

Research Article

Novel Plant Protection Regulation: New Perspectives for Organic Production

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Abstract: So called 'active substances' (A.S.) which are allowed in organic production are regularly criticized for different reasons. Previously, although permitted in organic farming, some substances were not approved under EU general plant protection products regulations; they were removed due to their toxicity or other characteristics (persistence, broad spectrum). Recent approbations under different new Articles of the EC regulation 1107/2009 gave rise to substances granted without maximum residue limits. We have previously described 'approved basic substance' (Art. 23) as potential candidates for organic farming; here we describe low-risk substances (Art. 22) as new implements for substitution of controversial organic biopesticides and consequently as candidates for substitution (Art. 24).

Keywords: low-risk substance; Article 22; candidate for substitution; Article 24; Regulation (EC) No. 1107/2009; Regulation (EC) No. 889/2008, Annex II

1. Introduction

The implementation of EC Regulation No. 1107/2009 [1,2] initiated a number of new types of substances, compared to previous European pesticide regulations. Of these, 3 types of substances are of importance for organic farming: "basic substances", "low-risk substances" and "candidates for substitution". Quite recently, the two first categories were established in an effective way. Although we described the interest of the type "basic substances" in a previous paper [3], interest in the low-risk substances for organic farming has not been previously described.

There are currently 18 approved basic substances, with 12 authorized in organic production. Of the 6 others, 4 will be authorized from the next vote at the Regulatory Committee of Organic Production (RCOP). There are currently 11 approved low-risk substances, with 9 authorized in organic production. Of the 2 others, all will be authorized from the

next vote at the Regulatory Committee of Organic Production (RCOP) and the next low-risk substance laminarin is already allowed in organic production.

The latest cited type, "candidates for substitution", has yet to be seriously considered, since few substances allowed in organic farming are listed in the corresponding Annex including the copper compounds class. Of the 77 substances initially enlisted as "candidates for substitution" 7 are already non-renewed.

The categories were created at the origin of the general EC Plant Protection Product Regulation No. 1107/2009 by corresponding distinct Articles, but have only recently been implemented: the first basic substance was approved in 2014, the first low-risk substance was approved in 2015 and the "candidates for substitution" list was only published in 2015. These categories are distinct and have no possibility of having substances in common at the same time.

These general EC plant protection product Regulation dispositions were taken without consideration of the status in Organic Production for the corresponding substances: some were already allowed in organic farming (i.e. micro-organisms, ferric phosphate or calcium hydroxide) and some not. Criteria for inclusion in the corresponding list of “*candidates for substitution*” did not consider the Organic Production allowance status.

2. Low-Risk Substances

Recently created [1] by the Article 22 of the EC Regulation No. 1107/2009 [2], the “*Low-risk Substances*” category is now in operation with 11 approvals at the EU level [4]. Low-risk substances are regular active substance under EC Regulation No. 1107/2009 [2] with specific criteria for approval. Low-Risk substance status is granted during approval or renewal, most of them have no maximal residue limit (MRL) with a high potential for inclusion in the Organic Farming regulation (EC) No. 889/2009 [5] Annex II. Some of the low-risk substances are already allowed in organic production. Initial candidates described as low-risk during their approval renewal include ferric phosphate and the *Isaria fumorosea* strain Apopka 97; these were already allowed in organic production. A number of low-risk substances were approved later, due to the fact that most of them (8 out of the 11) were microorganisms, and are automatically allowed in organic farming. Bio-sourced and mainly plant defence enhancers used as crop protection are also obvious candidates for inclusion. Diverse biorational candidates have already been submitted and some have already been taken into consideration by the Expert Group for Technical Advice on Organic Production (EGTOP) [6]. Low-risk status is granted by the European commission. Originally, the same criterion was adopted for all types of active substances (chemical, micro-organism and semiochemicals). These specifications were established and listed in the point 5 of Annex II [2]. Starting (in) 2013, some modifications were discussed and adopted in 2017.

2.1. Criteria Modifications

Recent EU modifications of the cut-off criteria for low-risk active substances were approved by the PAFF Committee in March 2017. These adjustments allocated criteria for two distinct categories, compared to the initial considerations: micro-organisms and active substance other than a micro-organism. For the micro-organisms category, a new criterion of lacking multiple resistance to anti-microbials used in human or animal medicine is added. For the active substance other than a micro-organism, a distinction is made between synthetic and naturally occurring active substances: either from animal, mineral, vegetal origin or emitted by natural sources such as pheromones and semiochemicals. For chemical substances, the initial criteria were retained [7].

2.2. List of Approved Low-Risk Substances

Following the initial ferric phosphate and *Isaria fumorosea* strain Apopka 97 renewal [8,9], two natural substances, COS-OGA and cerevisane, were approved [10,11]. Subsequently, only micro-organisms were approved: «Pepino Mosaic Virus strain CH2, isolat 1906», «*Trichoderma atroviride* SC1», «*Saccharomyces cerevisiae* strain LAS02», «Mild Pepino Mosaic Virus VX1», «Mild Pepino Mosaic Virus VC1», «*Bacillus amyloliquefaciens* strain FZB24», and «*Coniothyrium minitans* strain CON/M/91-08» [12–18].

2.3. Ongoing Inclusion of Low-Risk Substances in Organic Farming

Following approval, the two new natural substances with no direct biocidal activity, COS-OGA and cerevisane, were submitted for inclusion in Annex II of Regulation (EC) No. 889/2008. COS-OGA as hydrolysed shrimp extract and pectin was validated by EGTOP [6]. Cerevisane as cell walls of a *Saccharomyces cerevisiae* strain is also likely to be validated in the near future, as a natural substance or as substance obtained from micro-organism. Both substances were granted without maximum residue limits (MRL). Laminarin, which was previously allowed in organic production and without maximum residue limits (MRL), was recently renewed as low-risk substance.

3. Candidates for Substitution

Defined in Article 24 [2], candidates for substitution (77 substances) must meet one or more of the additional criteria laid down in point 4 of Annex II, and are active substances approved for a period not exceeding 7 years. Listed under separate regulations [19], these substances of concern with ADI, ARfD or AOEL significantly lower than those of the majority of the approved active substances within groups of substances/use categories - with two of the criteria (both toxicological and environmental) to be considered as bioaccumulative and toxic (PBT) substances or considered as persistent, toxic, neurotoxic, immunotoxic, carcinogen, toxic for reproduction or considered to have endocrine disrupting properties) - are encouraged to be substituted by a new substance of less concern.

3.1. Organic Substances Listed in the Candidates for Substitution Regulation Annex

Because of their toxicity, persistence and bioaccumulative properties, two substances allowed in organic production are recorded in the list of candidates for substitution [19]. Lambda-cyhalothrin as synthetic is only allowed in traps for organic production. Good Agricultural Practices (GAP Table) of the corresponding plant protection products with Market Authorizations exhibit no such uses as hatches and traps, thus, substitution or removal from organic regulation Annex II of this substance would not cause any

negative effects for organic production.

Copper compounds (variants copper hydroxide; copper oxychloride; copper oxide; Bordeaux mixture and tribasic copper sulphate) are also present in this list, not due to their intrinsic toxicity to humans at high doses, since they are essential minerals [20], but mainly due to their persistence in environment. Reduction of copper compound uses from 6 to 4 kg/ha/year is envisaged by European Commission after EFSA evaluation for approbation renewal early in 2019. While copper is needed by plants [21] and animals [22], it can be harmful to humans, animals and plants when present in the environment in significant amounts.

4. Discussion: Consideration by Organic Farming Sector

4.1. Low-Risk Substances

An increase in the number of low-risk substances is predictable, either due to approbation renewals of existing substances of low concern or from *de novo* candidacy of recent substances. The recent modification of the criteria is not a source of concern since “*low-risk*” substances would exhibit high maximum residue limits (MRL); the uppermost value per default would be of 0.01 mg/kg, according to Art 18(1)(b) of Regulation (EC) No. 396/2005 [23]. As a possible example, maltodextrin is one of the recently approved substances with no MRL; this natural substance may be granted with the “*low-risk*” status during future renewal. Its inclusion in Annex II of regulation 889/2008 has already been requested. Maltodextrin as a low concern substance of plant origin could be of importance considering the actual demand on broad spectrum insecticides in organic production (i.e. spinosad, azadirachtin). Possible future “*low-risk*” substances (i.e. during renewal) of interest for organic production may be defined as “non-biocide” substances. Several substances may be considered as being similarly allowed in organic production, such as laminarin (renewed with “*low-risk*” status) or fenugreek, or not allowed in organic production such as ascorbic acid or Terpenoid blend QRD-460 (candidate for organic production inclusion).

4.2. Candidates for Substitution

The list of candidates for substitution, defined in 2015 [19], is still unchanged and no further impact is expected on organic production. No substance, “*candidates for substitution*”, was positively detached from the list by abstraction of one of the conditions and removal of the “*candidates for substitution*” status. Most substances removed from this status are now non-approved following the non-renewal

proposition voted at the Standing Committee on Plant, Animal, Food and Feed (PAFF Committee) i.e. linuron, fipronil, isoproturon, imazosulfuron, amitrole, mecoprop and triasulfuron. Only imazamox, pendimethalin and prosulfuron were recently reapproved with the “*candidates for substitution*” status maintained for 7 years. Following this development, lambda-cyhalothrin may be removed without causing any problem for organic production.

However, copper compounds substances are now under the renewal process. The proposed end of approval (January 2018) date was postponed to January 2019 during last PAFF Committee of 2017. While copper compounds substances are granted with the “*candidates for substitution*” status, issue may be a renewal for 7 years or a non-renewal. Later, if renewed, the question of further limitations for this substance (i.e. quantities, number of applications like in the bromadiolone case) will undergo as for other previously renewed “*candidates for substitution*”.

5. Conclusion

“*Low-risk substances*” is clearly an expanding category of low concern crop protection products and most of them are of interest for plant protection in the organic production, as the recent reception by EGTOP demonstrates [6].

The number of “*candidate for substitution*” substances is not subject to increase since most newly or ongoing European approved substances are below the corresponding toxicological cut-off criteria. From this point of view, further impact on organic production is expected to be limited: no further substance allowed in organic production will be listed in the “*candidate for substitution*” list. However, the presence of the “copper compounds” substance in this list is problematic as the impact of the non-renewal of copper compounds could be disastrous for organic vine production.

Overall, these two new categories are beneficial developments for organic production because they provide a proof of an overall decline of the toxicity of the approved active substances.

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