



July 2012

## **MEET (CHEMICAL) AGRICULTURE: The 120-day derogation - One year ahead, what happened?**

The “120-day derogation” is a rule in EU pesticide legislation that allows Member States (MS) to use non-authorized pesticides. The authorizations are granted directly by MS on the basis of a danger, which cannot be controlled by any other means. Last year, PAN-Europe published a report on the use of this derogation over the period that spanned from 2007 to 2010, showing an explosion in the number of authorizations. More than one year after the first report, the question is: was there any improvement? PAN-Europe analyzed the use of this derogation during 2011. We observed a decrease of 30% in the number of authorizations compared to 2010, but with numbers remaining on a very high level when compared to previous years. France, Portugal and Greece are the top derogation granters with 32, 30 and 21 each. Around 75% of the authorizations were for products listed in Annex 1 (approved for some use); however, several derogations were granted for banned products many of which repeatedly over the years for the same active substances. Examples of these products are dichloropropene, an illegal pesticide and a genotoxic substance used in huge quantities or dichlorvos, another illegal pesticide, with harmful neurotoxic properties. Alternatives are readily available but there is no control if member states even considered them. Furthermore, the fact that so many derogations are repeated points to a lack of development of alternative measures. PAN-Europe perceives that the entire process lacks transparency and urges the Commission to take a more pro-active role. PAN-Europe believes it is essential to make publicly available detailed information on the granted derogations and on the use of alternatives. Taking in consideration that many authorizations are granted for the same active substances over the years, the Commission also needs to exert a higher control on why alternative measures are not being used or developed. This is even more important when the new Common Agriculture Policy, set for 2014, introduces Integrated Pest Management (IPM) as a mandatory practice for farmers.



# Introduction

## The 120-day derogation rule of 1107/2009

In the beginning of 2011, PAN-Europe report *Meet (Chemical) Agriculture – The world of backdoors, derogations, sneaky pathways and loopholes – Part 1: The 120-days derogation*, called the attention to one of the many derogation processes in EU pesticide legislation. The “120-day derogation” that allows EU MS the use of illegal pesticides for almost a full crop season, on the condition of “unforeseen danger” where no alternatives are available. PAN-Europe analysis showed that from 2007 to 2010 the number in derogations exploded from 59 to 321 cases.

In June 2011, the new EU Regulation 1107/2009 entered into force and Art. 8.4 was replaced by Art. 53. The word “unforeseen” ceased to appear and the use of non-authorized pesticides for a period not exceeding 120-days was granted when “a danger which cannot be contained by any other reasonable means” was in place. The wording in the new regulation remained similar, with MS having to “immediately inform the other member states and the Commission of the measure taken, providing detailed information about the situation and any measures

taken to ensure consumer safety”. The entire process continues to take place behind closed doors, in the Standing Committee meetings of DG SANCO. The lack of transparency in all steps is striking. No information is publicly available concerning the causes of danger, intended applications, volumes of use, or of measures taken to ensure consumer safety. It is also not clear if MS are providing the “detailed information” required by legislation. In some occasions, MS ask for derogations for commercial products and or commercial formulations instead of the active substance, showing a lack of knowledge on the entire process. Several MS repeat derogations for the same active substance within the same year or subsequent years. For example, in 2011 both Greece and Cyprus asked twice for derogations for the active substance abamectin while Germany since 2007 as asked derogations, in some occasions twice in the same year for chlorpyrifos or its ethyl and methyl variants. Are these for the same use? If yes, are there alternatives being tested or under development?

# Article 53

## Emergency situations in plant protection

1. By the way of derogation from Article 28, in special circumstances a Member State may authorize, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger, which cannot be contained by any other reasonable means.

The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

2. The Commission may ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 1 month of the date of the request.

3. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

(a) may or may not extend the duration of the measure or repeat it; or

(b) shall withdraw or amend its measure.

4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release



## One Year Ahead, What Happened?

After the publication of the PAN-Europe's report, several members of the European Parliament raised concerns over the increased number of derogations. The Commission acknowledged that in most cases they did not know why the number of derogations augmented. Further highlighting that the responsibility was entirely of the MS granting the authorizations, but anticipating that a new guideline concerning the evaluation and decision-making process underlying these authorizations was needed. The Commission also assumed that many of the derogations were for minor use crops. So, one year after our report and all the concerns raise, did anything change? Was there an overall decrease or increase in the number of derogations? Did the number of countries asking for derogations change? Has the Commission through SANCO adopted a tougher control of the granted derogations and their implications on minimum risk levels (MRL) and consumer safety? Are MS presenting more detailed justifications? Was there any attempt to make the process more transparent? Were decisions taken in case of repeated use by the Regulatory procedure Art. 79(3)? Finally, Art. 53 states that derogations should only be granted when no viable alternative exists, but are these alternatives being tried out at all? Are MS justifying why alternatives are not viable? And, when they are not viable or not existent is there any work being developed on alternatives?

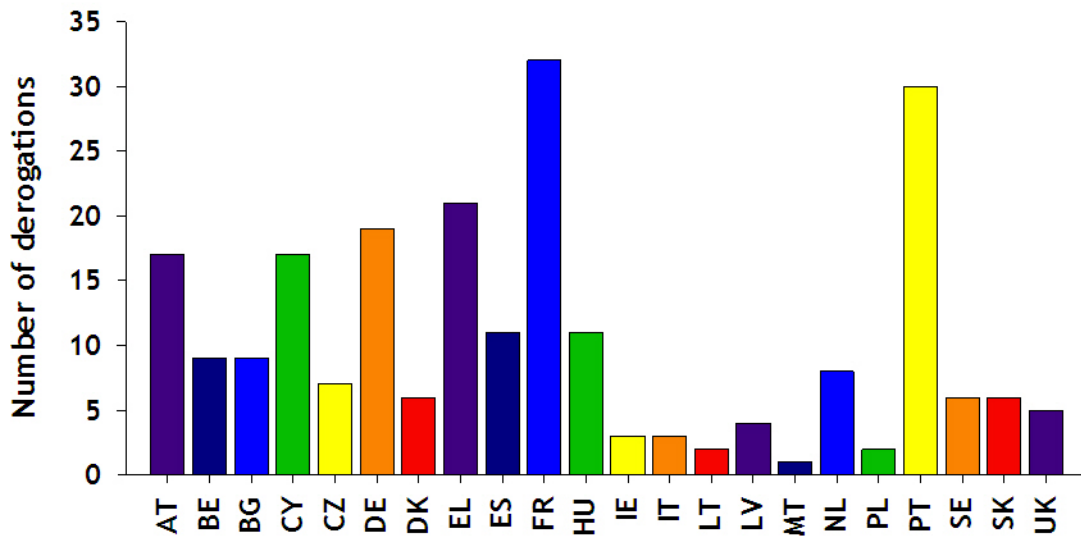






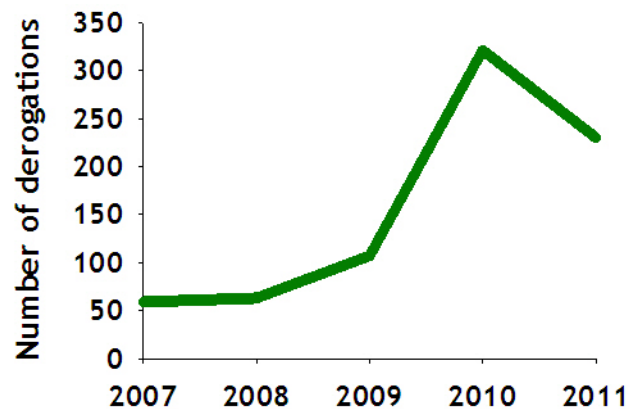
# Analysis

## The 120-day derogation in 2011



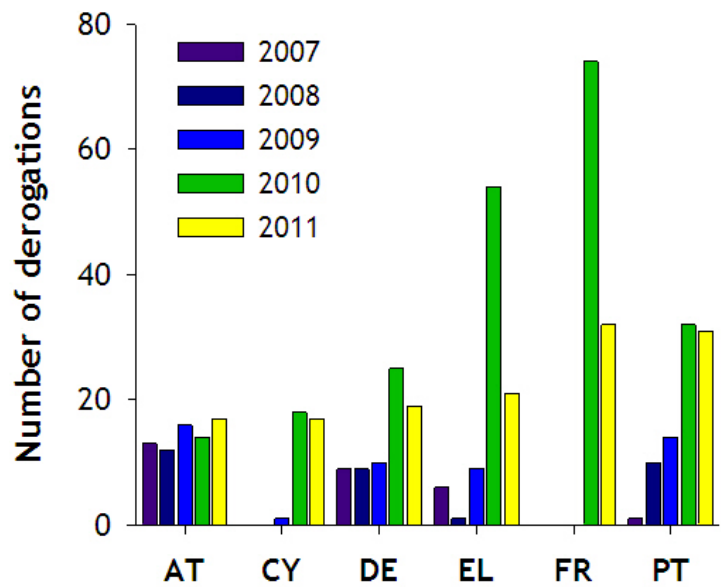
Number of derogations granted by MS in 2011

During 2011, 22 different EU countries informed the European Commission of 230 derogations for 127 different active substances. This represents a decrease of almost 30% in relation to 2010 but still very far from the numbers of previous years. The number of MS granting derogations and the number of active substances also decreased in comparison with 2010, from 24 to 22 and 152 to 127, respectively. Estonia, Luxembourg, Finland, Romania and Slovenia did not grant any derogation during 2011.



Number of derogations granted by year (2007-2011)

In 2011, France and Portugal lead with 32 and 30 derogations each. Followed by Greece, Germany, Cyprus and Austria all with over 15 derogations. For the majority of the countries, the number of derogations is similar to 2010, but still higher than previous years. A positive sign might be coming from last year champions France and Greece that granted approximately less 60% of derogations than in 2010. One element of the reduction could be related with the extension of the authorization by MS, under Annex I, to other uses. In that case they do not have to apply for Art. 53 anymore, but it is difficult to get a clear picture here.

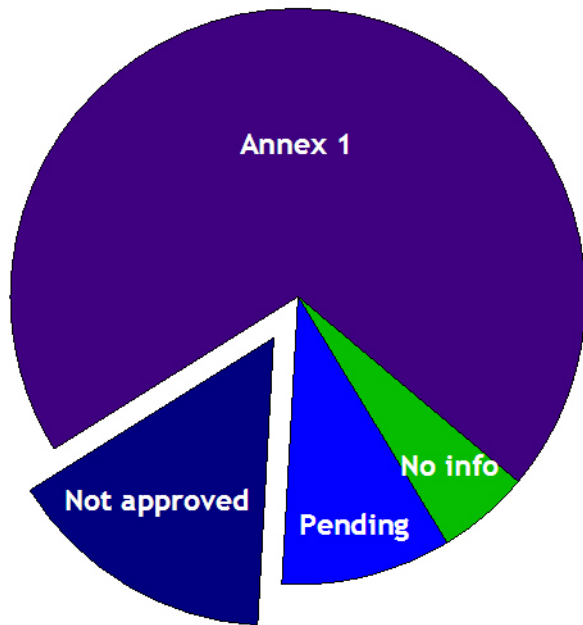


Number of derogations granted by the top-5 MS in 2011 (2007-2011)

The majority of the derogations in 2011 were for products listed in Annex 1, which are not approved for the country in question or for that specific use. Eleven derogations were granted for the insecticide chlorpyrifos and its methyl and ethyl variants. Exposure to chlorpyrifos has been linked with several development and neurological diseases and despite having been banned for residential use continues to be applied in agricultural areas. A recent study indicates serious brain damage after exposure to chlorpyrifos during development (Rauh, 2012).

Other 19 derogations were granted to the neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid and thiamethoxam), which have been related with behavioral alterations, and bee declines worldwide. A final example is that of fipronil granted four authorizations in 2011. Conversely, in 2012 on the request of Germany to raise MRLs for fipronil in poultry fat under Art. 53, EFSA determined that the use of fipronil in potatoes required not only the amendment of the existing MRLs for poultry fat but also for other varieties of meat and milk. Concluding that a long-term consumer health risk could not be excluded by the use of fipronil on potatoes. The legislation sets that MS granting derogations have to define or adapt a MRL when one is not available or applicable. However, it is not clear if member states are doing this properly and there are only faint signs of control by DG SANCO on this important element of consumer protection.

Rauh V. A. et al (2012) Brain anomalies in children exposed prenatally to a common organophosphate pesticide. PNAS 109(20): 7871-7876.



EU status of authorized substances

Of greater concern were the 15% of derogations granted in 2011 for products that are not approved for use in EU or have been excluded from Annex 1. These include products classified as carcinogens like the soil fumigants 1,3-dichloropropene and metam sodium (recently approved again) or the organochlorine pesticide dichlorvos.

In 2010, 1,3-dichloropropene was granted 19 derogations from seven different countries and five of those countries repeated the derogation during 2011. There is no publicly available information of the intended applications but it seems clear that it remains being customarily used despite its

withdraw from Annex 1 in 2007. In 2010 EFSA reiterated that the concerns identified

by the use of 1,3-dichloropropene could not be eliminated. Taking in consideration the high volumes of application that are usually required we can only imagine the environmental risks and negative impact on soil fauna. Furthermore, there is a long list of alternative IPM techniques like crop rotation, fallow periods, compost application, soil heating, covering of crops and the use of resistant varieties to name a few. And, the continue use of soil fumigants discourages the use of those techniques.

Since 2008, the year it was prohibited, Spain repeatedly granted derogations for dichlorvos and again in 2011. A RAASF alert was emitted during 2011 for cucumbers with ten times the allowed MRL for dichlorvos (0.11 mg/kg vs 0.01 mg/kg). Dichlorvos is highly toxic to humans and the environment and several alternatives exist including other active substances and attract-and-kill traps.

Finally, 10% of the derogations were granted to products that are pending their evaluations like the new insecticide emamectin benzoate (6 derogations, 3 of which by Portugal) and other 5% to products that are not registered as active substances, like the antibiotic streptomycin (3 derogations).





## Conclusion

Despite the reduction in the number of derogations for 2011 and expectedly for 2012 there is still a massive use of the “120 day derogation”, with the entire system surrounded by a lack of information and transparency. Exceptional measures should truly be exceptional and MS granting authorizations have to justify in detail the adoption of those measures to the Commission and other member states. The Commission needs to guarantee that member states take the “120 day derogation” process seriously.

Granting derogations cannot be the easy way out, with farmers requesting the use of unauthorised pesticides and MS need to make available to the Commission and other authorities the data that sustains their decision. Currently, it remains not clear if and how member states justify the granted derogations to the Commission and other MS or how these special circumstances are defined as no information is publicly available. It is not even clear, if the Commission and other MS have access to essential information pertaining the authorization. Including the inevitability of utilization, intended uses, volume and scales of application. Leaving many open questions on how the Commission and relevant authorities control the authorization and the enforcement of existent legislation. From our analyses it is highly likely that the “120-day derogation” remains being misused.

Another point of concern is the use of repeated derogations for the same active substance within the same and consecutive years. As there is no public information available PAN-Europe can merely speculate on intended uses. Yet, it seems suspicious that so many similar exceptional occasions occur in successive years in the same countries. If alternatives exist why are they not being used and if not existent why have they not been developed. Over the last years, the Commission has promoted the sustainable use of pesticides and is implementing IPM techniques in the new Common Agriculture Policy (CAP). However, by allowing the repeated use of dangerous chemicals the Commission is jeopardizing the enforcement of those measures and the replacement of these pesticides by less damaging ones or non-chemical alternatives but also of further innovation. The Commission needs to assume a more active role in the entire process and not claim a lack of knowledge on why authorizations are being granted.



# Recommendations

For each authorization, MS need to comply with the legislation and provide detailed information to the Commission and other MS. Justifying the use of that specific substance. Demonstrating why existent alternatives are not viable. Providing sound evidence that MRLs are in compliance with the legislation. And finally, that there is no increase on environmental or health risks. The Commission can devise a model to be filled for each authorization. These documents can consequently be made publicly available to evade the current lack of transparency in the derogation process.

Authorizations for minor use crops should not be granted through Article 53. A new process for those products should be devised.

Repeated authorization for an active substance for the same use should not be endorsed and the Commission should prohibit this through the Regulatory procedure foreseen in Art. 53.

DG SANCO should suggest a panel of independent experts on IPM to decide if the claims "danger " and "other reasonable means" from MS are valid. PAN-Europe envisions that the number of derogations could be brought back substantially. After the authorizations are granted the Commission also needs to ensure that all rules and provisions are enforced. This could be achieved by independent control and verification.

The Commission and MS need to take the Directive on the sustainable Use of Pesticides serious, put non-chemical crop protection first and make use of existent alternatives mandatory instead of granting authorizations. Fostering research and innovation for the development of new non-chemical alternatives to avoid the dependency of industry interests.

The Commission and the Member States need to take the Directive on the sustainable Use of Pesticides serious, put non-chemical crop protection first and make use of existent alternatives mandatory instead of granting authorizations. They should also foster research and innovation for the development of new ones.



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