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ARTICLE

Expansion of the Low-Risk Substances in the Framework of the European Pesticide Regulation (EC) No 1107/2009

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Abstract

Signed in 2009, the plant protection Commission Regulation EC No 1107/2009 created a new category of active substances, the low-risk substances, with specific status defined in Article 22. The initial and specific criteria, not suitable for microorganisms and natural substances, were modified in 2018, and the first low-risk substance, allocating Part D of Regulation EC No 540/2011, was granted in the same year. Since then, thirty-three low-risk substances have been granted with this specific status through approvals and renewals, while a larger list of potential low-risk substances from already-approved active substances was published. This list is only exploited during renewals, and this process would take another five years to complete. After four years of the implementation of this status, the number of such substances is still low, but is intended to increase slowly. Two more low-risk substances are already pending in 2021, which will bring the number of low-risk substances to thirty-five, while the initial list of potential low-risk substances (only renewals) included fifty-seven substances.

Keywords: active substances; Article 22; biocontrol agents; low-risk; Regulation (EC) No 1107/2009

I. Introduction

The ongoing European Union (EU) plant protection Commission Regulation EC No 1107/2009 (PPP Reg)[1] introduced many changes from the previous Directive 91/414/EEC.[2] One major change was the implementation of a new category of active substances: the low-risk substances.[3] Their specific status is defined in Article 22 of the PPP Reg, which allows an initial approval for fifteen years by way of derogation from Article 5 as described and published online only recently.[4] The specific status can also be granted during renewal of an approved

[1] Regulation (EC) No 1107/2009 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. OJ L 309/1.

[2] PA Marchand, "Basic Substances: An Approval Opportunity for Low Concern Natural Products under EU Pesticide Regulation" (2015) 71 Pest Management Science 1197; PA Marchand, "Basic and Low Risk Substances under European Union Pesticide Regulations: A New Choice for Biorationals Portfolio of Small and Medium-Sized Enterprises" (2017) 57 Journal of Plant Protection Research 433; M-C Vekemans and PA Marchand, "The Fate of Biocontrol Agents under the European Phytopharmaceutical Regulation: How This Regulation Hinders the Approval of Botanicals as New Active Substances" (2020) 27 Environmental Science and Pollution Research 39879.

[3] K Czaja, K Góralczyk, P Strucinski, A Hernik, W Korcz, M Minorczyk, M Łyczewska and JK Ludwicki, "Biopesticides – Towards Increased Consumer Safety in the European Union" (2015) 71 Pest Management Science 3.

[4] DC Robin and PA Marchand, "Low-Risk Substances, New Effective Category of Biocontrol Agents as Lever for Durable Crop Protection Products" (2021) 5 Chronicle of Bioresource Management 9.

active substance. Corresponding specific market authorisations are defined by Article 47(1). After approval, low-risk active substances shall be listed separately in Part D of Regulation EU No 540/2011.[5] Upstream, the criteria of this specific status are defined in Annex II, but the status is only granted during approval or renewal. Downstream, only the low-risk plant protection products are allowed to use the term "authorised as a low-risk plant protection product in accordance with Regulation (EC) No 1107/2009" in their advertisements. This term cannot be used as a claim on the label of the plant protection product (Article 66).

II. Material and methods

1. Regulation analysis

The EU Pesticides Database[6] was used to detect low-risk substances and the status (approved, non-approved, removed, withdrawn) of each active substance. Corresponding linked Implementing Regulations attached to each active substance were found using the same method and cross-verified with Implementing Regulation (EU) 540/2011. The EU law database for *Eur-Lex* was also used to track each Implementing Regulation publication.[7]

2. Low-risk substance approval pathway

Low-risk substance applications do not exist since low-risk status is only granted in draft proposals voted on at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).[8] Regular application as an active substance is compulsory.

3. Potential low-risk substance list

The Commission (Directorate General for Health and Consumers; DGSANCO) organised a working group in 2017 in order to refine previously defined criteria for low-risk substances. This work was later published updating Annex II point 5 of Regulation (EC) No 1107/2009, and it provided a list of potential low-risk substances from already-approved active substances.[9] Since no direct transfer or granting of the defined list was acknowledged at that time, the transfer operation to low-risk status was determined to be finalised during individual active substance renewals.

III. Results

The first low-risk substance, *Isaria fumosorosea* strain Apopka 97, was granted by a renewal in 2015.[10] Later, approvals of new active substances as low-risk were

[5] Implementing Regulation (EU) No 540/2011 of 25 May 2011; Implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153/133.

[6] Pesticides Database v2.2 <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as> (last accessed 3 May 2021).

[7] Access to the Official Journal, *Eur-Lex* (online) <https://eur-lex.europa.eu/oj/direct-access.html?locale=en> (last accessed 30 November 2021).

[8] Marchand (2015), supra, note 2.

[9] PA Marchand, "Novel Plant Protection Regulation: New Perspectives for Organic Production?" (2018) 4 Organic Farming 3.

[10] Commission Implementing Regulation (EU) 2015/306 of 26 February 2015 renewing the approval of the active substance *Isaria fumosorosea* strain Apopka 97 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 56/1.

voted for. Natural substances comprise COS-OGA,[11] cerevisane,[12] ABE-IT 56,[13] lavandulyl senecioate,[14] ferric pyrophosphate,[15] sodium hydrogen carbonate,[16] 24-epibrassinolide[17] and germinated seeds of sweet *Lupinus albus*.[18] Micro-organisms include Pepino mosaic virus strain CH2 isolate 1906,[19] *Trichoderma atroviride* SC1,[20] *Saccharomyces cerevisiae* LAS02,[21] mild Pepino mosaic virus strain CH2 isolate VX1,[22] mild

[11] Commission Implementing Regulation (EU) 2015/543 of 1 April 2015 approving the active substance COS-OGA, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 90/1.

[12] Commission Implementing Regulation (EU) 2015/553 of 7 April 2015 approving the active substance cerevisane, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 92/86.

[13] Commission Implementing Regulation (EU) 2019/676 of 29 April 2019 approving the low-risk active substance ABE-IT 56 (components of lysate of Saccharomyces cerevisiae strain DDSF623), in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2019/3050. OJ L 114/12.

[14] Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 approving the active substance Lavandulyl senecioate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2020/2994. OJ L 151/3.

[15] Commission Implementing Regulation (EU) 2020/1018 of 13 July 2020 approving ferric pyrophosphate as low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2020/4604. OJ L 225/9.

[16] Commission Implementing Regulation (EU) 2020/1263 of 10 September 2020 approving the active substance sodium hydrogen carbonate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2020/5988. OJ L 297/1.

[17] Commission Implementing Regulation (EU) 2021/427 of 10 March 2021 approving the active substance 24-epibrassinolide as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/1514. OJ L 84/21.

[18] Commission Implementing Regulation (EU) 2021/567 of 6 April 2021 approving the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/2066. OJ L 118/6.

[19] Commission Implementing Regulation (EU) 2015/1176 of 17 July 2015 approving the active substance Pepino mosaic virus strain CH2 isolate 1906, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 192/1.

[20] Commission Implementing Regulation (EU) 2016/951 of 15 June 2016 approving the low-risk active substance *Trichoderma atroviride* strain SC1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2016/3609. OJ L 159/6.

[21] Commission Implementing Regulation (EU) 2016/952 of 15 June 2016 approving the low-risk active substance *Saccharomyces cerevisiae* strain LAS02 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2016/3616. OJ L 159/10.

[22] Commission Implementing Regulation (EU) 2017/406 of 8 March 2017 approving the low-risk active substance mild Pepino mosaic virus isolate VX1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2017/1478. OJ L 63/83.

Pepino mosaic virus strain CH2 isolate VC1,[23] *Bacillus amyloliquefaciens* strain FZB24[24] and *Pasteuria nishizawae* Pn1.[25] Renewals of substances from Part A (or Part B) of Implementing Regulation (EU) 540/2011[26] into Part D has occurred for ferric phosphate,[27] laminarin[28] and blood meal[29] as natural substances, together with *Coniothyrium minitans* strain CON/M/91-08,[30] *Ampelomyces quisqualis* strain AQ10,[31] *Clonostachys rosea* strain J1446,[32] *Bacillus subtilis* strain IAB/BS03,[33] *Verticillium albo-atrum* strain WCS850,[34] *Phlebiopsis gigantea* strain VRA 1835, *Phlebiopsis gigantea* strain VRA 1984, *Phlebiopsis gigantea* strain FOC PG 410.3[35] and

[23] Commission Implementing Regulation (EU) 2017/408 of 8 March 2017 approving the low-risk active substance mild Pepino mosaic virus isolate VC1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2017/1474. OJ L 63/91.

[24] Commission Implementing Regulation (EU) 2017/806 of 11 May 2017 approving the low-risk active substance *Bacillus amyloliquefaciens* strain FZB24, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2017/3042. OJ L 121/31.

[25] Commission Implementing Regulation (EU) 2018/1278 of 21 September 2018 approving the low-risk active substance *Pasteuria nishizawae* Pn1 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2018/5506. OJ L 239/4.

[26] Marchand (2015), supra, note 2.

[27] Commission Implementing Regulation (EU) 2015/1166 of 15 July 2015 renewing the approval of the active substance ferric phosphate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 188/34.

[28] Commission Implementing Regulation (EU) 2018/112 of 24 January 2018 renewing the approval of the low-risk active substance laminarin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2018/0247. OJ L 20/3.

[29] Commission Implementing Regulation (EU) 2021/413 of 8 March 2021 renewing the approval of the low-risk active substance blood meal in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/1444. OJ L 81/32.

[30] Commission Implementing Regulation (EU) 2017/842 of 17 May 2017 renewing the approval of the low-risk active substance *Coniothyrium minitans* strain CON/M/91-08 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2017/3208. OJ L 125/16.

[31] Commission Implementing Regulation (EU) 2018/1075 of 27 July 2018 renewing the approval of the active substance *Ampelomyces quisqualis* strain AQ10, as a low-risk active substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2018/4861. OJ L 194/36.

[32] Commission Implementing Regulation (EU) 2019/151 of 30 January 2019 renewing the approval of the active substance *Clonostachys rosea* strain J1446 as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2019/634. OJ L 27/26.

[33] Commission Implementing Regulation (EU) 2019/1605 of 27 September 2019 approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2019/6866. OJ L 250/49.

[34] Commission Implementing Regulation (EU) 2019/1675 of 4 October 2019 renewing the approval of the active substance *Verticillium albo-atrum* strain WCS850 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2019/7073. OJ L 257/6.

[35] Commission Implementing Regulation (EU) 2020/1003 of 9 July 2020 renewing the approval of the active substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances in accordance

Akanthomyces muscarius strain Ve6[36] as microorganisms. All of these are biocontrol agents (BCAs),[37] and most of them are allowed in organic production (OP) since all microorganisms (not from genetically modified organisms (GMOs)) are automatically allowed, except for herbicides, although no herbicide is a low-risk active substance at this time.[38] Details of entry into Part D,[39] dates and BCA origins together with the OP status of all twenty-nine of the approved low-risk substances are given in Tables 1–6. Ongoing processed qualifications (up to thirty-four of them) are also included (Fig. 1).

The list of potential low-risk substances[40] from the substances listed in Part A (or Part B) was later published in 2018. This list of substances has been partially processed during renewals but was not followed in its entirety as garlic was not proposed as low-risk during voting at the PAFF Committee in December 2020 and was only renewed in Part B (instead of Part D) of Implementing Regulation (EU) 540/2011.[41] Later, *Streptomyces* K61 (formerly *S. griseoviridis*) was also not renewed as low-risk, although it was proposed at low-risk in the first instance.[42] These results are shown in Tables 2 and 3 for microorganisms and natural substances.

Moreover, of the approved potential low-risk substances, seven (five natural substances and two microorganisms) were not supported for renewal by applicants and ran out of approval[43] (ie ammonium acetate, FEN 560 (fenugreek seed powder), pepper dust extraction residue (PDER), sodium aluminium silicate, sea-algae extract (formerly sea-algae extract and seaweeds), *Trichoderma polysporum* strain IMI 206039 and *Spodoptera exigua* nuclear polyhedrosis virus). Furthermore, initial potential low-risk substances could be non-renewed after re-evaluation (ie *Pythium oligandrum* M1).[44]

Of these thirty-three approved low-risk substances, most of them are fungicides (n = 19; 61%) (Figure 2), with second place going to elicitors (n = 5; 15%) and only a few (n = 1 or 2; 3% or 6%) insecticides, molluscicides, attractants and plant growth regulators.

with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2020/4543. OJ L 221/127.

[36] Commission Implementing Regulation (EU) 2021/134 of 4 February 2021 renewing the approval of the low-risk active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/527. OJ L 42/4.

[37] DC Robin and PA Marchand, "Biocontrol active substances: evolution since the entry in vigour of Reg. 1107/2009" (2019) 75 Pest Management Science 950.

[38] Pesticides Database v2.2, supra, note 6.

[39] Marchand, supra, note 9; DC Robin and PA Marchand, "Evolution of Regulation (EU) No 540/2011 since Its Entry into Force" (2019) 7 Journal of Regulatory Science 1.

[40] Commission notice of 27 July 2018 concerning a list of potentially low-risk active substances approved for use in plant protection (2018/C 265/02). OJ C265(4)/8.

[41] Commission Implementing Regulation (EU) 2021/129 of 3 February 2021 renewing the approval of the active substance garlic extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/517. OJ L 40/11.

[42] Commission Implementing Regulation (EU) 2021/853 of 27 May 2021 renewing the approval of the active substance *Streptomyces* strain K61 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/3571. OL L 188/56.

[43] Pesticides Database v2.2, supra, note 6.

[44] Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance *Pythium oligrandum* strain M1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10332/2021 Rev. 0) during Standing Committee on Plants, Animals, Food and Feed, Section Phytopharmaceuticals – Legislation, 19–20 May 2021 (SANTE/10330/2021 Rev. 0).

Table 1. Characteristics of approved low-risk substances.

Substance	Function	Regulatory statute	Date	Organic production statute	Origin	
Isaria fumosorosea, Apopka strain 97	Insecticide	Renewal	2015	Allowed	Microorganism	
COS-OGA	Fungicide	Approval	2015	Allowed	Natural substance	Plant/ animal
Cerevisane	Elicitor	Approval	2015	Allowed	Natural substance	Microbial
Ferric phosphate	Molluscicide	Renewal	2015	Allowed	Natural substance	Mineral
Pepino mosaic virus strain CH2, isolate 1906	Elicitor	Approval	2015	Allowed	Microorganism	
Trichoderma atroviride SC1	Fungicide	Approval	2016	Allowed	Microorganism	
Saccharomyces cerevisiae LAS02	Fungicide	Approval	2016	Allowed	Microorganism	
Mild Pepino mosaic virus strain CH2, isolate VX1	Elicitor	Approval	2017	Allowed	Microorganism	
Mild Pepino mosaic virus strain CH2, isolate VC1	Elicitor	Approval	2017	Allowed	Microorganism	
Bacillus amyloliquefaciens strain FZB24	Fungicide	Approval	2017	Allowed	Microorganism	
Coniothyrium minitans strain CON/M/91-08	Fungicide	Approval	2017	Allowed	Microorganism	
Laminarine	Fungicide	Renewal	2018	Allowed	Natural substance	Plant
Ampelomyces quisqualis strain AQ10	Fungicide	Approval	2018	Allowed	Microorganism	
Pasteuria nishizawae Pn1	Fungicide	Approval	2018	Allowed	Microorganism	
Clonostachys rosea strain J1446	Fungicide	Renewal	2019	Allowed	Microorganism	
ABE-IT 56	Elicitor	Approval	2019	Ongoing	Natural substance	Microbial
Bacillus subtilis strain IAB/BS03	Fungicide	Renewal	2019	Allowed	Microorganism	
Verticillium albo-atrum strain WCS850	Fungicide	Renewal	2019	Allowed	Microorganism	
Lavandulyl senecioate	Attractant	Approval	2020	Allowed	Natural substance	Plant
Phlebiopsis gigantea strain VRA 1835	Fungicide	Renewal	2020	Allowed	Microorganism	
Phlebiopsis gigantea strain VRA 1984	Fungicide	Renewal	2020	Allowed	Microorganism	
Phlebiopsis gigantea strain FOC PG 410.3	Fungicide	Renewal	2020	Allowed	Microorganism	
Ferric pyrophosphate	Molluscicide	Approval	2020	Not allowed	Natural substance	Mineral
Sodium hydrogen carbonate	Fungicide	Approval	2020	Not allowed	Natural substance	Mineral

(*Continued*)

Table 1. (*Continued*)

Substance	Function	Regulatory statute	Date	Organic production statute	Origin	
Blood meal	Attractant	Renewal	2021	Not allowed	Natural substance	Animal
24-Epibrassinolide	Plant growth regulator	Approval	2021	Not allowed	Natural substance	Plant
Akanthomyces muscarius strain Ve6	Insecticide	Renewal	2021	Allowed	Microorganism	
Aqueous extract from the germinated seeds of sweet *Lupinus albus*	Fungicide	Approval	2021	Not allowed	Natural substance	Plant
Pepino mosaic virus, European (EU) strain, mild isolate Abp1	Fungicide	Ongoing approval	2021	Allowed	Microorganism	
Pepino mosaic virus, Chilean (CH2) strain, mild isolate Abp2	Fungicide	Ongoing approval	2021	Allowed	Microorganism	
Bacillus amyloliquefaciens AH2	Fungicide	Approval	2021	Allowed	Microorganism	
Calcium carbonate	Repellent	Renewal	2021	Not allowed	Mineral	
Potassium hydrogen carbonate	Fungicide	Renewal	2021	Allowed	Mineral	
Purpureocillium lilacinum strain 251	Nematicide	Ongoing renewal	2021	Allowed	Microorganism	
Purpureocillium lilacinum strain PL11	Nematicide	Approval voted	2021	Allowed	Microorganism	
Bacillus amyloliquefaciens IT-45	Fungicide	Ongoing approval	2022	Allowed	Microorganism	
Metarhizium brunneum strain M43	Fungicide	Ongoing approval	2022	Allowed	Microorganism	
Spodoptera exigua multicapsid nucleopolyhedrovirus	Insecticide	Ongoing approval	2022	Allowed	Microorganism	

Table 2. Evolution and characteristics of potential low-risk substances from the 2018 list: microorganisms renewed as low-risk.

Microorganism substance[a]	Function	Date
Spodoptera exigua nuclear polyhedrosis virus	Insecticide	2017
Ampelomyces quisqualis strain AQ10	Fungicide	2018
Gliocladium catenulatum strain J1446	Fungicide	2019
Akanthomyces muscarius Ve6 (formerly *Verticillium lecanii* strain Ve6)	Insecticide	2021
Phlebiopsis gigantea (several strains)	Fungicide	2020
Verticillium albo-atrum (formerly *Verticillium dahliae*) strain WCS850	Fungicide	2019

[a] Directly allowed in organic production.

Table 3. Evolution and characteristics of potential low-risk substances from the 2018 list: microorganisms still not low-risk.

Microorganism substance[a]	Function	Regulatory statute	Date
Adoxophyes orana GV strain BV-0001	Insecticide	Renewed in Part B, ongoing renewal	2012
Bacillus amyloliquefaciens subsp. *plantarum* D747	Fungicide	Renewed in Part B	2014
Bacillus firmus I-1582	Nematicide	Renewed in Part B	2013
Bacillus pumilus QST 2808	Fungicide	Renewed in Part B	2014
Bacillus subtilis str. QST 713	Bactericide, fungicide	Part A extended	2020
Bacillus thuringiensis subsp. *aizawai* strains ABTS-1857 and GC-91	Insecticide	Part A extended	2020
Bacillus thuringiensis subsp. *israeliensis* (serotype H-14) strain AM65-52	Insecticide	Part A extended	2020
Bacillus thuringiensis subsp. *kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348	Insecticide	Part A extended	2020
Beauveria bassiana strains ATCC 74040 and GHA	Insecticide	Part A extended	2020
Candida oleophila strain O	Fungicide	Renewed in Part B	2013
Cydia pomonella Granulovirus (CpGV)	Insecticide	Part A extended	2020
Helicoverpa armigera nucleopolyhedrovirus (HearNPV)	Insecticide	Renewed in Part B	2013
Metarhizium anisopliae var. *anisopliae* strain BIPESCO 5/F52	Insecticide	Part A extended	2020
Pythium oligandrum M1	Fungicide	Part A proposed for non-renewal	2021
Spodoptera littoralis nucleopolyhedrovirus	Insecticide	Renewed in Part B	2013
Streptomyces K61 (formerly *S. griseoviridis*)	Fungicide	Renewed but no low-risk in Part B	2021
Trichoderma asperellum (formerly *T. harzianum*) strains ICC012, T25 and TV1	Fungicide	Part A extended	2020
Trichoderma asperellum (strain T34)	Fungicide	Part A extended	2020
Trichoderma atroviride (formerly *T. harzianum*) strains IMI 206040 and T11	Fungicide	Part A extended	2020
Trichoderma atroviride strain I-1237	Fungicide	Renewed in Part B	2013
Trichoderma gamsii (formerly *T. viride*) strain ICC080	Fungicide	Part A extended	2020
Trichoderma harzianum strains T-22 and ITEM 908	Fungicide	Part A extended	2020
Trichoderma polysporum strain IMI 206039	Fungicide	End of approval	–
Zucchini yellow mosaic virus, weak strain	Elicitor	Renewed in Part B	2013

[a] Directly allowed in organic production.

Table 4. Evolution and characteristics of potential low-risk substances from the 2018 list: natural substances renewed as low-risk.

Substance	Function	Date	Organic production statute	Origin
Blood meal	Repellent	2021	Allowed	Animal
Calcium carbonate	Repellent	2021	–	Mineral
Potassium hydrogen carbonate	Fungicide	2021	Allowed	Mineral

Table 5. Evolution and characteristics of potential low-risk substances from the 2018 list: potential low-risk natural substances not renewed.

Substance not renewed[a]	Function
Ammonium acetate	Attractant
FEN 560 (fenugreek seed powder)	Insecticide
Pepper dust extraction residue (PDER)	Repellent
Sea-algae extract (formerly sea-algae extract and seaweeds)	Plant growth regulator
Sodium aluminium silicate	Repellent

[a] End of approval.

Table 6. Evolution and characteristics of potential low-risk substances from the 2018 list: natural substances still not low-risk.

Substance	Function	Regulatory statute	Date	Organic production statute	Origin
Aluminium ammonium sulphate	Repellent	Part A	Extension of the approval periods	Not allowed	Plant
Ascorbic acid	Fungicide	Approved in Part B	2014	Not allowed	Plant
Fat distillation residues	Repellent	Part A	Extension of the approval periods	Allowed	Animal
Fatty acids C7–C20	Insecticide, acaricide, herbicide, plant growth regulator	Part A	Extension of the approval periods	Not allowed	Plant
Garlic extract	Repellent	Renewed in Part B	Renewal in 2021 but no low-risk	Allowed	Plant
Gibberellic acid	Plant growth regulator	Part A extended	Ongoing renewal	Not allowed	Plant
Gibberellin	Plant growth regulator	Part A extended	Ongoing renewal	Not allowed	Plant
Heptamaloxyloglucan	Elicitor	Part A extended	Ongoing renewal	Not allowed	Plant

(*Continued*)

Table 6. (*Continued*)

Substance	Function	Regulatory statute	Date	Organic production statute	Origin
Hydrolysed proteins	Insecticide	Part A	Extension of the approval periods	Allowed	–
Limestone	Repellent	Pending in Part D	–	–	Mineral
Maltodextrin	Insecticide	Approved in Part B	2013	Allowed	Plant
Plant oils/rape seed oil	Insecticide, acaricide	Part A	Extension of the approval periods	Allowed	Plant
Prohexadione	Plant growth regulator	Part B	Extension of the approval periods	Not allowed	–
Quartz sand	Repellent	Part A	Extension of the approval periods	Allowed	Mineral
Repellents by smell of animal or plant origin/ fish oil	Repellent	Part A	Extension of the approval periods	Allowed	Animal
Repellents by smell of animal or plant origin/ sheep fat	Repellent	Part A	Extension of the approval periods	Allowed	Animal
Straight chain lepidopteran pheromones (SCLP)	Attractant	Part A	Extension of the approval periods	Allowed	Animal
Sulphur	Fungicide, acaricide, repellent	Part A	Extension of the approval periods	Allowed	Mineral
Urea	Insecticide	Part A	Extension of the approval periods	Not allowed	Mineral

Following on from the function analysis, an analysis of the effective usages of low-risk substances is also important. The distribution of crop usages for approved low-risk substances shows that field usages are not the main use domain for low-risk substance (only 18% and 21% for cereal and other arable crops, respectively). Low-risk BCAs are mainly usable for market gardening (70%) and viticulture (52%), as is shown in Figure 3. Thus, all crops are impacted, even if field crops have fewer low-risk active substances to protect them despite the fact that they represent large areas or even a high percentage of all crops.

The same analysis may be done for potential low-risk substances. Of these twenty-nine remaining substances, most of these are fungicides (n = 15; 30%) (Figure 4), with second place going to insecticides (n = 15; 30%) and only a few acaricides, molluscicides, attractants, plant growth regulators, elicitors, nematicides, bactericides and herbicides.

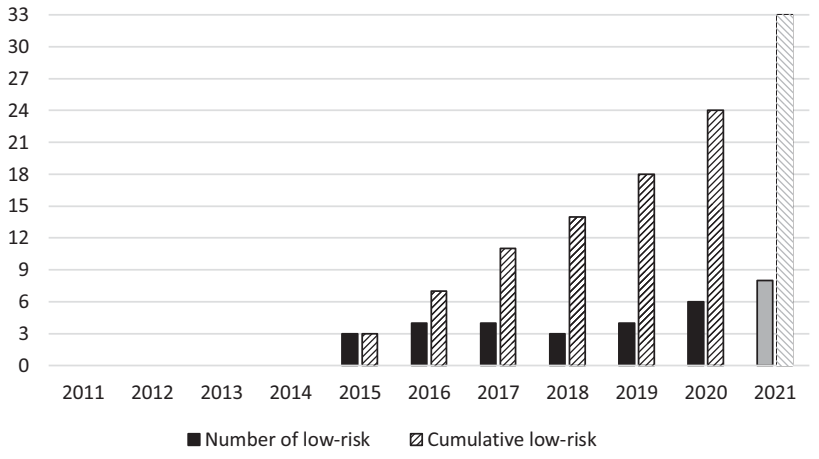

Figure 1. Evolution of low-risk substances since 2011.

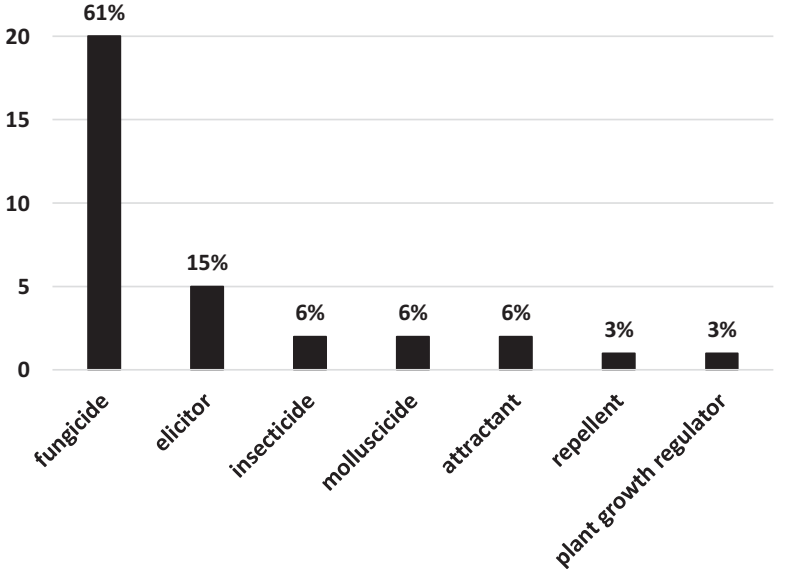

Figure 2. Functions and distribution of approved low-risk substances.

IV. Discussion

The implementation of low-risk substances is a slow and complicated process,[45] since potential low-risk substances from the initially described list of approved active substances were only considered during renewal after ten or more years of approval and not immediately after publication of the Commission notice in 2018 concerning potential low-risk active substances. In fact, the status of the corresponding listed substances was not rapidly and directly modified to low-risk.

[45] B Brielbeck, "Low Risk Substances, Complexity made Comprehensible" (2018) SCC Conference <http://www.ceureg.com/22/docs/presentations/9_Brielbeck_2018-10_CEUREG.pdf> (last accessed 29 November 2021); OEPP, "PP 1/296 (1) Principles of Efficacy Evaluation for Low-Risk Plant Protection Products" (2017) 47 Bulletin OEPP/EPPO Bulletin 297.

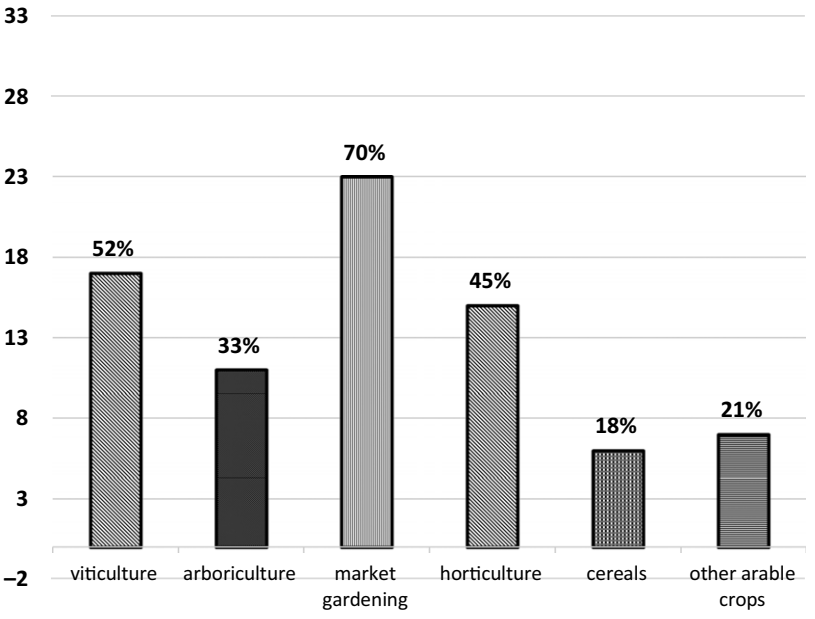

Figure 3. Crop usages and distribution of low-risk substances.

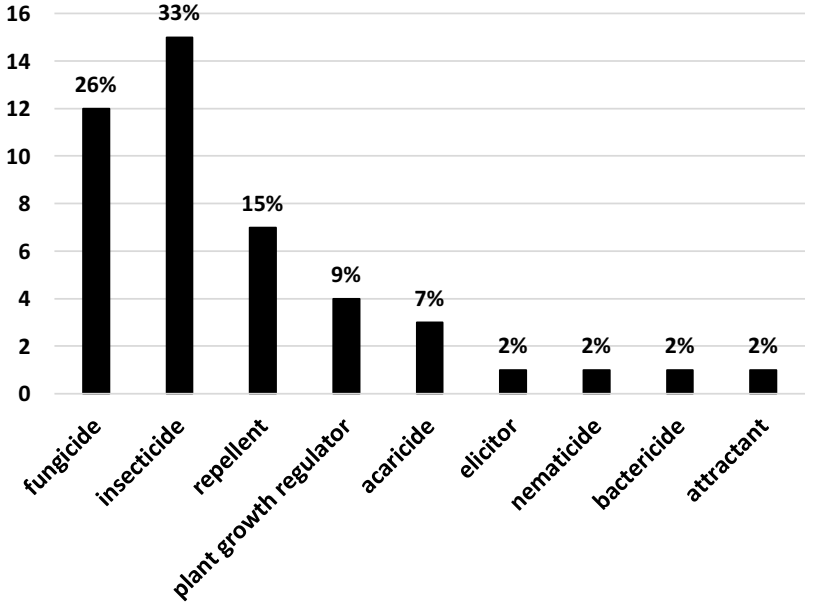

Figure 4. Functions and distribution of potential low-risk substances.

Therefore, only thirty-four low-risk substances are currently effectively approved, corresponding to twenty (62%) microorganisms and fourteen (38%) natural substances, despite the concept being voted in twelve years ago in 2009, and up to thirty-five or more will be effectively approved in 2021 (Table 1). Only thirteen low-risk substances were renewed (seven

microorganisms and six natural substances), and twenty were newly approved (twelve microorganisms and eight natural substances) as low-risk in Part D (Table 1).

Nevertheless, twenty-nine potential low-risk substances are still approved as active substances in Parts A or B (from an initial fifty-seven active substances) with no low-risk status. This illustrates the slow pace of the implementation of low-risk substances, as only renewal time was considered for potential low-risk substances. The direct qualification of low-risk status could expand the low-risk substances number to seventy-five, but the legislator did not choose to take such an approach. However, many active substances from the list of potential low-risk active substances are under renewal procedures, ongoing for vote (ie *Purpureocillium lilacinum* strain 251)[46] or recently granted (ie *Akanthomyces muscarius* strain Ve6, 24-epibrassinolide, germinated seeds of sweet *Lupinus albus* and *Bacillus amyloliquefaciens* AH2, Pepino mosaic virus, EU strain, mild isolate Abp1, Pepino mosaic virus, CH2 strain, mild isolate Abp2 and calcium carbonate),[47] together with ongoing initial approval (ie *Purpureocillium lilacinum* PL 11).[48]

Approximately fifteen new applications for microorganisms are pending with similar profiles that could be granted a low-risk status (eg *Bacillus* spp.), especially groups of active substances ordinarily included in Annex IV with no maximum residue limits (MRLs).[49] Indeed, most of the thirty-three approved low-risk substances (n = 29; 88%) have their MRLs assigned to Annex IV of Regulation EC No 396/2005, and the latest approved substances may also be qualified later with this status. The consequence of this could be that only existing (approved) substances without MRLs or potentially without MRLs at the time of approval might be more easily qualified as low-risk substances.

In fact, more biocontrol agent (BCA) applications have been submitted since the constant and significant decrease in allowed chemical active substances, increasing the panel

[46] Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance *Purpureocillium lilacinum* strain 251 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12462/2020).

[47] Commission Implementing Regulation (EU) 2021/1448 of 3 September 2021 renewing the approval of the low-risk active substance calcium carbonate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/6446. OJ L 313/15; Commission Implementing Regulation (EU) 2021/917 of 7 June 2021 approving the low-risk active substances Pepino mosaic virus, EU strain, mild isolate Abp1 and Pepino mosaic virus, CH2 strain, mild isolate Abp2 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/3967. OJ L 201/19; Commission Implementing Regulation (EU) 2021/134 of 4 February 2021 renewing the approval of the low-risk active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2021/527. OJ L 42/4; Commission Implementing Regulation (EU) 2021/427 of 10 March 2021 approving the active substance 24-epibrassinolide as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/1514. OJ L 84/21; Commission Implementing Regulation (EU) 2021/567 of 6 April 2021 approving the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/2066. OJ L 118/6.

[48] Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the new active substance *Purpureocillium lilacinum* strain PL11 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10418/2021). Opinion favourable.

[49] M Charon, D Robin and PA Marchand, "The Major Interest for Crop Protection of Agrochemical Substances without Maximum Residue Limit (MRL)" (2019) 23 Biotechnologie, Agronomie, Société et Environnement 22.

of potential low-risk substances. However, constant reports are showing the difficult level of access of BCAs to this status, making this status almost a Holy Grail.[50] Nevertheless, Figure 1 illustrates a constant increase in low-risk active substances, although a direct transfer of potential could trigger a boost to this category (Figure 2). In fact, the focus on more low-risk active substances should not only consider the number of substances, but also the corresponding new functions, modes of action or expanded product types (Figure 3).

1. Plant protection product-level considerations

Approval as low-risk substances is one step in the process, but later market authorisations are require to generate low-risk products. This step officially takes 120 days (Article 47), but unfortunately, in fact, the average real delay is significantly longer.[51] This point should be improved in order to respect the PPP Reg and to increase the number of low-risk product implementations in fields. However, recent approvals[52] of active substances or proposals[53] as low-risk substances are encouraging.

The BCAs and, of course, particularly the low-risk products have regularly been considered as exhibiting lower efficiency than plant protection products from chemical active substances,[54] but these criticisms, as far as they are founded, become obsolete and questionable in light of the drastic reduction of active substances, mainly chemicals. In view of their lower efficiency, the risks associated with these BCAs, particularly in terms of eco-toxicity, are clearly lower.[55]

2. Organic plant protection considerations

In terms of the characteristics of and interest in these low-risk substances, inclusion in the plant protection annex of the Organic Regulation is also an issue. While low-risk microorganism substances are automatically allowed in OP (except for GMOs), natural low-risk substances (from plant, mineral, animal and bacterial origin) must apply with

[50] European Court of Auditors, "Sustainable Use of Plant Protection Products: Limited Progress in Measuring and Reducing Risks" (2020) 5 Special Report 1, Points 36 and 37 <https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=53001> (last accessed 29 November 2021).

[51] DG Health and Food Safety. Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the Authorisation of Plant Protection Products. DG(SANTE) 2017-6250-MR:1-30, DOI: 10.2875/580084 (2017); European Parliament and Council. REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL On the experience gained by Member States on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides (2020), COM/2020/204 final.

[52] DG Health and Food Safety, supra, note 51.

[53] Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10762/2021) (SANTE/10760/2021); Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance *Metarhizium brunneum* strain M43 as a low-risk active substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10278/2021) (SANTE/10276/2021).

[54] E Böckmann, F Feldmann and U Vogler, "'Current-IPM-Fit': A New Proposal for Enhanced Efficacy Labelling of Plant Protection Products" (2019) 126 Journal of Plant Diseases and Protection 385.

[55] E Kohlschmid and D Ruf, "Is the Risk for Soil Arthropods Covered by New Data Requirements under the EU PPP Regulation No. 1107/2009?" (2016) 23 Environmental Science and Pollution Research International 23884.

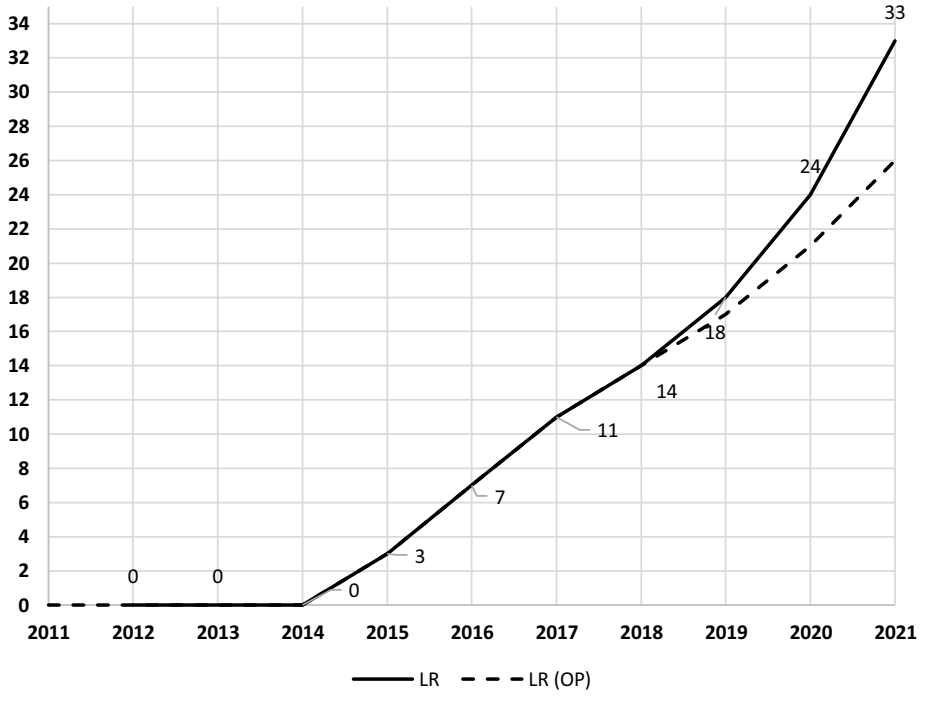

Figure 5. Evolution of low-risk substances (LR) included in organic production (OP).

an individual inclusion request dossier to be allowed in OP.[56] Inclusion in the OP plant protection annex is almost always achieved for every low-risk substance (except for herbicides), with twenty-six of the thirty-three (79%) low-risk substances authorised in OP (Figure 5 & Table 1). Similarly, thirty-four of the forty-three potential low-risk substances from the 2018 list are already allowed in OP (Tables 3 & 6). Figure 5 shows a recent shift in OP because many natural substances have recently been approved as low-risk substances and have not yet applied for inclusion in OP or have not yet been validated by the Regulatory Committee on Organic Production (RCOP).[57] Note that the latest Expert Group for Technical Advice on Organic Production (EGTOP) report validated the substance ABE-IT 56,[58] which should later become allowed in OP. This slow process cannot be sped up, as applications of natural substances for OP, instead of direct inclusion for microorganisms, are compulsory and at the national level before evaluation by EGTOP in case of national endorsement. The latest approved low-risk substances, for instance, could not be directly taken into consideration by self-referral at the EGTOP level, although this was suggested at the EU level, and even less automatically validated in OP plant protection[59] (except for herbicide uses) in Annex I.[60] However, in the recent "PPP" Annex I of OP,

[56] Marchand, supra, note 9.

[57] Committee on Organic Production (RCOP) <https://ec.europa.eu/transparency/comitology-register/screen/committees/C06500/consult?lang=en> (last access 29 November 2021).

[58] EGTOP reports on organic production. The reports are produced by the expert group for technical advice on organic production <https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en> (last access 29 November 2021).

[59] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007. PE/62/2017/REV/1. OJ L 150/1.

[60] Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists. C/2021/5149. OJ L 253/13.

low-risk natural active substances have been listed in subcategory 2 separately from other active substances (in subcategory 4), while low-risk microorganisms (listed in Part D of Regulation EC No 540/2011) have been listed in subcategory 3 with other microorganism active substances. This development of low-risk natural active substances in OP indicates a specific consideration, although the inclusion process is very similar to that of other active substances. This distinction and favourable position, together with the specific interest in low-risk active substances for OP already described previously,[61] may also represent a strong signal for new inclusions. Only four low-risk natural active substances are currently listed, not taking into consideration the transfer to a low-risk substance seen in the recent potassium hydrogen carbonate renewal. This acknowledgement in OP plant protection is also of economic importance for BCA manufacturers, as 10% of the surface of Europe is already under OP rules.[62] Research programmes are currently underway at Institut Technique de l'Agriculture Biologique (ITAB) to consider the earlier application to OP for recently approved low-risk natural active substances or those undergoing ongoing approval in order to reduce the delay between approval and OP validation.

In fact, all low-risk active substances, except for herbicides and plant growth regulators, can and should apply for an OP plant protection insertion since automatic inclusion (of low-risk active substances) has not been validated; there are no challenges in this category for function or crop usages with respect to the selection of low-risk substance applications.[63] However, all low-risk microorganisms are automatically listed in Annex I, Part 3 of Implementing Regulation (EU) 2021/1165,[64] and virtually all low-risk natural substances that have been proposed have been validated in Annex I, Part 2, such as laminarin, COS-OGA,[65] cerevisane[66] and ABE-IT 56.[67] For BCA companies managing low-risk active substance, this specific goal of allowing such natural substances in OP could also be an economical consideration in order to increase possible sales, as 10% of the land surface in the Europe is under OP rules and needs specific allowances.[68] As a matter of fact, the organic sector is constantly triggering these applications, although the final inclusion choice is a Member State decision based on the EGTOP evaluation. At present, inclusion dossiers for the latest approved low-risk active substances are in the process of being put together.

V. Conclusions and perspectives

The evolution of low-risk substances, despite showing a regular increase, is slow, and the benefit of this status has not been fully exploited through the conversion of the

[61] Marchand, supra, note 9.

[62] H Willer, J Trávníček, C Meier and B Schlatter, "The World of Organic Agriculture Statistics and Emerging Trends 2021" (2021) FiBL & IFOAM Organics International 1 <https://www.fibl.org/fileadmin/documents/shop/1150-organic-world-2021.pdf> (last accessed 23 November 2021).

[63] EGTOP, "Final Report on Plant Protection Products II" (2014) <https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/egtop-final-report-plant_protection_products-ii_en_1.pdf> (last accessed 23 November 2021).

[64] EU, supra, note 60.

[65] EGTOP, "Final Report on Plant Protection Products III" (2016) <https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/final_report_egtop_plant_protection_iii_0.pdf> (last accessed 23 November 2021).

[66] EGTOP, "Final Report on Plant Protection Products IV" (2019) <https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/final-report-egtop-plant-protection-iv_en.pdf> (last accessed 23 November 2021).

[67] EGTOP, "Final Report on Fertilisers IV and Plant Protection Products VI" (2021) <https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/egtop-report-fertilisers-iv-and-plant-protection-products-vi_en.pdf> (last accessed 23 November 2021).

[68] Willer et al, supra, note 62.

entire list from 2018 of potential low-risk substances, with twenty-nine active substances being approved but still without this status. Such an adoption would represent a big step towards partially rectifying the lack of usage diversity of low-risk active substances. Although 2021 will again, following on from 2020 (Figure 5), grant a significant number of low-risk substance statuses, this progress will lead to only a small proportion (n = 35; 7.8%) of the maximum number of active substances being approved by the end of 2021 (estimated at 450). This is also not sufficient to impact positively the expansion of BCAs and the reduction of the Harmonised Risk Indicators, two of the pillars of Directive 2009/128/EC.[69] In conclusion, the direct transfer of potential low-risk substances would also remove the distortion of concurrence between recently approved low-risk substances and substances listed in 2018 and approved only a few years before but that will have to wait for their renewal ten years hence, such as *Bacillus pumilus* QST 2808 or maltodextrin. This approach to processing and converting the twenty-nine latest potential low-risk active substances may be a coherent application of the Green Deal,[70] and furthermore, the possible improvement of the PPP Reg[71] may also trigger a better approval process for low-risk substances as *de novo* active substance candidates. This massive conversion would also increase the visibility of low-risk active substances (from 7.5% to up to 14% of the active substances) and low-risk plant protection product availability, as well as reduce criticisms regarding pesticides and pesticide regulation.[72] In particular, this conversion would increase the available function diversity of the low-risk active substances and reduce the significant proportion of fungicides in the low-risk active substance category. Ongoing and further modification to Annex II of the PPP Reg[73] for microorganisms and the proposal of granting a low-risk status for many ongoing microorganisms are positive signs for visibility, together with high number of low-risk active substances in 2021 (n = 10; +40%).[74]

[69] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. OJ L 309/71; DC Robin and PA Marchand, "Evolution of Directive (EC) No 128/2009 of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve the Sustainable Use of Pesticides" (2019) 7 Journal of Regulatory Science 1.

[70] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. The European Green Deal. (2019) OJ C 640/1.

[71] C Frederiks and JHH Wesseler, "A Comparison of the EU and US Regulatory Frameworks for the Active Substance Registration of Microbial Biological Control Agents" (2019) 75 Pest Management Science 87.

[72] S Stehle and R Schulz, "Pesticide Authorization in the EU – Environment Unprotected?" 22 Environmental Science and Pollution Research 19632.

[73] Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms (SANTE/10686/2021); Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (SANTE/12040/2020); Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms (SANTE/12042/2020); Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms (SANTE/10716/2021).

[74] Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance *Metarhizium brunneum* strain M43 as a low-risk active substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10278/2021) (SANTE/10276/2021); Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of

Finally, all of these levers being orientated in the same direction could strengthen the perception of the low-risk status amongst prescribers, users, operators and customers, thus opening up a wider range of usages and thus reaching even more targets. Ultimately, this should be coupled with the encouragement of BCA applications, even an initial application as low-risk, and a real and specific evaluation[75] of BCAs[76] should be organised during the ongoing update of the PPP Reg[77] at the EU level, ten years after its implementation.

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Competing interests. The authors declare none.

the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11266/2021) (SANTE/11264/2021).

[75] Vekemans and Marchand, supra, note 2; S Mladenović, "The Role of the European Food Safety Authority in the Active Substance Approval and Renewal Procedures within the EU Pesticide Policy" (2021) 90 Правни факултет Универзитета у Нишу 165.

[76] V Storck, DG Karpouzas and F Martin-Laurent, "Towards a Better Pesticide Policy for the European Union" (2017) 575 Science of the Total Environment 1027.

[77] E Bozzini, "EU Pesticide Regulation: Principles and Procedures" in *Pesticide Policy and Politics in the European Union* (London, Palgrave Macmillan 2017) pp 27–56.

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