

**Request for internal review under title IV of the Aarhus Regulation**

**of Commission Implementing Regulation (EU) 2022/708 of 5 May 2022** amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distillation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea (the “**Contested Act**”)

Submitted by POLLINIS, a non-governmental organisation having its offices at 10 rue Saint-Marc, Paris, France, represented by Nicolas Laarman

To the European Commission, Directorate General for Health and Food Safety (DG SANTE)

Pursuant to Article 10 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Union institutions and bodies (the “**Aarhus Regulation**”) and Commission Decision 2008/50/EC of 13 December 2007 laying down detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts.

## 1. BACKGROUND AND CONTESTED ACT

Boscalid is an active substance used in plant protection products of the SDHI (succinate dehydrogenase inhibitors) family. It was first approved in the EU by Commission Directive 2008/44/EC of 4 April 2008, which included boscalid in Annex I of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as of 1 August 2008.

With the entry into force of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Directives 79/117/EEC and 91/414/EEC (the “**PPP Regulation**”), the active substances included in Annex I to Directive 91/414 were deemed to have been approved and were listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances.

The approval of the active substance boscalid was due to expire on 31 July 2018.

BASF submitted an application for renewal in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances (the “**Renewal Regulation**”), as provided for in Articles 14 *et seq.* of the PPP Regulation.

In June 2018, as the approval of boscalid was likely to expire before a decision was taken on its renewal, the European Commission extended its approval period until 31 July 2019<sup>1</sup>. In May 2019, as the renewal procedure was still pending, the approval period of boscalid was extended for another year, until 31 July 2020<sup>2</sup>. Similar decisions were taken in June 2020<sup>3</sup> and, again, in June 2021<sup>4</sup>, thus postponing the expiry date of the approval of boscalid to 31 July 2022.

1 Commission Implementing Regulation (EU) 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, bentiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazin, fluoxastrobin, folpet, foramsulfuron, formetanate, *Gliocladium catenulatum* strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor.

2 Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, bentiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole.

3 Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, bentiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor.

4 Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, bentiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to

# POLLINIS

The Contested Act extends until 31 July 2023 the approval period of the active substance boscalid. It is the fifth consecutive decision taken to extend the approval period of boscalid, thus bringing the overall extension period up to five years.

---

C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea.

## 2. ADMISSIBILITY OF THE REQUEST FOR INTERNAL REVIEW

Pursuant to Article 10 of the Aarhus Regulation, any non-governmental organisation that meets the criteria set out in Article 11 is entitled to make a request for internal review of an administrative act on the grounds that such an act contravenes environmental law.

### 2.1. POLLINIS meets the criteria set out in Article 11 of the Aarhus Regulation

POLLINIS submits the following documents, as listed in points 1-3 of the Annex to the Commission Decision 2008/50/EC of 13 December 2007 laying down detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts :

1. Statute of POLLINIS (in French) (Annex 1);
2. Annual activity reports of POLLINIS for the years 2020 and 2021 (in French) (Annexes 2A & 2B);
3. Copy of POLLINIS' legal registration with the French authorities (in French) (Annexes 3A, 3B & 3C).

POLLINIS meets all the criteria set out in Article 11 of the Aarhus Regulation

(a) POLLINIS is an independent non-profit-making legal person in accordance with a Member State's national law or practice: as shown by its Statutes (Annex 1) and by the copy of its legal registration as a non-profit association (Annexes 3A, 3B and 3C), POLLINIS is an independent legal person incorporated in the form of a non-profit association under French law;

(b) POLLINIS has the primary stated objective of promoting environmental protection in the context of environmental law: as stated in Article 1 of its Statutes (Annex 1), POLLINIS' objectives are: to stop the extinction of pollinators and, more generally, to stop the extinction of insects and biodiversity; to promote an environment favourable to pollinators, through a new European agricultural model; to mobilise citizens, scientists and experts in favour of the preservation of pollinators and their habitats, through conservation projects; to study pollinators and their environment and make them known to the public;

(c) POLLINIS has existed for more than two years and is actively pursuing the objective referred to under (b): as evidenced by its legal registration documents (Annexes 3A, 3B and 3C), POLLINIS was created in 2012 and has therefore existed for ten years. The annual activity reports (Annexes 2A and 2B) provide evidence that POLLINIS is actively pursuing the objectives mentioned above, and all of its activities are directly aimed at environmental protection;

(d) the subject matter in respect of which the request for internal review is made is covered by its objective and activities: the present request seeks to revoke the extension of the approval of boscalid. This objective is fully in line with POLLINIS's statutory purpose and activities for the protection of pollinators and the environment and for the promotion of an

# POLLINIS

agriculture that is respectful of the environment. To name but some examples, these activities include a court action against the French State for its failure to ensure adequate assessment of the impacts of pesticides on the environment prior to granting marketing authorisations, an action for annulment against the European Commission against its refusal to grant POLLINIS access to documents regarding the adoption process of the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus spp.*, solitary bees) under Regulation (EC) 1107/2009 or various actions against SDHIs (including the co-financing of an independent scientific study on adverse effects of SDHIs on human cells, bees, earthworms<sup>5</sup>, the handing-over of a petition, signed by more than 420 000 citizens, for reassessment of all SDHIs with protocols adapted to their specific mode of action and the application of the principle of precaution in the meantime, as well as the submission of a petition to the European Parliament in accordance with Article 227 TFEU).

## 2.2. The Contested Act is an administrative act in accordance with Article 2(1)(g) of the Aarhus Regulation

Under Article 2(1)(g) of the Aarhus Regulation, an “administrative act” is defined as “any non-legislative act adopted by a Union institution or body, which has legal and external effects and contains provisions that may contravene environmental law within the meaning of point (f) of Article 2(1).”

The Contested Act fulfils all these requirements<sup>6</sup>:

(a) The Contested Act is a non-legislative act adopted by a Union institution

In accordance with Article 289 TFEU, “[l]egal acts adopted by legislative procedure shall constitute legislative acts”. The Contested Act was not adopted by such a legislative procedure. Rather, it is an implementing regulation in accordance with Article 291 TFEU, adopted by the European Commission on the basis of Article 17 of the PPP Regulation.

(b) The Contested Act has legally binding and external effects

In accordance with Article 288 of the TFEU, a regulation is binding in its entirety and directly applicable in all Member States. The binding nature of the Contested Act derives from Article 4 through 24 of the PPP Regulation, which confers implementing powers on the Commission for the approval of active substances, including the power to renew, extend, withdraw or modify such approval. The Contested Act is based, more specifically, on Article 17, which confers on the Commission the power to adopt a regulation extending an approval beyond its expiry date. Such regulation has binding and external effects, in particular on the marketing authorisations of plant protection products containing that substance.

---

5 <https://www.pollinis.org/admin/wp-content/uploads/2019/11/etude-sdhi-benit-rustin-2019.pdf>

6 The Commission has already found admissible a request for internal review of a regulation on extension based on Article 17 of the PPP Regulation, thus considering that such regulation falls within the scope of the Aarhus Regulation: European Commission, Reply to the internal review request concerning the Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (“**Commission reply to PAN Europe’s request for internal review**”).

(c) The Contested Act contains provisions that may contravene environmental law within the meaning of Article 2(1)(f) of the Aarhus Regulation

Under Article 2(1)(f) of the Aarhus Regulation, environmental law means “*Union legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Union policy on the environment as set out in TFEU: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems*”.

Because of the potential harm inherent to active substances, there is no doubt that a decision to extend the approval of an active substance has the potential to contravene environmental law. The present request challenges the Contested Act – more specifically, the extension of the approval duration of boscalid until 31 July 2023 – on the basis that this extension contravenes, in particular, (i) the precautionary principle as provided for in Article 191(2) TFEU and in Article 1(3) of the PPP Regulation; (ii) the requirement to ensure a high level of protection of both human health and the environment, as provided for in Articles 168(1) and 191(2) TFEU, in Articles 35 and 37 of the Charter of Fundamental Rights of the EU and in Article 1(3) of the PPP Regulation; as well as (iii) various provisions of the PPP Regulation that contribute to the pursuit of the objectives of EU policy on the environment.

### 3. LEGAL FRAMEWORK OF THE APPROVAL OF ACTIVE SUBSTANCES

The approval of active substances composing plant protection products is regulated by Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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 (the “**PPP Regulation**”).

The PPP Regulation entered into force on 14 June 2011. It was adopted on the basis of Article 37(2) EC (now, after amendment, Article 43(1) TFEU) concerning the common agricultural policy, Article 95 EC (now Article 114 TFEU) concerning the approximation of laws which have as their object the internal market, in relation, notably, to the environment, and Article 152(4)(b) EC (now, after amendment, Article 168(4)(b) TFEU) concerning public health.

Article 1 of the PPP Regulation states, in paragraph 3, that **its purpose is to ensure a high level of protection of both human and animal health and the environment**, and in paragraph 4, that **its provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment**.

Under Article 28(1) of the PPP Regulation, a plant protection product is not to be placed on the market or used unless it has been authorised in the Member State concerned in accordance with the PPP regulation. Under Article 29(1)(a) of the PPP Regulation, Member States may only authorise a plant protection product containing active substances that have been approved at EU level.

The approval of active substances at EU level is regulated by Articles 4 through 24 of the PPP Regulation.

**Approval criteria.** An active substance may only be approved if plant protection products containing that active substance are expected to meet certain criteria set out in Article 4 of the PPP Regulation. Among these criteria, they must have no immediate or delayed harmful effect on human health, on animal health or on groundwater and no unacceptable effects on the environment<sup>7</sup>. As stated by General Advocate Kokott, “*Article 4 essentially sets out two conditions for the approval of an active substance. First, its use in plant protection products may not have any harmful effect on human health [...]. Second, there may not be any unacceptable effects on the environment. If the approval does not satisfy those requirements it is unlawful*”<sup>8</sup>.

**Burden of proof.** As stated by the Court of justice, “*it is for the applicant to prove that the active substance [...] fulfils the relevant criteria laid down by [the PPP] regulation. That obligation contributes to achieving compliance with the precautionary principle by ensuring that there is no presumption that active substances and plant protection products have no harmful effects*”<sup>9</sup>.

---

7 PPP Regulation, Article 4(3).

8 Opinion of Advocate General Kokott, 17 September 2020, *Bayer CropScience AG and Bayer AG v. Commission*, C-499/18 P, paragraphs 44-45.

9 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 79. See also PPP Regulation, Article 4(1) and Article 7(1), as well as Recital 8 : “*The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*”

The applicant for the approval of an active substance must therefore demonstrate that the substance has no harmful effects on human health, animal health and groundwater and no unacceptable effects on the environment. This also applies at the renewal process<sup>10</sup>.

**Duration of approval and renewal.** According to Article 5 of the PPP Regulation, first approval of an active substance shall be for a period not exceeding 10 years. After that, the approval may be renewed, if the applicant establishes the criteria for approval are still met, for a period not exceeding 15 years<sup>11</sup>. These are maximum time periods. As emphasised in the Recitals to the PPP Regulation: *“In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate to the possible risks inherent in the use of such substances.”*<sup>12</sup>

**Renewal process of an active substance.** Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation No 1107/2009 (the **“Renewal Regulation”**), lays down the renewal procedure.

An application for the renewal of an approval of an active substance must be submitted no later than three years prior to its expiry date<sup>13</sup>. The Renewal Regulation sets specific deadlines that must be observed at each step of the renewal procedure so as to ensure that the duration of the procedure as a whole does not exceed three years<sup>14</sup>.

Where the application is admissible, the rapporteur Member State must, after consulting the co-rapporteur Member State, prepare and submit a draft renewal assessment report, in principle, no later than 20 months before the expiry of the approval<sup>15</sup>. This draft renewal assessment report is made available to the public for the submission of written comments<sup>16</sup>. EFSA then has five months to adopt a conclusion, in light of scientific and technical knowledge, on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the PPP Regulation<sup>17</sup>. Where EFSA considers that additional information is necessary, a period not exceeding one month is set for the applicant to supply such information. The rapporteur Member State must evaluate the additional information received within 60 days from the date of receipt, and send its evaluation to EFSA<sup>18</sup>.

---

10 PPP Regulation, Article 14(1): *“On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied”*. See also CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraph 72: *“It must be borne in mind that under Article 14(1) of Regulation No 1107/2009 the approval of an active substance is, on application, to be renewed where it is established that the approval criteria provided for in Article 4 of that regulation have been satisfied. Article 14(1) of Regulation No 1107/2009 provides that an active substance is to be approved if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of Annex II to that regulation, plant protection products containing that active substance meet the requirements provided for in Article 4(2) and (3) thereof.”*

11 PPP Regulation, Article 14(2).

12 PPP Regulation, preamble, Recital 15.

13 PPP Regulation, Article 15(1); Renewal Regulation, Article 1(1).

14 CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraph 82.

15 Renewal Regulation, Articles 11(1) and 6(3).

16 Renewal Regulation, Article 12.

17 Renewal Regulation, Article 13(1).

18 Renewal Regulation, Article 13(3).



## POLLINIS

Within six months from the date of receipt of the conclusion of EFSA, the Commission must present a renewal report and a draft regulation to the Standing Committee on Plants, Animals, Food and Feed (“**SCoPAFF**”). The regulation on renewal is adopted by the Commission, on the basis of the renewal report and taking into accounts comments submitted by the applicant<sup>19</sup>.

---

<sup>19</sup> Renewal Regulation, Article 14.

#### 4. GROUNDS OF REVIEW

The Contested Act is based on Article 17 of the PPP Regulation, which reads as follows:

*“Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.”*

Along with boscalid, the Contested Act extends the approval periods of 41 other active substances. According to its Recitals: *“Due to the fact that the assessment of the substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal. It is therefore necessary to extend their approval periods”*<sup>20</sup>.

The Contested Act is, at least insofar as boscalid is concerned, unlawful and must be reviewed:

- The Contested Act is based on an interpretation of Article 17 which is contrary to the precautionary principle, to Article 191(3) TFEU, and to other provisions of the PPP Regulation **(4.1)**:
  - (a) Article 17 of the PPP Regulation must be interpreted and applied in accordance with the precautionary principle
  - (b) In accordance with the precautionary principle, extensions must remain limited in time and take into account the possible risks to human or animal health or to the environment. In particular:
    - (i) any extension granted under Article 17 must necessarily be temporary and limited in time;
    - (ii) the decision on extension must take into account possible risks to human or animal health or to the environment. The approval may not be extended where significant data gaps create uncertainty as to the existence or extent of those risks or where evidence or reasonable doubt exists that a substance is harmful.
  - (c) The Commission’s powers to withdraw an approval under other provisions of the PPP Regulation do not exempt it to comply with the precautionary principle when implementing Article 17.
- The Contested Act is in breach of the terms of Article 17 of the PPP Regulation **(4.2)**:
  - (a) the condition that the delay must be owing to reasons beyond the control of the applicant is not satisfied;
  - (b) the time length of the extension period does not comply with the requirements of Article 17.
- The Contested Act does not state sufficiently the reasons on which it is based **(4.3)**.

---

<sup>20</sup> Contested Act, Recital 5.

**4.1- Infringement of the Treaties or of any rule of law relating to their application: The Contested Act was adopted in breach of Article 191 TFEU, the precautionary principle, and various provisions of the PPP Regulation.**

**a) Article 17 of the PPP Regulation must be interpreted and applied in accordance with the precautionary principle**

In its reply to a request similar to the present request, filed by Pan Europe against Regulation (EU) 2021/2068 of 25 November 2021 (which extended the approval period of 9 active substances), the European Commission argued as follows:

*“Article 17 of the PPP Regulation lays down, in an exhaustive manner, the conditions under which the Commission must postpone the expiry of approval periods, i.e. that it appears that the approval is likely to expire before a decision has been taken on renewal, and that the reasons for the expected delay are beyond the control of the applicant. Where these conditions are fulfilled, the Commission is not only empowered to rightfully adopt such decisions in the form of an Implementing Regulation, but the wording of Article 17 (“shall”) even obliges the Commission to adopt such legal acts extending the approval period of the substances concerned.”<sup>21</sup>*

The Commission’s interpretation of Article 17 is, however, inconsistent with the purpose of the PPP Regulation, which is to ensure a high level of protection of the environment and human health, and in clear breach of the precautionary principle, with which the provisions of the PPP Regulation must comply.

Article 17 must be interpreted in light of other relevant provisions of the PPP Regulation (including, in particular, the criteria set out in Article 4 and the maximal approval time period provided for in Article 5) and in accordance with the precautionary principle and with its purpose of ensuring a high level of human health and environmental protection.

***Ensuring a high level of protection of both human and animal health and the environment.*** A high level of protection of human and animal health and the environment are fundamental requirements of EU law, expressly guaranteed by Articles 35 and 37 of the Charter of Fundamental Rights of the EU and by Article 168(1) and Article 191(2) of the Treaty on the functioning of the European Union (the “TFEU”). Accordingly, “[t]he European Union is called upon to ensure a high level of protection and improvement of environmental protection”<sup>22</sup>, and “[t]hat protection takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial”<sup>23</sup>.

These protection objectives are explicitly reiterated by Article 1 paragraphs 3 and 4 of the PPP Regulation, according to which:

*“3. The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal*

<sup>21</sup> Commission reply to PAN Europe’s request for internal review, Annex, p. 2.

<sup>22</sup> CJEU, Judgment, 28 July 2016, *Association France Nature Environnement*, C-379/15, paragraph 35.

<sup>23</sup> General Court, Judgment, 17 March 2021, *FMC Corporation v. Commission*, T-719/17, paragraph 59 and cited case-law. See also PPP Regulation, preamble, Recital 24 : “the objective of protecting human and animal health and the environment should **take priority** over the objective of improving plant production”.

*market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.*

4. *The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.”*

**Compliance with the precautionary principle.** The precautionary principle “is a general principle of EU law requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, **to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests**”<sup>24</sup>. The Court of justice of the EU has specifically held that there is “an obligation on the EU legislature, when it adopts rules governing the placing on the market of plant protection products, such as those laid down in Regulation No 1107/2009, **to comply with the precautionary principle**”<sup>25</sup>, in order to ensure a high level of protection of human health and of the environment.

**Therefore, provisions of the PPP Regulation must be interpreted and applied in a manner that is consistent with the precautionary principle. Any provision of the PPP Regulation or any interpretation thereof that contradicts the precautionary principle must be set aside.**

The precautionary principle applies, in particular, to the assessment of active substances<sup>26</sup>, whether it is when it is first approved or upon renewal. While Article 17 allows the Commission to derogate to the maximal approval period set out in Article 5, it does not allow the Commission to derogate from the precautionary principle. The Commission remains bound by the precautionary principle when it decides on any extension.

In light of the above, the Commission cannot rely solely on the wording of Article 17(1) (“*shall be adopted*”) to consider that it has no choice but to extend the approval whenever that approval is likely to expire before a decision has been taken on renewal for reasons beyond the control of the applicant. Such literal interpretation of Article 17(1) clearly violates the precautionary principle and should be set aside.

Besides, it must be noted that, under Article 17(1), the decision on extension “*shall be adopted in accordance with the regulatory procedure referred to in Article 79(3)*”. The fact that it must be submitted to the SCoPAFF confirms that the decision on extension is not purely automatic but requires a more complex assessment, including that of health and environmental issues.

**b) In accordance with the precautionary principle, extensions must remain limited in time and take into account the possible risks to human or animal health or to the environment**

In accordance with the precautionary principle and in order to ensure a high level of protection of human health and the environment, any extension granted pending reassessment must be limited in time (i). Furthermore, any decision on extension must take into account the possible risks to human

24 See e.g. General Court, Judgment, 17 March 2021, *FMC Corporation v. Commission*, T-719/17, paragraph 62; General Court, Judgment, 16 September 2013, *Animal Trading Company (ATC) BV et al. v. Commission*, T-333/10, paragraph 79; General Court, Judgment, 17 March 2016, *Zoofachhandel Züpke GmbH et al. v. Commission*, T-817/14, paragraph 51.

25 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 42.

26 CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraphs 124-127.

or animal health or to the environment. Accordingly, the Commission may not extend the approval period in the event of data gaps or insufficient data regarding the risks to human or animal health or to the environment, or where there exists proof or reasonable doubt that the substance is harmful or in the event of data gaps or insufficient data regarding the risks to human or animal health or to the environment (ii).

***i) Extension under Article 17 is a transitory measure, which, in accordance with the precautionary principle and with the provisions of the PPP Regulation, must necessarily be temporary and limited in time***

As stated in the Recitals to the PPP Regulation: “***In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate to the possible risks inherent in the use of such substances.***”<sup>27</sup> According to Article 5 of the PPP Regulation, first approval of an active substance shall be for a period not exceeding 10 years. After that, the approval may be renewed – provided it is established that the criteria for approval are still met – for a period not exceeding 15 years<sup>28</sup>. These are maximum time periods.

This is why Articles 11 through 14 of the Renewal Regulation fix specific time periods that must be observed by the applicant, the rapporteur Member State, EFSA and the Commission, at each step of the reassessment procedure. As stated by the Court of Justice, “[t]he imposition of those periods and the requirement that they be observed are [...] consistent with **the requirement that the duration of the procedure as a whole not exceed three years, as is clear from Article 1(1) of Implementing Regulation No 844/2012**”<sup>29</sup>.

Admittedly, Article 17 allows the Commission, as an exception to the time periods set in Article 5 of the PPP Regulation and in the Renewal Regulation, to deviate from these time periods. It allows the Commission, as a transitory measure, to extend the duration of the approval when that approval is likely to expire before a decision has been taken on renewal. However, precisely because of its exceptional nature, Article 17 must be applied restrictively and, in any event, in accordance with the precautionary principle. Such an extension, which departs from applicable rules, must necessarily be temporary and limited in time. Article 17 cannot be used to palliate systematic and repeated delays in the renewal procedure, or to extend the approval time period beyond reasonable time. An indefinite extension of an approval after its expiry date would be contrary to the precautionary principle and to the objective pursued by the PPP Regulation of ensuring a high level of protection of human and animal health and of the environment<sup>30</sup>.

In the present case, the approval of boscalid was due to expire four years ago, on 31 July 2018. The Contested Act postpones its expiration to 31 July 2023, thus bringing the overall extension period to five years (which is half the duration of the maximum approval period), and its overall approval period to fifteen years. An extension of that duration can no longer qualify as a mere “extension”; it is, *de facto*, a new approval (5 years is, for instance, the duration of the last renewal of the approval of the active substance glyphosate). An extension of that duration clearly exceeds what Article 17 permits.

---

27 PPP Regulation, preamble, Recital 15.

28 PPP Regulation, Article 14(2).

29 CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20, paragraph 82.

30 General Court, Judgment, 17 March 2021, *FMC Corporation v. Commission*, T-719/17, paragraph 188; General Court, Judgment, 6 octobre 2021, *Sipcam Oxon SpA v. Commission*, T-518/19, paragraph 101.

Accordingly, by extending the approval of boscalid for up to five years, the Commission has exceeded the powers conferred on it under Article 17 of the PPP Regulation.

***ii) Decisions on extension must take into account possible risks to human or animal health. The approval may not be extended where significant data gaps create uncertainty as to the existence or extent of those risks or where evidence or reasonable doubt exists that a substance is harmful***

The precautionary principle means that where there is uncertainty as to the existence or extent of risks to human health or to the environment, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent<sup>31</sup>. The institutions are even required to take appropriate measures to prevent specific potential risks to human health or to the environment arising from a substance, when solid and convincing evidence, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety of that substance<sup>32</sup>.

The Court of Justice held “*that the EU legislature ought to establish a normative framework that ensures that the competent authorities have available to them, when they decide on [the approval of active substances], sufficient information in order adequately to assess, in accordance with the requirements of the precautionary principle, the risks to health resulting from the use of those active substances and those plant protection products*”<sup>33</sup>. In particular, “*it is for the applicant to prove that the active substance (...) fulfils the relevant criteria laid down by [the PPP] regulation. That obligation contributes to achieving compliance with the precautionary principle by ensuring that there is no presumption that active substances and plant protection products have no harmful effects*”<sup>34</sup>.

The applicant for the approval of an active substance must therefore demonstrate that the substance has no harmful effects on human health, animal health and groundwater and no unacceptable effects on the environment<sup>35</sup>. This also applies at the renewal process<sup>36</sup>; the applicant for renewal thus bears the burden of proving the efficacy and safety of the substance in question<sup>37</sup>.

31 CJEU, Judgment, 6 May 2021, *Bayer CropScience AG v. Commission*, C-499/18, paragraph 80 ; CJEU, Judgment 1 October 2019, *Blaise and Others*, C-616/17, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 43.

32 General Court, Order, 15 May 2013, *Germany v. Commission*, T-198/12 R, paragraph 72. See also CJEU, Judgment, 3 December 2015, *PP Nature-Balance Lizenz GmbH v. Commission*, C-82/15 P, paragraph 24.

33 CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20, paragraph 127. See also CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 47.

34 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraphs 79-80. See also CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraph 128. See also PPP Regulation, Article 4 paragraph 1 and Article 7 paragraph 1, as well as Recital 8 : “*The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*”

35 PPP Regulation, Article 4(1) and Article 7(1).

36 PPP Regulation, Article 14(1): “*On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied*”. See also CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraph 72: “*It must be borne in mind that under Article 14(1) of Regulation No 1107/2009 the approval of an active substance is, on application, to be renewed where it is established that the approval criteria provided for in Article 4 of that regulation have been satisfied. Article 14(1) of Regulation No 1107/2009 provides that an active substance is to be approved if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of Annex II to that regulation, plant protection products containing that active substance meet the requirements provided for in Article 4(2) and (3) thereof.*”

37 General Court, Judgment, 28 May 2020, *Agrochem-Maks d.o.o. v. Commission*, T-574/18, paragraph 121.

In particular, under Article 8(5) of the PPP Regulation, the applicant must provide scientific peer-reviewed open literature on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years. This requirement serves to ensure the quality and independence of the assessment of an active substance.<sup>38</sup> Furthermore, as part of the assessment to be undertaken, EFSA and the Commission “are of necessity bound to take into account relevant evidence other than the tests, analyses and studies submitted by the applicant that might contradict the latter”<sup>39</sup>. With that in mind, “it is the duty of the competent authorities, in particular, to take account of the most reliable scientific data available and the most recent results of international research and not to give in all cases preponderant weight to the studies provided by the applicant”<sup>40</sup>. In the event that the competent authorities come to the conclusion that, having regard to all the information at their disposal, an applicant has not established to the required standard that the conditions governing the approval applied for are satisfied, they are bound to decide that the application should be rejected, there being no need, in order to reach that conclusion, to undertake a second assessment<sup>41</sup>.

As a consequence, where data are missing on potential effects of the substance on human health or on the environment<sup>42</sup>, or where the data supplied by the applicant are not supported by scientific peer-reviewed open literature, the substance should neither be approved nor renewed.

In light of the foregoing, if Article 17 allows – on a temporary and exceptional basis – the Commission to postpone the expiry date of an approval until a decision is taken on renewal, such decision must take into account the possible risks to human or animal health or to the environment. Besides, the duration of the extension must be proportionate to those risks. In this respect, the longer the extension, the more caution is required.

Likewise, Article 17 cannot be used to extend the approval of substances in respect of which the dossier is incomplete or significant data gaps prevent finalising its assessment. Such an extension would run contrary to the provisions of Articles 4 and 7 of the PPP Regulation and to the precautionary principle. It would encourage the industry to provide dossiers with missing information or to delay the supply of necessary information for as long as possible – especially in respect of substances which are likely not to be renewed –, knowing that the approval of the substance will be automatically extended in the meantime anyway.

Therefore, and in particular, the Commission may not extend the approval in respect of substances for which the current state of science is not expected to lead to renewal, nor:

- where data gaps or the absence of scientific peer-reviewed literature are such as to create uncertainty as to the existence or extent of risks to human or animal health or to the environment; nor
- if proof or reasonable doubt exists that substance is harmful for human or animal health or for the environment.

At the outset, it should be noted that, although the rapporteur Member State considered that the criteria set out in Article 4 of the PPP Regulation were met (despite the absence of a full dossier), it

38 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 89.

39 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 93.

40 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 94.

41 CJEU, Judgment, 1 October 2019, *Blaise and Others*, C-616/17, paragraph 95.

42 See e.g. General Court, Judgment, 28 May 2020, *Agrochem-Maks d.o.o.*, T-574/18 (confirmed on appeal by CJEU, 9 December 2021, *Agrochem-Maks d.o.o v. Commission*, C-374/20 P).

## POLLINIS

identified one critical area of concern (risk for child residents for use on grape, peas and beans), as well as a risk to bee development stage, requiring expert consultation<sup>43</sup>. Besides, EFSA found, upon review of the Draft Renewal Assessment Report, that additional information was necessary in order to complete the assessment (see below in section 4.2(a)).

As shown in Annex 4 (*Environmental contamination and adverse effects*), data gaps and shortcomings in the risk assessment, as well as a number of scientific peer-reviewed studies prove, or at the least raise reasonable doubts regarding the risks of boscalid for human health and the environment, which prevent its extension for yet another year.

The risks posed by SDHIs in general are pointed out in the scientific alert submitted by several scientists in 2017 to the French authorities. This alert was supported by 450 scientists, in an op-ed published in 2020<sup>44</sup>. The French National commission on ethics and alerts in public health and the environment (*Commission nationale de la déontologie et des alertes en matière de santé publique et d'environnement* (cnDAspe)) – which was in charge of assessing the alert submitted to the French authorities – found, on the basis of the overall scientific evidence available, that the scientific data on the dangers and risks of SDHI fungicides are reliable and raise serious doubts about hazards that are not currently taken into account in the EU risk assessment procedures<sup>45</sup>.

With regard to boscalid in particular, a number of data gaps, including lack of peer-reviewed studies on health and environmental risks, such as endocrine disrupting properties, create uncertainty as to both the existence and extent of risks to human or animal health or to the environment.

Besides, while few peer-reviewed studies focus on the potential adverse effects of boscalid, most of these studies show that boscalid does have adverse effects on non-target species (see Annex 4: *Boscalid environmental contamination and adverse effects*), and that boscalid presents serious risks to the environment as well as a threat to human health .

Accordingly, the precautionary principle prevents its renewal under Article 17.

It should also be added that the benefits of boscalid are in themselves disputable. The efficacy of boscalid is hampered, in particular, by the resistance developed by the moulds it is supposed to kill<sup>46</sup>.

---

43 Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. BOSCALID Volume 1. RMS: Slovakia. Co-RMS: France. (the “**Draft Renewal Assessment Report**”).

44 [https://www.lemonde.fr/sciences/article/2020/01/21/pesticides-sdhi-450-scientifiques-appellent-a-appliquer-le-principe-de-precaution-au-plus-vite\\_6026712\\_1650684.html](https://www.lemonde.fr/sciences/article/2020/01/21/pesticides-sdhi-450-scientifiques-appellent-a-appliquer-le-principe-de-precaution-au-plus-vite_6026712_1650684.html).

45 CnDAspe, Avis relatif au signalement sur de possibles risques liés aux fongicides agissant par inhibition de la succinate déshydrogénase (SDHI), délibéré le 24 octobre 2019 en réunion plénière, p. 1 : « *Les données scientifiques présentées par l'équipe de chercheurs sur les dangers des fongicides SDHI sont de qualité et posent un doute sérieux sur des dangers qui ne sont pas actuellement pris en compte dans les procédures de toxicologie appliquées selon la réglementation européenne concernant la mise sur le marché des produits phytosanitaires.* »

46 See e.g. Vielba-Fernández A, Polonio Á, Ruiz-Jiménez L, de Vicente A, Pérez-García A, Fernández-Ortuño D., “Resistance to the SDHI Fungicides Boscalid and Fluopyram in *Podosphaera xanthii* Populations from Commercial Cucurbit Fields in Spain”. *J Fungi* (Basel). 2021 Sep 8;7(9):733. doi: 10.3390/jof7090733. PMID: 34575771; PMCID: PMC8464660; Mostafanezhad, H., Edin, E., Grenville-Briggs, L.J. et al., “Rapid emergence of boscalid resistance in Swedish populations of *Alternaria solani* revealed by a combination of field and laboratory experiments”. *Eur J Plant Pathol* 162, 289–303 (2022). <https://doi.org/10.1007/s10658-021-02403-8>.



**c) The Commission’s powers to withdraw existing approvals under other provisions of the PPP Regulation do not exempt it from complying with the precautionary principle when implementing Article 17**

In its reply to Pan Europe’s request for review of Regulation (EU) 2021/2068, the European Commission contends that application of Article 17 does not prevent the Commission “*from taking other measures, such as amendments or withdrawals of existing approvals pursuant to Article 21 of the PPP Regulation or as emergency measures*”<sup>47</sup>. However, the Commission’s powers to withdraw existing approvals under other provisions of the PPP Regulation do not render the Contested Act any less unlawful.

**First**, neither Article 21 (Review of approval) nor the provisions of chapter IX (Emergencies) of the PPP Regulation provide for adequate procedures in respect of substances for which the approval period has expired.

Under Article 21 of the PPP Regulation, the Commission may review the approval of an active substance at any time and must, if it concludes, upon review, that the approval criteria provided in Article 4 are no longer met, withdraw or amend the approval. Article 21 lays down specific procedural requirements, including the Commission’s obligation to inform the Member States, EFSA and the producer of the active substance, and to set a period for the producer to submit its comments. These procedural requirements may not be appropriate in relation to substances which are anyway under reassessment. Furthermore, Article 21 allows the Commission to review substances during their approval period (and which, therefore, are presumed to be safe), without having to wait for the end of the approval period. Whereas substances that have exceeded their approval period should no longer be considered safe; on the contrary, it is incumbent on the producer to prove their efficacy and safety<sup>48</sup>. The inadequacy of the review procedure to substances under reassessment is further illustrated, in particular, by the fact that Article 21(3) of the PPP Regulation does not provide for the possibility to suspend an approval ; under that provision, the Commission may only “*withdraw or amend the approval*”<sup>49</sup>.

Likewise, the provisions of Chapter IX are meant for emergency measures, allowing the Commission to take immediate restrictive measures where “*it is clear that an approved active substance [...] is likely to constitute a serious risk to human or animal health or the environment*” (Article 69) or, “*in cases of extreme urgency*” (Article 70). The application of these provisions requires proof of clear and serious risks to human or animal health or the environment or extreme urgency, which is a particularly high threshold, and which is clearly inadequate here.

**Second**, and in any case, the Commission’s powers under Article 21 and under Chapter IX of the PPP Regulation have no bearing on its obligation to comply with the precautionary principle when deciding on extension under Article 17 of the PPP. These provisions cannot justify systematic, repeated and prolonged extensions, for years, of the approval of substances that are potentially harmful, without any consideration of the risks to either human or animal health or the environment.

---

47 Commission reply to PAN Europe’s request for internal review, pp. 4-5.

48 PPP Regulation, Article 14(1); General Court, Judgment, 28 May 2020, *Agrochem-Maks d.o.o. v. Commission*, T-574/18, paragraph 121; CJEU, Judgment, 9 December 2021, *Agrochem-Maks d.o.o. v. Commission*, C-374/20 P, paragraph 72.

49 General Court, Order, 8 April 2021, *CRII-GEN v. Commission*, T-496/20, paragraph 22.

**Finally**, in practice, it often happens that approvals are extended, sometimes for years, only to be not renewed at the end of the renewal process. In its reply to PAN Europe’s request, the Commission relies, in particular, on the example of two substances, chlorpyrifos-methyl and chlorpyrifos, for which the Commission adopted a non-renewal decision without awaiting the completion of the peer review on all remaining criteria, “*due to the severity of concerns clearly preventing a non-renewal*”<sup>50</sup>. However, in both instances, the approval was due to expire on 30 June 2016<sup>51</sup>, and the non-renewal decision was taken only in January 2020<sup>52</sup>. In the meantime, both approvals were extended without any consideration for safety concerns.

To name but a few other examples: the approval of oxasulfuron<sup>53</sup>, which was due to expire on 13 June 2013, was extended for several years, until the Commission decided, in July 2018, its non-renewal, due to a large number of data gaps preventing its risk assessment in several areas. The approval of mancozeb, which was due to expire on 30 June 2016, was extended for several years, until the Commission decided, in December 2020, its non-renewal, due, in particular, to concerns regarding reproductive toxicity and endocrine disrupting properties<sup>54</sup>. The approval of bromoxynil, which was due to expire on 28 February 2015, was extended for several years until the Commission decided, in September 2020, its non-renewal, due, in particular, to a risk to child residents from non-dietary exposure as well as a high risk to wild mammals from dietary exposure<sup>55</sup>. The approval of beta-cyfluthrin, which was due to expire on 31 December 2013, was extended for several years, until the Commission decided, in June 2020, its non-renewal due, in particular, to an unacceptable risk to workers loading and sowing seeds treated with that substance as well as a high risk to residents, to non-target arthropods and to aquatic organisms<sup>56</sup>. This list goes on.

It thus occurs frequently – if not systematically – that substances that are harmful or potentially harmful for human or animal health or for the environment are, nevertheless, automatically extended for years after the date of expiry of their approval, without any consideration for safety. Meanwhile, plant protection products containing those substances remain on the market. This misuse of Article 17, of which the Contested Act is an illustration, prioritises economic interests over human health and environmental protection and is in clear breach of the precautionary principle.

---

50 Commission reply to PAN Europe’s request for internal review, Annex, p. 5.

51 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, Annex, entries 111 and 112.

52 Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl; Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos.

53 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, Annex, entry 42; Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 concerning the non-renewal of approval of the active substance oxasulfuron.

54 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, Annex, entry 114; Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb.

55 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, Annex, entry 85; Commission Implementing Regulation (EU) 2020/1276 of 11 September 2020 concerning the non-renewal of the approval of the active substance bromoxynil.

56 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, Annex, entry 48; 2020/892 of 29 June 2020 concerning the non-renewal of the approval of the active substance beta-cyfluthrin.

An application of Article 17 in accordance with the precautionary principle, as explained above, would prevent these unacceptable yet frequent situations.

**In light of the above, the Contested Act is unlawful because it is based on an interpretation of Article 17 that is contrary to the precautionary principle. Should the Commission consider that the wording of Article 17 prevents it from applying it in a manner consistent with the precautionary principle, then Article 17 itself should be considered unlawful. In any case, the Contested Act infringes upon the precautionary principle and should be reviewed in accordance with said principle as well as with Article 191 TFUE and with the provisions and purpose of the PPP Regulation<sup>57</sup>.**

#### **4.2- Infringement of the terms of Article 17 of the PPP Regulation.**

##### **a) The condition that the delay must be owing to reasons beyond the control of the applicant (Article 17(1) of the PPP Regulation) is not satisfied**

Pursuant to Article 17 paragraph 1, an extension may only be granted when the renewal procedure has been delayed “*for reasons beyond the control of the applicant*”.

The Commission states, in the Recitals to the Contested Act, “*that the assessment of the substances has been delayed for reasons beyond the control of the applicants*”. However, the Contested Act does not indicate what those reasons are and does not give any explanation as to why the Commission considers those reasons to be beyond the control of the applicant.

The approval of boscalid was due to expire on 31 July 2018. Accordingly, the application for renewal should have been submitted, at the latest, on 31 July 2015, and the supplementary dossiers, at the latest, on 31 January 2016<sup>58</sup>. The supplementary dossiers made available to the public are dated 16 January 2016, which suggests that the deadline was met.

If no element was missing, the rapporteur Member State (Slovakia) was supposed to submit a draft renewal assessment report no later than 12 months after that<sup>59</sup> – thus, by the end of January 2017. However, the Draft Renewal Assessment Report was only established in November 2018, and

---

57 This analysis is shared by the European Parliament: see e.g. Resolution of 10 June 2021 on Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxylglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (2021/2706(RSP)).

58 PPP Regulation, Article 15(1); Renewal Regulation, Articles 1(1) and 6(3). Prior to the entry into force of Implementing Regulation (UE) 2020/103 of 17 January 2020 amending the Renewal Regulation, the supplementary dossiers had to be filed 30 months (vs 33 now) before the expiry of the approval.

59 Renewal Regulation, Article 11(1). Since the entry into force of Implementing Regulation (UE) 2020/103 of 17 January 2020 amending the Renewal Regulation, the rapporteur Member State now has 13 months after the supply of the supplementary dossiers.

## POLLINIS

subsequently submitted to public consultation between 25 January and 27 March 2019. The reasons for the 22 month-delay in the submission of the Draft Renewal Assessment Report are unclear. It appears, however, from that draft report, that there were several data gaps in the dossier.

Following the issuance of the Draft Renewal Assessment Report, EFSA was supposed to adopt its conclusion on whether boscalid can be expected to meet the approval criteria – in principle, within 5 months from the end of the public consultation (thus, before end August 2019)<sup>60</sup>.

Admittedly, this 5-month period may be extended when EFSA considers that additional information from the applicant is necessary<sup>61</sup>. However, such extension cannot exceed 3 months<sup>62</sup>: EFSA must set a period not exceeding one month for the applicant to supply that information. The rapporteur Member State must then, within 60 days from the date of receipt of the additional information, evaluate that information and send its evaluation to EFSA.

Yet, in the case of boscalid, to this day, more than three years after the end of the public consultation, neither a revised draft assessment report nor EFSA's opinion has been adopted.

According to EFSA (in response to POLLINIS' enquiries):

*“The reason for the delay in the reassessment process of Boscalid is because EFSA is waiting for the revised renewal assessment report (RAR) that should be provided by the rapporteur Member State (RMS, in this case - SK) following the submission of additional data from the applicant, in order to resume the peer review process.*

*Indeed, in September 2019, according to the Article 13 of Regulation (EU) No 844/2012, EFSA requested the applicant to provide additional information that should be assessed and included in a revised RAR to be submitted to EFSA. When the revised RAR will be submitted, the process will be re-started accordingly.”*

POLLINIS has requested further information from both the Commission and EFSA in order to ascertain the reasons for the delay in the reassessment procedure. At the time of the submission of the present request for internal review, these requests are still pending<sup>63</sup>.

At this stage, nonetheless, the data gaps identified in the Draft Renewal Assessment Report and the fact that EFSA had to request additional information from the applicant suggest that the applicant may have contributed, at least in part, to the delay in the renewal procedure. It suggests that the applicant failed to provide, or was not diligent enough in providing the data and information necessary for the reassessment of boscalid.

---

60 Renewal Regulation, Article 13(1).

61 Renewal Regulation, Article 13(3).

62 Article 13(3a) of the Renewal Regulation also provides for additional time when it is necessary to carry out an assessment of the potential endocrine disrupting properties of a substance in accordance with the new criteria introduced by Regulation (EU) 2018/6051. However, according to the Recitals to the Contested Act, boscalid is not among the substances for which such an assessment was deemed necessary.

63 On 2 June 2022, POLLINIS filed with the European Commission (DG SANTE) an application for access to documents (registered under reference number GESTDEM 2022/3212). A distinct application for public access to documents was submitted to EFSA on 9 June 2022 (registered under reference number PAD 2022/091). Both applications are still pending due to time limit extensions. The replies from the Commission and EFSA are expected, respectively, by 15 July 2022 and 21 July 2022.

Therefore, and in any event, the requirement that the delay is due to reasons beyond the control of the applicant is not met.

**b) The time length of the extension period does not comply with the requirements of Article 17 of the PPP Regulation**

Pursuant to Article 15 of the PPP Regulation, an application for renewal must be submitted “*no later than three years before the expiry of the approval*”. This means that, provided that the applicant has supplied all the necessary data and information, the authorities are expected to – and can – perform the reassessment within this 3-year period.

While Article 17 of the PPP Regulation provides for the possibility that the renewal procedure may take longer than expected, and allows the Commission to extend the approval period in that event, the duration of the extension may not be set arbitrarily.

Article 17(1) provides that the expiry of the approval period be postponed “*for a period sufficient to examine the application*”. Moreover, according to Article 17(3):

*“The length of [the extension] period shall be established on the basis of the following:*  
*(a) the time needed to provide the information requested;*  
*(b) the time needed to complete the procedure;*  
*(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.”*

This means that the time length of the extension must be based on an assessment of the time needed to complete the reassessment, and be specific to the circumstances of each renewal application or process. Furthermore, the length of the extension period must be consistent with and proportionate to the time actually needed for the reassessment of the active substance.

In the case of boscalid – in fact, of all the 42 substances extended by the Contested Act – the approval period was extended every year, since 2018, for one more year. Clearly, for each of these extensions, the extension period was not based on an assessment of the time needed to examine the application; rather, the Commission applied automatically a one-year extension period. In its reply to PAN Europe’s request against Regulation 2021/2068 (in which all 9 substances were, similarly, extended by periods of one year), the Commission explains that:

*“The extensions provided for in the Commission Regulation were limited to one year. In fact, the Commission, in its extension decisions, opts for extension for a limited period of time (that is extended again if necessary), rather than a one-off longer extension period.”*

Therefore, from the Commission’s own admission, the Commission applies an automatic extension of one year (that is extended every year if necessary) for all substances under renewal, irrespective of the time that would be sufficient or necessary to examine the application. This practice is inconsistent with the requirements of Article 17.

Furthermore, the Contested Act extends the approval of boscalid until 31 July 2023, thus bringing the duration of the extension period to five years. Given that the application for renewal was submitted three years prior to the expiry of the initial approval, this brings the duration of the

renewal procedure to eight years. If some delays may happen due, as the Commission puts it, “to the complexity of the assessment or to a need for more in-depth exploration of specific aspects of the risk assessment”<sup>64</sup>, none of these reasons can justify an extension for so many years.

The overall length of the extension period is inconsistent and disproportionate with the necessary time. In fact, the duration of the extension has by far exceeded the time needed to complete the reassessment.

The Contested Act is, therefore, in breach of the requirements of Article 17 of the PPP Regulation.

### 4.3- Breach of the obligation to state reasons

Pursuant to Article 296 TFEU and in accordance with Article 41(2)(c) of the Charter of Fundamental Rights of the European Union, legal acts must state the reasons on which they are based.

The purpose of that obligation is (i) to provide the person or NGO concerned with sufficient information to make it possible to ascertain whether the act is well founded or whether it is vitiated by a defect which may permit its legality to be contested before the Courts of the European Union and (ii) to enable the latter to review the legality of that act<sup>65</sup>. According to settled case-law, the statement of reasons required under the second paragraph of Article 296 TFEU must be appropriate to the measure in question and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent court to carry out its review<sup>66</sup>.

Compliance with that obligation is particularly important, in the context of the Aarhus Regulation, in order to enable NGOs to fully understand the reasons behind decisions that may contravene environmental law and to exercise their rights to internal review and access to justice under Title IV of the Aarhus Regulation.

When the Commission extends the approval of an active substance on the ground that its reassessment has been delayed for reasons beyond the control of the applicant, the statement of reason must specify the reasons for the delay and why these reasons are considered to be beyond the control of the applicant. Without concrete explanations on the reasons for the delay, NGOs are not in a position to ascertain whether or not the conditions under Article 17 are truly met, and thus to ascertain whether the decision on extension is vitiated by a defect that may be contested before the courts of the EU. In particular, when the renewal process has been delayed because EFSA requested additional information from the applicant, NGOs must be able to ascertain why that information was not supplied by the applicant at an earlier stage, and whether the applicant was diligent in supplying that information in accordance with EFSA’s request. At the very least, the statement of reasons must be specific to the renewal process of each substance at stake, based on the

---

64 Commission reply to PAN Europe’s request for internal review, Annex, p. 2.

65 General Court, judgment, 15 April 2011, *Czech Republic v Commission*, T-465/08, paragraph 162; Judgment, 28 May 2020, *Agrochem-Maks d.o.o. v. Commission*, T-574/18, paragraph 58.

66 General Court, judgment, 15 April 2011, *Czech Republic v Commission*, T-465/08, paragraph 163; Judgment, 28 May 2020, *Agrochem-Maks d.o.o. v. Commission*, T-574/18, paragraph 59.

circumstances of each case, rather than set out in a generic manner for all substances the approval of which is extended.

In the present case, the Recitals to the Contested Act merely indicates, for all 42 substances concerned by the extension, “*that the assessment of the substances has been delayed for reasons beyond the control of the applicants*”, without any further explanations. The exact same reason was given for the four previous extensions. Such a generic and vague reasoning is clearly insufficient and in breach of the Commission’s duty to state reasons. In particular, it does not enable NGOs to ascertain whether the condition, that the delay must be owing to reasons beyond the control of the applicant, is satisfied, nor to challenge it in an effective manner.

This failure to state reasons was also pointed out by the European Parliament in relation to the previous extensions<sup>67</sup>.

Accordingly, if the Commission were to reject the present request and to confirm the extension of boscalid, it must explain why the renewal process has been delayed for over four years and why it considers that the applicant did not contribute to that delay.

## 5. Conclusion

In this request for internal review, POLLINIS has put forward legal arguments and facts raising serious doubts about the lawfulness of the Contested Act.

POLLINIS hereby asks the Commission to review, in consultation with EFSA, its decision to extend the approval of boscalid until 31 July 2023 in accordance, in particular, with the precautionary principle and in order to ensure a high level of protection of both human and animal health and the environment.

---

<sup>67</sup> See e.g. Resolution of 10 June 2021 on Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 (which extended the approval periods of boscalid and other substances until 31 July 2022), Recital D.