The regulatory obstacles to bio-control agents from Directive (EC) No 128/2009

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ABSTRACT

The EC Directive No 128/2009 (SUD) establishes a regulatory framework for Community action to achieve the sustainable use of pesticides (phyto-pharmaceuticals Regulation (EC) No 1107/2009) and promotes the use of Bio-Control Agents (BCA) for complementing, replacing or substituting for the use of chemical pesticides, although they do not have the same pattern of usages. To measure the effectiveness of this Directive (SUD), under renewal as a regulation (SUR), different indicators were set-up. Having previously qualified the evolution of BCA (entries and exits) approvals and their slow increase, we are now focusing on ways to promote BCAs more quickly. This is possible through the use of 120 days temporary or emergency authorizations under the plant protection products regulation, before approval of an active substance, if the uses are orphan. These emergency authorizations are also accounted for under the EC Directive No 128/2009 (SUD) as harmonised risk indicators (HRI) n°2. Indeed, these emergency authorizations targeted at Bio-Control Agents could be a way to accelerate their way to market. Not only are they not privileged choices by EU Member States but they remain clearly inferior to chemical ones in most cases; derogations for BCA in the last 3 years are only account for a maximum of 30% of the total amount of active substances! Thus, the SUD Directive, which was expected to promote and enhance BCA implementation is proving to be ineffective in its objective through rapid market accession by emergency authorizations.

Keywords: phyto-pharmaceuticals Regulation (EC) No 1107/2009, emergency derogation; Sustainable Use Directive (EC) No 128/2009; Bio-control Agents, harmonised risk indicators

1. Introduction

Bio-control Agents (or BCAs) are “Bio-pesticides”, generally referring to non-chemical crop or plant protection products (PPP) and/or post-harvest treatments or products. These are considered phytopharmaceuticals products (or PPPs) and consist of single molecule or extracted mixtures, microorganisms, semiochemicals and natural substances from mineral, animal, mineral, microbial or plant origin. We have previously considered their development in another paper. (Robin & Marchand, 2019a).

In the EU, the sustainable use of pesticides is governed by Directive (EC) No 128/2009 (EC, 2009a), which established a framework for Community action aimed at achieving the sustainable use of pesticides (EU, 2024a), and managed under PPP Regulation (EC) No 1107/2009 (EC, 2009b) and the associated Implementing Regulation (EU) No 540/2011 (EU, 2011), in order to reduce the risks and impacts of pesticide use on

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human health and the environment (Carisio, 2024), and promote the use of Integrated Pest Management (IPM). Following our studies on results derived from these Directive (Robin & Marchand, 2019b) and the evolution of BCA (Marchand, 2023a) we show here that gaps still exist in the drive to achieve these outcomes, even after 14 years of existence.

2. Material and methods

The raw data were recovered from the website EUR-Lex (EU, 2024b) for the Implementing Regulation (EU) No 540/2011 (EU, 2011). Information regarding other relevant Directives were obtained from the Official Journal of the European Union. Our previous Databases (Robin & Marchand, 2019a) built for biocontrol agent (BCA) evolution and development analyses, such as microorganisms, natural substances and semi chemicals, managed and governed by PPP Regulation (EC) No 1107/2009, were also exploited. These Databases provide the current status of concerned PPP active substances, including approval and date of approval, low risk (Robin & Marchand, 2022a), natural substance or microorganism. Ultimately, Emergency Authorizations (EU, 2024b) of BCA are reviewed at the EU level.

3. Results

Directive (EC) No 128/2009 is currently composed of 6 chapters, 24 articles and 4 annexes. Emergency derogations are shown in Table 2 of Section 3 of the Annex IV of the SUD Directive (EC, 2010; EU, 2019), which is similar to Table 1 of Robin et al. 2019 (Robin & Marchand, 2019c). the evolution of the risk indicators for operators and applicators in fields is intended to decrease with the reduction in the intrinsic toxicity of active substances with Market Authorizations by replacing old active substances by more modern ones, especially biocontrol agents. Harmonised risk indicators (HRI) were dedicated to this survey task. HRIs are divided in two sections HRI_1 for active substances with official Market Authorizations (Robin, 2019c) while HRI_2 was dedicated to one-off authorizations. Although the first one (HRI_1) is effectively slowly decreasing the registration and use of higher risk active substances, the second one, corresponding to emergency authorisations (HRI_2) is unfortunately exhibiting an increase through time (+41%) (EU, 2024c). These harmonised risk indicators (HRI) are published yearly, describing the evolution of pesticides as active substances (AS) (HRI_1) and emergency authorizations (HRI_2). While BCAs should be promoted since most of them are naturally present in environment, they are treated as chemicals in HRI_2 as well as HRI_1. The necessary boost for BCA AS is clearly impaired by the SUD directive for both HRIs. First, HRI_1 does affect a similar weight coefficient to BCAs and chemical AS in the different categories, although no chemicals are low risk substances. Secondly, for the same reason, HRI_2 does not mark any difference nor stimulation for BCA versus chemicals. This clearly demonstrates that emergency authorisations are still being granted for chemical pesticides, in addition to pending substances.

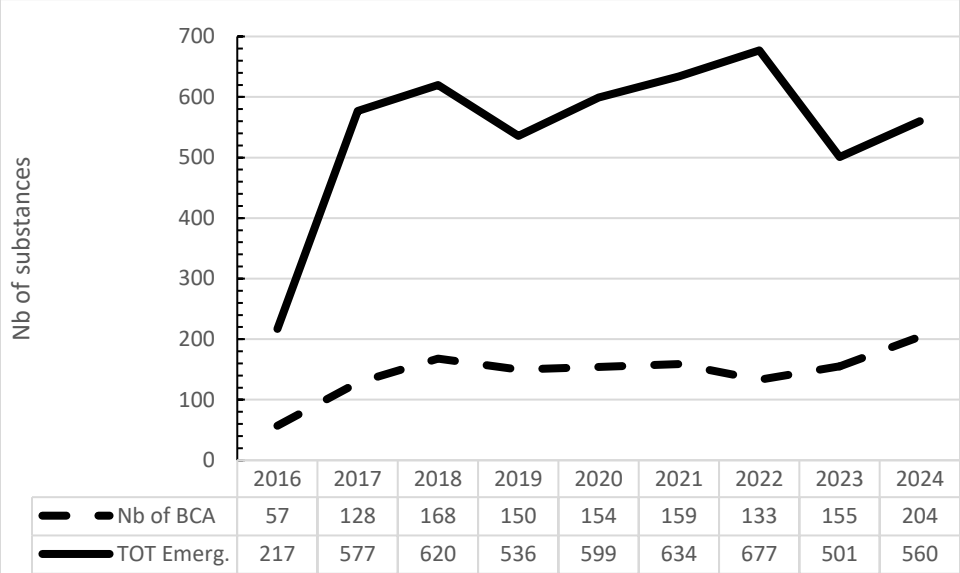

Figure 1: Emergency authorisation granted since 2016 (total in straight black; hatched for BCA)

Legend: in black line, total emergency authorisation, in doted biocontrol agent emergency authorisation

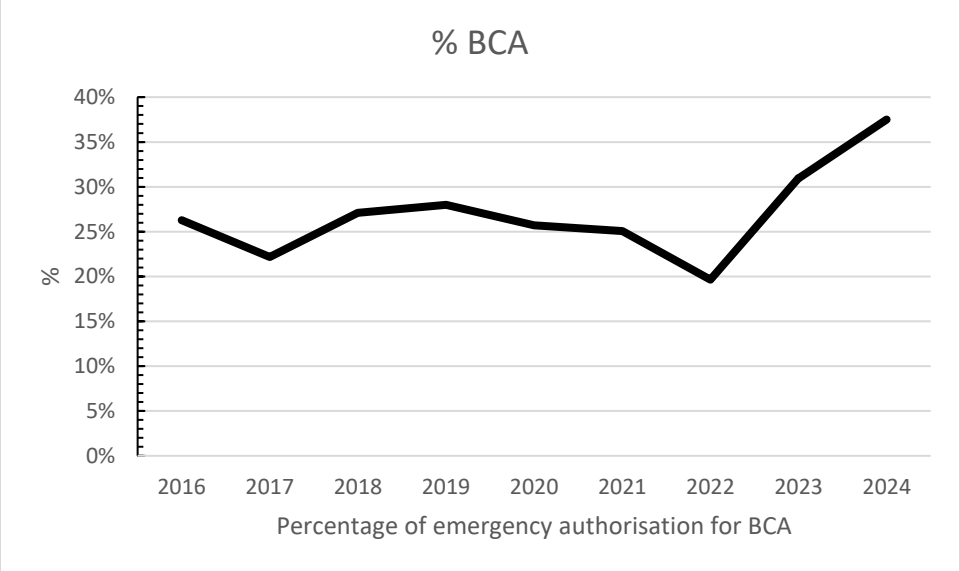

Figure 2: Percentage of emergency authorisation for BCA granted since 2016.

Development of the Emergency derogations

In Europe, emergency authorisations (derogations) are managed by Article 53 of the PPP Regulation (EU, 2024b), in order to grant temporary authorizations for non-allowed usages for approved AS or any usage for non-approved AS. As SUD Directive is promoting the use of BCAs AS, an emphasis for BCAs should therefore be expected through years, since chemical AS are expected to decrease and BCA to increase, in number and percentage of the total AS. However, even if chemical AS are indeed decreasing in the quantities being used, an analysis of emergency authorisations granted over time shows a stable situation both in number (Figure 1) and percentages (Figure 2) for BCAs between 2017 and 2023. Since 2023, number of BCAs in the emergency derogations began to increase significantly and in an encouraging way, in amount and moreover percentage of the total Article 53 of the PPP regulation.

The total number per year of emergency authorisations for BCA is clearly not progressing since the maximum observed in 2018 (Figure 1) is only slightly exceeded by 2022 value. Thus, emergency authorisations for BCA are low and the agreements are mainly being given to existing chemical AS (and in a very small part to existing BCA). This is not surprising since weight for ongoing AS (chemical or BCA) are largely higher (x 64) than any approved AS (x 16 at max even for existing cancerogenic, mutagenic or reprotoxic (CMR) AS or candidates for substitution (CfS) (Robin & Marchand, 2022b), x 1 for low-risk AS and x 8 for the rest of AS). Configuration of HRIs are not taking in consideration residues from the corresponding AS (Charon et al., 2019).

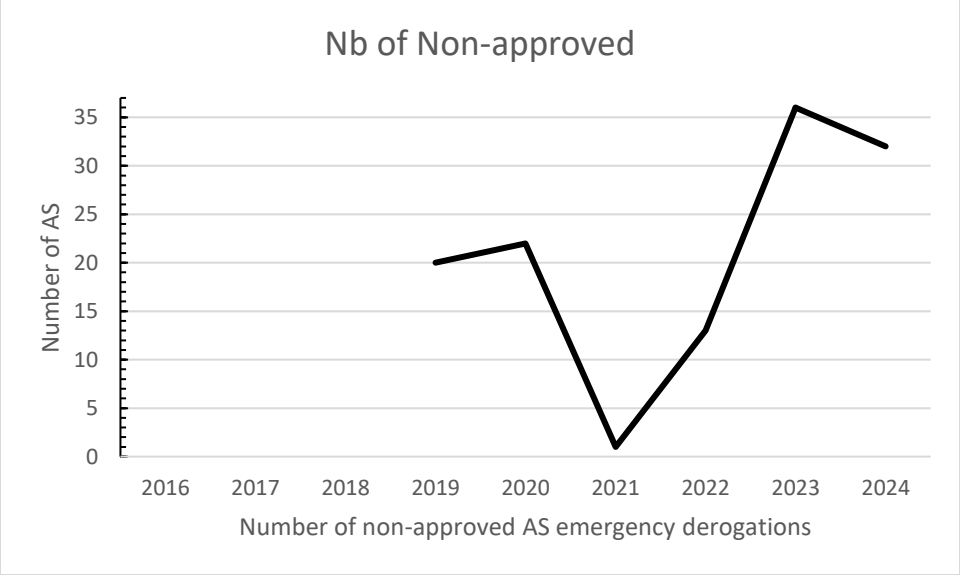

Figure 3: Emergency authorisation granted for non-approved AS since 2016

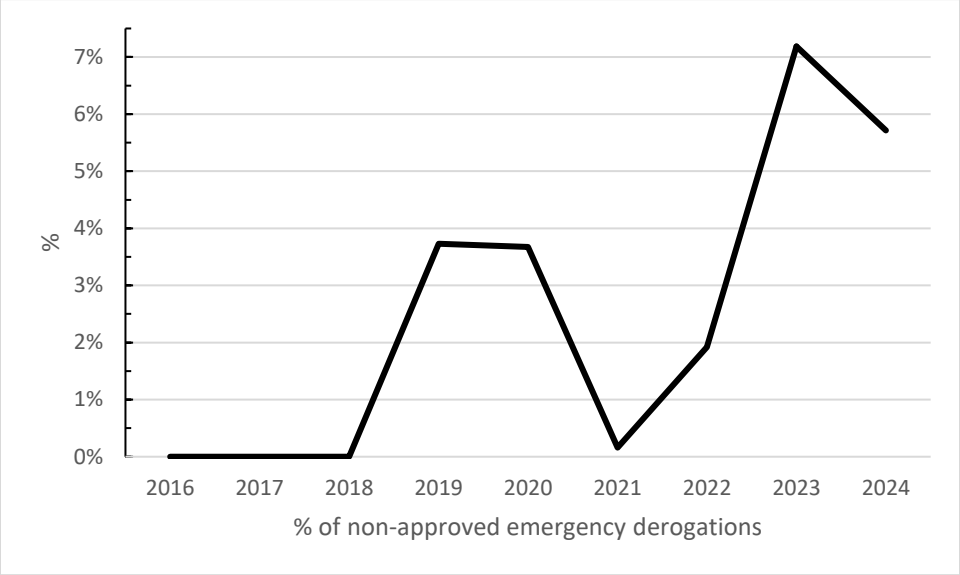

Figure 4: Percentage of emergency authorisation for non-approved AS granted since 2016

Ratio of the emergency authorisations for BCA

Not only are emergency authorisations low in number for BCA AS and are not increasing, but they are also stable in percentage terms, which is concerning if they are expected to eventually supplant chemical AS (Fig 2). The consolidated value for 2023 was established at 30% and the actual temporary value for 2024 is slightly increasing with more than 30% in the beginning of July. This means that BCA AS were not being favoured in the delivery of emergency authorisations until 2023 and even less so in ongoing pending BCAs, because the total percentage has not increased significantly. This situation is all the more concerning as we have included basic substances (Marchand, 2015) in these BCA AS emergency authorisations, even if their respective weight is zero for SUD. A slight tremor was observed at the end of July with already three exemptions for BCAs out of 96 in total (32%), with even few pending BCA (i.e. *Phthorimaea operculella* granulovirus).

Non-approved pending substances

Following this last consideration on emergency derogations granted for non-approved or pending BCA AS, we analysed data corresponding to this situation. The distinction between non-approved or pending BCA AS may be difficult at this stage since all ongoing AS applications are not immediately converted as “pending” in the EU pesticide database and some derogations do not trigger PPP AS applications although it may be compulsory. Albeit, during the initial years (2016-2018) no pending AS were granted, the global data exhibited a slight increase since 2019 in both quantity (Fig 3) and percentage (Fig 4).

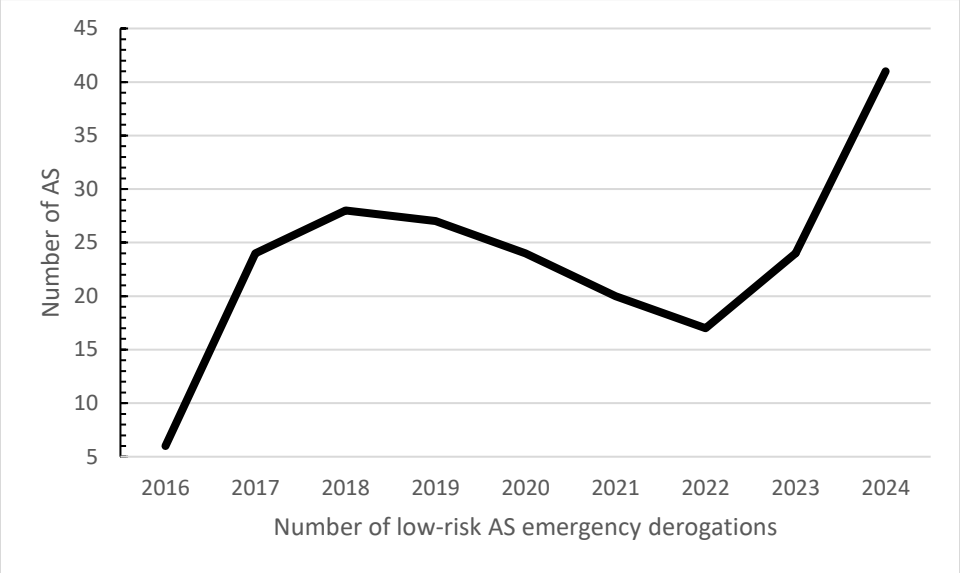

Figure 5: Emergency authorisation granted for low-risk AS since 2016

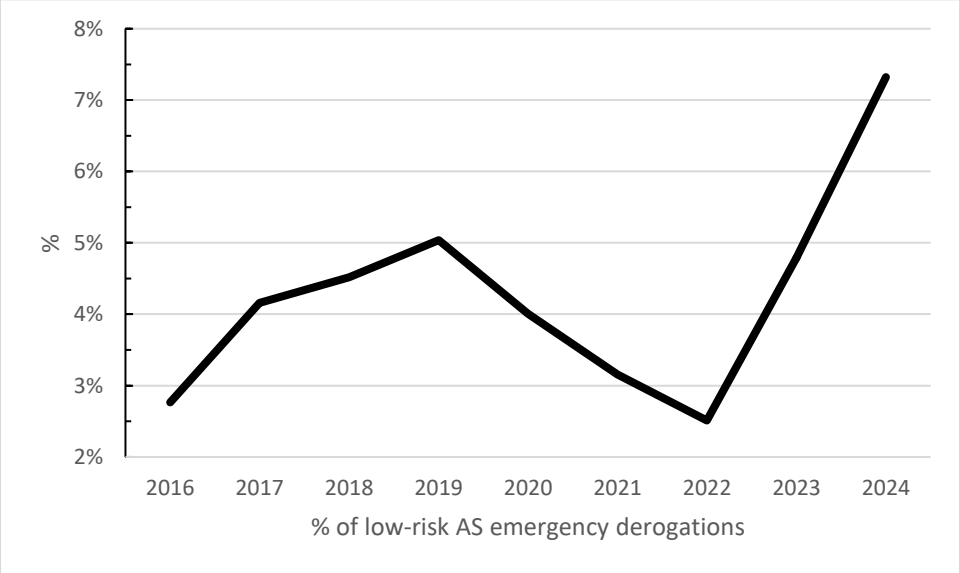

Figure 6: Percentage of emergency authorisation for low-risk AS granted since 2016

Low-risk substances

Since all low-risk substances are BCA AS, it seemed interesting to exhibit corresponding curves for this particular sub-part of the BCA universe. Results show, in Figure 5 and 6 not only a very small amount of emergency authorisation granted for low-risk AS, thus a small corresponding percentage, but also a global decrease in both through the years.

HRI_2 Risk indicator

Corresponding risk HRI_2, is even increasing through years, indicates the resistance to ending the use of chemical substances, even if their existence is threatened (EU, 2024c). We are also seeing exemptions being made for chemical substances that are now unapproved, even if this possibility would seem superficially to be very difficult because this is often contested (EU, 2021).

4. Discussion

One of the major purposes of the Directive (EC) No 128/2009 was to achieve the sustainable use of pesticides and promote the uptake of BCA AS (EC, 2009a). Quite a few reports or analyses on the results of the initial implementation of Directive (EC) No 128/2009 (Robin & Marchand, 2019c) are now available, since the SUD is under renewal as SUR.

The development of BioControl Agents can be achieved through the facilitation of approvals previously undertaken (i.e. modification of Annexe II), or by boosting the ongoing BCAs by emergency derogations, although the delivery of a derogation (Art. 53) for a non-approved substance is scarce due to the costs discussed previously. However, it seems that emergency derogations for ongoing BCA are not favoured. The first explanation is purely regulatory: the uses for an emergency exemption must be orphans and the remaining relative abundance of chemical substances does not allow many exemptions for the most important uses which would allow BCAs to be boosted. They must therefore obtain a full marketing authorization to start being sold without any temporary boost or promotion. The small amount and percentage of low-risk BCA AS could be explained by the relative specificity of target of BCA AS compared to chemical AS. Therefore, extension of uses through emergency derogations may be more complicated to propose for active substances with sharper usages or fewer target possibilities. Regarding the derogations granted for BCA AS this point is encouraging since HRI_2 coefficient for non-approved AS is really high (x 64), and that it is the main brake for Member States (M.S.). It also it is this same reason that favours already approved substances, even chemical ones, on the part of M.S. However, the rapid decrease of the global number of AS (Marchand, 2023b), especially chemical ones may also contribute to a shift also in the emergency derogation choices.

5. Conclusion

The implementation of the Directive (EC) No 128/2009 was also intended to promote and stimulate biocontrol agents (BCA) at PPP Regulation (EC) No 1107/2009. This goal can be achieved through the promotion of BCA approvals or the temporary validation of BCA Market Authorisations (Article 53 of the same PPP regulation). If the first triggering effect was observed for BCA in the last few years, unfortunately only for micro-organisms, we do not observe an increase of BCA emergency derogations, both in amount and in relative percentage. This lever is therefore not being effectively exploited to increase the progress of biocontrol. Beginning of 2024 could be a turning point, with encouraging signs: an increase in the percentage of BCA and pending BCA granted.

6. Acknowledgements.

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7. Declaration of Conflicting Interest.

Authors declare no conflict of interest.

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