Prohibited Pesticide Authorisations

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Continued state of phytosanitary emergency threatens health and the environment

ecologistas en acción

Title
Emergency derogations of banned pesticides.

The permanent state of phytosanitary emergency threatens health and the environment

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Executive summary

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 ('the Plant Health Regulation') prohibits the placing on the market of active substances and pesticides containing such substances if they have adverse effects on human or animal health or on the environment.

This ban means that the use of active substances that are classified as mutagenic, carcinogenic or toxic for re-production (in category 1A or 1B) and those that, because of their ability to alter the hormonal system, may cause harmful effects on human health or on non-target organisms cannot be authorised..

Only when exceptional "plant health emergency" situations occur and the authorities wish to re-establish control over a danger that cannot be managed by other reasonable means, does Article 53 of the Regulation provide for the authorities to grant **emergency derogations** for the use of unauthorised and prohibited pesticide substances. These emergency derogations must be scientifically justified, be for specific uses and for a limited period of time not exceeding 120 days.

Only when exceptional "plant health emergency" situations occur and the authorities wish to re-establish control over a danger that cannot be managed by other reasonable means, does Article 53 of the Regulation provide for the authorities to grant emergency derogations for the use of unauthorised and prohibited pesticide substances. These emergency derogations must be scientifically justified, be for specific uses and for a limited period of time not exceeding 120 days.

The number of emergency derogations authorised in the Spanish State between 2013 and 2019 was 462. In 2019, the Directorate General for Agricultural Health granted 33 emergency derogations for pesticide products that allowed the use of pesticides in higher concentrations or in different uses than those authorised. Eight of the 32 active substances contained in the 33 emergency authorisations were not authorised because of their high toxicity or because their authorisation had not been requested by the manufacturer and 13 were identified as endocrine disrupters, substances with the capacity to alter the hormonal balance.

The data describe a decrease in the number of authorisations granted, as there were 33 in 2019 compared to 64 in 2018. However, as of 31 July 2020, the Directorate-General for Agricultural Health has granted 31 of these emergency authorisations, so we will have to wait to see whether the 2019 decrease is timely or marks a downward trend in the use of this type of exception.

On the other hand, many of these authorisations, such as those for the pesticides 1,3 dichloropropene and chloropicrin, are repeated year after year without justifying the existence of a pest or the lack of effective substitutes.

The routine use of emergency derogations by the Administration encourages the use of extremely dangerous plant protection products and hinders the development of safer alternatives.

The data collected in this report demonstrate the need for the administration to evaluate more effectively and justifiably requests for emergency derogations, so that those granted respond to a real and justified phytosanitary emergency. If this is not done, human health and the environment will suffer the consequences of allowing the use of active substances which were not authorised precisely because of their high risk.

Introduction

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009[1] ('the Plant Protection Regulation') provides that no active substance or plant protection product containing such a substance may be placed on the market if it has adverse effects on human or animal health or on the environment.

An active substance[2] is the active ingredient of the pesticide or pesticide. In other words, that which causes the death of the target organism (animal, plant or micro-organism) that it is intended to eradicate.

For the approval of the use of an active substance, industry must provide data, evidence and assessments demonstrating the safety of the substance for all other living non-target organisms, including humans. Or, in the absence of such a zero risk, demonstrate that the remaining risk is minimal and controlled.

In accordance with the objective of the Plant Health Regulation to protect human health, the **use of active substances which are classified as mutagenic, carcinogenic or toxic to reproduction in** category **1A or 1B** (substances known or suspected to be inherently dangerous, based on the existence of evidence in humans for those classified as 1A, or based on the existence of evidence in animals for those classified as 1B) cannot **be authorised. Nor are those considered to have endocrine disrupting properties** that may cause adverse effects on human health or on non-target organisms.

Pesticide users in Europe can use products containing any of the 478 approved substances. In contrast, a total of 890 active substances are not available because they are not authorised or are banned due to their high hazard and lack of effective controls to mitigate their risks.

In addition, the substances are authorised for specific uses and crops. That is to say, a substance may be authorised, for example, for pest control on strawberries but not on cereals; for treatment of ornamental plants but not for treatment of crops intended for human consumption; etc.

1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

2 Active substances" are defined as those, including micro-organisms having general or specific action against harmful organisms or on plants or plant products (Article 2.2 of the Plant Health Regulation). The term 'substance' is defined as chemical elements and their natural or manufactured components, including all impurities inevitably resulting from the manufacturing process (Article 3(2) of the Plant Health Regulation).

The concept of "harmful organisms" refers to any species, strain or biotope belonging to the animal or plant kingdom or pathogenic agent harmful to plants or plant products (Article 3.7 of the Plant Health Regulation).

The term 'plants' is defined as living plants and living parts of plants, including fresh fruit, vegetables and seeds (Article 3(5) of the Plant Health Regulation).

The concept of "plant products" refers to products of plant origin which are unprocessed or have undergone only simple operations such as milling, drying or pressing, but excluding plants (Article 3(6) of the Plant Health Regulation).

Table 1 Active substances in the EU on 31 August 2020

Authorized	478
Unauthorized	890
Forbidden	45
Pending approval	15

However, every year European industry uses unauthorized substances because the Plant Health Regulation allows their use in two situations: to conduct experiments or tests for research and development purposes and, above all, to deal with plant health emergencies.

The following pages analyse the situation of emergency derogations in Spain. First, a short explanation is given of the procedure for emergency derogations. It then briefly analyses its application in Europe and, more extensively, in Spain, together with the toxicity of the substances permitted by this exception.

Finally, the results obtained are discussed and our recommendations and proposals for improvement are set out.

The use of unauthorised substances: the emergency derogations

The Plant Health Regulation provides for two exceptions to its general principle that only approved substances may be placed on the market or used.

These two exceptions are plant health emergencies and the conduct of experiments or tests for research and development purposes.

The exception due to emergency situations is also known as the **120-day rule of derogation.** This rule allows an EU Member State, in special circumstances, to authorise, for a period not exceeding 120 days, the co-marketing of pesticides containing prohibited or non-approved active substances. They would then be approved **for a controlled and limited use, provided that this exceptional measure was necessary to control a hazard that cannot be managed by other reasonable means**.

The derogation provided for in Article 53 of the Plant Health Regulation allows the competent authorities responsible for granting emergency derogations a high degree of discretion. This is because it is not defined what is meant by controlled or limited use of the plant protection product, nor what is considered to be reasonable means or an emergency situation.

The Regulation stipulates that the state authorising the derogation must inform the other EU countries and the European Commission, which may request an opinion from the European Food Safety Authority (EFSA). The Commission may thus issue a decision which may extend the duration of the measure or repeat it, or amend or withdraw it.

However, in practice the European Commission neither endorses nor verifies the content of the emergency derogations granted by any of the Member States, including Spain. [3]

Even if the Commission were to request an opinion or scientific or technical assistance from EFSA, this would not mean that the Commission was verifying or evaluating the content and the decision taken by the national authorities. In fact, in the European Commission's view, "it is not the role of the European Food Safety Authority (EFSA) to monitor emergency authorisations". [4]

Only if necessary, the Commission can take a decision on when and under what conditions the Member State may or may not extend the duration of the authorisation, or repeat it, or whether it should withdraw or amend it. And normally the European Commission does not

3 EUROPEAN COMMISSION in response to a question from Ecologists in Action on 23 March 2020 [Europe Direct-101000606225]

4 Answer to a question by MEP Ernest Urtasun from the Commissioner for Health and Food Safety, Ms Kyriakides, on behalf of the European Commission on 30 June 2020 [EN E-002367/2020], available at: https://www.europarl.europa.eu/doceo/document/E-9-2020-002367-ASW_ES.html (consultation date: 12 August 2020)

intervine. In fact, it has only done so on two recent occasions since the entry into force in December 2009 of Regulation 1107/2009.[5]

In other words, in practice there is no preventive control, or any other type of control, by the European authorities. Therefore, the responsibility for emergency derogations granted by the Spanish State lies entirely with the competent Spanish body, the Dirección General de Sanidad de la Producción Agraria

5 In particular in the cases of Romania and Lithuania for the emergency derogations granted to neonicotinoid plant protection products, formulated with clothianidin or imidacloprid in the case of Romania and with thiame-toxam in the case of Lithuania (Commission implementing decision (EU) 2020/152 of 3 February 2020 and Commission implementing decision (EU) 2020/153 of 3 February 2020).

Implementation in the EU of the exceptional authorisations in 2019

A total of 518 emergency derogations were granted in the EU in 2019, 18% of which were for unauthorised active substances, while the remaining 82% allowed pesticides for uses other than those authorised.

This high number of emergency derogations of pesticides places European agriculture in a constant state of phytosanitary derogation and the use of unauthorised chemicals as the only effective tool. This situation is contrary to the required Integrated Pest Management[6] , according to which the last option for the treatment of a pest is the use of pesticides and they should only be used when other methods (cultural, biological, etc.) have been discarded because of their ineffectiveness.

However, a distinction must be made between emergency derogations that allow the use of pesticides for uses other than those approved and those that allow the use of substances that are not authorised for any use.

By way of example, Germany exceptionally authorised a total of 51 pesticides, only 4 of which, i.e. 8%, were substances not authorised for any use by the EU. Spain, on the other hand, granted 33 emergency derogations, 24% of which allowed the use of products not authorised because of their serious danger to human health and the environment.

6 Integrated Pest Management means "the careful consideration of all available methods of plant protection and the subsequent integration of appropriate measures to prevent the development of populations of harmful organisms and to keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. Integrated Pest Management emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and promotes natural pest control mechanisms" (Article 2(6) of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides).

Table 2 Emergency derogations allowed in the EU in 2019

Country	Exceptional Auth. No.	Unauthorised	Percentage
Cyprus	0	0	0%
Slovenia	11	0	0%
Netherlands	3	0	0%
Malta	0	0	0%
United Kingdom	11	0	0%
Slovakia	31	1	3%
France	68	5	7%
Germany	51	4	8%
Croatia	10	1	10%
Italy	65	7	11%
Denmark	6	1	17%
Belgium	29	5	17%
UE average	18,5	3,4	18%
Austria	45	9	20%
Sweden	5	1	20%
Finland	17	4	24%
Spain	33	8	24%
Ireland	4	1	25%
Portugal	26	8	31%
Latvia	18	6	33%
Romania	3	1	33%
Greece	47	16	34%
Lithuania	14	5	36%
Bulgaria	4	2	50%
Estonia	2	1	50%
Luxembourg	2	1	50%
Poland	6	3	50%
Czech Republic	6	4	67%
Hungary	1	1	100%

Implementation of the excepcional authorisations in the Spanish State in 2019

Table 3 **Number of emergency derogations granted in Spain in 2019**

	2013	2014	2015	2016	2017	2018	2019
Number of exceptional authorisations	76	92	71	63	63	64	33

During 2019, the General Directorate of Health of Agricultural Production of the Ministry of Agriculture, Fisheries and Food (MAPA) granted 33 emergency derogations, 8 allowed the use of non-authorised substances and 15 allowed the use of pesticides for other than authorised uses. Between 2013 and 2019, 462 emergency authorisations were granted in Spain[7].

The number of emergency authorisations granted tripled in the years 2012 to 2016 as a result, as justified by the Spanish administration, "of the serious shortage of plant protection products for pest control, due to the loss of active substances under the EU review programme and the more restrictive conditions of use of many of the plant protection products after the renewal of the authorisation"[8].

However, if there are alternatives, they should be used, and if not, they should be developed. The continuous use of emergency derogations by the Administration encourages the use of dangerous phytosanitary products, hinders the development of safer alternatives, and discourages the innovation demanded by the Spanish Administration itself[9].

In this way, the Spanish authorities undermine the objective of protecting human health and the environment of the Plant Health Regulations.

In 2019 there is a significant decrease compared to the average of 66 allowed between 2013 and 2019 and 64 allowed in 2018.

We are confident that this decline marks a new policy of greater rigour and less discretion on the part of the MAPA in granting emergency derogations. However, as of 30 July 2020, 31 emergency derogations have been granted by Spain in 2020.

7 Data provided by the Directorate General for Health of Agricultural Production.

8 The annual results of the National Plan for the Sustainable Use of Plant Protection Products published on the website of the Ministry of Agriculture, Fisheries and Food, show in section 4 the emergency derogations granted since 2013.

9 PESTICIDE ACTION NETWORK Europe, Meet (Chemical) agricultura: The 120-day derogation-One year ahead, what happened?, Julio 2012, https://www.pan-europe.info/old/Resources/Reports/PAN%20Euro- pe%20-%202012%20-%20Meet%20(chemical)%20agriculture%20-%20The%20120-day%20derogation.pdf (Accessed on 18 February 2019)

Emergency derogations for pesticides authorised for other uses

Of the 33 emergency derogations granted by MAPA during 2019, 25 were for active substances of pesticides authorised for other uses.

For a pesticide to be authorised in an EU country, the health and environmental risks of the uses for which authorisation is sought must be assessed.

The new uses allowed by the emergency derogations are very diverse, from pest control by means of insecticides, bactericides, nematicides, fungicides, to the regulation of the control of the normal development of the plant by means of phytoregulators.

Member States are allowed such discretion that they grant authorizations for the use of these substances to modify the vegetative state of plants, while authorizing post-emergence and harvest treatments. This seems to be contrary to the purpose of emergency derogations, which should be aimed at treating 'special circumstances' which would have to be limited to pests which cannot be predicted and cannot be controlled by other means.

One case that exemplifies the very broad discretion enjoyed by the Directorate General for Agricultural Health is the exceptional authorisation of pesticides formulated on the basis of gibberellic acid to delay the ripening of persimmon on the tree and flowers. The exceptional authorisation allows the use of higher doses than those stipulated in the authorisation granted for the use of this product in the Spanish State.

The condition put forward by the Directorate General is that "the cultivation of persimmon is acquiring great development in different areas of the Spanish geography". The existence of a danger is justified by the need to extend the marketing capacity and increase the absorption capacity of the market, for which it is necessary to delay the ripening of the fruit and keep it on the tree longer.

The justification does not prove any special condition to need higher doses than those authorized. However, the Directorate General has granted this exceptional authorisation repeatedly in the years 2016, 2018, 2019 and 2020 in a total of 14 times since 2011 as a growth regulator for oranges and persimmons.

These data show the routine and non-exceptional nature of emergency derogations in the Spanish State.

In order to avoid the repetition of emergency derogations of authorised pesticides for other uses, Regulation 1107/2009 on plant protection products provides for the manufacturer to apply for a minor use authorisation or to extend the scope of his authorisation.

In both cases, the manufacturer is obliged to assess the health and environmental impacts of new uses. While the Spanish authorities cannot oblige the applicant to submit such applications, the European Commission determines that they should strongly encourage companies to do so.

It is a matter of concern that one of the most effective tools for reducing the number of emergency derogations and improving the evaluation of pesticides used is not compulsory. Instead, it depends on the will of the manufacturer and the 'encouraging' efforts of the Directorate General, which declares that it has no information on this subject, and we fear that its efforts in this matter are clearly insufficient[10].

Table 4 Emergency derogations allowed in 2019 for pesticides authorised for other uses

ACTIVE SUBSTANCE	USE/PLAGUE	CROPS
(Z)-11-HEXADECENNIAL	INSECTICIDE, CATERPILLARS	KHAKI, POMEGRANATE
(Z)-13-OCTADECENNIAL	INSECTICIDE, CATERPILLARS	KHAKI, POMEGRANATE
AUREOBASIDIUM PULLULANS	BACTERICIDE, ERWINIA AMYLOVORA	PERAL
AZOXYSTROBIN	FUNGICIDE, PYRICULARIA ORYZAE	RICE
BETA-CYFLUTHRIN	INSECTICIDE, TREATED SEEDS	TRAILER
BOSCALID	FUNGICIDE, BOTRITIS, BOTRYOSPHAERIA DOTHIDEA	PISTACHO
CLETHODIM	HERBICIDE,	GRASS, OPIUM POPPY
COPPER OXIDE	CRYPTOGAMIC DEFOLIATOR DISEASES	CONFERENCES
CYANTRANILPROLE	INSECTICIDE, FLY (DELIA ANTIQUA)	ONION, GARLIC
CYMOXANIL	FUNGICIDE, MILDEW	OPIUMBER
DIFLUBENZURON	INSECTICIDE, LOCUST	HEDGEROWS AND PASTURES
DIFLUBENZURON	INSECTICIDE, LOCUST (AERIAL APPLICATION)	HEDGEROWS AND PASTURES
EMAMECTIN	INSECTICIDE, RED PALM WEEVIL	PALMS
FAMOXADONE	FUNGICIDE, MILDEW	OPIUMBER
FLUDIOXONIL	FUNGICIDE, RHIZOCTONIA SOLANI, PYTHIUM ULTIMUM	RICE SEED
FLUOPICOLIDE	FUNGICIDE, MILDEW	HOP
FLUXAPYROXAD	FUNGICIDE, RHIZOCTONIA SOLANI, PYTHIUM ULTIMUM	COTTON SEED
FOSETYL	FUNGICIDE, MILDEW	HOP
GIBBERELLIC ACID	PHYTOREGULATOR, DELAY ADURATION	KHAKI
LAMBDA-CYHALOTRIN	INSECTICIDE, APHIDS	BLUEBERRIES
LAMBDA-CYHALOTRIN	INSECTICIDE, BACTROCERA OLEAE	OLIVE TREE
LAMBDA-CYHALOTRIN	INSECTICIDE, OPEROPHTERA BRUMATA (LEPIDOPTERA)	BLUEBERRIES
OXAMYL	NEMATICIDE, DITYLENCHUS	ONION
PYRACLOSTROBIN	FUNGICIDE, ALTERNARIA ALTERNATA	MANDARINO
PYRACLOSTROBIN	FUNGICIDE, BOTRYTIS, BOTRYOSPHAERIA DOTHIDEA	PISTACHO
PYRIMETHANIL	FUNGICIDE, ALTERNARIA SPP (POST HARVEST)	KHAKI
SPINETORAM	INSECTICIDE, DROSOPHILA SUZUKII	BLUEBERRIES
SPIROTETRAMAT	INSECTICIDE, PULGONES Y PSÍLIDOS	CELERY
THIOPHANATE-METHYL	FUNGICIDE, DIPLODIA CORTICOLA	ALCORNOQUE

10 AGRICULTURAL PRODUCTION HEALTH DIRECTORATE, Response of 25 August 2020 to a request for information, measures to encourage requests for minor uses.

Emergency derogations of non-authorised products for any use

The 2019 data show that MAPA granted eight emergency derogations of plant protection products formulated on the basis of unauthorised active substances. These substances had been declared unauthorised either because of their toxicity which is an unacceptable risk to human health or the environment, or in the case of four of them (clothianidin, dichlorvos, natural seed extract of camellia and thidiazuron) because no application for authorisation was made, which means that they have not undergone a process of risk assessment and their risks are not well known.

Table 5 **Emergency derogations allowed in 2019 for unauthorised pesticides**

ACTIVE SUBSTANCE	PLAGUE	CROPS
1,3-DICHLOROPROPENE	DISINFECTION	VID
1,3-DICHLOROPROPENE	DISINFECTION	VARIOUS FRUITS, VEGETABLES, ETC
1,3-DICHLOROPROPENE+CHLOROPICRIN	DISINFECTION	VARIOUS FRUITS, VEGETABLES, ETC
CHLOROPICRIN	DISINFECTION	VARIOUS FRUITS, VEGETABLES, ETC
CLOTHIANIDIN	INSECTICIDE-TREATED SEEDS	TRAILER
DICHLORVOS	INSECTICIDE, FRUIT FLY	CITRUS FRUITS
NATURAL SEED EXTRACT OF CAMELLIA SP	MOLLUSCICIDE, APPLE SNAIL, POMACEA SP	RICE
PROPANIL	BAD HERBS	RICE
THIDIAZURON	DEFOLIANT: ANTICIPATE HARVEST	COTTON

Toxicology of the 8 active substances not allowed in the Spanish State in 2019

1, 3 dichloropropene

In addition to Spain, this dangerous toxin was exceptionally authorised in Greece, Italy and Portugal.

The EU rules that do not authorise this active substance are decision 2007/619/EC and decision 2011/36/EU. The latter explains with the following arguments its non-authorisation:

"In particular, there are concerns about the exposure of consumers to eleven unidentified manufacturing impurities. In addition, the following were not adequately addressed: the potential contamination of groundwater by 1,3-dichloropropene; (EZ)-3-chloroacrylic acid, a major toxic derivative of its breakdown; and eleven unidentified manufacturing impurities; there is also the potential risk of long-range transport through the atmosphere of ten manufacturing impurities. On the other hand, the risk to non-target organisms was not demonstrated to be acceptable".

Unfortunately, this substance is currently awaiting further authorisation. The difference between unauthorised and prohibited active substances is that while the former can be re-authorised, the latter is not allowed.

However, this new authorisation attempt process is suspended pending a report from the European Chemicals Agency on the possible classification of 1,3-dichloropropene as a mutagenic substance. Should it be classified as such, the pesticide could be banned.

Official toxicological profile:

CASE NUMBERT: 33956-49-9

May be fatal if swallowed and enters respiratory tract; toxic if swallowed; toxic in contact with skin; very toxic to aquatic life; very toxic to aquatic life with long lasting effects; flammable liquid and vapour; causes severe eye irritation; harmful if inhaled; causes skin irritation; may cause allergic skin reaction; may cause respiratory irritation.

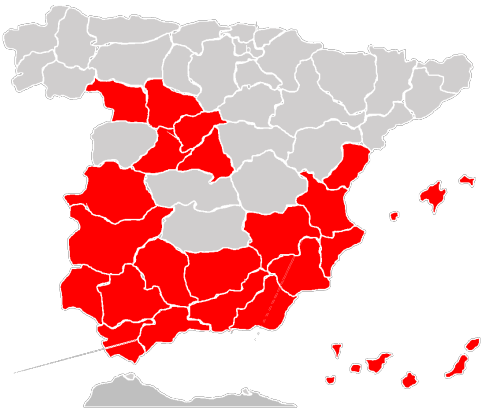
In 1999 the Agency for Cancer Research of the WHO listed 1.3 dichloropropene as a possible human carcinogen[11].

11 AGENCIA PARA LA INVESTIGACIÓN DEL CÁNCER (IARC), Re-evaluation of some organic chemicals, hidrazine and hydrogen peroxide. Vol. 71, 1999, pp. 933-945, https://monographs.iarc.fr/wp-content/uploads/2018/06/mono71-41.pdf (fecha de consulta: 9 de septiembre de 2020).

It is used by means of emulsifiable formulations through the drip net, or through injections into the soil in pre-planting or pre-sowing, requiring sealing with a roller or the use of a water-proof plastic.

In 2019 this active substance was allowed to be used for soil disinfection in tomato, pepper, melon, artichoke, broccoli, lettuce and ornamental plant crops.

The areas marked in red indicate the provinces where their use was authorised[12].



The authorisation decision is dated 21 December 2018, although it was subsequently extended up to nine times.

However, at EU statistical level it is counted as a single authorisation. But far from being negligible, as discussed elsewhere in this report, this accounting has implications for harmonised risk indicators for pesticides[13].

In addition to the exceptional authorisation described for this potent toxin, the MAPA granted a further authorisation for the disinfection of soil for vine cultivation.

And as in the previous case, the date of the resolution is 21 December 2019 and was modified, extending its territorial scope on five occasions.

Chloropicrin

This pesticide has been authorised in Spain, Italy and Portugal.

The EU rules that do not allow the use of this active substance are Decision 2008/934/EC and Regulation 1381/2011. The latter states the following:

"It presents an unacceptable risk for workers. The ex- position of the groundwater could not be reliably assessed, due to the lack of data on the metabolite dichloronitromethane

12 This and the other maps have been made using an Excel template by Excel&VBA, available at: https://excelyvba.com/provincias-espana-excel/

13 The Directive on the Sustainable Use of Pesticides defines a risk indicator as "the result of a method of calculation used to assess risks from pesticides to human health or the environment" (Article 3(7) of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides).

and the impurities contained in the manufactured active substance. Insufficient data were available to draw conclusions on the risks to sediment dwelling organisms, bees, earthworms and non-target plants. A high risk to aquatic organisms, birds and mammals could be established. Exposure of surface water and sediment could not be reliably assessed due to lack of data on chloropicrin and dichloronitromethane me-tabolite. Exposure to airborne phosgene concentrations could not be reliably assessed. A high risk of long-range transport through the atmosphere could be established".

Unfortunately, as in the case of 1,3-dichloropropene, despite its high danger, a new attempt at authorisation is currently pending.

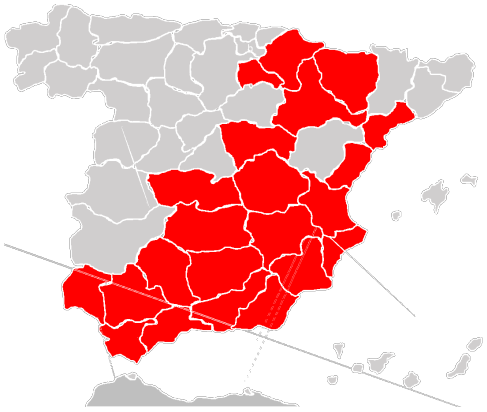
As a curiosity, this poison was used in large quantities during the First World War and was stored during the Second World War. Fortunately, it is no longer used for military purposes, although due to emergency derogations it is still used in agriculture[14].

Official toxicological profile:

CASE NUMBER: 76-06-2

According to the harmonised classification and labelling of the CLP Regulation, this substance is fatal if inhaled; harmful if swallowed; causes severe eye irritation; causes skin irritation and may cause respiratory irritation.

In the same way that 1,3-dichloropropene is used by means of emulsion formulations through the drip net, or through injections to the soil in pre-planting or in pre-planning. However, in the case of chloropicrin it is necessary to cover the soil with a virtually impermeable or totally waterproof film.

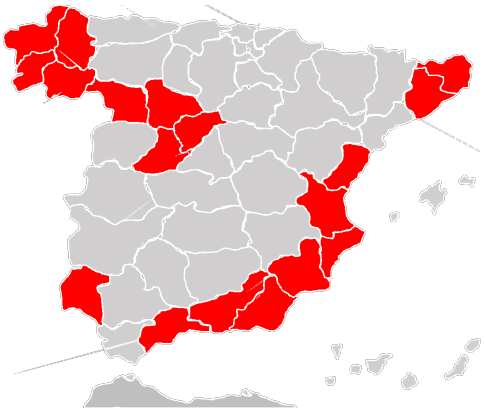


Its exceptional authorisation made it possible to use it on pepper, tomato, labacinth, cucumber, aubergine, strawberry, raspberry and blackberry crops. The date of its authorisation was 21 December 2018, and it was extended three times.

14 CENTER FOR DISEASE CONTROL AND PREVENTION (CDC), THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), Chloropicrin (PS): Lung Damage Agent, https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750034.html (Accessed on 9 September 2020)..

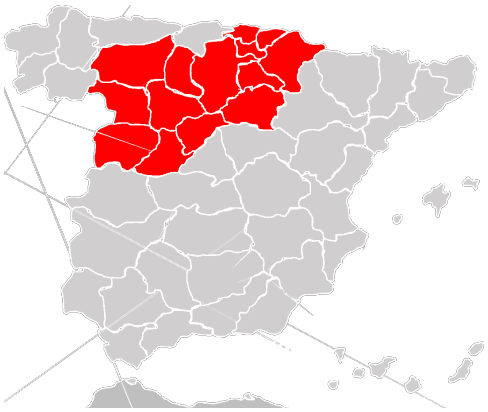
1,3-dichloropropene+chloropicrin

A third resolution of 21 December 2018 of the Directorate-General for Agricultural Health has exceptionally authorised the combined use of the active substances 1,3-dichloropropene and chloropicrin for soil disinfection in tomatoes, peppers, melons, aukes, broccoli, lettuce and ornamental plants. The initial resolution was extended five times.



Clothianidin

This neonicotinoid insecticide was exceptionally allowed during 2019, in addition to Spain, in Austria, Belgium, Finland and Poland. In the case of Spain it was authorised in combination with the authorised active substance beta-cyfluthrin for use on treated beet seed.



With regard to the risks of this active substance, Regulation 485/2013 states

"The [European Food Safety] Authority identified for certain crops an acute risk to bees from plant protection products containing the active substances clothianidin, thiamethoxam or imidacloprid. In particular, it identified high acute risks to bees from exposure to dust on some crops, from the intake of residues of contaminated pollen and nectar on others and from exposure to guttating[15], the case of maize. In addition, unacceptable risks due to acute or chronic effects on survival and development of colonies cannot be excluded in the case of several crops.

15 Gutting is a process that occurs inside the plant during which water from the leaf edges is expelled to the outside through special pores (hydatid) as a result of high pressure on the root. This water comes largely from the plant's xylem system so it is mainly composed of water, but may contain small amounts of nutrients and dissolved sugars. ROYAL BRINKMAN, What is guttation? https://royalbrinkman.es/centro-de-conocimiento/cuidado-del-cultivo/que-es-la-gutacion (Accessed on 9 September 2020)

Furthermore, the Authority identified data gaps for all crops assessed, in particular with regard to the long-term risk to bees from exposure to dust, residues in pollen and nectar and exposure to guttating.

The manufacturer subsequently withdrew its application for renewal and the authorisation expired on 31.01.2019.

Official toxicological profile:

CASE NUMBER: 210880-92-5

According to the harmonised classification and labelling of the CLP Regulation, this substance is very toxic to aquatic life; very toxic to aquatic life with long-lasting effects: and harmful if swallowed.

Dichlorvos

The use of this insecticide was allowed in Spain in 2019 for the treatment of fruit flies in citrus fruits destined for export to the USA. In this respect, the Directorate General for Agricultural Health and Production clearly states that the purpose of the exceptional authorisation of dichlorvos-based phytosanitary products is to treat a quarantine pest[16] not in Spain but in the USA. He goes on to say that the reason for the decision and therefore the exceptional authorisation is the "citrus export protocol signed with the USA".

On the subject of trade agreements and the granting of emergency derogations, Mrs Kyriakides (now European Commissioner for Health and Food Safety), on behalf of the European Commission, in reply to a question from the European Parliament, replied on 28 April 2020[17] as follows:

> "There is no link between the granting of an exceptional authorisation by a Member State and trade agreements with third countries".

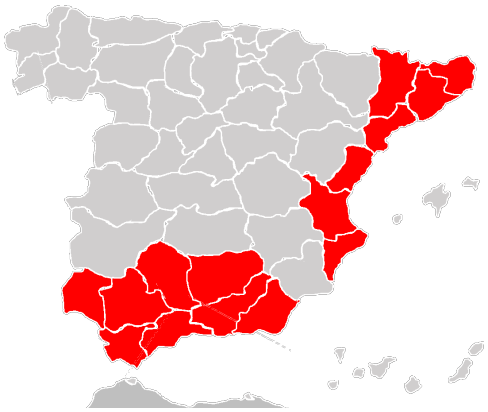
In other words, trade agreements do not provide a basis for emergency derogations for the use of plant protection products, so this decision should not have been granted.

With regard to the rules that do not authorize their use, only point out that they do not exist since their authorization has not been requested.

Official toxicological profile:

16 The International Plant Protection Convention (available at: https://www.boe.es/buscar/doc.php?id=BOE- A-2006-15001) defines "quarantine pest" as a "pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled".

17 EUROPEAN COMMISSION, reply to a parliamentary question (E-001378/2020) by the Spanish Europarligneur Ernest Urtasun.

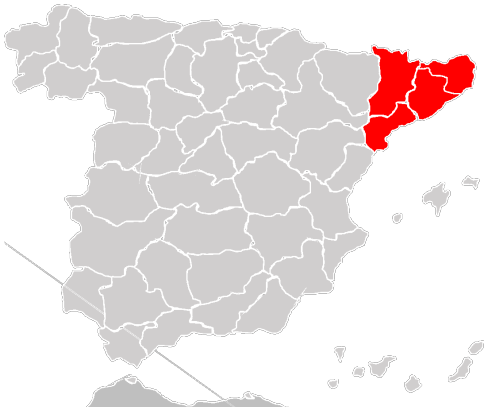


According to the harmonised classification and labelling of the CLP Regulation, this toxin is fatal if inhaled; toxic if swallowed; toxic in contact with skin; very toxic to aquatic life; and may cause an allergic reaction on the skinl.

Camellia seed extract

(Natural seed extract of Camellia)

This molluscicide was allowed in Spain in 2019 to combat the apple snail in rice crops. Its authorisation has never been requested, nor does it have an official toxicological profile, so we do not know its risks, if any.



Propanil

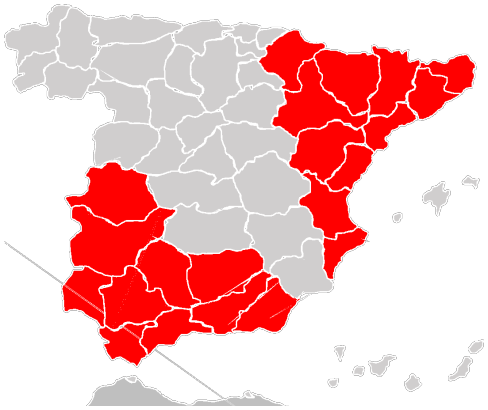
This herbicide was exceptionally authorised in 2019 in Spain and Greece, in the case of Spain, for the control of narrow leaf weeds in rice.

Regarding the risks, it is worth mentioning the areas of concern expressed by the European Food Safety Authority (EFSA) regarding the last attempt, which failed as the two previous attempts in 2008 and 2011. EFSA in December 2018[18] indicated that the evaluation of this pesticide could not be completed because there was insufficient information available.

18 EUROPEAN FOOD SAFETY AUTHORITY (EFSA), Peer review of pesticide risk assessment of the active substance propanil of 20 December 2018, https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5418 (Accessed on 9 September 2020)

In addition, it proposed to classify propanil as a category 2 carcinogen and, although it considered that the conditions for classifying it as an endocrine disruptor for human health were not met, it concluded that this pesticide affected the hormonal system, probably because of its anti-androgenic properties. It therefore stated that further research should be carried out in order to reach a clear conclusion on possible adverse effects caused by its endocrine activity.

Among other negative conditions, EFSA further concluded that there was an acute risk for herbivorous birds, a high long-term risk for insectivores, birds and herbivorous mammals for all representative uses of propanil. To this must be added the high risk identified for soil organisms.



Finally, the applicant withdrew its request for authorisation, so that this pesticide cannot currently be marketed or used, except for emergency derogations, such as the one granted in 2019.

Official toxicological profile:

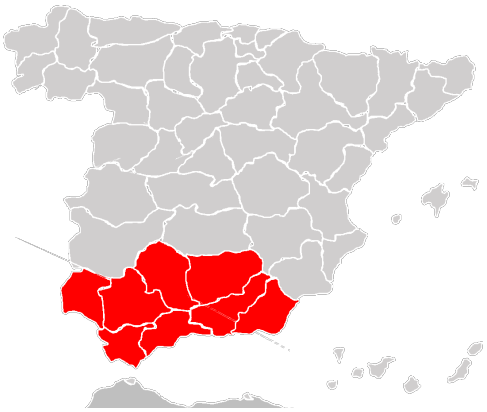
According to the harmonised classification and labelling of the CLP Regulation, this active substance is very toxic to aquatic life and harmful if ingested.

Thidiazuron

In 2019 this phytoregulator was only authorised in the Spanish state as a defoliant in the cultivation of cotton with the aim of anticipating the harvest. This is contrary to Article 53 of Regulation 1107/2009, since it is not possible to identify the anticipation of the harvest as a phytosanitary danger for economic reasons.

The rule preventing the placing on the market of this active substance, due to the voluntary withdrawal of the applicant, is Decision 2008/296.

Official toxicological profile:



According to the classification and labelling of the CLP Regulation, this phytoregulator is harmful in contact with the skin; causes severe eye irritation; is harmful if inhaled; causes skin irritation; and may cause respiratory irritation.

The repetition of emergency derogations

As already mentioned, several are the requirements that Regulation 1107/2009 considers necessary to be able to grant an exceptional authorisation, including the existence of a special circumstance and a danger that must be unforeseeable (Article 34 of Law 43/2002, of 20 November, on plant health).

These two requirements seem to militate against the repetition of the emergency derogations granted. Unfortunately, neither the Directorate-General for Agricultural Health nor the European Commission supports the same interpretation, since the reality, as shown in Table 6, paints a contrary picture. The supposed exceptionality of this type of authorisation is transformed into a routine act that is repeated year after year, making it impossible to develop and use new techniques and pesticides that are less harmful to the environment and human health.

Table 6 **Repetitions of emergency derogations allowed in 2019**

ACTIVE SUBSTANCE	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
(Z)-11+(Z)-13-OCTADECENAL										1	1
(Z)-11-HEXADECENAL										1	1
(Z)-13-OCTADECENAL											
(Z)-9-HEXADECENAL+(Z)-11-HEXADECENAL								1			
1,3-DICHLOROPROPENE	3	2	3	3	4	4	5	3	2	2	2
1,3-DICHLOROPROPENE+CHLOROPICRIN			1	2	3	2	4	2	1	2	1
AUREOBASIDUM PULLULANS					1	1	1	1	1	1	1
AZOXYSTROBIN					2			2	1	2	1
AZOXYSTROBIN+DIFENOCONAZOLE					1	1					
BETA-CYFLUTHRIN											1
BOSCALID											
BOSCALID+PYRACLOSTROBIN					1	1		1			1
CHLOROPICRIN			1		2	2	4	2	1	1	1
CLETHODIM							1	1	1	1	1
CLOTHIANIDIN											1
COPPER OXIDE									1		1
CYANTRANILPROLE								1	3	3	1
CYMOXANIL											
CYMOXANIL+FAMOXADONE							1	1	1	1	1
DICHLORVOS	1	1	1	1		1	1	1	1	1	1
DIFLUBENZURON		1			2	3	1	1	1		2
EMAMECTIN		2	2	1	1	2	1	1	1	1	1
FAMOXADONE											
FLUDIOXONIL			1	2	2	2	1				2
FLUDIOXONIL+CYPRODINIL						1					
FLUOPICOLIDE							1				
FLUOPICOLIDE+FOSETYL											1
FLUXAPYROXAD							1	1			1
FOSETYL					1	2	1	2	2		
FOSETYL+PROPAMOCARB			1	1							
GIBBERELLIC ACID				1	1	1	2	2	3	3	1
LAMBDA-CYHALOTRIN					3	4	2	4	3	2	3

ACTIBE SUBSTANCE	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NATURAL SEED EXTRACT OF CAMELLIA SP					2	2	3	2	1	1	1
OXAMYL						2	1		1	1	1
PROPANIL			1	1		1	1	1	1	1	1
PYRACLOSTROBIN		1	1	1	2	3	2	1	1	2	2
PYRIMETHANIL									1	1	1
SPINETORAM					2	2		1	3	2	1
SPIROTETRAMAT				2	2	4	3	2	3	3	1
THIDIAZURON			1				1	1	1	1	1
THIOPHANATE-METHYL					1	1	1	1	1	1	1

With regard to repetitions, the European Commission - in response to a question from Ecologistas en Acción[19] - points out that, as such, the repeated granting of emergency authorisations [emergency derogations] is not necessarily illegal, provided that the strict conditions of "Article 53 [...] of Regulation (EC) No 1107/2009 are met to ensure that the application for emergency authorisations remains an exception under the Act".

And while the Commission notes that it will "continue to monitor the granting of emergency authorisations [...], in particular those granted repeatedly", this is more a declaration of intent than a monitoring exercise. As indicated above, it is only recorded that it has intervened on the two occasions mentioned above, concerning Romania and Lithuania, and their granting of emergency authorisations for three neonicotinoid insecticides.

The guide[20] to the interpretation of emergency derogations produced by the Commission, which unfortunately is not binding on the Member States, determines in a generic way - with regard to the repetition of concessions - that the authorising Member State must implement a process of seeking alternatives and must explain how this process is progressing.

This guide for the repetition of emergency authorisations of non-authorised substances determines that, only in very exceptional cases, repetition of these authorisations may still be necessary. For these cases it sets out the following requirements:

- "The applicant must provide economic evidence that the socio-economic system cannot be changed within one year and that it is necessary to continue temporarily with the unapproved active substance to avoid unacceptable harm to local society
- "Use should be limited by establishing a maximum frequency of treatment per unit of production (field or farm) that encourages the maximum combined use of other existing, partially effective measures".
- "A research programme should be established to seek alternative acceptable solutions. Annual reports should be made available to the Commission and the Member States, including details of the objectives of the programme, a specific timetable and the efforts planned and made".

None of the emergency derogations granted by the Directorate-General for Agricultural Health in 2019, nor in previous years, nor those allowed in 2020, met these requirements which, according to the Commission's Guide, enable the granting of emergency authorisations. Therefore, we can consider that we are facing an irregularity sustained by the Directorate General and allowed by the European Commission due to lack of supervision.

19 EUROPE-DIRECT in response to a question from Ecologists in Action (Europe Direct-101000661375).

20 COMISIÓN EUROPEA, Working document on emergency situations according to article 53 of Regulation (EC) Nº1107/200. SANCO/10087/2013 rev. 0, https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_wd_emergency_authorisations_article53_en.pdf (fecha de consulta: 15 de agosto de 2020).

Harmonised risk indicator for emergency derogations

The recent Directive (EU) 2019/782 introduces two harmonised risk indicators for pesticides. Their function is to serve as a tool for assessing the performance of Member States in their efforts to reduce the risks arising from the use of these toxins.

The second of these indicators is based on the number resulting from the multiplication of emergency derogations granted in a year for each pesticide by the corresponding risk weighting of each of these products.

The European Commission, in its analysis of the period 2011 to 2017, concludes that "although the harmonised risk indicator 2 for the EU shows an increase of 50% [...], for Spain this indicator shows a decreasing trend after 2014[21]".

We are unable to assess this conclusion as the data are unfortunately not publicly available due to reasons of confidentiality and statistical secrecy.

However, an indicator based on the number of emergency derogations and not on the surface area treated or another more objective parameter leads to confusion and error, since it makes it possible to link emergency authorisations and thus reduce the assessment of the indicator.

For example, the active substance 1,3-dichloropropene has a risk weighting of 64 because it is not authorised.

In 2019, the Directorate-General for Agricultural Health granted three emergency derogations for pesticide products containing this active substance, giving it a risk indicator of 192.

Harmonised risk indicator 2= no. of emergency derogations × risk weighting= 3 × 64 =192.

However, if we consider the number of modifications to the three ex- ceptional authorisations that increased their territorial scope, the number of emergency authorisations rises to 22 and the value of the risk indicator rises to 1,408.

This describes the futility of harmonised risk indicator 2, which depends on the grouping or separation of emergency derogations by the competent authorities of the Member States and, in the case of Spain, by the Directorate-General for Agricultural Health.

21 EUROPE-DIRECT in response to a question from Ecologists in Action (Europe Direct-101000661375)..

Endocrine Disruptors and Exceptional Authorisations

What are hormonal contaminants?

The ability of some chemicals to interfere with the hormonal or endocrine system of many animal species, including humans, and to cause adverse health effects has been known since the early 20th century.

Endocrine disruptors (EDCs) interfere with the natural action of hormones, alter balance and can alter physiology throughout a person's life from fetal development to adulthood[22].

If the alteration occurs during the formation of organs, for example during foetal development, it can lead to malformations, pathologies or irreversible diseases. Some DBS can produce epigenetic changes[23], i.e. modifications in the expression of genes that can be transmitted to descendants resulting in adverse effects on daughters, sons, granddaughters and grandchildren of exposed individuals.

Known health effects

Hormonal contaminants are associated with major diseases[24,25,26]:

Damage to the fertilising reproductive system: reduced semen quality and infertility, congenital malformations of the urogenital tract such as cryptochidism (no testicular descent) and hypospadia (abnormal position of the opening of the urethra)..

Damage to the pregnant reproductive system: precocious puberty, reduced fertility, polycystic ovarian syndrome, reduced fertility, adverse pregnancy outcomes, endometriosis and uterine fibroids (non-cancerous tumours).

Tumours **in** hormone-dependent **organs**: breast cancer, ovarian cancer, prostate cancer, testicular cancer, thyroid cancer.

Alterations in the development of the neurological system: cognitive or behavioural

22 A. C. Gore, V. A. Chappell, S. E. Fenton, J. A. Flaws, A. Nadal, G. S. Prins, J. Toppari, and R. T. Zoeller. Endocrine Society statement 2EDC-2: The Endocrine Society's Second Scientific. Statement on Endocrine Disrupting Chemicals. (Endocrine Reviews 36: E1-E150, 2015) doi: 10.1210/er.2015-10..

23 Epigenetic modifications are changes in the expression of genes that are not due to changes in the DNA sequence (not due to mutations). There are several mechanisms of epigenetic changes, including methylation of cytosine residues in DNA, modification of histones or alteration of microRNA expression.

24 Ibid 14.

25 25 Bergman A, et al, editors. State of the science of endocrine disrupting chemicals, 2012. Geneva. UNEP/WHO; 2013. http://www.who.int/ceh/publications/endocrine/en/index.htm

26 Andreas Kortenkamp A et al. STATE OF THE ART ASSESSMENT OF ENDOCRINE DISRUPTERS. Final Report. Project Contract Number 070307/2009/550687/SER/D3. Annex 1. SUMMARY OF THE STATE OF THE SCIENCE. Revised version. Brussels: European Commission, DG Environment, 29 January 2012. http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf

deficits (hyperactivity, difficulty in concentrating, loss of memory, hearing loss, lack of motor coordination, learning difficulties, etc.)

Metabolic diseases: metabolic syndrome, diabetes and obesity.

Disorders of the neuroimmunological system: myalgic encephalopathy/ chronic fatigue syndrome/postviral fatigue syndrome (MS/CFS/PVF), fibromyalgia and multiple sclerosis.

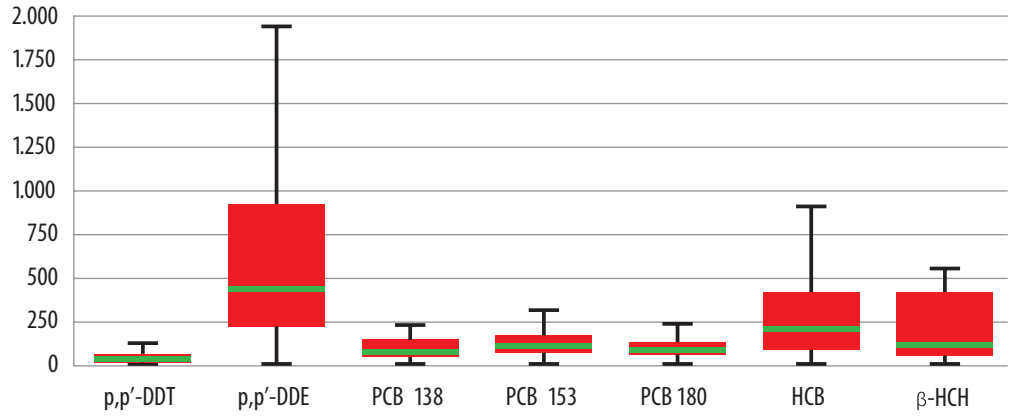
Cardiovascular diseases: endocrine disruptors that act as obesogens or diabetics increase the risk of cardiovascular diseases. In addition, new studies suggest a direct relationship between some endocrine disruptors and cardiovascular disease.

Unique characteristics of endocrine disruptors

1 Can act at very low doses

Like hormones, **endocrine disruptors can cause effects at very low exposure doses**. These are equivalent to the exposure levels found in the population due to air pollution in homes, pesticide residues in food or the presence of endocrine disrupters in consumer items. Thus, figure 1 shows how the concentrations of various pesticides with oestrogenic capacity (DDT, DDE[27], HCB[28], HCH29[29]) in a representative sample of the Spanish population are in the range of 10 to 8,000 ng/g. That is to say, at concentrations higher than those that these pollutants can produce oestrogenic effects (100 pg/g to 10 ng/g).

Figure 1 Concentrations of 7 Persistent Organic Pollutants (POPs) in the Spanish population



Source: Miquel Porta, Elisa Puigdomènech, Magda Gasull and Magda Bosch de Basea. Distribution of serum concentrations of persistent organic compounds (POPs) in a representative sample of the general population of Catalonia. Barcelona: Department of Health of the Government of Catalonia, IMIM and Autonomous University of Barcelona, 2009

27 Dichlorodiphenyl dichloroethylene (DDE) is one of the most common degradation products of the insecticide DDT.

28 Hexachlorobenzene.

29 Hexachlorocyclohexane or lindane.

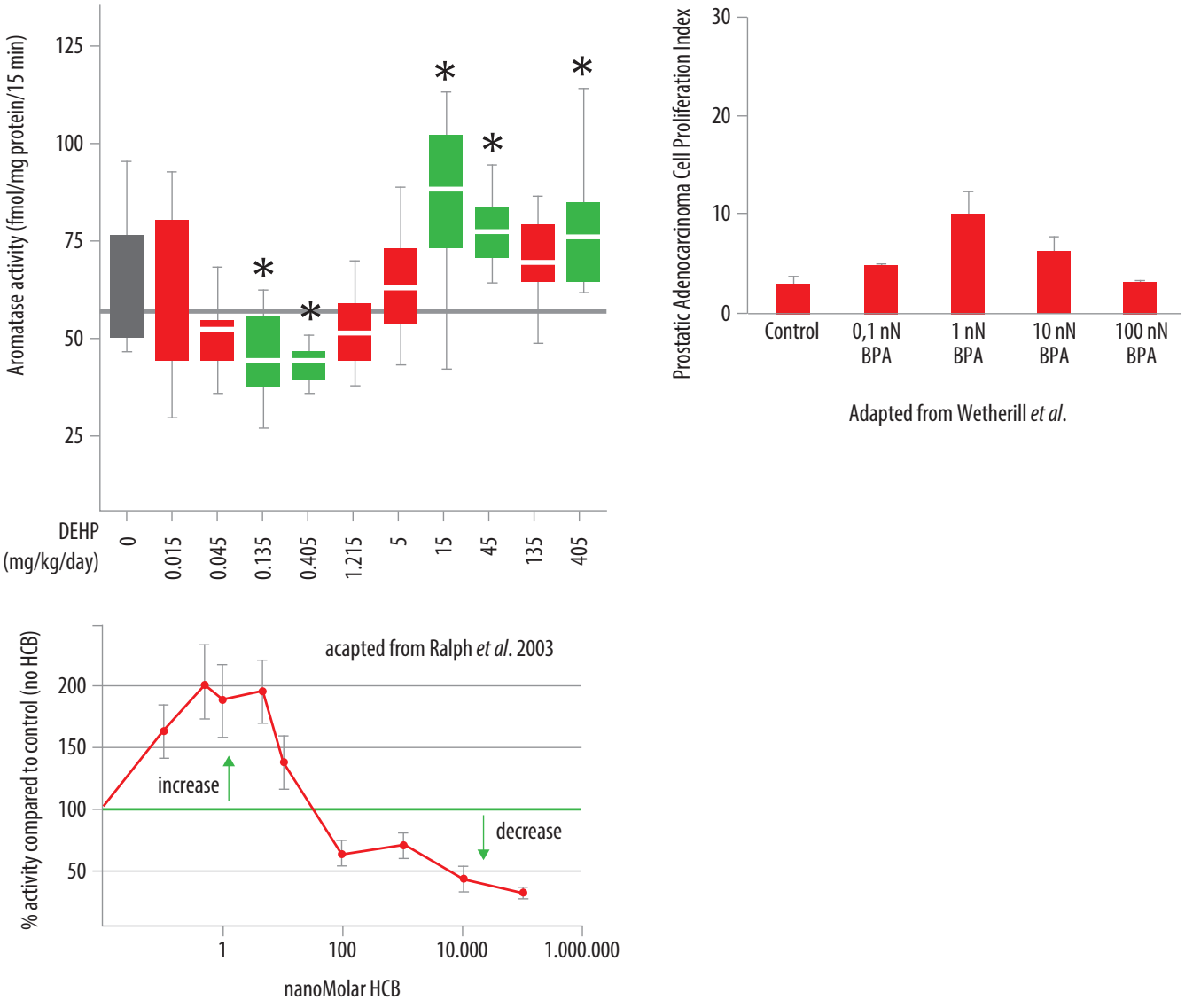
2 Importance of the time of exposure

The timing of exposure to substances with the capacity to alter the hormonal system is very important. If it occurs during the early stages of life, characterised by rapid cell differentiation and organ formation, it can lead to irreversible injuries resulting in pathologies or diseases that do not manifest themselves until childhood or adulthood. For this reason, pregnancy, childhood and adolescence are stages of special vulnerability to exposure to these substances..

3 The exposure dose does not determine the effect

The dose-effect relationship is not linear: the lower exposure dose does not always correspond to a lower adverse effect, as can be seen in the examples in figure 3. Thus, the highest adverse effects of exposure to HCB (hexachlorobenzene) are observed at low doses, and in the case of BPA (bisphenol A) at intermediate doses.

Figure 2 **Examples of non-linear dose-response curves.**

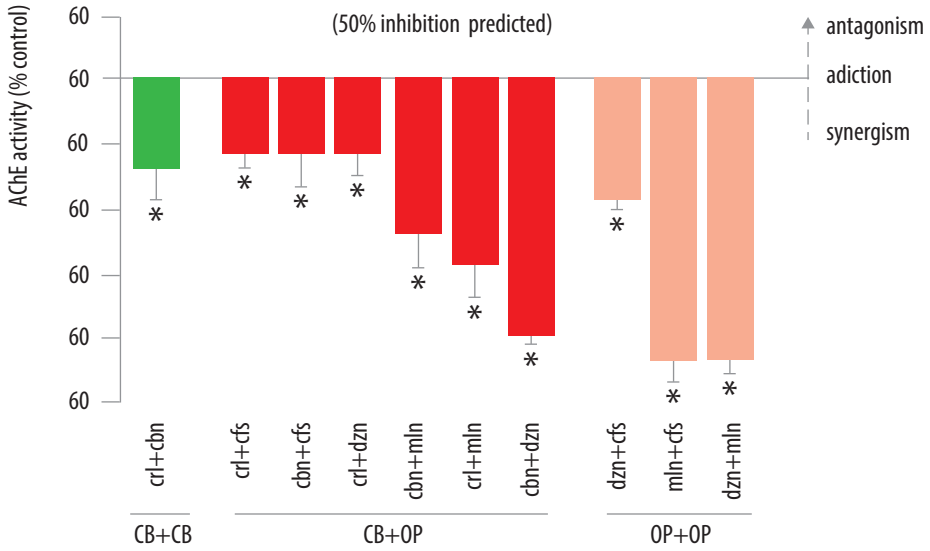


Source: Myers P. &Hesler W. Does 'thedosemakethepoison? Extensiveresultschallenge a coreassumption in toxicology. EnvironmentalHealth News. April 30, 2007.

3 Cocktail effect

Endocrine disruptors can, like other toxic substances, act together additively or synergistically, so that the effects of exposure to a mixture of EDCs can be enhanced. Thus, exposure to low doses of a mixture of EDC pesticides can cause negative effects at exposure levels considered safe for the individual substances in the mixture (see Figure 4).

Figure 4 Combined effect (cocktail) of pesticides on the inhibition of acetylcholinesterase activity



Source: Andreas Kortenkamp, Thomas Backhaus and Michael. FaustState of the Art Reporton Mixture Toxicity. Final Report. ExecutiveSummary. 22 December 2009. StudyContractNumber 070307/2007/485103/ETU/D.1..

4 Possibility of a latency period

The negative effects of endocrine disrupters can manifest themselves many years after exposure occurs. In addition, the effects of prenatal exposure occur mainly in adulthood.

Of the 32 different active substances allowed in the emergency derogations granted by the Spanish state in 2019, 13 of them (41%) are listed as endocrine disrupters. This constitutes an additional danger to that arising from the use of the emergency authorisations.

Table 7 Endocrine disrupters in the 2019 derogations

ACTIVE SUBSTANCE	APPROVED	ENDOCRINE DISRUPTOR
(Z)-11-HEXADECENNIAL	X	
(Z)-13-OCTADECENNIAL	X	
1,3-DICHLOROPROPENE	NOT AUTHORISED	
AUREOBASIDIUM PULLULANS (STRAINS DSM 1490 AND DMS 14941)	X	
AZOXYSTROBIN	X	Category 3
BETA-CYFLUTHRIN	X	Category 3
BOSCALID	X	Category 1
CHLOROPICRIN	NOT AUTHORISED	
CLETHODIM	X	Category 2
CLOTHIANIDIN	NOT AUTHORISED	Category 2
COPPER OXIDE	X	
CYANTRANILPROLE	X	
CYMOXANIL	X	
DICHLORVOS	NOT AUTHORISED	
DIFLUBENZURON	X	
EMAMECTIN	X	
FAMOXADONE	X	Category 3
FLUDIOXONIL	X	Category 3
FLUOPICOLIDE	X	
FLUXAPYROXAD	X	
FOSETYL	X	
GIBBERELLIC ACID	X	
LAMBDA-CYHALOTRIN	X	PAN Europe+Category 2
NATURAL SEED EXTRACT OF CAMELLIA SP	NOT AUTHORISED	
OXAMYL	X	PAN Europe+Category 3
PROPANIL	NOT AUTHORISED	
PYRACLOSTROBIN	X	Category 3
PYRIMETHANIL	X	PAN Europe
SPINETORAM	X	
SPIROTETRAMAT	X	Category 2
THIDIAZURON	NOT AUTHORISED	
THIOPHANATE-METHYL	X	Category 1

This table has been made with the 53 endocrine disrupting pesticides recognised by the organisation PAN Europe and the 162 identified by the European Commission. In the latter case, the Commission distinguished three categories:

- Category I for pesticides recognised as endocrine disrupters.
- Category II for active substances suspected of being endocrine disrupters. These are substances for which there is some evidence that adverse endocrine effects may occur in humans or in populations living in the environment, but where the evidence is not strong or convincing enough to classify the substance in Category I.
- Category III for active substances for which there is some in vitro or in vivo evidence of interference with the endocrine system, but no evidence of an adverse effect on intact organism.

How are emergency derogations requested and authorised in the Spanish State?

In Spain the procedure for authorising an exceptional derogation is summarised in the following three pointss:

- Agricultural associations usually apply to the competent regional authorities for exceptional derogations. These requests usually have no justification beyond generic considerations.

- The competent body of the Autonomous Community must first assess the non-existence of the exceptional authorisation requested, although in general the applicant is not required to prove the existence of a pest or the territory where it has supposedly been detected. Once assessed, the Autonomous Community requests a derogation from the Ministry of Agriculture, Fisheries and Food.

- The Directorate-General for Health and Agricultural Production must assess the application and decide on its content, authorising or refusing the exceptional authorisation.

Once authorisation has been granted, responsibility for control lies with the Autonomous Communities.

Some conclusions

On the basis of the above, we conclude that the exceptional derogations authorised in the Spanish State can be considered a routine administrative procedure without justification, which is repeated year after year and does not comply with the requirements of Article 53 of the Plant Health Regulations.

This is even more worrying when, thanks to this type of temporary authorisations, the use of non-approved substances of high toxicity is allowed, as is the case with 1,3 dichloropropene and chloropicrin.

Requirements that should be met for granting emergency derogations:

- Ensure the protection of human health and the environment.
- The use of the active substance must be limited to a certain species or group of species causing the pest to be controlled.
- Documentary and scientific justification as to why the substances/products authorised in the Act - and which have therefore undergone a process of evaluation of their efficacy and possible adverse effects on the environment, flora, fauna and humans - are not a reasonable alternative for the same pest and crop, as required by Article 53 of the Plant Health Regulation.
- The authorisation must specify the conditions and the territory of application, which in most cases must be limited locally, which means that temporary authorisations should not be granted that affect an entire autonomous community or province. In fact, the use of these substances must be limited to farms where the presence of the pest has been proven, so the exceptional authorisation must specify the farms or plots to be treated, indicating their cadastral reference.
- The non-repetition rule should be generally applied for all types of temporary rights and, unless there is strong evidence that the pest is continuing, no further emergency derogations should be granted. This principle should be reinforced in the event that the repetition of emergency derogations temporarily authorises non-approved active substances, as this should be avoided by all available means.
- Only in very exceptional cases can pesticides containing non-approved substances be reauthorised, and only to treat pests that cannot be controlled by other means. In these cases, the administration should be obliged to make its actions public and to encourage research into alternative cultural or biological methods, prioritising and shortening the periods of authorisation of this type of product.
- The applicant must provide evidence that the temporary use of the unapproved substance is necessary to avoid unacceptable harm to society in the territory where the pesticide is to be used and that it is not economically viable to modify the agronomic system within one year.
- The implementation of a research programme to find more acceptable alternatives for human health and the environment.

In Spain, emergency derogations lack many of the above-mentioned points, which puts health and the environment at risk.

Our proposals

- The **applicant must prove the existence of the pest by** means of samples and analyses that determine it.
- On the basis of these analyses, the harmful organism to be controlled must be specified, as well as the **admissible threshold for considering it a pest.** This threshold must be published in official documents.
- **The application** and the authorisation, if granted, must be limited geographically to the parcels of land on the farm **where the pest was detected.**
- **Conduct an examination of the alternatives.** Before deciding on the applications, the administration must check that the applicant has carried out an analysis of the alternatives. It must also assess whether it has adequately justified the absence of other reasonable means of controlling the pest.

  To do so, it can rely on the recommendations of independent advisors and open a period of public consultation. In this consultation, third parties affected by the authorisation may submit information regarding the impacts on health, the economy or the environment that the authorisation may cause.
- **Justify and accredit with scientific documentation the reasons** why the active substances and products authorised - and published in the Ministry's Register of Phytosanitary Products, for the same crop and pathogen - are not a valid alternative to exceptionally authorised pesticides.

  If it is considered that these authorised products are not effective or are useless, it must be considered that, in the processes of evaluation of effectiveness and adverse effects on the environment, flora, fauna and people, they have not been properly carried out as required by the Phytosanitary Regulations. Therefore, this evaluation process must be carried out again.
- Where alternatives exist, **those that are least hazardous to health and the environment** should be **chosen**.
- **Avoiding the repetition of emergency derogations**, for which the Directorate General for Health and Agricultural Production must analyse the effectiveness of the derogations granted and use this knowledge as a source of information in the approval of other emergency derogations.
- To **gather information from the Autonomous Communities** on applications received, on convictions made, on open disciplinary proceedings, etc., in order to analyse the effectiveness of the emergency derogations.
- **Improve the information available to the public.** The administration must provide information on the website of the Ministry of Agriculture on the emergency derogations granted, including the cadastral reference of the properties where unauthorised substances are being used, as well as information on the authorisations refused and the reasons for rejection.
- **Comply with the law**.

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