Courtesy translation for the purpose of the consultation procedure – the final administrative rule will only be published in Dutch

Administrative rule on the eligibility criteria for a fast-track procedure ("Verduurzamingsloket") for plant protection products that contribute to sustainable agriculture – version for public consultation

#### **Preamble**

The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) aspires to facilitate the availability of sustainable plant protection products (PPP) and biocides in order to contribute to the political and societal goal of sustainability<sup>1</sup>. One of the actions the Ctgb takes in this context is setting up a fast-track procedure (in Dutch "Verduurzamingsloket") for plant protection products that contribute to sustainable agriculture. Through this procedure, applications for PPP that contribute to resilient and sustainable crop cultivation in the Netherlands are processed through a fast-track procedure, as laid down in the administrative rule *Toelatingsprocedure gewasbeschermingsmiddelen en biociden Ctgb 2024* (administrative rule on the authorisation procedure for plant protection products and biocides). The establishment of this fast-track procedure is in line with various motions adopted by the House of Representatives calling for faster processing of PPP that contribute to sustainability. The present administrative rule regulates eligibility for the fast-track procedure.

To determine which PPP applications contribute to resilient and sustainable cultivation in the Netherlands, clear and unambiguous criteria are needed. As these criteria have not yet been established elsewhere, Ctgb has drawn them up. In establishing these criteria, the relevant legal frameworks (the PPP Regulation (EC) No 1107/2009³), the Sustainable Use Directive (SUD; Directive 2009/128 EC) and the proposal for a Regulation on a Sustainable Use of Pesticides (SUR proposal; proposal for Regulation (EC) 2021/2115⁴) as well as the Dutch *Toekomstvisie Gewasbescherming 2030* (future vision plant protection 2030) and the associated Implementation Programme were taken into account.

The PPP Regulation distinguishes between regular and low-risk active substances and plant protection products.
The PPP Regulation lists the criteria that evaluate active substances from consideration as

The PPP Regulation lists the criteria that exclude active substances from consideration as low-risk substances. These hazard criteria concern, for example, the toxicity of the substance to aquatic organisms and reproductive toxicity. In the context of the fast-track procedure, these hazard criteria are used as a proxy for non-toxic or selectively toxic properties of the active substance in a PPP.

 The SUR proposal distinguishes between chemical and non-chemical plant protection products and aims to reduce the use of chemical PPP. Non-chemical PPP include products based on natural substances of biological origin and products based on substances identical to natural substances of biological origin, such as micro-organisms, semiochemicals (e.g. pheromones) and plant extracts.

<sup>&</sup>lt;sup>1</sup> <u>Multiannual strategy 2024 - 2027 | Publication | Board for the authorisation of plant protection products and biocides (ctgb.nl)</u>.

<sup>&</sup>lt;sup>2</sup> See the motion by members De Groot and Boswijk and the motion by members Bisschop and Van Campen.

<sup>&</sup>lt;sup>3</sup> Regulation (EC) No 1107/2009: see <u>EUR-Lex - 02009R1107-20221121 - EN - EUR-Lex (europa.eu)</u>

<sup>&</sup>lt;sup>4</sup> Proposal for a regulation on the sustainable use of plant protection products: see <u>EUR-Lex - 52022PC0305 - EN - EUR-Lex (europa.eu)</u>.

<sup>&</sup>lt;sup>5</sup> See Regulation (EC) No 1107/2009, Annex II, Section 5.1.1(a) for the criteria for active substances other than micro-organisms

• The *Uitvoeringsprogramma Toekomstvisie Gewasbescherming 2030* <sup>6</sup> describes a sustainable agriculture based on resilient plants and cultivation systems in the Netherlands. If PPP are used, this is done according to the principles of integrated pest management (IPM). PPP should have as few side effects as possible, so that they do not break down the resilience of the system, but rather support it. <sup>7</sup>

Based on these sources, the Ctgb established the following criteria concerning eligibility for the fast-track procedure.

## An application meets the criteria for the fast-track procedure if:

- 1. It concerns an application for authorisation of a plant protection product with at least 1 new use in the Netherlands, and
- 2. all active substances in the plant protection product in question belong to at least one of the following categories:
  - a. (expected) low-risk substances;
  - b. living micro-organisms (including viruses);
  - c. non-chemical substances with non-toxic or selectively toxic effects, such as:
    - all semiochemicals (including pheromones);
    - plant extracts with non-toxic effects or selectively toxic effects;
    - nature-identical substances (such as dsRNA, antibodies, peptides) with selective-toxic effects.

Article 2 of this administrative rule details these criteria. The criteria have been drawn up by Ctgb because they have not (yet) been laid down elsewhere in legislation. If harmonised criteria are drawn up in the European Union, the Ctgb will reconsider the criteria for the fast-track procedure. Importantly, the fast-track procedure only relates to processing time, not to the assessment or its outcome.

Annex II provides a provisional list of active substances that meet the criteria for the fast-track procedure.

<sup>&</sup>lt;sup>6</sup> Uitvoeringsprogramma Toekomstvisie gewasbescherming 2030: see <u>Uitvoeringsprogramma Toekomstvisie</u> gewasbescherming 2030 | Kamerstuk | Rijksoverheid.nl.

<sup>&</sup>lt;sup>7</sup> Similar text can be found in the Sustainable Use Directive (2009/128/EC): "Pesticides used should be as targeted as possible and have the least side effects on human health, non-target organisms and the environment." Sustainable Use Directive: see <a href="Consolidated TEXT: 32009L0128 - EN - 26.07.2019">Consolidated TEXT: 32009L0128 - EN - 26.07.2019</a> (europa.eu).

Administrative rule of the Board for the Authorisation of Plant Protection Products and Biocides of xxxx 2023, on the establishment of a fast-track procedure for plant protection products that contribute to sustainable agriculture

The Board for the Authorisation of Plant Protection Products and Biocides,

Having regard to the administrative rule on the *Toelatingsprocedure gewasbeschermingsmiddelen en biociden Ctgb 2024*, read in conjunction with Articles 4:81 to 4:84 of the *Algemene Wet Bestuursrecht*,

#### **Decision:**

#### **Article 1. Definitions**

For the purposes of this administrative rule, the following definitions apply:

- a. Ctgb: Board for the authorisation of plant protection products and biocides;
- b. Pheromone: a type of semiochemical as referred to in EU guideline SANTE/12815/2014.
- c. Use: uses according to Article 33 of Regulation (EC) No 1107/2009;
- d. *Plant protection product*: plant protection product as referred to in Article 2(1) of Regulation (EC) No 1107/2009;
- e. Low-risk substance: low-risk active substance as referred to in Article 22 and Annex II, point 5 of Regulation (EC) No 1107/2009 and Implementing Regulation (EU) No 540/2011, Part D (Low-risk active substances);
- f. Micro-organism: micro-organism as referred to in Article 3(15) of Regulation (EC) No 1107/2009;
- g. Semiochemical: substance or mixture of substances released by plants, animals and other organisms to communicate, as referred to in EU guideline SANTE/12815/2014;
- h. Commission Implementing Regulation (EU) No 540/2011: Commission 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;
- i. Regulation (EC) No 1107/2009: 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 (OJEU, L 309);
- j. Regulation (EC) No 1272/2008: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;
- k. Potential low-risk substance: active substance listed in the European Commission Notice concerning a list of potentially low-risk active substances approved for use in plant protection of 27 July 2018, whose approval has not been renewed or has expired since the publication of this list and whose current classification corresponds to the criteria for a low-risk substance referred to in Article 22 and Annex II, point 5 of Regulation (EC) No 1107/2009;
- I. Fast-track procedure (in Dutch "Verduurzamingsloket"): the fast-track procedure through which the Ctgb processes applications for authorisation of plant protection products that contribute to resilient and sustainable cultivation, as referred to in the Ctgb 2024 administrative rule on the authorisation procedure for plant protection products and biocides;
- m. *Active substance*: active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009.

## Article 2. Criteria for processing through the fast-track procedure

- 1. This administrative rule defines how the Ctgb determines whether an application for authorisation of a plant protection product is processed through the fast-track procedure, as referred to in the Ctgb 2024 administrative rule on the authorisation procedure for plant protection products and biocides.
- 2. The following types of applications for both professional and non-professional use are eligible for the fast-track procedure processing, provided the application meets the criteria set out in paragraph 3 of this article:
  - a. An application for authorisation of a plant protection product in the Netherlands, including a mutual recognition;
  - b. An application to extend an authorisation of a plant protection product with a new use in the Netherlands.
- 3. All active substances in this plant protection product belong to at least one of the following categories:
  - a. (potential) low-risk substances;
  - b. living micro-organisms (including viruses);
  - c. non-chemical substances with non-toxic or selectively toxic effects.
- 4. An active substance is considered non-chemical in the context of the fast-track procedure if it is of natural origin, or identical to a substance of natural origin (including dsRNA, antibodies and peptides).
- 5. An active substance shall be considered non-toxic or selectively toxic in the context of the fast-track procedure if it is a semiochemical, and/or the active substance meets the criteria for low-risk substances other than micro-organisms, as referred to in Regulation (EC) No 1107/2009, Annex II, point 5.1.1, opening words and (a). Both active substances that are or should be classified as acutely toxic to aquatic organisms and active substances that are or should be classified as chronically toxic to aquatic organisms are excluded from processing via the fast-track procedure.

#### **Article 3. Entry into force**

- 1. This administrative rule will be published in the Government Gazette with explanatory notes.
- 2. This administrative rule takes effect from the day after the date of issue of the Government Gazette in which this administrative rule is published.

## Annex I. Decision tree criteria fast-track procedure

- 1. Is the active substance approved as a low-risk substance?
  - a. Yes  $\rightarrow$  The substance meets the criteria for the fast-track procedure.
  - b. No  $\rightarrow$  Proceed to step 2.
- 2. Is the active substance included in the list of potential low-risk substances and has its approval not been renewed (or expired) since the list was drawn up?
  - a. Yes  $\rightarrow$  The substance meets the criteria for the fast-track procedure.
  - b. No  $\rightarrow$  Proceed to step 3.
- 3. Is the substance a semiochemical?
  - a. Yes  $\rightarrow$  The substance meets the criteria for the fast-track procedure.
  - b. No  $\rightarrow$  Continue to step 4.
- 4. Is the substance a living micro-organism (including viruses)?
  - a. Yes  $\rightarrow$  The substance meets the criteria for the fast-track procedure.
  - b. No  $\rightarrow$  Proceed to step 5.
- 5. Is the substance non-chemical (i.e. of natural origin or identical to a substance of natural origin (including dsRNA, antibodies and peptides)?
  - a. Yes → Continue to step 6
  - b. No  $\rightarrow$  The substance does not meet the criteria for the fast-track procedure.
- 6. Is the substance non-toxic or selective-toxic?
  - a. Yes  $\rightarrow$  The substance meets the criteria for the fast-track procedure.
  - b. No  $\rightarrow$  The substance does not meet the criteria for the fast-track procedure.

# Annex II. Provisional list of substances meeting the criteria for the fast-track procedure

IMPORTANT NOTE. The list below is a provisional list. When this administrative rule comes into force, an up-to-date list will be published, including the most recent classification of all active substances. This list will be updated at least after each SCoPAFF meeting on regulation of plant protection products and after each plenary meeting of the European Risk Assessment Committee (RAC) and based on the most up-to-date classifications and the decision tree from Annex I. The up-to-date list will be published on the Ctgb website.

Active substances meeting the criteria of the fast-track procedure: (potential) low-risk substances excluding micro-organisms and semiochemicals

24-Epibrassinolide

ABE-IT 56

Aluminium ammonium sulphate

Aqueous extract from the germinated seeds of sweet Lupinus albus

Blood meal

Calcium carbonate

Cerevisane

COS-OGA

Dodecyl acetate

Fat distillation residues

Fatty acids C7 to C20 (Pelargonic acid (CAS 112-05-0))

Ferric phosphate

Ferric pyrophosphate

Gibberellic acid

Gibberellins

Heptamaloxyloglucan

Hexadecyl acetate

Hydrolysed proteins

Laminarin

L-Ascorbic acid

Lavandulyl senecioate

Limestone

Maltodextrin

Plant oils / Rape seed oil

Potassium hydrogen carbonate

Prohexadione

Quartz sand

Repellents by smell of animal or plant origin/ fish oil

Repellents by smell of animal or plant origin/ sheep fat

Sodium hydrogen carbonate (low risk active substance)

Sulphur

Urea

Active substances meeting the criteria of the fast-track procedure: micro-organisms

Akanthomyces muscarius Ve6 (formerly Lecanicillium muscarium strain Ve6) Ampelomyces quisqualis strain AQ10 Aureobasidium pullulans (strains DSM 14940 and DSM 14941)

Bacillus amyloliquefaciens (formerly subtilis) str. QST 713

Bacillus amyloliquefaciens AH2

Bacillus amyloliquefaciens IT-45

Bacillus amyloliquefaciens MBI 600

Bacillus amyloliquefaciens strain FZB24

Bacillus amyloliquefaciens subsp. plantarum D747

Bacillus pumilus QST 2808

Bacillus subtilis strain IAB/BS03

Bacillus thuringiensis subsp. Aizawai strain ABTS-1857

Bacillus thuringiensis subsp. Aizawai strain GC-91

Bacillus thuringiensis subsp. Aizawai strains ABTS-1857, GC-91

Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52

Bacillus thuringiensis subsp. Kurstaki strain ABTS 351

Bacillus thuringiensis subsp. Kurstaki strain EG 2348

Bacillus thuringiensis subsp. Kurstaki strain PB 54

Bacillus thuringiensis subsp. Kurstaki strain SA 11

Bacillus thuringiensis subsp. Kurstaki strain SA 12

Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA 12 and EG 2348

Beauveria bassiana 203

Beauveria bassiana IMI389521

Beauveria bassiana PPRI 5339

Beauveria bassiana strain 147

Beauveria bassiana strain ATCC 74040

Beauveria bassiana strain GHA

Beauveria bassiana strain NPP111B005

Beauveria bassiana strains ATCC 74040 and GHA

Candida oleophila strain O

Clonostachys rosea strain J1446 (Gliocladium catenulatum strain J1446)

Coniothyrium minitans Strain CON/M/91-08 (DSM 9660)

Cydia pomonella granulovirus (CpGV)

Helicoverpa armigera nucleopolyhedrovirus (HearNPV)

Isaria fumosorosea Apopka strain 97 (formerly Paecilomyces fumosoroseus)

Metarhizium brunneum strain Ma 43 (formerly Metarhizium anisopliae var anisopliae)

Metschnikowia fructicola strain NRRL Y-27328

Mild Pepino Mosaic Virus isolate VC 1

Mild Pepino Mosaic Virus isolate VX 1

Paecilomyces fumosoroseus strain Fe 9901

Pasteuria nishizawae Pn1

Pepino mosaic virus (PepMV) Chilean (CH2) strain, mild isolate Abp2 (PEPMVO)

Pepino mosaic virus (PepMV) European (EU) strain, mild isolate Abp1 (PEPMVO)

Pepino mosaic virus strain CH2 isolate 1906

Phlebiopsis gigantea strain FOC PG 410.3

Phlebiopsis gigantea strain VRA 1835

Phlebiopsis gigantea strain VRA 1984

Pseudomonas chlororaphis strain MA342

Pseudomonas sp. Strain DSMZ 13134

Purpureocillium lilacinum PL 11

Purpureocillium lilacinum strain 251 (former Paecilomyces lilacinus strain 251)

Pythium oligandrum M1

Saccharomyces cerevisiae strain LAS02

Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004

Spodoptera littoralis nucleopolyhedrovirus (SpliNPV)

Streptomyces K61 (formerly S. griseoviridis)

Streptomyces lydicus WYEC 108

Trichoderma afroharzianum strain T-22 (Formerly Trichoderma harzianum strain T-22)

Trichoderma asperellum (formerly T. harzianum) strain ICC012

Trichoderma asperellum (formerly T. harzianum) strain T25

Trichoderma asperellum (formerly T. harzianum) strain TV1

Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1

Trichoderma asperellum strain T34

Trichoderma atrobrunneum (formerly Trichoderma harzianum) strain ITEM 908

Trichoderma atroviride (formerly T. harzianum) strain T11

Trichoderma atroviride (formerly T. harzianum) strain T11 and IMI 206040

Trichoderma atroviride AGR2

Trichoderma atroviride AT10

Trichoderma atroviride strain I-1237

Trichoderma atroviride strain SC1

Trichoderma gamsii (formerly T. viride) strain ICC080

Trichoderma harzianum strains T-22 and ITEM 908

Verticillium albo-atrum (formerly Verticillium dahliae) strain WCS850

## Active substances meeting the criteria of the fast-track procedure: semiochemicals

- (E)-11-Tetradecen-1-yl acetate
- (E)-5-Decen-1-ol
- (E)-5-Decen-1-yl acetate
- (E)-8-Dodecen-1-yl acetate
- (E,E)-7,9-Dodecadien-1-yl acetate
- (E,E)-8,10-Dodecadien-1-ol
- (E,E)-8,10-Dodecadien-1-yl acetate
- (E,Z)-2,13-Octadecadien-1-yl acetate
- (E,Z)-3,13-Octadecadien-1-yl acetate
- (E,Z)-3,8-Tetradecadien-1-yl acetate
- (E,Z)-7,9-Dodecadien-1-yl acetate
- (E,Z,Z)-3,8,11-Tetradecatrien-1-yl acetate
- (Z)-11-Hexadecen-1-ol
- (Z)-11-Hexadecen-1-yl acetate
- (Z)-11-Hexadecenal
- (Z)-11-Tetradecen-1-yl acetate
- (Z)-13-Octadecenal
- (Z)-7-dodecen-1-yl acetate
- (Z)-7-Tetradecenal

- (Z)-8-Dodecen-1-ol
- (Z)-8-Dodecen-1-yl acetate
- (Z)-8-Tetradecen-1-ol
- (Z)-8-Tetradecen-1-yl acetate
- (Z)-9-Dodecen-1-yl acetate
- (Z)-9-Hexadecenal
- (Z)-9-Tetradecen-1-ol
- (Z)-9-Tetradecen-1-yl acetate
- (Z,E)-7,11-Hexadecadien-1-yl acetate
- (Z,E)-9,11-tetradecadien-1-yl-acetate
- (Z,E)-9,12-Tetradecadien-1-yl acetate
- (Z,Z)-3,13-Octadecadien-1-yl acetate
- (Z,Z)-7,11-Hexadecadien-1-yl acetate
- 1-Decanol

Dodecan-1-ol

n-Tetradecyl acetate

Rescalure

Straight Chain Lepidopteran Pheromones

Tetradecan-1-ol

Z,Z-3,13-Octadecadienyl Acetate

Active substances meeting the criteria of the fast-track procedure: other non-chemical substances with non-toxic or selective-toxic effects

Aluminium silicate (aka kaolin)

Carbon dioxide (active substance)

Fatty acids C8-C10 methyl esters (CAS 85566-26-3) (Methyl octanoate (CAS 111-11-5); Methyl decanoate (CAS 110-42-9))

Fatty acids: potassium salt - caprylic acid

Iron sulphate

Kieselgur (diatomaceous earth)

Methyl decanoate (CAS 110-42-9)

Methyl octanoate (CAS 111-11-5)

Pelargonic acid (CAS 112-05-0)

Terpenoid blend QRD-460

Thymol