

Basic Substances under EU Pesticide Regulation: An Opportunity for Organic Production?

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Abstract: Some of the active substances allowed in organic production are now approved as basic substances under the EU plant protection products regulation. Previously, all organic farming permitted active substances were approved as conventional plant protection products. In accordance with the criteria of Article 23 of the EU regulation (EC) No 1107/2009, basic substances are granted without maximum residue limits and have a good prospect for being included in Annex II of organic farming Regulation (EC) 889/2008. In fact, most of them are already permitted in organic farming. At this stage, it seems desirable to organize applications in order to avoid duplications and to clarify strategy across Europe. This organization should be planned in order to identify corresponding knowledge and data from field experiments, and to further constitute the most crucial issues related to organic production. A work of this nature was initially supported by IFOAM-EU for lecithin, calcium hydroxide and *Quassia* extract. The Institut Technique de l'Agriculture Biologique (ITAB) was previously engaged in a large-scale approval plan motivated by the continuous demand for the regularization of compounds/substances already in use and has a mandate for testing and approving new compatible substances. Thus, the horsetail extract (*Equisetum arvense*) was the first approved basic substance and ITAB has obtained 11 of the 15 basic substances approved at the EU level.

Keywords: Article 23; basic substance; Regulation (EC) No 1107/2009; Regulation (EC) No 889/2008, Annex II

1. Introduction

Recently created [1] by Article 23 of EC Regulation No 1107/2009 [2], the “Basic Substances” category is now operative with 15 approvals at the EU level [3]. Basic Substances are plant protection products with specific criteria for approval. Consequently, this status specified no maximal residue limit and high potential for inclusion in the Organic Farming regulation (EC) No

889/2009 [4] Annex II. Clearly, bio-sourced and traditional botanical extracts (as decoction, herbal tea...), light supports/aids, and plant defence enhancers used as crop protection are obvious candidates. Diverse applicants were engaged for different initial reasons and have succeeded in their applications. These biorational candidates clearly targeted the organic agriculture crop protection market or were even carried out by the organic sector itself.

2. First Implication of the Organic Sector: Implementing Regulation EU No 354/2014

Annex II of organic farming regulation for exclusively managing plant protection substances was previously focused on products of low concern, although some of them were not approved under general pesticide regulations [1]. Horizontal harmonization of pesticide regulation in organic farming was clearly needed and was achieved after a substantial change in 2014 following few years of unchanged situation. Thus, when the Implementing Regulation (EU) No 354/2014 [5] came into full force, Annex II of organic farming regulation was widely modified. Indeed, Implementing Regulation (EU) No 354/2014 suppressed quite a number of substances from Annex II and some others will or may follow in the future for a number of reasons, including: candidate substances for substitution, non-renewal of the approval following decision of the applicants, toxicological concerns, or limited economic interest.

This last category clearly corresponds to the basic substances definition in Recital 18 of Regulation (EC) No 1107/2009 [1]. Some parties believe that this decrease in the number of substances was very important, but these adjustments regarding general pesticide regulation were necessary and were taken on legal grounds. Although the existence of traditional plant protection products (PPP) is evident in Organic Farming, their EU approval under general regulations is compulsory. This action was called horizontal legislation alignment by DGAgri in Recital 6 of Implementing Regulation (EU) No 354/2014:

“As regards the horizontal legislation for plant protection products, Commission Implementing Regulation (EU) No 540/2011... it is appropriate to adapt the relevant parts of Annex II to Regulation (EC) No 889/2008 to that list. In particular, gelatine, rotenone extracted from Derris spp. and Lonchocarpus spp. and Terphrosia spp., diammonium phosphate, copper octanoate, potassium aluminium (aluminium sulphate, kalinite), mineral oils and potassium permanganate should be deleted from that Annex” [5].

Some other substances were maintained in Annex II as described in the Recital 7 of Implementing Regulation (EU) No 354/2014:

“As regards the active substances lecithin, quassia extracted from Quassia amara and calcium hydroxide for which applications for approval have been already submitted to the Commission under Regulation (EC) No 1107/2009, it is appropriate at this stage to keep them exceptionally on the list in Annex II to Regulation (EC) No 889/2008 until their assessment is finalised. In view of the conclusions of the assessment the Commission will take appropriate action regarding the presence of the three substances concerned on the list in Annex II to Regulation (EC) No 889/2008”.

This was the case for lecithin, calcium hydroxide and Quassia maintained in Annex II as the application Dossiers were constituted and submitted. Accordingly, these applications permitted the approval of the first 2 of these 3

substances. Quassia dossier is currently waiting for the outcome by the European Food Safety Authority (EFSA).

While certain applications were individually launched [6] without any contact or collusion between applicants, nor coordination, some approvals were organized by the organic farming sector [4]. We believe that these applications need to be organized now, and even driven through an organizational strategy by the organic farming sector itself, especially for its needs at EU level.

2.1. Current Implications for Organic Farming

2.1.1. Interest

Initial interest was manifested by the organic sector. Furthermore, as soon as the candidate substance is identified as not being a biocide, foodstuff or from edible vegetable or animal origin, it is entitled and even preferred. Initially, the organic sector proposed a list of potential candidate substances [7], but, at the same time, some small- and medium-sized enterprises started to investigate this opportunity [8]. Moreover, some Member States also applied for basic substances [9]. Following, horsetail extract (*Equisetum arvense*) [10] approval, the French Institut Technique de l'Agriculture Biologique (ITAB) obtained approvals for 8 more basic substances [6].

2.1.2. Organic Farming: Source of Candidates Dossiers

A primary list of possible basic substances is maintained by DGSanté [7]. Although this list was informative in the beginning and is still helpful while being constantly updated, the number of items recorded is quite restrictive compared to the vast field of possible applications. Even only considering the traditional organic uses or biodynamic preparations of botanicals, the list is impressive. Envisaged botanicals at the fourth stage of the previous plant protection products regulation [11] and previous substances not approved [12] may also be good candidates.

2.1.3. Affordability of the Approval Process

Regarding cost, no fee is charged [3]. Dossiers applications are accessible to any growers' association or technical organization. These light financial charges explain the high level of applications, although these applications fit perfectly Recital 18 (page 3 of plant protection products Regulation) [1]:

“Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use”.

However, for the constitution of chapter number 3 of the application (agricultural uses or Good Agricultural Practices, utility or efficacy) field trials are at same level of cost for chemicals, bio-control agents or organic farming biopesticides; idem for ecotoxicological tests requirements (i.e. bees or earthworms trials).

3. Consideration by Organic Farming Sector: Recent Impact

Although, these applications have been spontaneous, it is clear that regulation of the approved basic substances by the organic farming sector is needed. Until now, all approved substances reached the Annex II categorization and were, according to our point of view, eligible to organic farming and most of them are candidates. Considering this emphasis of candidacy, the organic farming sector should not be alarmed by the multiplication of substance applications since most of them have no biocidal properties at all. For instance, a recent plant seed extract may be a good candidate [13] as sunflower oil is undergoing the application process. Of course, mild biochemicals or herbicides may apply and succeed, but are likely to be excluded by organic farming rules, although they may still be considered by some countries outside the EU [14]. Considering this surge in applications, after a few approvals, including the two maintained substances in Annex II by Implementing Regulation (EU) No 354/2014, another modification of this Annex was published early in 2016 corresponding to a reorganization [15].

The entry into force of the last modification of the Annex II of organic farming regulation (Implementing Regulation (EU) No 2016/673 [15]) links to an extensive change of this annex. The sub-class of “Basic substances” box was generated and corresponding criteria designated for substances only for the control of pests and diseases.

“Only those basic substances within the meaning of Article 23(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council [2] that are covered by the definition of “foodstuff” in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [16] and have plant or animal origin”.

Thus, insecticides and fungicides were clearly included, together with plant strengtheners, repellents and lure compounds, whereas substances used as herbicides are excluded. It could therefore be concluded that direct inclusion in Annex II of approved basic substances may occur when these criteria are respected and corresponding substance may be used directly after approval in organic production.

3.1. Uncertainties

Because application does not mean approval and since the pathway is quite an obstacle course, not all applications end up with a positive vote. Admissibility is one of the deciding steps together with the outcome from EFSA [3] and the final decision from the Commission. In this journey, small Non-Governmental Organization applicants may find the application process more difficult than official European Member States’ governmental agencies. Few dossiers have already been rejected (non-approbation), or are expected to

be rejected, although they are of interest for organic farming. The main question raised is the final issue of the claimed usages (good agricultural practices), especially of the so called “orphans”. If these orphan or minor uses are not fulfilled by the way of these basic substances, it is unlikely that small- and medium-sized enterprises would invest millions of Euros for such substances if they were freely available on the non-plant protection products market.

3.2. Questioning

Suspected toxicity is the main argument for the non-approval of an evaluated applied Basic Substance. Maximum residue limits arising from these considerations may be the key point. Are these substances recyclable as regular active substances (plant protection products)? Are the same substances as active substances giving rise to plant protection products with maximum residue limits good candidates and of interest from the organic farming point of view? Is this line of questioning in organic farming similar to the current H2020 “EU Framework Programme for Research and Innovation” [17] SFS-08 research program “Organic inputs—Contentious inputs in organic farming” [18]?

4. Conclusion

Basic Substances are effective as a new category of mild crop protection products. Some are of interest for organic farming or even driven by the organic production sector itself. Aside from this, approved Basic Substances suitable for organic farming Annex II will increase content of this annex with numerous approved basic candidates. Questions are already being raised by Member States unaware of the work of diverse applicants (organic farming Non-Governmental Organizations, Member States, small- and medium-sized enterprises) regarding officially permitted substances. Not overcoming the regulatory prerogatives of the Expert Group for Technical advice on Organic Production (EGTOP) and the Regulatory Committee on Organic Production (RCOP), the question is asked about the collection, the organization and the rule of these candidacies and applications by organic farming parties in the near future and ultimately, the acceptance or not by the organic production sector itself.

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