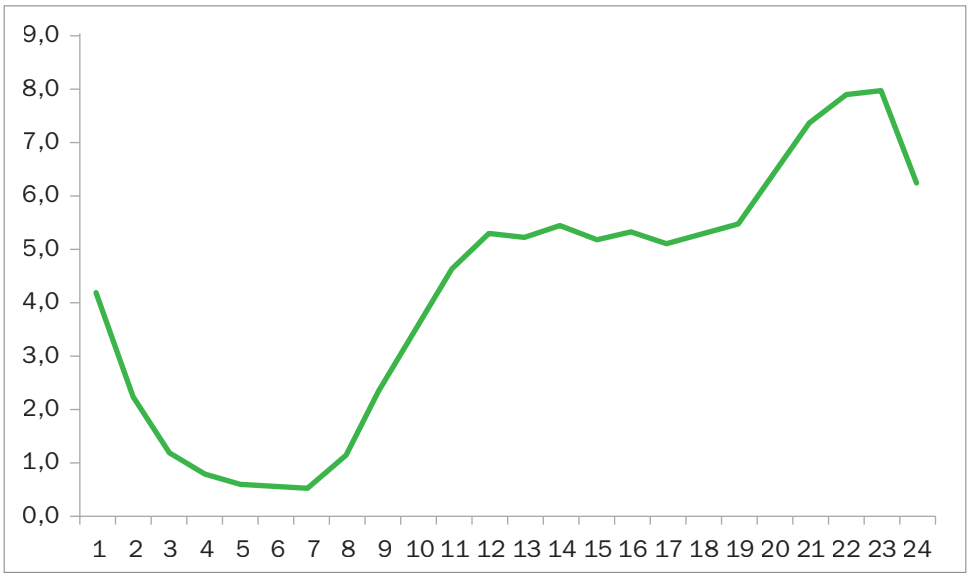
The months with the highest incidence of request by the toxic exposures are July (8.9%), May (8.8%), and March (8.7%), although the accumulated periods are the festive months.

Figure 3.1.7. Distribution of toxicological consultations by month of the year



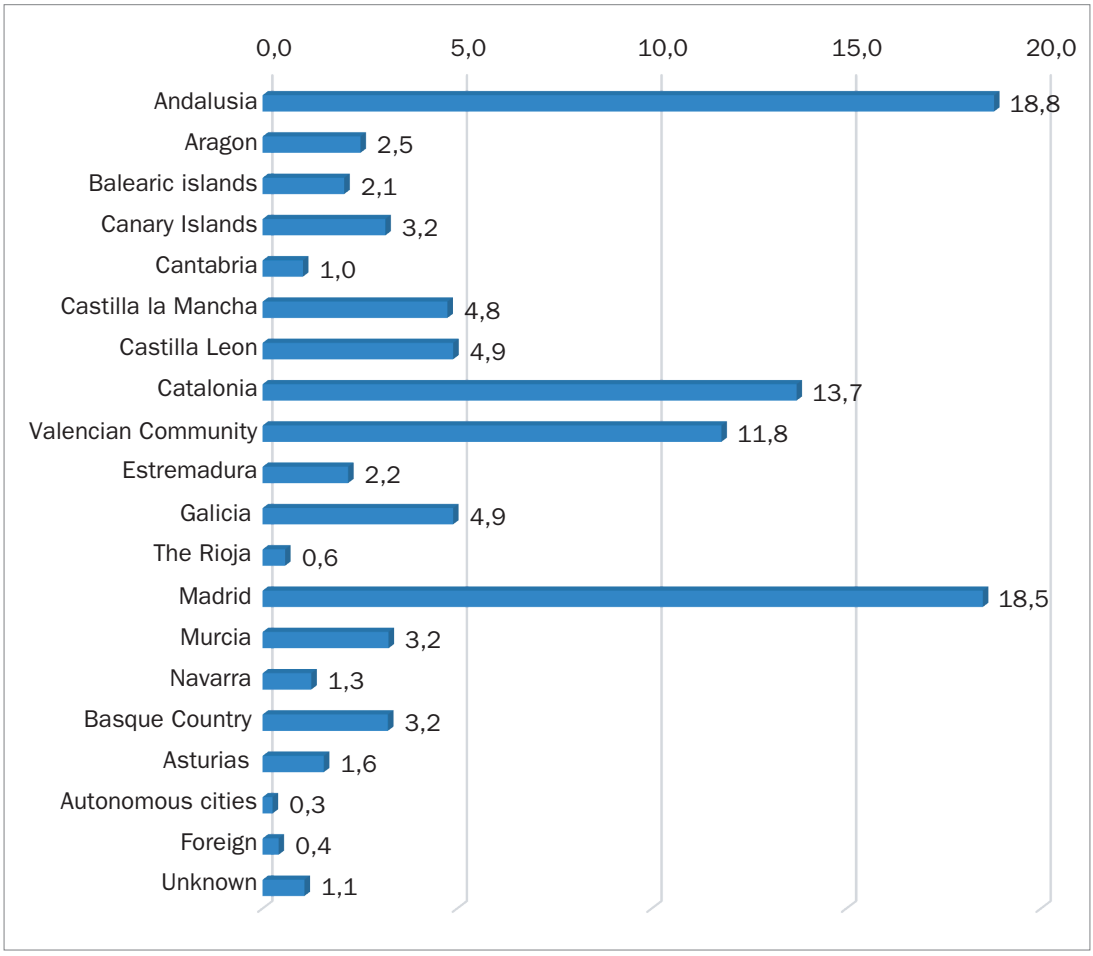
The time slot with the least number of intoxications occurs in the early morning, with a gradual increase towards midday, establishing a plateau of consultations throughout the day and with a maximum peak in the late afternoon and early evening (8.0%).

Figure 3.1.8. Hourly distribution of toxicological consultations



Finally, Figure 3.1.8 shows the distribution of consultations carried out by each Autonomous Community. The Autonomous Regions with the highest casuistry index are Andalusia (18.8%), Madrid (18.5%), and Catalonia (13.7%), coinciding with the population rate.

Figure 3.1.8. Distribution of consultations made by each Autonomous Community



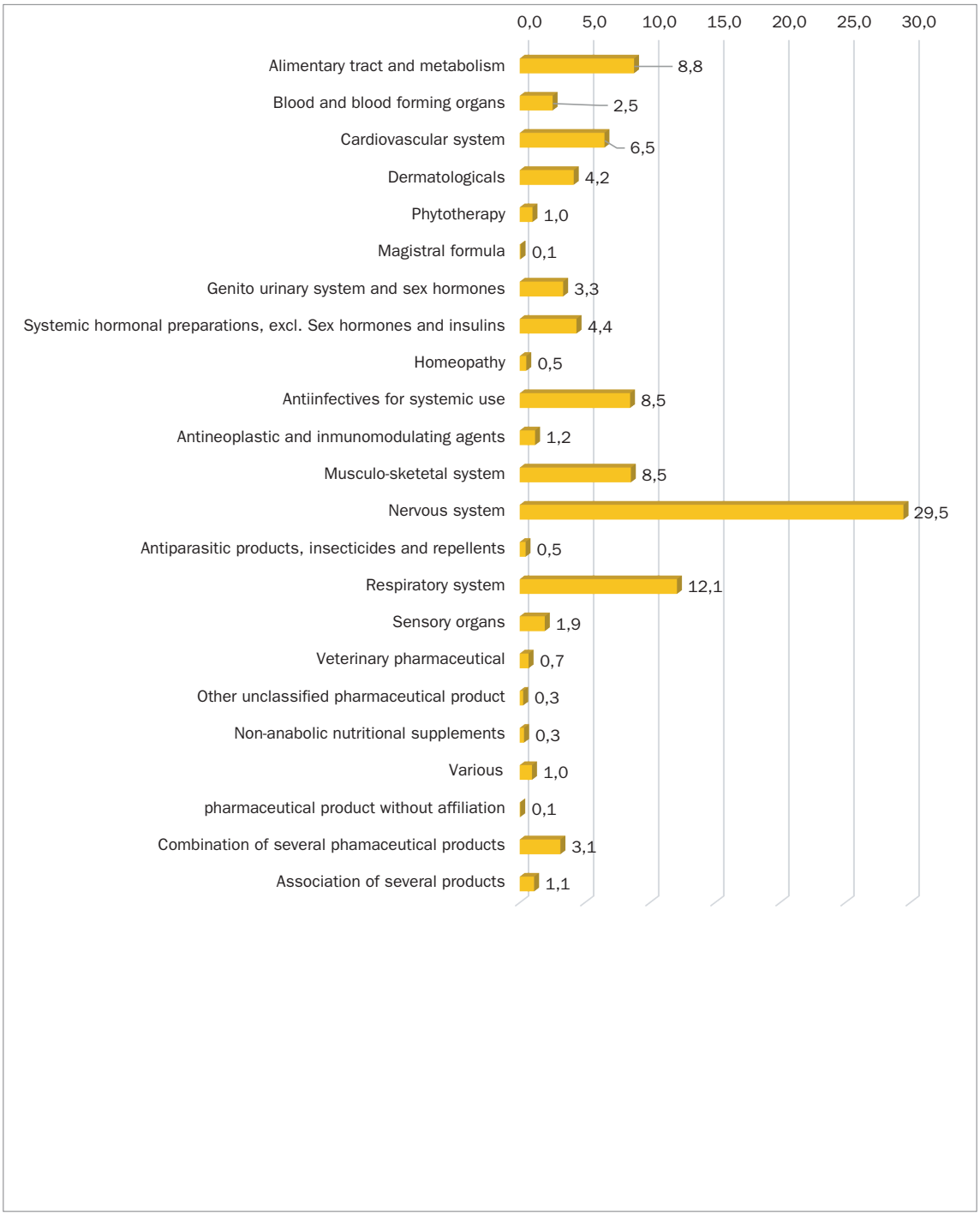
3.1.1. PHARMACOLOGICAL INTOXICATIONS

During 2019, 33,508 consultations have been attended due to humans exposures (51,8% from the whole received consultations).

In figure 3.1.1.1, we can see the distribution of the consultations attended by different types of medicines; we know the incidence of medications with a predominating effect in the Nervous System, highlighting intoxications caused by Benzodiazepines and Paracetamol, this last is the most involved producing intoxications during 2019.

Concerning previous years, the 2019 data maintain a similar trend of distribution in the intoxications by pharmaceutical products.

Figure 3.1.1.1. Distribution by type of pharmacological products

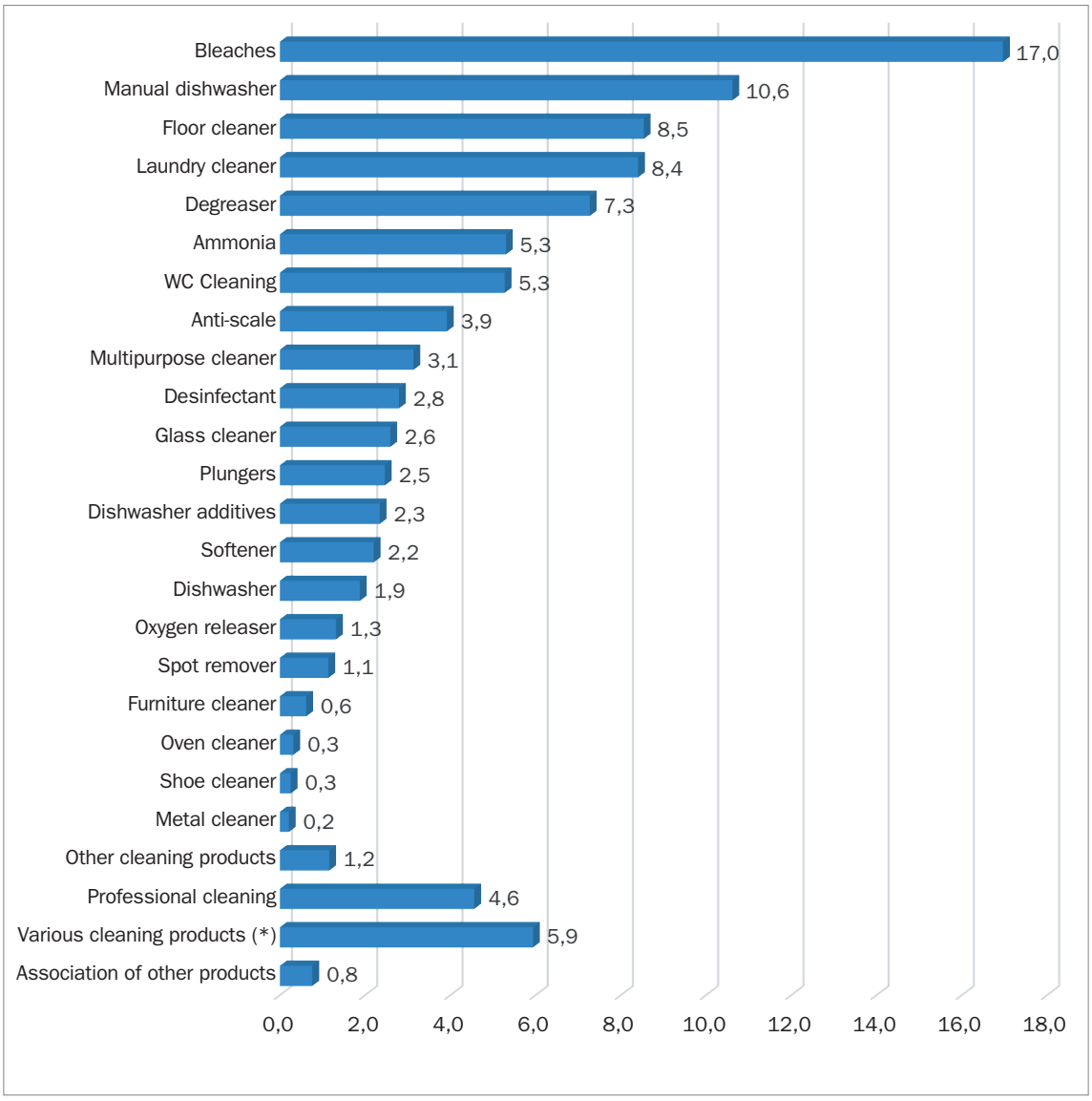


3.1.2. INTOXICATIONS BY CLEANING PRODUCTS

13,267 requests for human exposures have been attended to (20.2% of the total).

The bleaching products represent the highest cause of intoxication. (17.0%)

Figure 3.1.2.1. Distribution of toxicological consultations by type of cleaning products



3.1.3. INTOXICATIONS BY BIOCIDE PRODUCTS

6,030 consultations of intoxications in humans have been attended to (9.2% of the total)

Inside the predominant percentage that supposes the insecticides in the biocide products (23.6%), the pyrethroid insecticides group is the greatest in human intoxications, similar to previous years (83%).

Also the drop in human intoxications to cholinesterase inhibitory insecticides (organophosphates and carbamates) concerning previous years, and the minimal reference to organochlorine insecticides, are barely present on the market.

Figure 3.1.3.1. Toxicological consultations by biocidal products

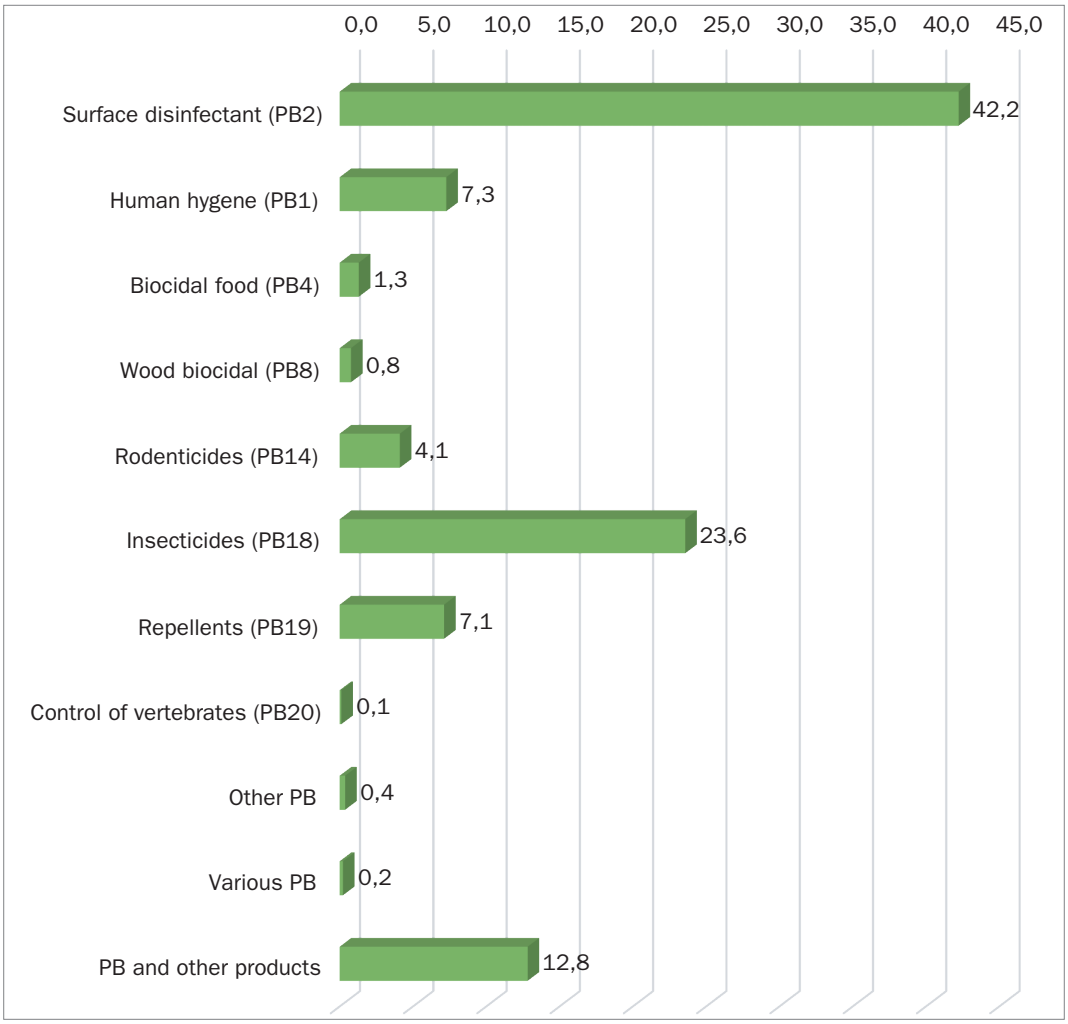
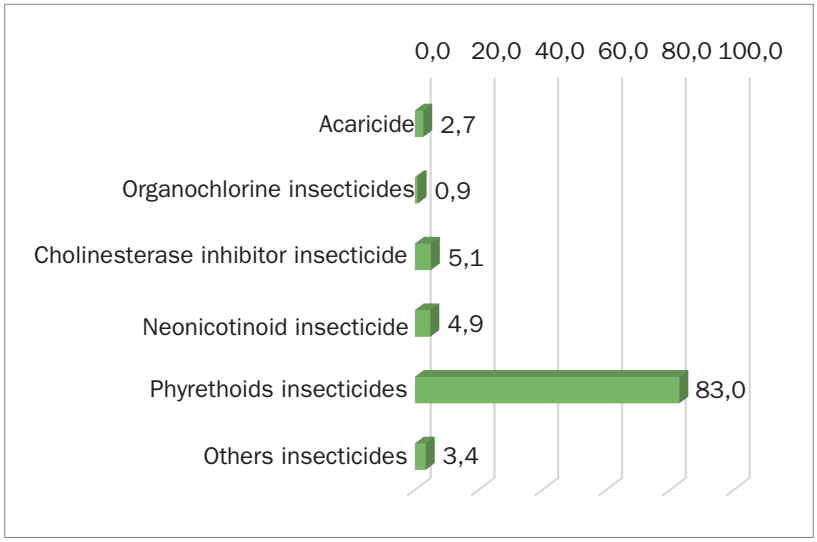


Figure 3.1.3.2. Breakdown of Toxicological Consultations for Insecticides

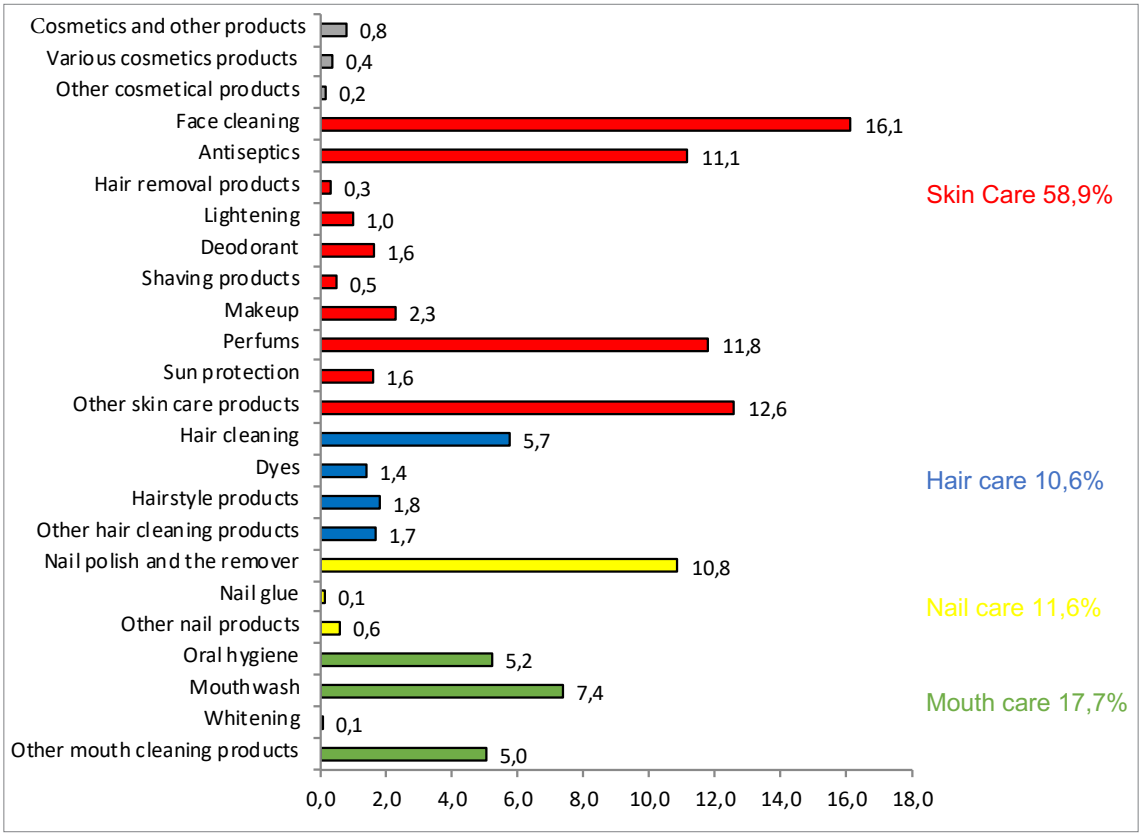


3.1.4. INTOXICATIONS BY COSMETIC PRODUCTS

3,948 consultations for intoxications in humans have been attended to (6.0 % of the total)

In figure 3.1.4.1., the different subgroups of cosmetics are highlighted in different colours: skin, mouth, nail and hair care cosmetics.

Figure 3.1.4.1. Toxicological consultations for exposure to cosmetic products.



3.1.5. INTOXICATIONS BY PHYTOSANITARY PRODUCTS

727 consultations of intoxications in humans have been attended (1.1% of the total).

In phytosanitary products, pyrethroid insecticides intoxications compared with biocides (although in half of its cases) are highlighted. The distribution of cholinesterase inhibiting insecticides (organophosphates and carbamates) is higher.

Figure 3.1.5.1. Consultations for toxic exposures to phytosanitary products

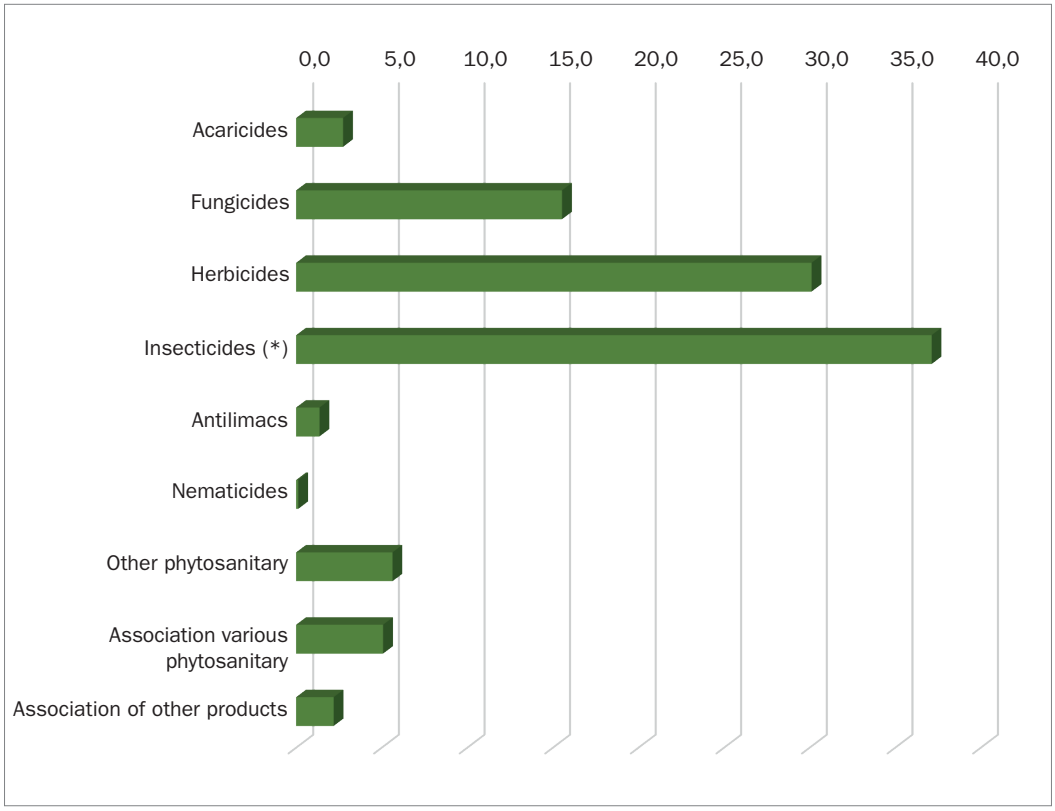
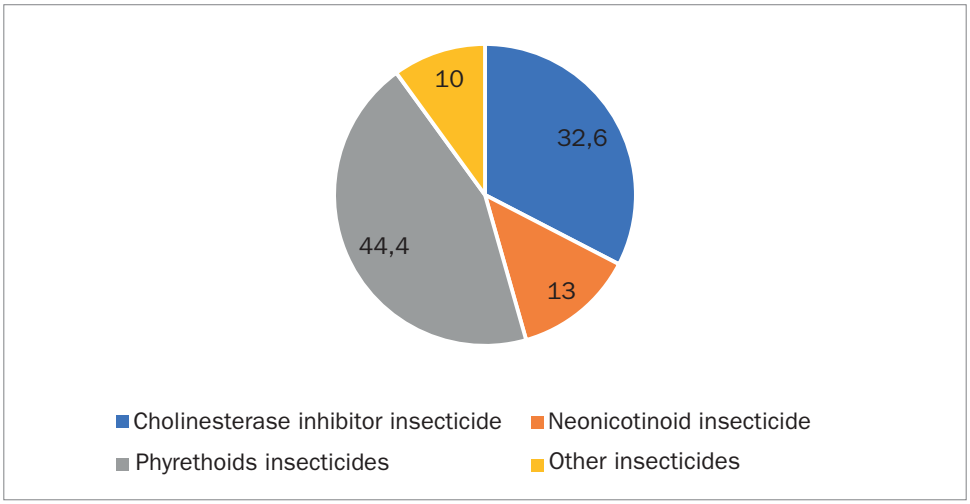


Figure 3.1.5.2. Consultations for toxic exposures to phytosanitary products Breakdown of insecticides



3.1.6. INTENTIONAL EXPOSURES

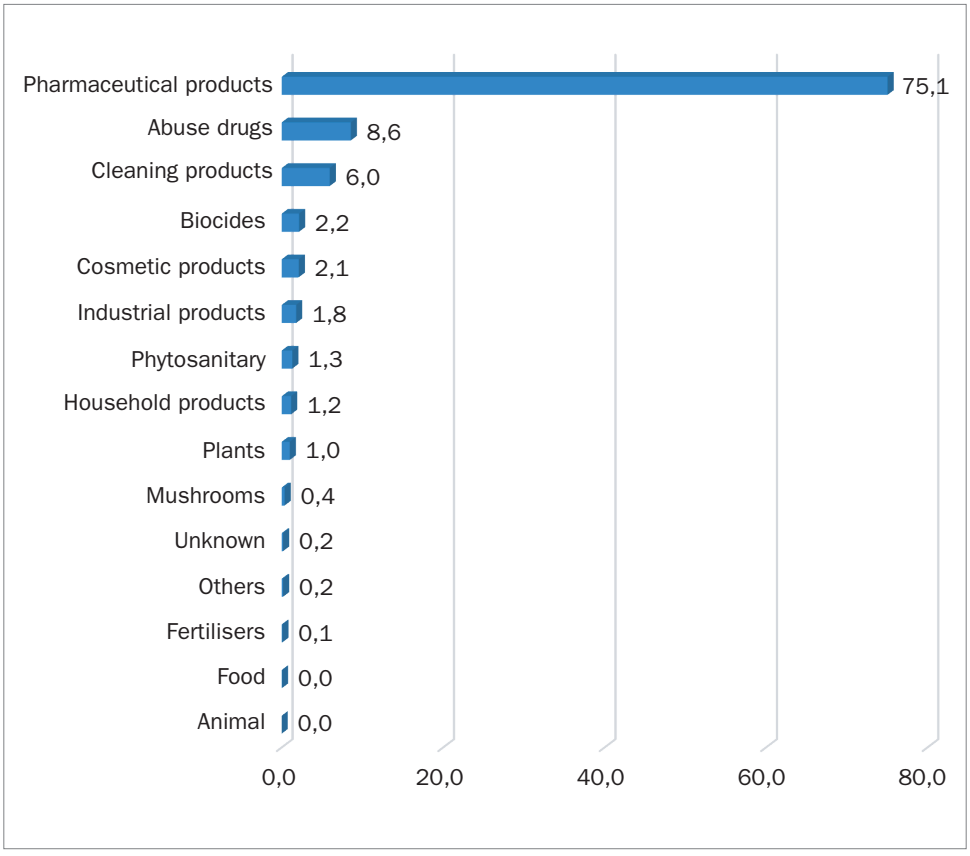
6,381 consultations have been attended due to intentional intoxications, which correspond to the 9,7 % of the total humans exposures. A detailed study of intentional intoxications is included because it is an object of particular interest.

Concerning this information, it is necessary to highlight that pharmaceutical products are the type of product especially majority, and responsible for autolysis attempts, following drug abuse and alcohol.

Likewise, and within medicines, those responsible for them are predominantly from the benzodiazepine pharmacological group.

Compared to previous years, the percentage of intentional intoxication has slightly increased.

Figure 3.1.6.1. Consultations for Intentional intoxications



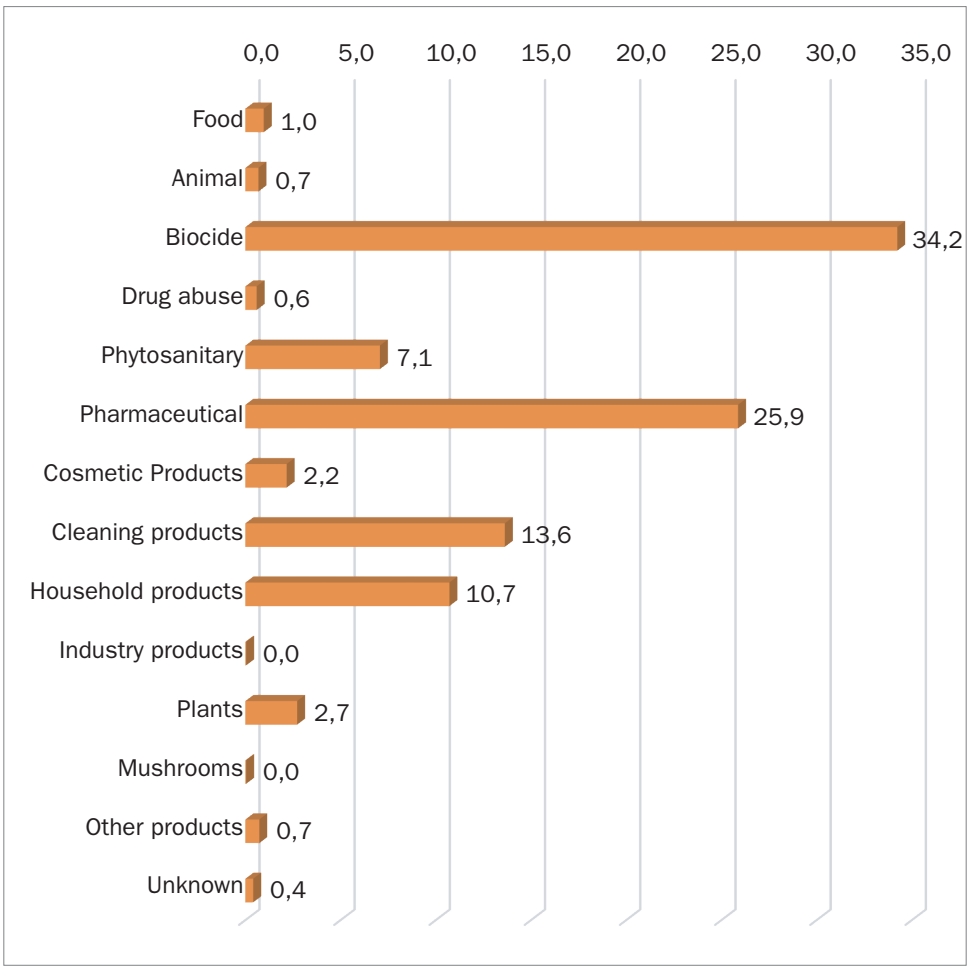
3.2. TOXIC EXPOSURES IN ANIMALS

During 2019, the SIT has attended 2,164 consultations of no human exposures.

After, the conclusions will be detailed to these dates, as well as the percentages made by the different types of products because of the animal intoxications.

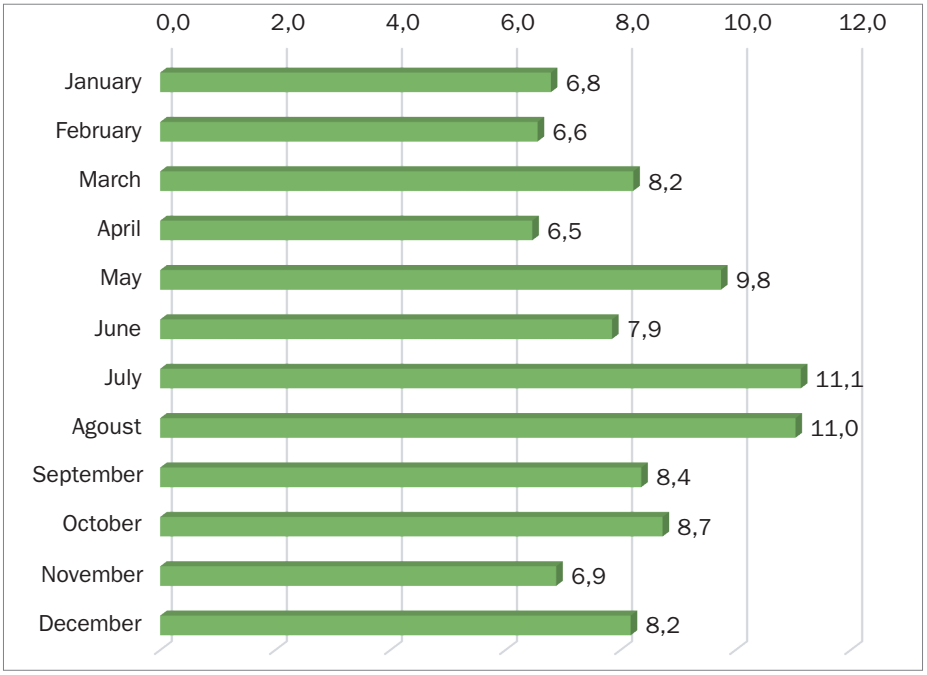
The type of product majorly implied in the no human exposures is a biocide (34.2%), followed by pharmacological products (25.95) and a cleaning products (20.2%).

Figure 3.2.1. Distribution of toxicological consultations in animals by type of product



The months with the highest incidence of consultations for toxic exposures in animals are July (11.1%), and August (11.0%), thus highlighting the summer season, coinciding similarly with the period of humans exposures.

Figure 3.2.2. Distribution of toxicological consultations in animals per month of the year



The predominant applicant to request information on these intoxications is a private individual without specific health training (57.7%), followed by a veterinary professional (41.6%). In animals, the highest percentage of consultations requested from professional centers stands out (almost half) compared with consultations in humans (third part).

Figure 3.2.3. Distribution of animal toxicology consultations by type of applicant

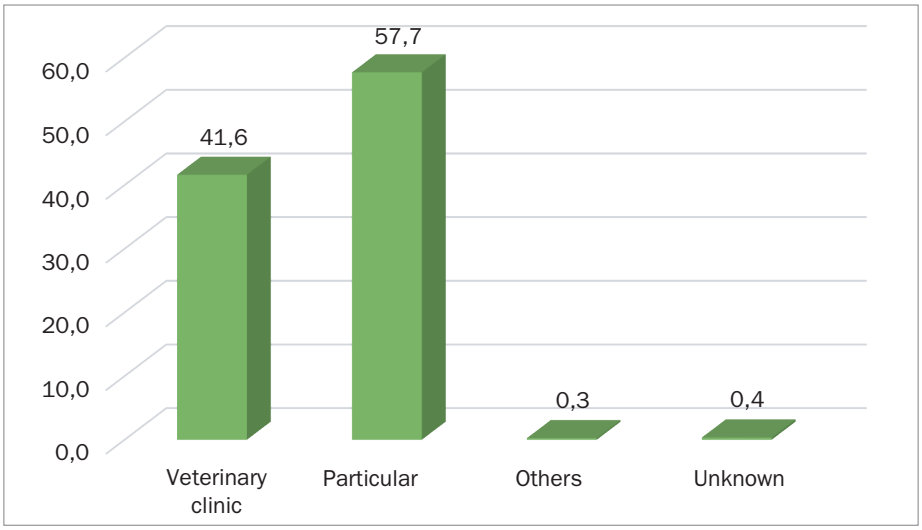
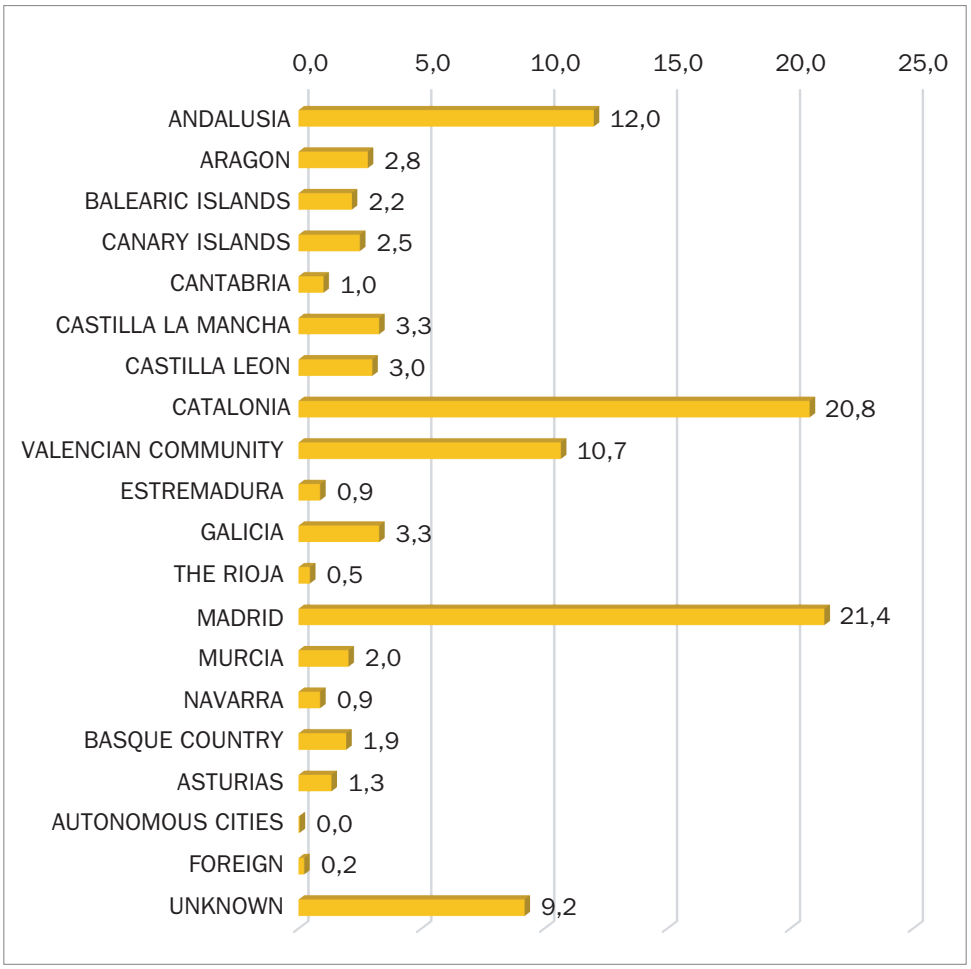


Figure 3.2.4. Distribution of toxicological consultations on animals by Autonomous Community



The Autonomous Communities with the highest rate of cases of intoxicated animals are Madrid (21.4%), Catalonia (20.8%), and Andalusia (12.8%). (Figure 3.2.4).

3.3. INFORMATIVE CONSULTATIONS

In 2019, the SIT has attended 11,878 informative consultations, no toxicological.

The following general statistical figures and study parameters are shown.

It is important to highlight that the informative consultations not related to toxic exposures represent around 15% of all the consultations effectuated (79,780).

These consultations are controlled through the data collected by the doctors. It is a service provider of information on toxicological matters and at the request of the citizen.

The majority of these consultations are pharmacological, or to consult product information without anybody intoxicated. The detail about the collection of data to be included in the data sheets is, therefore, less detailed than for toxicological consultations.

These include the collection and resolution of calls related to:

- Information about side effects of medications.
- Information about drug dosages.
- Possible medication interactions.
- Exposure to expired medications.
- Allergic reactions to medicines and other products.
- Pharmacokinetics information ((half-life, excretion, absorption...).
- Other consultations related to drugs.
- Contraindications and therapeutic indications.
- Elaboration and conservation of medicines.
- Medical consultations.
- Teratogenesis and effects on the infant resulting from exposure to substances.
- Intoxication prevention.
- Prevention measures in the work environment.
- Environmental toxicology.
- Product identification, composition, indications.
- About drugs (attention centers, analytical interferences…).
- Chemical substances manipulation.
- Contacts with the manufacturer (employment, composition, safety data sheet…).
- Medical-forensic consultations.
- Other consultations.

Figure 3.3.1. Monthly distribution of information consultations

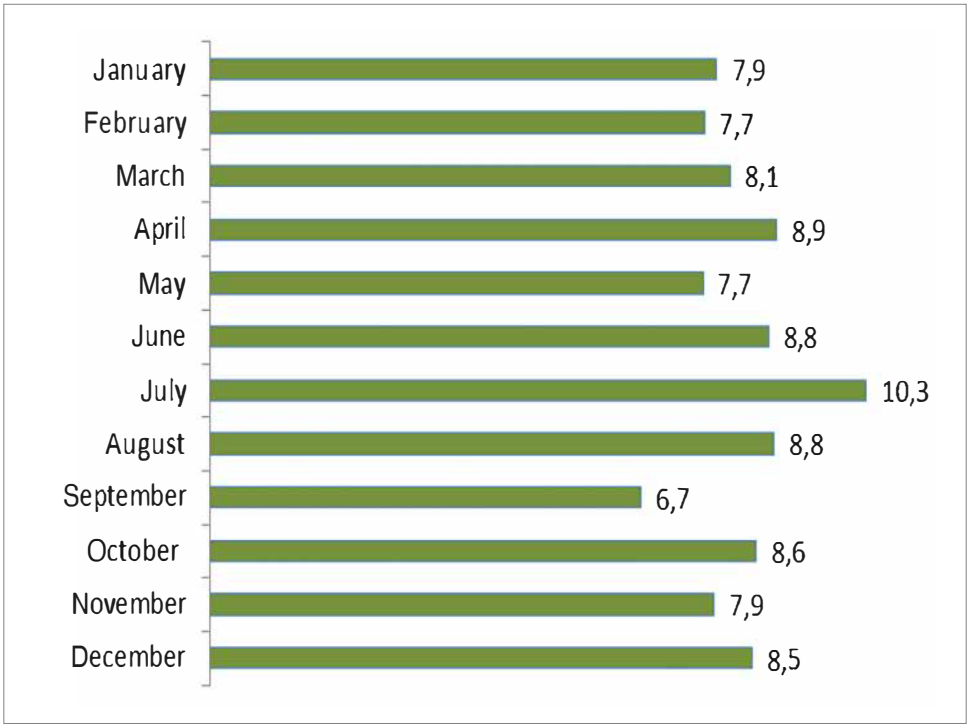


Figure 3.3.2. Hourly distribution of information consultations

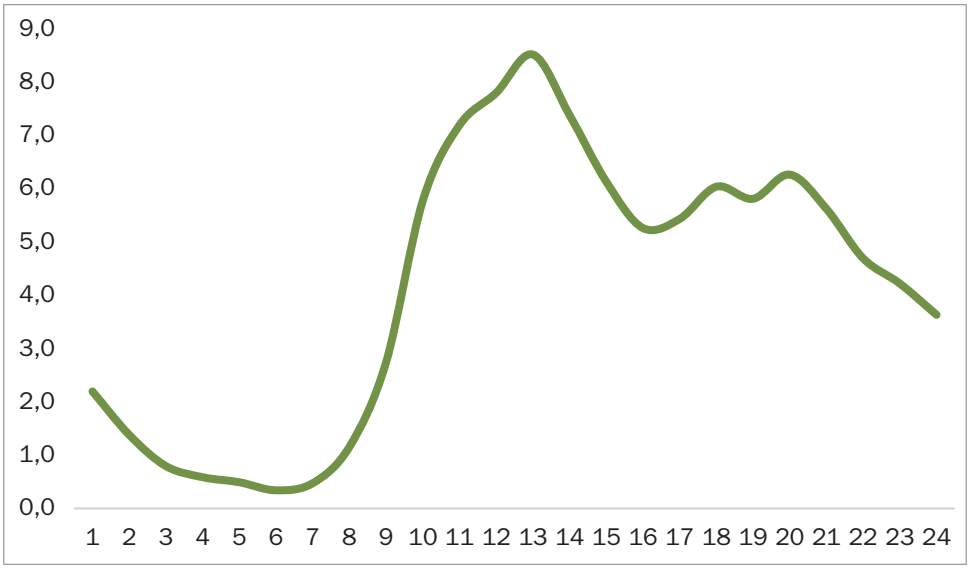
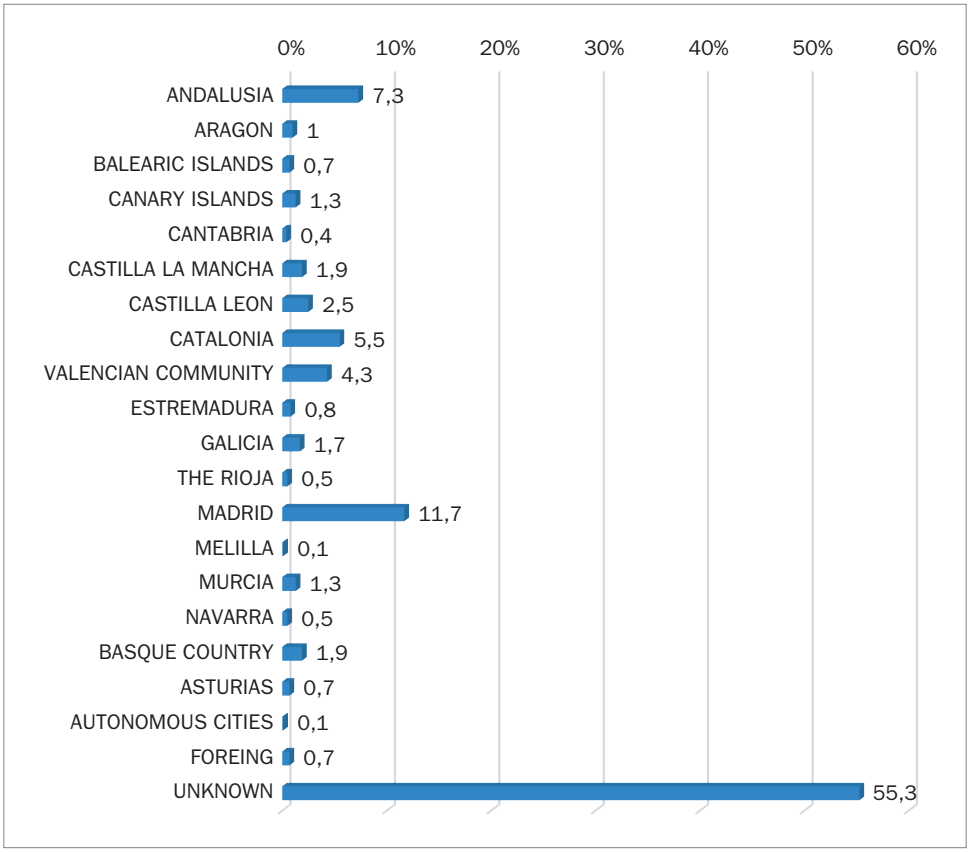


Figure 3.3.3. Distribution of information queries by Autonomous Community



4. REPORTS BY THE SIT MEDICAL STAFF IN 2019

During 2019, the medical staff has emitted 187 toxicological reports.

The classification of the reports emitted by the personal staff is determined by the petition or the subject, being cataloged as reports: M, ME, or IC (figure 10.3)

In the case of "*Reports M-19*", their opinions remitted after a detailed study of a requested subject, either from the Administration of Justice or from other institutions.

59 reports were notified and elaborated after petitions requested by the Justice Administration that after serving to the courts, as the information coming from the Administrations, health institutions or particulars, where a detailed study is solicited. These requests are awarded and carried out by the doctors of the SIT.

In the case of *"Reports ME-19",* the information is remitted by email early, these are applications from the public and do not require a specific toxicological evaluation.

122 reports were reported and elaborated after petitions requested by part of the usuaries and particulars, where the Head of Service answers by email in the same day by petition of the citizenship.

In relation to *"Reports IC"*, they are answers to the requests of health professionals in relation to a toxicological case, where the complementary information is sent by email.

6 reports were elaborated after petitions majorly solicited by professionals, emitted immediately by email. The required information related to any toxicological case requires complementary information previously exchanged by phone.

4.1. DESCRIPTION OF AN INTERESTING REPORT WITH MEDIA COVERAGE

Following a request by the Public Prosecutor of Barcelona, from the el Special Informatic Crime Service and following pre-trial nº 547/19, they requested "relative information to the SIT about the effects and characteristics of chlorite sodium."

The compound has been historically used as a disinfectant and cleaning products, similar to the bleaching effect, (sodium hypochlorite) as a biocide. Found to be increasingly marketed as a 28% concentrated aqueous solution on the social media market and for human consumption as a "miracle mineral supplement" (with its acronym in English, MMS).

In our advice M19 – 09344, elaborated by SIT and dated 23 de august of 2019, they informed about the toxicity of the product that has been sold by different social media as a mineral supplement to be mixed with an acidic substance like lemon juice and giving rise to the compound chlorine dioxide (ClO2). This chemical compound was enacted to treat distinct pathologies such as AIDS, acne, malaria, autism, infections, or cancer.

Diffused via social media, promoting its consumption as a miracle supplement, even though it was an obscure business method with serious health risks, and could even lead to death.

Our report concludes that it is not indicated for human use either for the treatment of any disease, because there aren't scientific studies that prove curative properties. Also that can produce after ingestion digestive, metabolic, pulmonary, and cerebral alterations, also being noticed by the *Food and Drug Administration* (*FDA*) about the dangers of the product and not being approved for any use, as it is confirmed by the organism as well by the Spanish Agency of Medicine and Health Products (AEMPS), an agency of the Spanish Ministry of Health and Consumer Affairs.

5. ACTIVITY OF THE DOCUMENTATION SECTION WITH REGARD TO NOTIFICATIONS OF THE CHEMICAL MIXTURES

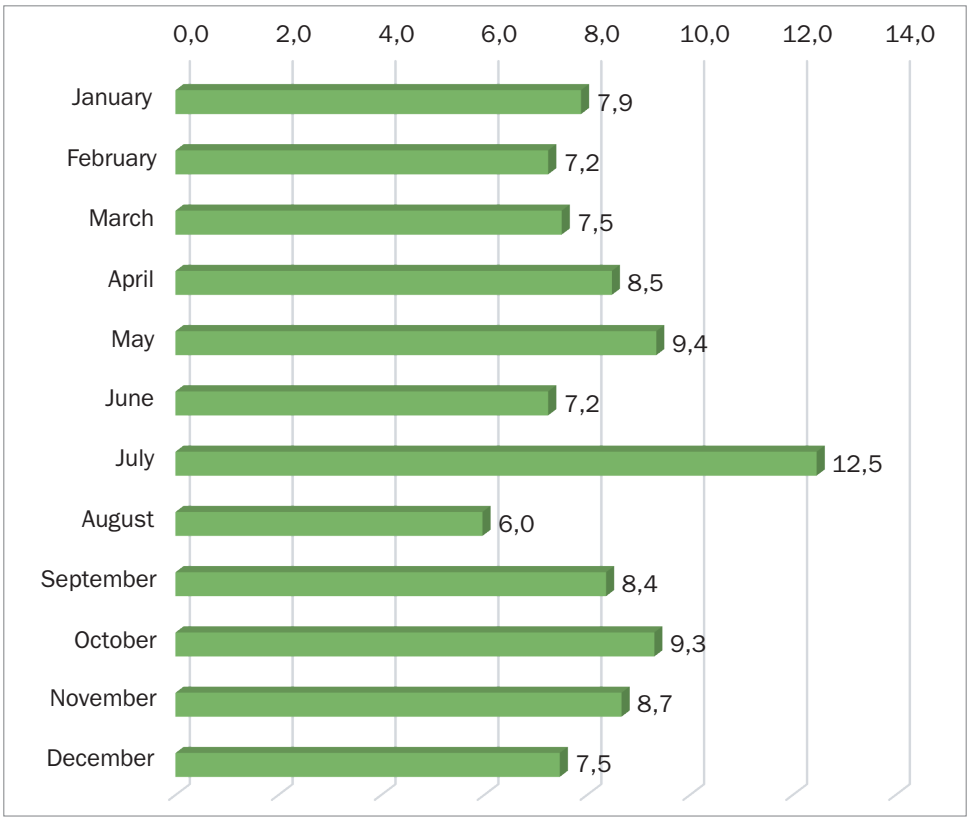
5.1. REPORTS EMITTED BY THE SIT DOCUMENTATION SECTION

The Documentation Section resolves the incidences and queries that the chemical companies have, the legislative point of view, and the procedure established to realize the notifications to the INTCF. At the same time gives technical support for the management of the technological applications developed by the New Technologies Department. These consultations are received from national and international companies that contact the Documentation Section by phone or email. They are handled rapidly, making a resolution follow-up.

During 2019, the Documentation Section has received 2,663 information requests, which have a solution in a short space of time, generally in the 24 hours workdays after the consultation.

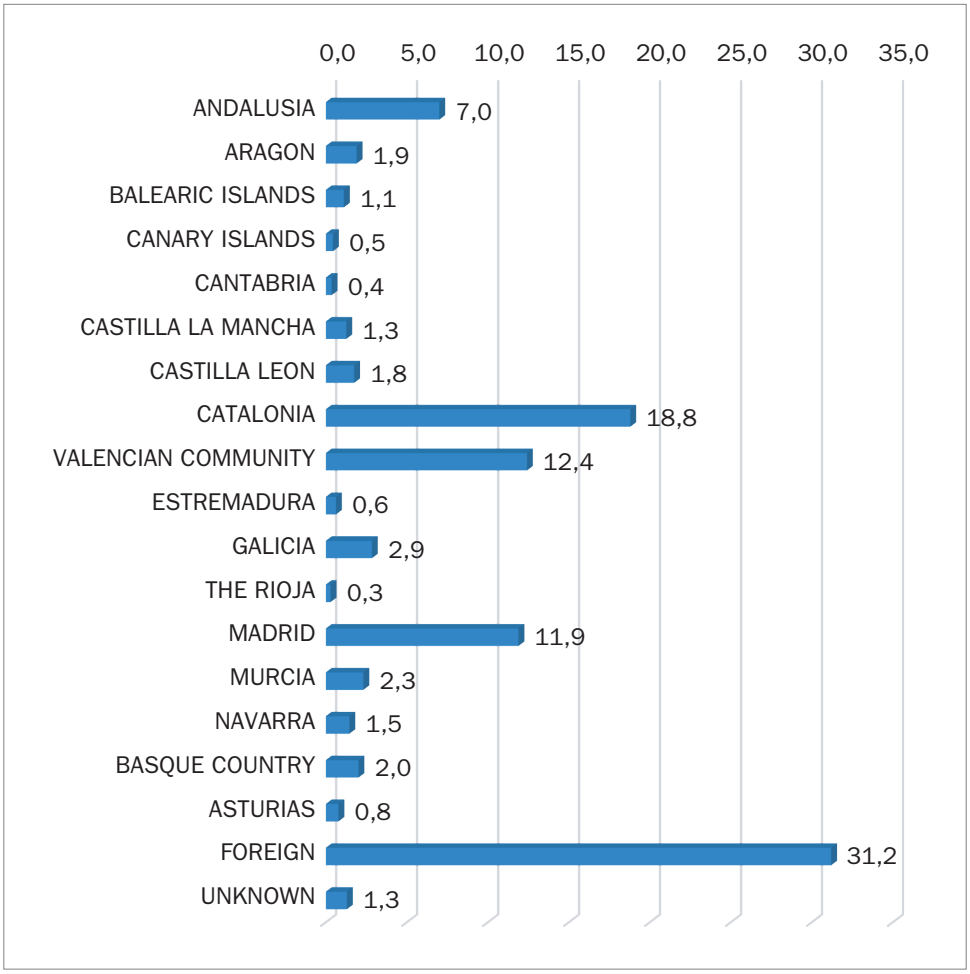
The information requests are received throughout the year, the majority in July (12,5%), May (9,4%), and October (9,3%)

Figure 5.1.1. Distribution of requests for information in the different months of the year



These consultations come from companies located at different Autonomous Communities. Like Catalonia (18,8%), Valencian Community (12,4%), Madrid (11,9%).

Figure 5.1.2. Distribution of requests for information by Autonomous Community



Likewise, numerous queries were received from foreign companies, which market their chemical mixtures in Spanish territory. Therefore, they must notify the INTCF, under the requirements established in Order JUS/909/2017, of 25 September. These queries represent 31,2% of the total questions received for resolution by the SIT Documentation Section.

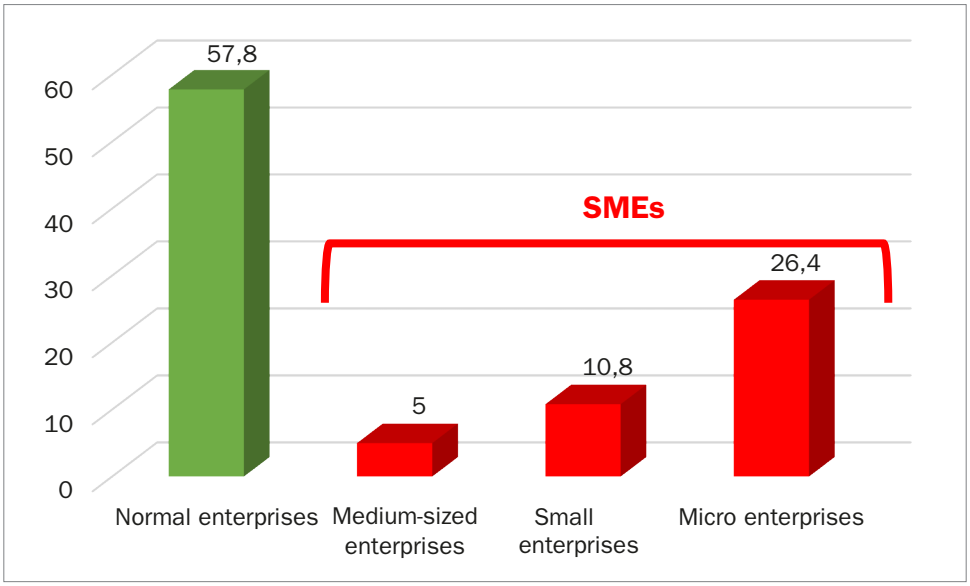
In 2019, these queries presented a hard increase comparing the ones handled in 2018 by foreign companies, which supposed the 23,1% from total consultations received in 2018.

5.2. COMPANIES REGISTERED IN THE COMPANY RELATIONS SYSTEM (SRE) IN 2019

During 2019, 535 new companies have joined the INTCF (SRE) to notify the mixtures they sell on the Spanish market and to enable SIT emergency doctors to provide a health response to exposure to the mixtures available in Spain.

From these new companies, 42,2% were SMEs, mainly Small -companies, constituted by less than 10 workers (26,4%)

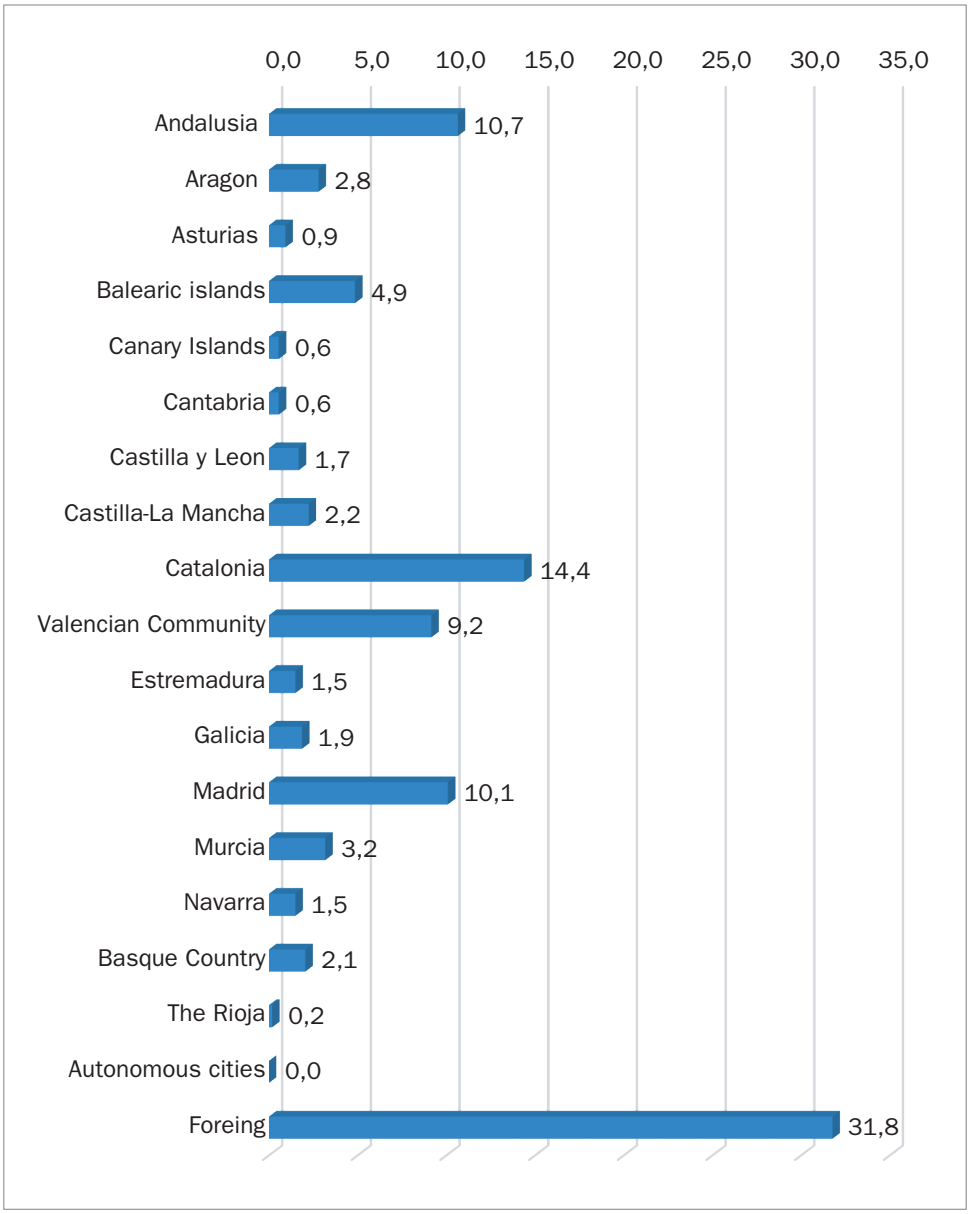
Figure 5.2.1. % of Companies registered in the SRE during 2019



The territorial distribution of the new companies registered in the on-line notification system during 2019 highlights the companies located in the autonomous community from

Catalonia (14,4%), Andalusia (10,7%), Madrid (10,1%), and the Valencian Community (9,2%). The increase of the companies registered from the Balear Islands, which represent 4,9% of the companies registered in the SRE this year.

Figure 5.2.2. Distribution of Companies registered with the SRE during 2019 by Autonomous Communities



The 68,2% of the new companies have been companies established in the national territory, while the other 31,8% were foreign companies, with the head office in the European Union. Concerning previous years, the increase continues due to foreign companies that commercialize the products in the national market. These companies account for the 17,7% of the companies registered in 2017, the 28,8% in 2018, and the 31,8% this year 2019.

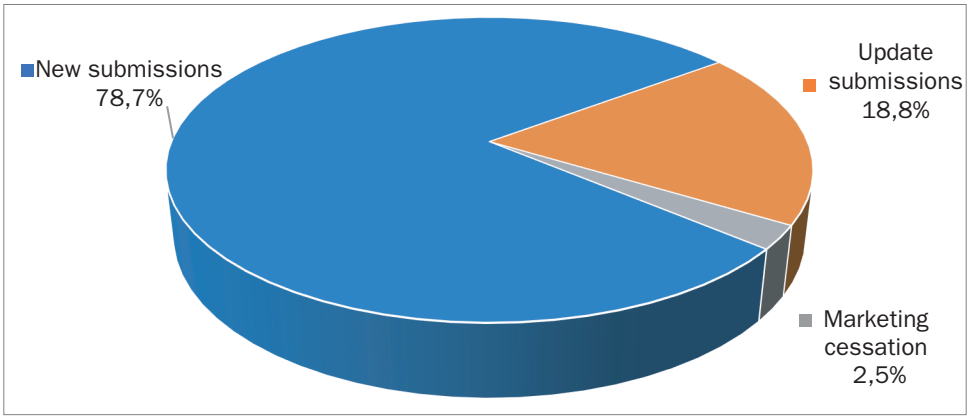
The incorporation of 535 new companies in 2019 is added to the 3,889 that were already registered in the SRE since 2015. so the 31st December 2019, 4,424 companies were

existing with the possibility to notify the necessary information about the products placed in the Spanish market, to allow the SIT physicians to provide an adecuate response in case of exposure to any of these mixtures.

These companies have submitted to the INTCF during 2019, a total of 8,569 notifications, through which they have notified a total of 41,339 chemical mixtures.

The products notified may be new mixtures reported for the first time to the INTCF (Registrations) in 78.7%: of the products notified, or modifications to previously notified products, either in their formulation or in other aspects of the marketing of the product (design of the labeling, size of the packaging, etc.) (18.8%). Finally, 2.5% of notifications correspond to cessation marketing product´s notifications and therefore had to be removed from the INTCF database.

Figure 5.3.1. Number of notifications according to the type of product notified



The distribution of the notified products according to company size and number of submissions during 2019 is shown in table 5.3.1.

Table 5.3.1. Distribution of notified products according to company size and number of submissions

TYPE OF COMPANY	%(nº submissions)	% (nº products)
Big Companies	46,3 (3.969)	51,6 (21.325)
Medium Companies	11,7 (1.006)	12,0 (4.971)
Little Companies	23,8 (2.037)	22,4 (9.276)
Micro Companies	18,2 (1.557)	14,0 (5.767)
Total	100,0 (8.569)	100,0 (41.339)

In the table 5.3.2. the distribution between type of company in relation to the type of notification submitted.

Table 5.3.2. Distribution between type of company in relation to the type of notification submitted

Type of company	New submission	Modification	Deletion	Total
Big Company	17.251 (41,7%)	3.663 (8,9%)	411 (1,0%)	21.325 (51,6%)
Medium	3.706 (9,0%)	820 (2,0%)	445 (1,1%)	4.971 (12,0%)
Little	6.914 (16,7%))	2.263 (5,5%)	99 (0,2%)	9.276 (22,4%)
Micro Company	4.659 (11,3%)	1.026 (2,5%)	82 (0,2%)	5.767 (14,0%)
Total	32.530 (78,7%)	7.772 (18,8%)	1.037 (2,5%)	41.339 (100,0%)

5.3. PARTICIPATION IN WORKING GROUPS BY THE DOCUMENTATION SECTION STAFF

During 2019, the Documentation Section has continued participating in the European harmonization process contemplated in the art. 45.4 from the Regulation CLP and in the implementation of Annex VIII (European Regulation (UE) nº 2017/542), through the elaboration of reports and studies, requested by the European Commission DG Internal Market, Industry, Entrepreneurship, and SMEs. Consumer, Environmental, and Health Technologies, participating in the Workshops organized by the European Commission and appertaining to the workgroups organized by the same one (WG). This harmonization must be finished by the 1st of January 2020, a date in which they must be available free of all the necessary resources, to notify product´s consumers.

Throughout 2019 this Section has participated in:

Interministerial meeting REACH CLP, for the discussion of consultations arising from implementing the Regulations REACH and CLP to the industrial sectors affected by this regulation. Representatives from different administrations attended these meetings; such as the Ministry of Industry, Trade and Tourism, Ministry of Labour and Social Economy, Ministry for the Ecological Transition and the Demographic Challenge, Ministry of Health, Consumption and Social Welfare, and the Ministry of Justice, represented by the National Institute of Toxicology and Forensic Sciences, together with the Associations and representatives of the different industrial sectors involved in the implementation of these Regulations.

Development of the technology program allows the notification of the information, including the chemical composition of all the classified mixtures, which could be dangerous because of their impact on health and physical effects. “ECHA WG IT is a member of the group tools user group,” created to develop the different technological resources. This collaboration has been realized elaborating reports, attending videoconferences and meetings of the working group, as well as participating in the pilot studies of IT developments promoted by the European Chemicals Agency (ECHA).

Development of the validation rules from the information remitted from the Chemical industry to the ECHA for its distribution to different designated bodies in each Member State. Participation in the working groups created for this development: ECHA WG on Validation Rules, incorporating a member in the working group, elaborating reports, and participating in the different Videoconferences to exchange opinions with the validation necessary rules in the remitted notifications by the chemical industry to the designated Organisms appointed by ECHA.

Development of the European notification Portal Participation in the significant study promote by the ECHA (v1), for the study of European notification portal (PCN), that must be available for January 2020, sharing the experience from the INTCF in the notification on-line platform (SRE system) already implemented in Spain.

Elaboration of the Guidances: Participation with a nominated member from the Documentation section, at the workgroups established in the European Commission "ECHA Guidance WG on Poison Centres," for the elaboration of the guidances edited by ECHA and the legal regulation impact for the appointed bodies in each Member State. This collaboration has been managed through report elaboration, participating in international videoconferences and Workshops.

Likewise, participates with a member nominated in the "ECHA expert for Partner Expert Group (PEG)" for the process consultation in the final elaboration of the "Guidance on harmonized information relating to emergency health response – Annex VIII to CLP".

Participation in the "Workability study concerning implementation of Annex VIII of CLP', to study the notification to the designated bodies regarding information received from sectors of the chemical industry. These represent a special casuistic to implement the CLP regulation (Manufacturers of cement, hydrocarbons, medicinal gases, etc.), using reports, videoconferences, and workshops.

During 2019, the SIT collaborates with European harmonization in the categories of the product type used by all member states in the poison centers, with the purpose of toxic vigilance and intoxication prevention.

Implementation of the Unique Formula Indentifier (UFI) that the companies will have to incorporate in the labels of the products they market. 'Workshop on the study on analysis, development, and testing of the Unique Formula Identifier (UFI) for information to be submitted to poison centers, according to article 45 (4) of EC regulation No 1272/2008 (CLP regulation)".

Reports request by the ECHA: During 2019, several queries have been requested by ECHA regarding specific aspects of notifications which have been answered based on the INTCF experience (Single Portal use, submission procedure, specific state fees in the notification process, acknowledgment receipt card of documentation received, etc.).

Reports solicited by the Ministry of Health, Consume and Social Welfare, for meetings on the harmonization of European legislation (CARACAL): numerous reports have been

elaborated for the Spanish authorities, with the finality to document the issues discussed at the meeting maintained with the European Commission, in Brussels.

Reports solicited by the Ministry of Health, Consume and y Social Welfare, for meeting with the European Commission to draft amendments to Annex VIII to the CLP Regulation (Inter-ministerial Coordination Group REACH matters). As well as mentioned before, there are several reports elaborated for the Spanish authorities. The purpose is to document the amendment of Annex VIII of the CLP Regulation planned for the following years.

Reports for the working group of the European Association of Intoxication Control Centres and Clinical Toxicology (EAPCCT): Through the workgroup 'EAPCCT Working Group on Poisons Centre Activities & European Regulatory Issues', contacting with the Poison Centers representatives in the meeting of European harmonization, as it is referred in the art. 45.4 Regulation (CE) Nº 1272/2008 from the Parliament and Council, from 16 of December 2008), through the emission of reports and comments in all the matters involved in the harmonization, informing the criteria and Spanish experience in notification process of chemical mixtures to the INTCF.

Informative meeting with the representant of the Spanish Chemical Industry: given the significant progress of the European harmonization that the spanish chemical industry must know for its adequation to new procedures, during 2019 numerous meeting have occurred with Federations, Associations and companies from different chemical sectors, such as the Federación Empresarial de la Industria Química Española (FEIQUE), Asociación española de fabricantes de pinturas y tintas de imprimir (ASEFAPI), Asociación de Empresas de Detergentes y productos de Limpieza (ADELMA), Federación Empresarial Catalana del Sector Químico (FEDEQUIM), Instituto Tecnológico del Plástico (AIMPLAS), Asociación Nacional de Perfumería y cosmética (STANPA), etc. with the purpose to let them know the notification process to INTCF and its modification purposes, as well as the new requirements for the implementation of European harmonisation that must be available by 1 January 2020.

Meetings with the Interministerial Commission for Food Management, as an official representation of the INTCF face the corresponding Plenary (CIOA).

Meeting with the Commission advisors to the Notified entity, created by the Health Products Committee of the Spanish Agency for Medicines and Healthcare Products (AEMPS), in the official representation of the INTCF.

6. SCIENTIFIC, EDUCATIONAL, AND DISSEMINATION IN MEDIA ACTIVITIES

6.1. PARTICIPATION IN RESEARCH PROJECTS AND COLLABORATION WITH OTHER INSTITUTIONS

Investigation project:

"Detergent capsules – accidentology project (laundry, dishwasher and others)".

Collaborating entities: International Association for Soaps, Detergents and Maintenance Products (AISE), SIT and other Antitoxic European Centers.

Period of execution: 2012-2020.

Resume of objectives: Retrospective study (2012- 2016) and prospective (2017-2020) of toxicovigilance to accidental exposures of cleaning products in capsule form (laundry, washers, and others), by referring the number of cases of patients exposed to such cleaning products in that commercial format.

From the SIT, the semestral dates are reported to improve the packaging properties and packaging design of commercialized products to make them safer, mainly directed to the child population because of its particularly attractive format. An estimate of the severity of each toxic exposure is also included.

Collaborations with other institutions:

- Member State Communicators Network meeting. (ECHA) - Helsinki.
- Workshop on the Appointed Bodies and Poison Centres - Use of the Poison Center Notifications database. (ECHA) - Helsinki.
- Confederación Española de Consumidores y Usuarios (CECU).
- Instituto Nacional de Seguridad y Salud en el Trabajo (INSST).
- Instituto de Toxicología de la Defensa. Ministerio de Defensa.
- Departamento de Toxicología Veterinaria. Facultad de Veterinaria. Cáceres.
- Confederación Nacional de Personas Sordas. Plataforma SVisual para la atención telefónica del SIT a personas sordas.
- Comisión Asesora del Organismo Notificado. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).
- Comité Científico de Productos Sanitarios. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).
- Departamento de Medicamentos Veterinarios. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).
- Comisión de implantes mamarios y afines. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).

- Comisión Nacional para el uso forense del ADN. Ministerio de Justicia.
- Comisión Interministerial para la Ordenación Alimentaria (CIOA). Agencia Española de Seguridad Alimentaria y Nutrición (AESAN).
- Grupo Interministerial de Coordinación de Asuntos REACH.
- Working Group on Poisons Centre Activities & European Regulatory Issues. European Association of Poison Centres and Clinical Toxicologists (EAPCCT)
- Meeting of the CARACAL Sub-group on ATPs to CLP. Comisión Europea, Bruselas.
- Guidance WG on Poison Centres. (ECHA)
- Partner Expert Group (PEG). (ECHA).
- WG IT tools. (ECHA).
- Federación Empresarial de la Industria Química Española (FEIQUE).
- Asociación española de fabricantes de pinturas y tintas de imprimir (ASEFAPI).
- Asociación de Empresas de Detergentes y productos de Limpieza (ADELMA).
- Federación Empresarial Catalana del Sector Químico (FEDEQUIM).
- Instituto Tecnológico del Plástico (AIMPLAS).
- Asociación Nacional de Perfumería y cosmética (STANPA).

6.2. SCIENTIFIC PUBLICATIONS

De la Oliva S, Mencías E, Conejo JL. Epidemiología de las intoxicaciones registradas en el Servicio de Información Toxicológica. En: Nogué Xarau, S. Toxicología Clínica. Bases para el diagnóstico y tratamiento de las intoxicaciones en los servicios de urgencias, áreas de vigilancia intensiva y unidades de toxicología. 1ª Ed. Barcelona: Elsevier España, S.L.U. 2019. 3-8.

Conejo JL, de la Oliva S, Mencías E. Los Centros Antitóxicos y el Servicio de Información Toxicológica. En: Nogué Xarau, S. Toxicología Clínica. Bases para el diagnóstico y tratamiento de las intoxicaciones en los servicios de urgencias, áreas de vigilancia intensiva y unidades de toxicología. 1ª Ed. Barcelona: Elsevier España, S.L.U. 2019. 303-307.

6.3. TEACHING AND TRAINING ACTIVITIES

Conejo JL. Presentación del SIT y su utilidad institucional. Ponente. En: Jornadas para el nuevo personal de la Guardia Civil. INTCF. 11 of January.

Martínez Arrieta, R. Futuro armonizado, Notificación a los PCC. Perspectivas actuales. Ponente. En: Jornada de Comisión Técnica de la Asociación de Empresas de detergentes y Productos de Limpieza, Mantenimiento y Afines (ADELMA). Madrid. 21 of February.

Conejo JL. Intoxicaciones por plantas. Casuística recogida. Clínica y tratamiento del intoxicado. Colaborador de prácticas. En: Semana botánica medicinal. Departamento de Botánica. Facultad de Farmacia de la Universidad Complutense de Madrid. INTCF. 18, 19 and 20 of March.

Martos C. Consecuencias para la salud por el mal uso de los gases industriales. Ponente. En: Jornada El gas, un aliado seguro. Confederación Estatal de Consumidores y Usuarios (CECU). Madrid. 24 of April.

Martínez Arrieta, R. Situación actual y armonización a nivel europeo de las notificaciones a los Poison Center. Ponente. En: Jornada Técnica de Fragancias. Comité Español de la Detergencia Tensioactivos y Afines (CED) y Asociación Española de Fragancias y Aromas Alimentarios (AEFAA). Barcelona. 25 of April.

De la Oliva S. El Servicio de Información Toxicológica: funciones, características y casuística en Veterinaria. Ponente. En: Jornada de Actualización en Toxicología Clínica y Veterinaria. Departamento de Toxicología. Facultad de Veterinaria. Cáceres. 6 of May.

Mencías E. Errores comunes en el paciente intoxicado y otros aspectos médico-legales. Ponente. En: XV Curso de Actualización en Urgencias. Hospital Clínico de Madrid. 29 of May.

Martínez Arrieta, R. Participation as speaker in three conferences: *"Principios básicos en la evaluación de riesgos."; "Principales factores en la evaluación de seguridad de los cosméticos de acuerdo con las recomendaciones del SCCSS" y "Toxicidad sistémica de cosméticos hoy. La visión desde un centro antitóxico".* En: IX Edición del Título Propio de Evaluación de la Seguridad y Expediente de Información del Producto Cosmético. Facultad de Farmacia de la Universidad San Pablo CEU. Madrid. 10 of June.

Martínez Arrieta, R. Notificación al INTCF: Artículo 45 del Reglamento CLP. Ponente. En: Jornada informativa sobre el Reglamento de Productos Biocidas. Ministerio de Sanidad, Consumo y Bienestar Social. Madrid. 6 of June.

Martínez Arrieta, R. Notificaciones al INTCF para un futuro armonizado con la Unión Europea". Ponente. En: Jornada Reglamento REACH y CLP. Novedades 2019. Instituto Tecnológico del Plástico (AIMPLAS). Valencia. 18 of September.

Martínez Arrieta, R. Armonización de las notificaciones a los Centros Antiveneno europeos. Situación actual y futuro armonizado. Reglamento CLP. Ponente. En: Jornada informativa sobre Notificaciones al INTCF. Asociación Química y Medioambiental del Sector Químico de la Comunidad Valenciana (QUIMACOVA). 19 of September.

Martínez Arrieta, R. Art. 45 del Reglamento CLP: Armonización europea de las notificaciones. Implementación en España. Ponente. En: Jornada informativa sobre la armonización europea de la notificación de fichas toxicológicas. Asociación Española de Fabricantes de Pinturas y Tintas de imprimir (ASEFAPI). Madrid. 21 of October.

Martínez Arrieta, R. Notificaciones al INTCF, Art. 45 del Reglamento CLP. Ponente. En: Jornada informativa sobre la armonización europea de la notificación de fichas toxicológicas. Asociación para el autocuidado de la salud (ANEFP) al Comité de Productos biocidas. Madrid. 1 of October.

Conejo JL. Curso de Actualización en Toxicología Clínica y Forense. Director y Coordinador. Centro de Estudios Jurídicos (CEJ). Madrid. 17, and 18 of October.

Mencías E. Base de datos SIT: Drogas y Estupefacientes. Ponente. En: Curso de Actualización en Toxicología Clínica y Forense. Centro de Estudios Jurídicos (CEJ). Madrid. 17 and 18 of October.

Conejero C. Tutor de Prácticas tuteladas. 6º promoción de Facultativos del INTCF. Centro de Estudios Jurídicos (CEJ). Madrid. 14 – 18 of October.

Ramón F. Tutor de Prácticas tuteladas. 6º promoción de Facultativos del INTCF. Centro de Estudios Jurídicos (CEJ). Madrid. 21 – 25 of October.

Conejo JL. Tutor de Prácticas tuteladas. 6º promoción de Facultativos del INTCF. Centro de Estudios Jurídicos (CEJ). Madrid. 28 - 31 of October.

De Miguel JL. Tutor de Prácticas tuteladas. 6º promoción de Facultativos del INTCF. Centro de Estudios Jurídicos (CEJ). Madrid. 4 – 8 of November.

Conejo JL. Exposiciones tóxicas a productos comprados por internet. Ponente. En: Jornada Ojo al clic. Confederación Estatal de Consumidores y Usuarios (CECU). Valencia. 22 of November.

Mencías E. Tóxicos y Antídotos. Ponente. En: Jornada Riesgos NRBQ: Una estrategia común. Centro Militar de Farmacia de la Defensa – Base Militar de San Pedro. Colmenar Viejo (Madrid). 27 of November.

Conejo, JL. Conference “Epidemias por opiáceos y opioides: una historia pendular”. VIII Ciclo de conferencias. Instituto de Toxicología de la Defensa. Madrid. 15 of February.

Conejo, JL. Conference “Drogas y conducción: experiencia sobre los controles de drogas en fluido oral”. VIII Ciclo de -conferencias. Instituto de Toxicología de la Defensa. Madrid. 15 of March.

Conejo, JL. Jornada “El gas, un aliado seguro”. Confederación Estatal de Consumidores y Usuarios (CECU). Madrid. 24 of April.

Conejo, JL. Jornada “Actualización en Toxicología Clínica y Veterinaria”. Departamento de Toxicología. Facultad de Veterinaria. Caceres. 6 of May.

Conejo, JL. Curso “Presentaciones eficaces en tribunales”. 10 horas. INTCF. Madrid, 8 and 9 of May.

Lázaro, I. Partner Expert Group Meeting – Guidance working group. Agencia Europea de Productos Químicos (ECHA). May.

Conejo, JL. Conferencia “La epidemia que muta: chemsex y bugchasing”. VIII Ciclo de conferencias. Instituto de Toxicología de la Defensa. Madrid. 17 of May.

Conejo, JL. Conferencia “Grandes catástrofes tóxicas: revisión desde el siglo pasado hasta el presente”. VIII Ciclo de conferencias. Instituto de Toxicología de la Defensa. Madrid. 14 of June.

Conejo, JL. Jornada “Intoxicaciones por sustancias químicas en el ámbito laboral”. PREVOR. Madrid, 25 of September.

Lázaro, I. WebEx – IT User group and Notification database. Agencia Europea de Productos Químicos (ECHA). 1 of October.

Lázaro, I. Update v.2.0 – Duty holders. CARACAL Comisión Europea. Bruselas. October.

Personal médico y de Documentación. Curso “Actualización en Toxicología Clínica y Forense”. 10 horas. Centro de Estudios Jurídicos (CEJ). Madrid. 17 and 18 of October.

Conejo, JL. “Member State Communicators’network meeting”. Agencia Europea de Productos Químicos (ECHA). Helsinki. 23 - 25 of October.

Lázaro, I. Partner Expert Group Meeting – Guidance working group. Agencia Europea de Productos Químicos (ECHA). November.

Conejo, JL. Conferencia “Estado actual de las armas químicas”. VIII Ciclo de conferencias. Instituto de Toxicología de la Defensa. Madrid. 15 of November.

Conejo, JL. “Jornada de la Comisión de Seguridad y Salud Laboral”. Instituto Nacional de Seguridad y Salud en el Trabajo (INSST). Madrid. 21 of November.

De la Oliva, S. Conejo, JL. Jornada “Riesgos NRBQ: Una estrategia común”. Centro Militar de Farmacia de la Defensa (CEMILFAR) – Base Militar San Pedro. Colmenar Viejo (Madrid). 27 of November.

Lázaro Trueba, I. WebEx – Notification portal and database. Agencia Europea de Productos Químicos (ECHA). 3 of December.

Lázaro Trueba, I. Conejo, JL. “Workshop on the Appointed Bodies and Poison Centres - Use of the Poison Center Notifications database” Agencia Europea de Productos Químicos (ECHA). Helsinki. 9 – 11 of December.

Amat, M. De la Oliva, S. Mencías, E. Conejo, JL. Visita institucional al Centro Militar de Farmacia de la Defensa (CEMILFAR). Colmenar Viejo (Madrid). 19 of December.

6.4. COLLABORATION WITH THE MEDIA THROUGH THE COMMUNICATIONS OFFICE OF THE MINISTRY OF JUSTICE

9 of January. Article. “Exposición accidental al polvo de fentanilo”. Magazine Técnico-Sanitaria Zona TES.

21 of January. Article. “Efectos toxicológicos de las grayanotoxinas”. Newspaper El País.

5 of February. Interview. “Bacterias en los alimentos recalentados y sus efectos”. Onda Madrid.

7 of February. Article. “Datos epidemiológicos de las intoxicaciones por Productos de Limpieza doméstica”. Canal Sur Radio.

13 of February. Interview. “Toxiinfecciones alimentarias y muerte por Bacillus Cereus”. COPE Radio.

25 of March. Interview. “La importancia del Servicio de Información Toxicológica en el campo de la medicina forense”. Radio Nacional de España.

21 of June. Interview. “Picaduras por Carabela portuguesa y efectos producidos”. COPE Radio.

25 of June. Interview. “Intoxicaciones y toxiinfecciones alimentarias en verano”. Onda Madrid.

22 of September. Interview. “Picaduras por veneno de escorpiones y efectos producidos”. Cadena SER.

21 of October. Interview. “El beso del sueño. Efectos de la Doxilamina y Clonazepam”. Programa Víctimas del Misterio”. TVE-1.

22 of November. Interview. “El SIT y su repercusión en los consumidores y usuarios”. Coordinadora de Usuarios de la Sanidad, Salud, Consumo y Alimentación.

16 of December. Interview. “La posible toxicidad en el consumo de mariscos”. COPE Radio.

17 of December. Article. “Casuística de Intoxicaciones por óxido nitroso”. Magazine El País.

Between this group of work activities, it is essential to point out the interview done on the 22 of November for the Coordinator of Users of Health, Consumption, and Food that took place in the presentation at the Casa de la Ciencia (Valencia). The SIT presented the study of the casuistic recollected by the personal respect of the “Intoxication of Internet products,” during the Journey “Ojo al Clic” organized the 22 of November by the Confederation of Consumers and Users (CECU) with the collaboration of the Ministry of Health, Consumer Affairs and Social Welfare, and the Spanish Chemical Industry Business Federation (FEIQUE). Among the great variety of the products bought by social media, certain medicines, drugs, and cleaning products are more important than others, like nutritional supplements, anabolic, and non-anabolic.

The presentation generated a great social impact through the media which helped and collaborated in the Service through diverse interviews and their correspondent diffusion in social media (Twitter, Instagram…).