# Health benefits through the use of biocontrol for crop protection

To: the Minister of Agriculture, Fisheries, Food Security and Nature
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Gezondheidsraad

# contents

# summary

The use of chemical crop protection products in agriculture
poses risks to health and the environment. In the Netherlands and Europe
therefore the aim is to achieve a more sustainable agricultural system in which
the use of these resources is reduced as much as possible.
Part of the strategy is the use of biocontrol, a collective name
for organic and natural crop protection products.
Biocontrol includes macro-organisms (for example ladybirds)
bugs and parasitic wasps), and biopesticides such as micro-organisms
(bacteria, viruses and fungi), plant substances and signaling substances
(pheromones). In this advisory report, the Health Signaling Committee
and the health opportunities and risks of biocontrol in the environment
agriculture map, and what is needed to implement biocontrol
promote.

In the fourth quarter of 2025, the European Commission will present
proposals for accelerated authorisation procedures for biopesticides.
The conclusions and recommendations of the Commission are used as
input from the Ministry of Agriculture, Fisheries, Food Security and
Nature (LVVN) on these proposals.

**Chemical crop protection poses risks to health and**
**environment**

In 2020, the Health Council concluded that exposure to
chemical crop protection products can pose health risks
yield benefits for growers and local residents. There are indications for
links with Parkinson's disease. Links have also been found
between prenatal exposure to pesticides and
developmental disorders in children. Chemical crop protection
resources also harm the environment. They not only combat
the pests they target, but can also be very harmful
for other organisms. They also end up in the water, where they
Affect aquatic organisms. This leads to loss of biodiversity.
Furthermore, the resources can improve soil fertility and crop
affect health.

**Pressure to achieve legal targets is increasing**

To reduce the use of chemical crop protection products
Its legal objectives are urgently set. For example, the European Framework
Water Directive (WFD) on the quality of surface water and groundwater
water that meets the environmental quality standards for crop protection products
the water limits may no longer be exceeded by the end of 2027. The European

Commission finds that the Netherlands is unlikely to achieve the WFD targets partly due to structural exceedances of standards for crops protective equipment. This puts the agricultural sector under great pressure, and it is expected that compliance with EU requirements will be achieved through legal proceedings are enforced, just like with nitrogen.

**Using biocontrol methods can reduce risks**

With the *Crop Protection Vision 2030,* the Netherlands has the ambition expressed to have only very limited emissions by 2030 of crop protection products to the environment. In order to do that Integrated crop protection is used to achieve this *(Integrated Pest Management,* IPM), where biocontrol plays an important role plays. Biocontrol methods cannot completely eliminate chemical agents replace, but have many advantages. They often have a low toxicity, are rapidly degraded in the environment, leave little or no residue residues behind, the chance of resistance formation is smaller than with chemical crop protection, and they often only control the pest what they are aimed at. They can also improve soil quality.

**The admission procedure has several bottlenecks**

The Commission states that biocontrol is of great importance for the transition towards sustainable, future-proof agriculture. Based on However, research and interviews with experts and stakeholders indicate that various bottlenecks in the approval procedure for biocontrol-Methods. For macro-organisms, approval is regulated on a country-by-country basis. Extensive EU-wide assessment frameworks exist for biopesticides for admission. These are mainly focused on chemical agents. They exclude therefore does not correspond well to the mechanism of action of biopesticides and on the actual risk in practice. This leads to high data-requirements, high costs and long lead times. In addition, the Commission a lack of harmonisation, expertise and capacity in EU member states.

**Recommendations for better and faster admission and judgement**

The Commission makes the following recommendations to to accelerate and improve the approval of biocontrol:

*Biopesticides*

- Use a functional definition of biopesticides: Under biopesticides include microorganisms, botanical substances and signaling substances. The committee recommends a more specific definition of using biopesticides, which is in line with a proposal from the Board for the Authorisation of Plant Protection Products and biocides (CTgb):
  - all active ingredients based on living micro-organisms, and
  - natural or nature-identical substances that are either non-toxic or have a very specific mechanism of action.

Biopesticides that meet this definition can be more easily classified as low-risk substances are designated and an accelerated risk assessment is carried out to walk through.

- Use risk assessment in a targeted manner: Start with the question of what needs to be done are protected, and then investigate what could go wrong and how likely that is *(problem formulation* based on *pathways to harm).* This approach increases predictability, limits unnecessary animal testing and accelerates the assessment, while maintaining the level of protection.
- Use existing safety knowledge: When assessing micro-organisms and botanical substances would affect existing safety knowledge can weigh more heavily within the existing assessment frameworks, such as through the use of *Qualified Presumption of Safety* (QPS) lists of micro-organisms that are considered safe in principle considered in food and animal feed.
- Research new methods for assessment: The committee advises research into the application of *New Approach* Accelerate *Methodologies* (NAMs). These are new, often Animal-free methods for risk assessment. This also allows development of biopesticides is accelerated, at lower costs.
- Also weigh the benefits: The committee advises to possibilities of *risk-benefit assessments* for biocontrol In this case, in contrast to the current procedure, the benefits of a drug are taken into account in the approval process.
- Aim for an EU-wide approach: Before a product can be authorised within a specific EU zone requires mutual recognition between member states. Better mutual agreements and compliance with mutual acceptance of for example, exceptions to data requirements prevent files need to be re-evaluated.
- Use a separate framework for biopesticides: Some countries, such as the US has a separate regulatory framework for biopesticides. In this On average, more resources are allowed in countries because more customization is possible.
- Allow provisional authorisation: Biopesticides can be authorised under existing regulations are exempted from certain requirements, such as for example, the requirement that there is a residue limit for a substance on food must be. Provisional admission is valid for 3 years.

*Macro-organisms*

- Develop an assessment framework for macro-organisms: For macro-Organisms often lack an EU-wide assessment because they are under national regulations. The Commission recommends an EU-wide to develop an assessment framework that will allow them to assess more quickly can be.

**There are also bottlenecks in the application of biocontrol in practice**

The Commission points out that improvements are also needed in the area of the application of biocontrol in practice. Biocontrol is mainly

applied in greenhouse horticulture, but the number of resources available is in Open cultivation is still limited. There is also no financial incentive or compensation for growers who invest in biocontrol. The Commission notes that application of IPM is often too non-committal for growers: testing frameworks and enforcement is lacking. The laws and regulations surrounding exports are also a restriction. Based on phytosanitary requirements, export products may be no pests are present, but with biocontrol this is more difficult

To meet these requirements, it is often necessary to

chemical agents used.

**Recommendations for biocontrol application**

The Commission makes several recommendations for the application of to promote biocontrol in practice, such as:

- Increase the number of biocontrol agents per crop;
- Compensate costs for growers with subsidies and insurance and risk sharing for any harvest losses;
- Support growers through knowledge development, independent advice, innovation in pest monitoring and appropriate financial incentives;
- Make integrated crop protection both concrete and verifiable, by setting requirements and goals, registration according to a good

  to make the assessment framework mandatory and to implement targeted enforcement

  to deploy;
- Monitor registered biocontrol agents for potential effects to follow in practice;
- Better align EU-wide phytosanitary requirements for exports sustainability, for example by explicitly including biocontrol in EU phytosanitary protocols;
- Encourage information and clear labeling to increase public support

  to strengthen biocontrol.

# 01

# introduction

### 1.1 Reason

Biocontrol is a collective term for biological and natural pest control
pest control in horticulture and arable farming. This involves the use of
macro-organisms (ladybirds, parasitic wasps) and biopesticides
such as microorganisms (bacteria, viruses, fungi), botanical
substances and signal substances (pheromones). The use of biocontrol can
contribute to limiting the use of chemical-synthetic
crop protection products and thus reducing risks
for human and environmental health. In 2020, the
Health Council that exposure to chemical crop protection
resources should be reduced as much as possible. Broad implementation of
Biocontrol can contribute to this. The current European risk assessment
However, the authorisation procedure for biopesticides is an important
bottleneck in the sufficient and timely availability of biopesticides
for growers, especially in open fields. The application of
biocontrol in practice in the Netherlands in various ways
obstructed.

### 1.2 Purpose

In this advice, the Health and Environment Signaling Committee examines
what health opportunities and risks biocontrol offers, how
opportunities are better utilized and risks can be adequately managed, and
what is needed to promote the use of biocontrol.
The recommendations and conclusions of the committee serve as input
for the response from the Ministry of Agriculture, Fisheries, Food Security
heid and Nature (LVVN) on the proposals of the European Commission
for the adjustment of the authorisation procedures for biopesticides.1

### 1.3 Committee and working method

The Health and Environment Signaling Committee is a standing committee
of the Health Council, which issues advice on its own initiative
related to the living environment. The composition of the
Commission can be found at the back of the advice.

For this advice, interviews were held with ten experts in
crop protection, plant health, sustainable agriculture and ecotoxico-
logy. Relevant government institutions were also consulted, such as the
Board for the Authorisation of Plant Protection Products and Biocides
(Ctgb), the Netherlands Food and Consumer Product Safety Authority (NVWA), the Inspectorate
Living Environment and Transport (ILT) and the Central Bureau for the
Statistics (CBS). In addition, (interest) organizations in the field were
of agriculture and horticulture, development and production of crops
protective equipment and environmental protection invited to their
to share practical experiences and needs. The committee has, on the basis
solutions based on these conversations and literature research
inventoried to identify opportunities for health gain through the use of
to utilise biocontrol as much as possible.

## 1.4 Reading guide

In Chapter 2, the Committee discusses the scope and risks of the use of chemical-synthetic crop protection products, and legislation and policy to reduce the use of the resources.

In Chapter 3 she discusses the opportunities and risks for health and the environment through the use of biocontrol. In Chapter 4, the Commission discusses on the bottlenecks in the assessment procedure for biocontrol and does recommendations to accelerate and improve this. In Chapter 5 the Commission describes the obstacles to the application of biocontrol in practice and makes recommendations for improvement.

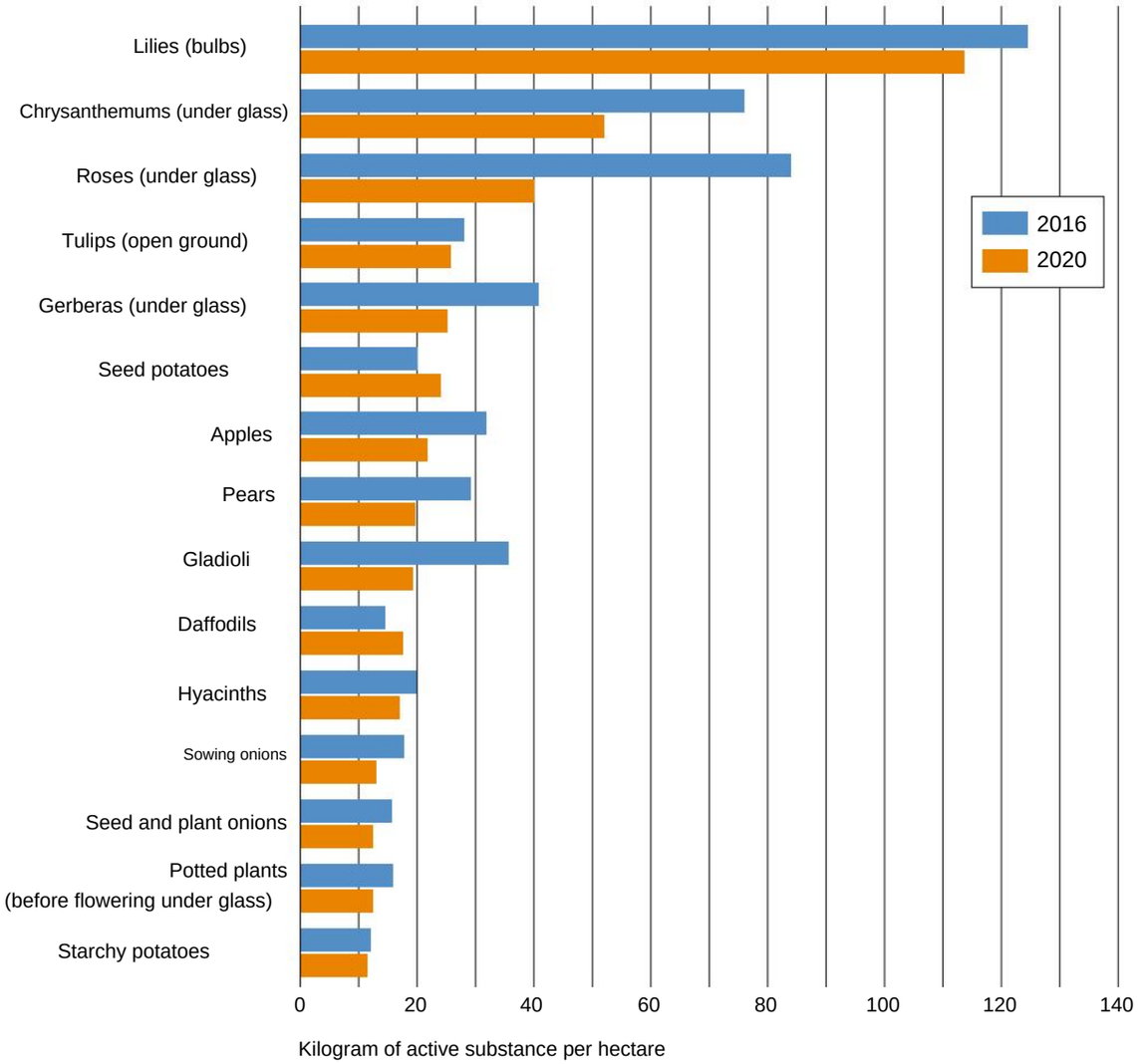
Chapter 6 contains a general conclusion.

# 02
# current approach to crop protection

Many chemical crops are used in Dutch agriculture
protective equipment is used. This poses risks to health
of people and the environment. Therefore, efforts are being made to limit
of the use of chemical agents. The agricultural sector is under
pressure to meet European environmental quality requirements and often
standards exceeded. Starting point of the policy for crop-
protection is integrated pest management (IPM), for example with
non-chemical alternatives.

**2.1 Extent of use** Effective
control of diseases, pests and weeds is
necessary for a profitable and high-quality agricultural and
horticulture. Many chemical-synthetic crops are used for this purpose
protective equipment is used. In the Netherlands, the use
from crop protection products per hectare to the highest within the
European Union. This is due to high pest pressure and crops
where many crop protection products are used.2

The largest volume of crop protection products is used in open
crops. In ornamental horticulture, the use per hectare is relatively high, while
The vast majority of greenhouse horticulture already uses biological control methods
(95% of the area in 9 greenhouse horticultural crops in 2020), although some
chemical residual use exists.3 In 2020, lily bulbs were among the
most resource-intensive crops (±114 kg/ha), followed by chrysanthemums
(±52 kg/ha) and roses (±40 kg/ha).4 See also figure 1.




Source: CBS

**Figure 1** Crops for which the most crop protection products are used in the Netherlands (kg active substance per hectare) in 2016 and 2020 (from [5])

There has been a downward trend in chemical sales since 2020
crop protection products.4 Total sales fell from 10 million kilos
active substance in 2020 to 7.5 million kilos of active substance in 2023.
The decrease is mainly due to the phasing out of the often extensive
use of the substance mancozeb. In 2018, resources on
based on mancozeb a substantial part of sales: 2.2 million kilos.

Climate change is likely to lead to more intensive use of
chemical crop protection products. Wetter periods can
cause more runoff of crop protection products and
at the same time for an increase in the use of fungicides and weed killers
pesticides, and higher temperatures can cause the
rise of new insect pests.6

## 2.2 Health risks

In 2020, the Health Council concluded that exposure to
chemical crop protection products pose a risk to health
poses a problem for residents living near agricultural plots, especially for growers and their
families.7 They are exposed to higher concentrations than people
who live further away from agricultural plots.

Based on foreign research, the Council found that
There were indications of an association between exposure to crops
protective equipment and the risk of damage to health, such as the
Parkinson's disease and developmental disorders in children. In the
However, in research the determination of exposure is often inaccurate.
This means that it is unclear exactly how big the risk is and what
crop protection products are responsible. An additional
analysis by the National Institute for Public Health and the Environment (RIVM)
confirms the findings of the Health Council and also sees signals
of the occurrence of COPD and leukemia, among other things, in growers and
residents of specific crops.94

In addition to the risks for growers and residents, there are also concerns among the population
concerns about consumer exposure through residues of
crop protection products in food. However, research shows that
the risks for consumers are low. The vast majority of the
foodstuffs remain below the Maximum Residue Limits (MRL) for
individual crop protection products. In 2023, 3% of the
samples an exceedance was found.8 However, MRLs are trade and
enforcement standards, no health-based advisory values that
indicate from which concentration of a substance exposure occurs
causes health damage. The MRLs are usually well below the
health-based advisory values. The RIVM calculated the
cumulative dietary exposure to crop protection products with
similar effects (including nervous system and thyroid) by
to add up residues in food.9,10 This showed that the margins between the
maximum daily cumulative exposure for 99.9% of the

population and the health advisory value by a factor of 100 or
amounted to more. This research shows that the combinations of groups
active substances (with similar effects) of those residues do not pose a risk
forms for public health.

Chemical crop protection products also end up in soil and
surface waters. This means that additional or heavier purification
steps needed to establish quality standards for drinking water sources
can comply (including activated carbon, advanced oxidation).11,12
In groundwater, the persistence of the agents and their
degradation products for long-term quality pressure.13,14 To the drinking water-
standards are generally met, but without reducing
chemical agents reduce the costs of drinking water production and
vulnerability to incidents.11 In addition, the European
Water Framework Directive (WFD) on the quality of surface water and
groundwater to ensure that the quality of drinking water sources does not deteriorate
may go.

Although all crop protection products have a European authorisation
must go through a procedure that involves health risks
assessed, this procedure can never completely exclude risks7 .
It is therefore advisable to focus on making crops more sustainable
to continue and intensify protection, as the Health Council
also advised in 2020. Strive for the lowest possible exposure
the starting point is the use of chemical crop protection agents.
Where use of these resources is unavoidable, a choice should be made
are chosen for the least harmful variant. This can also include crop-
protection through alternatives to chemical-synthetic agents
contribute to reducing use (see Chapter 3).
In addition, when crop protection products are approved, it is assumed
of correct use, while in practice there are often deviations from usage
regulations are noted. This can lead to a higher
exposure of growers, workers, residents, consumers and
ecosystems. Research by the NVWA at 150 companies showed that in
2019 only 63% of companies in the greenhouse horticulture and floriculture sector
complied with the guidelines for use.15 Since 2013, the NVWA has been reporting
a decline in compliance across several sectors and more intensive supervision has
no structural improvement has been achieved by 2024.16,17

When reducing the use of chemical crop protection products,
resources with a view to health gain, it is obvious to
to give priority to substances that belong to the *Candidates for Substitution* (CfS)
belong. These are active substances in crop protection products that
according to the European Commission should be replaced by
safer alternatives. They are approved for use in the EU, which
means that the use of these substances is considered safe,
but they have unfavorable properties such as bioaccumulation
(accumulation), persistence and a high degree of toxicity. In the Netherlands

In 2022, sales of CfS substances amounted to more than 700,000 kilos in total approximately 9.0 million kilos, or ±7.8%.4 CfS are mainly used in open crops (including potatoes, grains, fruit) and in ornamental horticulture (including flower bulbs), while greenhouse horticulture is characterised by the wide use of biological control agents show only residual use.3,18

## 2.3 Risks to ecosystems

Crop protection products often remain after use various environmental compartments and cause damage to non-target organisms. Pesticides (mostly crop protection resources) contribute to the decline of biodiversity, including loss of wild bees and other beneficial insects.19-24 The European Environment Agency (EEA) concludes that plant protection products are the main cause of the decline in insect populations in Europe.6 Bird populations in the Netherlands are also threatened by the use of crop protection products.25

The resources can end up in surface and groundwater, which poses a threat to the maintenance of groundwater-dependent nature and for aquatic organisms.26 Research from Leiden University and the RIVM shows that even if the concentrations of individual substances in surface waters remain within the water quality requirements, the combination of substances (cocktail effects) still leads to biodiversity loss can lead.27 In 2022, more than 20% of the measurement locations were without exceedances of water quality requirements still lead to an increase in the percentage of species calculated that could suffer (noticeable) damage. This increase was equal to or even higher than at locations with over-exceedances (pesticide atlas). Although the number of exceedances violations of water quality requirements for pesticides (mainly crop protection products) has decreased, according to exceedances still occur frequently.26 RIVM research shows that in agricultural and greenhouse horticultural areas 50-60% of the measuring points shows exceedances of environmental quality standards, with negative effects on aquatic ecosystems.28,29

Chemical crop protection products can be harmful in the long term have adverse effects on soil quality and health of crops. They penetrate the soil and can affect soil life there. and disrupt microbial balance. Studies show that repeated use of these agents leads to a decrease in soil fertility for example by reducing useful soil bacteria, fungi and soil fauna such as earthworms.30

## 2.4 Legislation and measures

In Dutch and European agriculture the balance between crop protection and the health of humans, animals and the environment under great pressure. Through legislation the government is trying to limit the use of to limit chemical crop protection products. The *Follow-up Advice*

*crop protection and local residents* of the Health Council has partly led to judicial bans on the use of crops protective equipment in lily cultivation near residential areas.36-40 In a In a recent ruling, the Administrative Jurisdiction Division of the Council of State that a grower must demonstrate that the use of crop protection products have no negative effects on adjacent Natura 2000 areas. If this cannot be done with certainty are excluded, a nature permit is required. In addition municipalities and provinces, within the framework of the Environmental Act, increasingly strict measures are being imposed on agricultural companies, in particular in drinking water and groundwater protection areas.

With the Crop Protection Vision 2030, the Netherlands has the ambition expressed to have virtually no emissions by 2030 to allow the release of crop protection products into the environment.4 This requires virtually no emissions from greenhouse horticulture and significant drift and yard-measures in open-field cultivation. Source-oriented measures are also needed, such as reducing the use of chemicals resources by setting a ceiling on the use of active substances for which the standard is exceeded. By the end of 2027, no exceedances of the water quality standards that are laid down in the WFD, including those for crop protection products.

The European Commission notes that the Netherlands is not meeting the WFD targets probably not achieved, partly due to structural exceedance of standards for crop protection products.31,32 Use of crop protection products resources is also a reason why the Netherlands fails to achieve the goals of the EU Birds Directive (EC) 2009/147 and the EU Habitats Directive, EEC and 92/43 (together VHR).32 This puts the agricultural sector in expectation under great pressure, comparable to the nitrogen problem. In addition, the European Commission aims for a 50% reduction use and risk of chemical pesticides in 2030.33

Against this background, policy pressure is increasing to increase the use of to limit chemical-synthetic agents.

## 2.5 Integrated Pest Management

The *National Action Plan for sustainable use of crop protection products 2022–2025* (NAP) contains concrete measures that are in line with European legislation on plant protection products (Directive 2009/128/EC) and focus on integrated crop protection *(Integrated Pest Management,* IPM) and non-chemical alternatives.34

The Ministry of Agriculture, Nature and Food Quality's *2030 Vision for Crop Protection* also LVVN outlines a transition to sustainable production with resilient plants and cultivation systems in which the use of chemical agents is avoided as much as possible and application is in accordance with IPM principles takes place.35

IPM aims for comparable yield and quality with less environmental impact by 8 interrelated principles, see table 1. The system shifts the emphasis to prevention (resilient breeds, biodiversity strips, balanced fertilization), monitoring (visual, trap techniques, pheromone-falls) and the use of threshold values when pests are detected or disease thresholds are exceeded. Only then do non-chemical methods and, as a last resort, targeted use of chemical agents. Resistance management, impact assessment of applied control strategies and mandatory documentation and training anchors the cycle. Since 2014, IPM has been legally required for professional crop protection within the EU framework for sustainable use of pesticides.

In this advice the committee focuses primarily on biocontrol as a component of IPM, because IPM is legally anchored and for professional use cherry is mandatory. There is also a broader system in which pest management is embedded in a cultivation system that actively collaborates with nature: *Integrated Crop Management* (ICM), but this is not legally enshrined. Where IPM mainly determines how pests and diseases are controlled step by step can be, ICM focuses on the entire system and landscape: soil, water, biodiversity, energy, labor, and the connection between plot and Environment. Biocontrol is also one of the building blocks of ICM.

**Table 1** Principles and measures of *Integrated Pest Management* (IPM)

| IPM principles | Possible measures |
|---|---|
| 1 Prevention and/or suppression of harmful organisms | • Mixed cropping or companion planting for greater biodiversity; • Adjust sowing time to avoid peak periods of pest pressure; • Optimize plant density for better air circulation; • Use of resistant or tolerant cultivars; • Balanced fertilization and irrigation to keep plants healthy; • *Mulching* to suppress weeds and regulate soil moisture; • Construction of hedges, flower strips and plot edges to create natural to promote enemies. |
| 2 Monitoring | Use of appropriate methods and tools (visual, pheromones, trap techniques, diagnostics) to detect harmful organisms to follow. |
| 3 Threshold values | Intervene only when pest or disease thresholds are reached have been exceeded. |
| 4 Non-chemical methods | Preference for mechanical, physical, biological or other methods as an alternative to chemistry. |
| 5 Selective application of pesticides | Targeted use of chemical agents that are least harmful to health, the environment and non-target organisms. |
| 6 Resistance management | Limiting resistance by alternating resources and methods, correct dosage and application. |
| 7 Impact assessment | Regular evaluation of the effectiveness of applied control strategies. |
| 8 Documentation and training | Maintaining records and ensuring sufficient knowledge and user training. |

# 03 biocontrol

The term biocontrol includes means of biological and natural Pest control. The use of biocontrol ensures the preservation of biodiversity, fewer remains in the environment and less chance on resistance development. The risks to health and the environment are limited. The effectiveness of biocontrol agents depends on the application, environmental factors and the cultivation systems used. Biocontrol agents are generally less effective than chemical resources, so they often have to be combined with additional measures.

## 3.1 Definition and delimitation

There is no clear and formal definition in the Netherlands and Europe of biocontrol or biopesticides. Interpretations of these terms vary between policy, science and industry. This advice focuses on biocontrol used as an umbrella term for all forms of biological and natural pest control: macro-organisms and biopesticides, see table 2. For biopesticides, the definition used is that which corresponds to the current European regulations for crop protection products: micro-organisms, signal substances and plant extracts and substances that be used as a crop protection agent.

**Table 2** Overview of biocontrol and mechanisms of action

| Category | Description | Examples | Mechanism of action |
|---|---|---|---|
| **Macro-organisms** | Natural enemies of pests (e.g. predators and parasitoids). | Ladybirds (against aphids), parasitic wasps (against various insect pests), predatory mites (against spider mites), nematodes | Predators that feed on pests |
| **Micro-organisms** | Viruses, bacteria and fungi, phages with a specific action against pests or diseases | • *Bacillus thuringiensis* (Bt), against caterpillars;<br>• the fungus *Beauveria bassiana* against insects;<br>• Trichoderma fungi that suppress other fungi;<br>Pseudomonas bacteria that inhibit diseases such as fire blight;<br>• Baculoviruses used against certain caterpillars (such as the Cydia pomonella granulovirus against apple cider moth). | Can kill pests or suppress pathogens through infection, competition or toxic substances. |
| **Signaling substances** | Pheromones or other attractants or disruptive substances that affect behavior or influencing insect communication. | Pheromone traps against moths | Pheromones and other signaling substances work through non-toxic mechanisms and are used to manipulate insect behavior |
| **Botanical substances** | Extracts of plants that are active against insects or fungi, for example | Pyrethrum extract (against insects), neem extract (insect repellent/ killing), garlic or pepper extracts, essential oils from e.g. oranges or cloves, (UV protection/defense against insects). | Toxic action (e.g. inhibition of enzymes) or non-toxic effect (such as a repellent effect (odor) or oily substances that act by suffocating target insects) |

Two other forms of biocontrol are not considered in this advice
taken into consideration: *Plant-Incorporated Protectants* (PIPs) and
biostimulants.

PIPs are active substances produced by genetically modified
modified crops and as a biological alternative to chemical
synthetic agents can be used. PIPs fall under both the
Plant Protection Regulation as the legal framework for genetic
modified organisms (GMOs), in which ethical and social
considerations are central. So far, there have been no
applications made for the use of a PIP as crop protection
resourse.

Biostimulants are substances or microorganisms that increase the efficiency of
improve nutrient uptake, plant resistance to abiotic
increase stress or the availability of nutrients in the soil
increase. They mainly play a supporting role within IPM, aimed
on strengthening overall plant health rather than direct
pest control, but can indirectly contribute to reducing
from the use of chemical-synthetic pesticides.
Biostimulants are not regulated as crop protection products and
therefore disregarded in this advice. The committee points out
Note that biostimulants sometimes contain the same active substances as
Biopesticides. It must be prevented that the authorisation and use of
Biostimulants serve as a back door to avoid stricter approval frameworks
to circumvent biocontrol.

## 3.2 Extent of use

There is an increasing trend visible in the use of biocontrol in
Netherlands. In 2020, approximately 95% of the area of 9 under-
greenhouse crops sought biological pest control with macro-organisms
applied. In 2012 this was still 78%.3 In 2021 and 2022 there was a rapid
rise in sales of microbiological fungicides and insecticides,
but in 2023 sales declined.4

According to Statistics Netherlands (CBS), the share of green crop protection in 2022 was
25% of the total use (in kilos) of crop protection products.18
This label has been introduced by manufacturers and is still in development. It is
assigned to active substances that are of natural origin or that
appear on the SKAL input list for certified organic cultivation and
under the European crop protection regulation as low-
have been classified as hazardous substances (see Ch4).

It is difficult to measure the use of biopesticides by the numbers
about green crop protection products as this label also includes substances
includes those that are still classified as chemicals in broader sales statistics
considered. Both the number of available resources and the number

Applications for authorisation of new biopesticides are EU-wide
roughly tripled over the past 20 years.

## 3.3 Benefits

The use of biocontrol can help to reduce the
use of chemical crop protection products, which causes the
associated risks to human health and the environment
decrease. In addition to these direct health benefits, there are also indirect
benefits for people and the environment.

When using biocontrol agents with a species-specific effect
become natural enemies, pollinators and other non-target organisms
saved, thus preserving biodiversity and ecosystem services
remain. However, this does not apply to all biopesticides. For example,
for example botanical substances such as pyrethrins toxic to a
broad group of organisms.

Biopesticides are less likely to be persistent than chemical-synthetic ones
resources. Living organisms complete their life cycle or
die off, and natural substances are generally destroyed in a short time
broken down. This implies that there is generally no accumulation in soil or
water occurs and hardly any residues remain on food or in the
environment.

Biocontrol agents hardly disrupt soil life and can
increase microbial diversity and plant resistance. Some bio-
Pesticides can even improve soil health, for example
by colonizing the root environment and suppressing disease
pathogens.36 Chemical-synthetic crop protection products
however, in the long term, can have adverse effects on the
soil quality and crop health.

Biocontrol agents reduce the risk of resistance compared to
chemical crop protection products due to their (combination of)
mechanisms of action (see also table 2). Against macro-organisms the
chance of resistance limited, although there are known cases of
evolved resistance to parasites.37 Application of whole
microorganisms or mixtures generally leave little to no
resistance shown; cross-resistance is limited and broad, non-specific
mechanisms of action are rare.38 Resistance to pheromones is
unlikely.39

Another advantage of many biocontrol agents is that they cause less nuisance
cause more harm to local residents than chemical agents. When using
pheromones, for example, do not produce toxic spray mist or solvent
odor. However, it must be clear to local residents what is being sprayed.
when using biocontrol agents. Many biopesticides require more frequent application
are applied, which means that a sprayer is seen in the field more often.

If residents do not know what is being sprayed, the spraying can may be perceived as more of a nuisance. Also the strong odor of Some resources may be perceived as a nuisance.

### 3.4 Effectiveness of biocontrol agents

The effectiveness of biocontrol varies greatly by agent. Table 3 shows illustration of that variation a number of examples are given of the measured effectiveness of biocontrol methods.

**Table 3** Effectiveness of different biocontrol methods

| Category | Effectiveness |
|---|---|
| *Bacillus subtilis* PTS394 (bacterial) | ~70% disease reduction in greenhouse and 74% in field; diluted doses are less effective.41 |
| *Bacillus subtilis* QST713 (bacterial) | 40-86% protection on tomato and 0-80% on lettuce, depending on dose and isolate 40 |
| Combinations of bacteria and yeasts | Reduce diseases by 50-60% and increase yields by approximately 58%.46 |
| Viral biopesticides | CpGV causes 81-99% larval mortality; MabrNPV + GV proteins increase infection effectiveness by 53% to 66%.45,47 |
| Entomopathogenic fungi (Beauveria) | Strains range from 76-100% mortality at high doses to only 19% in weak isolates.43 |
| Botanical biopesticides (neem, extracts) | Neem oil causes 95-98% mortality of mosquito larvae and ±80% in soybean aphids; field results vary.63 |
| Entomopathogenic nematodes | *S. pakistanense* and *S. balochiense* cause 95-98% lab mortality and 70-90% field mortality after repeated applications; *S. abbasi* approximately 77%.44 |
| *Steinernema adamsi* (nematode) | Lab mortality 74-100%; field mortality 56% with water formulation and 98% with alginate/CongoRed.42 |

The effectiveness of biocontrol agents depends on several factors. First of all, the amount and the way the drug is composed are stated important: a higher dose and a good formulation ensure usually for a reliable effect, while too low a dose can lead to leads to variable results and can even lead to tolerance in the pest lead.40,41 Circumstances also play a role. Heat, moisture, sunlight and soil acidity affect how long microorganisms and viruses remain active. Additives such as alginate or dyes protect the organisms from dehydration and UV light.42

The effectiveness also depends on which strain or species is used. Not all strains of mold or bacteria are equally powerful; some can kill almost all insects, while others only a small portion 40,43 Also the timing of the treatment and the number of times the fact that a remedy is applied influences the result: repeated treatments and the right time of application increase mortality of pests significantly. 44,45 Also combining different bio-control organisms or the addition of excipients may affect the effectiveness strengthen. Studies show that mixtures of bacteria, yeasts and fungi reduce the disease by about half and that extra proteins sometimes the infection of pests by viruses enlarge.46,47 Research further shows that the variability in effectiveness between plants and cultivation systems is large.40

Biocontrol agents can be chemical-synthetic crop protection agents
resources often do not replace them one-on-one and are most effective in
combination with other means or methods. Growers therefore have
Sufficient knowledge of specific biocontrol agents is required for biocontrol
to be able to use it successfully within an IPM system. This knowledge can
for example, gained through good monitoring of effectiveness
as part of IPM.

## 3.5 Risks

The use of macro-organisms in agriculture is expected to yield
no direct effects on health. Strict *pre-release testing,*
permit requirements and assessments (see Chapter 4) minimize risks
of the use of macro-organisms as crop protection agents.48,49
The main concern is the introduction of live (often exotic)
species. Non-target effects and (rare) invasiveness are
documented (for example *Harmonia axyridis).* Occasionally
intensive occupational exposure and allergic reactions
give.50

Risks of biopesticides for humans and the environment are being mapped out
as part of the approval procedure for crop protection products
resources (see chapter 4). For crop protection products,
looked at the risks arising from toxicity. Substances that a
pose a risk to human health and the environment are not
approved as a crop protection product, but non-target effects of
approved substances occur, such as mortality or sublethal effects in
pollinators/beneficial insects, including pyrethrum and certain
oils. For biopesticides, toxicity is not necessarily the most important
relevant effect. Microorganisms can be pathogenic and work
certain plant extracts not through toxicity, but for example by
suffocation. For direct effects such as suffocation, the effect
is limited to the plot on which the product has been applied, in contrast to
position to toxic substances that extend far beyond agricultural
system can have an effect on people and the environment.

Many microorganisms used in biocontrol applications
have a long history of safe use. Approved strains
must not be pathogenic (disease-causing) to humans.
Opportunistic infections in severely immunocompromised individuals are
rare. Occupational exposure to certain molds may cause allergic reactions
to provide sensitization. This is achieved by prescribing
Personal protective equipment for users. Botanical substances
may have toxic properties: pyrethrins may cause contact
allergies and, at high exposure, neurological effects.
Concentrates and some essential oils may irritate skin, eyes and/or
irritate the airways.51

In addition, there are categories of crop protection products that (still) not included in commonly used definitions of biocontrol.

In addition to PIPs, there are *novel* biocontrol agents, including agents based on RNA interference (RNAi), peptides and antibodies.

The safety of these substances must be ensured when used as crop protection means can be demonstrably substantiated in accordance with the regulations for an active substance of Regulation (EC) 1107/2009.

However, the assessment framework for these resources is still under development.

In the meantime, some initial scientific guidelines and case studies have been applications available, including through the Organization for Economic Cooperation and Development (OECD) and the European Food Safety Authority (EFSA).

Careful risk assessment tailored to the substance or category and admission procedures ensure minimization of risks and promote the availability of safe resources. The Commission therefore outlines possibilities for improvement in the next chapter of the existing risk assessment procedure. The Netherlands can also play an active role by providing expertise from a scientific perspective to contribute research and admissions practice to international work-groups and regulatory processes. The Netherlands can also serve as a test environment serve for responsible introduction and evaluation of promising technologies. This contributes to both innovation and risk-control in sustainable crop protection.

## 3.6 Broader perspective

The transition to more use of biocontrol and less use of chemical crop protection products do not stand alone, but is part of a broader transition to sustainable agriculture and a healthy living environment. Biocontrol is embedded in IPM, aimed at pest control involving the use of chemicals by a range of measures is being significantly reduced. The impact can still reach further when *Integrated Crop Management* (ICM) is deployed in place of IPM. ICM, of which biocontrol is also a part, is focused on the entire system and landscape: soil, water, biodiversity, energy, labor, and the connection between the plot and its surroundings. This has positive effects on environmental quality and the food chain.

The Commission underlines the importance of this coherence: only using biocontrol without adapting the rest of the cultivation system, produces suboptimal results. Only when a resilient cultivation system is built – with resilient breeds, diversity in the landscape and good soil management – can biocontrol reach its full potential? achieve as part of a sustainable solution.

Overlap and synergy between policies for climate, biodiversity, nature, water and health should be actively sought. For example: if in the context of climate adaptation, the focus is on more green-blue penetration (hedges, ditch banks) in the rural area, the operation of biocontrol more effective because natural enemies can work better

overwinter and spread. Conversely, broad application of
biocontrol to achieve the objectives of the European Biodiversity Strategy
and national insect strategies, as less use of
chemical agents directly lead to the recovery of insect populations.

From a *One Health* and *Planetary* Health perspective, this integration is
even more essential. These concepts emphasize that the health of
people are inextricably linked to that of animals (wildlife and livestock) and
the ecosystem as a whole, and with societal systems.
Public health can thus serve as an overarching argument to
to take measures that may be primarily considered from an environmental perspective
introduced, following the recommendation of the European Environment Agency.81
In this way, it can be explained to the public and growers, for example, that
Creating flower strips reduces pesticide use and thus
reduces health risks to their family and environment.

# 04
# admission procedure

Biopesticides go through a risk assessment procedure before
they are allowed onto the market. However, this procedure is designed
on chemical agents, which leads to delays and high costs.
The Committee makes recommendations for risk assessment and authorisation
to improve and accelerate, both for biopesticides and for
macro-organisms.

## 4.1 Risk assessment and authorisation

All crop protection products must have a marketing authorisation before being allowed onto the market.
complete a comprehensive risk assessment. The EU Authorisation Regulation
(EC) 1107/2009 provides the legal framework for this. This Regulation is
originally developed for the approval of chemical agents,
but is also applied to biopesticides.

The admission procedure consists of 2 steps. First, the active
substance assessed at EU level for hazardous properties and residues
in food in relation to the *Maximum Residue Limits.* A designated
Rapporteur Member State carries out the assessment and prepares a draft
assessment report. Other Member States and EFSA then provide
comments in a *peer review round.* Based on this, the
European Commission or the substance will be included on the list of approved
approved active substances. This is followed by national approval of the
final product containing the approved substance. This involves
use in a specific crop and under specific conditions
assessed before the product can actually be marketed
This includes, among other things, the risks of the product for
users (growers) and local residents, the environmental risks in the use-
context (emission routes, local water protection) and effectiveness
(effectiveness). This two-phase system is relatively slow and taxing, especially
for smaller product developers.52

Biopesticides often do not fit well into the assessment regime because
their properties may differ significantly from those of
chemical-synthetic crop protection products. This is how it works
biopesticides to kill living organisms, complex mixtures and minimal
human exposure. The EU has recognised this and has taken various
adjustments made to the data requirements and assessment
to better tailor principles to the specific nature of biopesticides.
In 2017, Annex II of Regulation (EU) No 1107/2009 was amended
2017/1432), which allows active substances to be considered
for the low-risk predicate. Criteria for this include low
toxicity, rapid degradation, no accumulation or persistent
properties. Substances that meet these criteria have a longer
approval period (15 years instead of 10). In the Netherlands,
Applying to the Ctgb for authorisation of products based on low-risk
Substances are then prioritized. This offers opportunities to
to accelerate and bring biopesticides onto the market for a longer period
to take.

In 2022, the data requirements and the harmonized assessment revised framework for micro-organisms as plant protection products (Regulations (EU) 2022/1439-1441). This revision introduces a *fit-for-purpose approach,* which improves risk assessment tailored to the biological properties of the microorganism.53 The assessment framework includes specific microbiological considerations points, such as possible pathogenicity (degree of likelihood that causes the disease), the presence of transmissible antibiotics resistance genes (AMR genes), the formation of (secondary) meta-bolites, and the habitat and population dynamics of the microorganism in the environment.53,54 All biopesticides other than microorganisms are still based on data requirements for chemical substances assessed.

## 4.2 Bottlenecks

Despite the recent revisions, the Commission notes that the largest bottleneck in the approval procedure for biopesticides that the risk-Assessment and admission are slow. This has two main causes.

Firstly, the risk assessment frameworks and admission requirements are not yet always sufficiently tailored to the nature of biopesticides. With the exception of microorganisms, the various biopesticides using the same data requirements as for chemical agents assessed. The nature of the exposure route and However, potential health risks vary greatly between biocontrol categories. Living agents such as microorganisms require for a different assessment than mixtures of botanical substances or pheromones. Where microorganisms mainly address environmental and health issues calls related to their behavior in practice, it revolves around botanical substances to determine the variation in composition and signal substances mainly because exposure is usually low due to administration in dispensers or traps.53,55,56 For botanical substances and signal substances with a non-toxic mechanism of action guides the current framework for risk assessment to unnecessary data requirements. In the case of microorganisms discussions about a non-proportionately broad (literature) study on (not relevant) metabolites.57,58,59

The second sticking point, according to the Commission, is that at European and national level there is a lack of harmonization, capacity and specialist expertise. Despite the extensive implementation European harmonization is subject to partial aspects by a variable national implementation is regularly reassessed.56 This is because applicants for risk assessment substantiated data requirements may be allowed to lapse. A rapporteur Member State assesses the dossier and in EFSA's *peer review ,* other Member States can dispute this, and require additional study. This means that files will be (partly) re-examined evaluated and agreements are made about the acceptance of each other's reviews slow to come about.52,53,56

Actively promoting the marketing of low-risk
biological alternatives to chemical crop protection products
is seen as an important route to reduce the environmental impact
to reduce the use of chemical agents.52 Currently, only a
limited share of active substances in biopesticides as low-risk substances
noted. This is the result of the slow and expensive procedure and the
heavy data requirements. However, it is also because the criteria for
low-risk substances that are naturally occurring and not pungent
defined. There are many guidelines for signal substances and botanical substances
not binding or still incomplete. This gives rise to varying interpretations and
delays recognition as a low-risk substance. These bottlenecks mean that
large number of microorganisms and some pheromones not approved as
being a low-risk substance, while it is due to the more favourable risk profile
would be expected.51

The data-intensive and therefore expensive European admission route
leads to companies launching innovations outside the EU sooner.
In a recent survey of industry and expert respondents, approximately 67% said
to waive EU registration due to data requirements and other
regulatory hurdles.1 This harms both European
competitive position as achieving reduction targets for chemical
crop protection products, because promising agents are
European agricultural practice fails or fails to achieve.

## 4.3 Recommendations

To adequately tailor risk assessment frameworks and admission requirements
more tailor-made solutions are needed for the nature of biopesticides. The proposed
solutions can together ensure faster admission
process of biocontrol agents, while maintaining protection for humans
and environment.

### 4.3.1 Functional definition of biopesticides

The committee recommends a clear and functional definition of
to use biopesticides. This is more feasible in the short term than
a separate authorisation system for biopesticides. This definition should
to distinguish between microorganisms, pheromones and natural
substances, so that risk assessment and authorisation can be improved
tailored to the nature and effect of the drug.

The Commission advocates a definition that includes both the origin and the
mechanism of action of the substance as a starting point, in line with the
proposal from the Ctgb:60

- all active ingredients based on living micro-organisms, and
- natural or nature-identical substances that are non-toxic
  have a mechanism of action (e.g. pheromones, certain
  oily or inorganic substances, substances that induce resistance in plants
  induce) or a very specific mechanism of action (e.g.
  certain microorganisms).

This definition identifies natural substances with a broadly toxic or non-selective mechanism excluded, where biopesticides consistently contribute to IPM/ICM goals and public health.39,52 Moreover, In the US, biopesticides are also defined as natural and non-toxic. Biopesticides that meet the definition proposed by the Ctgb can be more easily classified as low-risk substances and can be appropriate assessment framework to carry out a risk assessment more quickly. Such a definition could be included in the EU regulation in the short term are recorded.

### 4.3.2 Problem formulation/pathways to harm

The so-called *problem* formulation approach helps to identify risks to set up targeted assessments of biocontrol agents. Instead of standard tests the assessment starts with the question of what needs to be done are protected, what can go wrong and how likely that is.61 This creates testable assumptions *(risk hypotheses)* about how damage would occur. can occur. Then, with *pathways to harm,* the chains of investigated events that should all take place before damage can occur. If any of the steps occur If the risk is not realistic, it is considered negligible.62

This approach is being further developed within the EFSA and OECD framework developed. The assessor and applicant first bring the relevant map mechanisms of action and routes to damage and estimate the probability per step. Only for plausible routes targeted qualitative and quantitative data collected. Another The advantage of this approach is that it becomes clear for which types microorganisms corresponding *pathways to harm* apply are. This makes it possible to adapt the risk assessment for an entire category of microorganisms.

The *problem formulation/ pathways to harm* approach is particularly suitable for biopesticides whose effects are not primarily toxic, such as suffocation or dehydration by botanical substances or pathogenicity of microorganisms. Extensive toxicity tests are often not required for this. testing is required. The approach prevents unnecessary data requirements and makes the assessment faster and more targeted, more transparent and more harmonized. This increases the predictability and efficiency of the risk assessment and contributes to a faster and fit-for-purpose authorization of microbial and other biocontrol products,61,62 while the level of protection is maintained. Because this approach is already proposed by EFSA and Wageningen University & Research (WUR) can this be implemented in one to two years.56,62,63 Subsequently, Training of assessors and the preparation of templates are necessary, but the basic principles are available.62 *Case studies* will have to demonstrate how much time is saved and for which classes of biopesticides this is makes sense.

### 4.3.3 Existing safety knowledge

The safety of some biocontrol methods is already known
available. For micro-organisms and botanical substances, the
Commission to give more weight to existing safety knowledge.
This includes, for example, *the history of safe use* for food
resources, such as traditional use and QPS lists.
The QPS list *(Qualified Presumption of Safety)* is the list developed by EFSA
maintained record of microorganisms which, after standardized
assessment and possibly with qualifications, in principle considered safe
considered for use in food and animal feed. This safety knowledge
can also be used as part of the *pathways to*
*harm.* In the case of signalling substances it can be assumed that the risk is low
substances that leave little or no residue, unless otherwise stated
clear contraindications exist. Use of existing safety
knowledge can be introduced within a few years.

### 4.3.4 New Approach Methodologies

Animal studies required in existing risk assessment procedures
can be replaced or supplemented by *New Approach*
*Methodologies* (NAMs). These are modern, often animal-free methods.
such as cell tests, omics and computer modelling (in silico methods).
For microorganisms, for example, a genome analysis can be performed on anti-
microbial resistance (AMR) provide clues, which in the absence of
ity or non-transferability extensive testing may be discontinued.60
For botanicals, metabolomics, chemical
to utilize fingerprinting and targeted bioassays to evaluate efficacy and safety
to substantiate mixtures.52

The committee recommends research into the application of NAMs in
to accelerate the assessment of biocontrol agents, similar to EFSA's
*Roadmap for action on NAMs.* 64 The acceptance of NAMs is still limited
and they are still not very formally recognized.60 Pilot cases, validation requirements,
Clear acceptance criteria and training of assessors are necessary so that
assessment bodies can consistently weigh NAM results.
*Problem formulation/ pathways to harm* can be used to identify the most
relevant NAMs are identified for the risk assessment, and
NAM results can then be included in the risk assessment procedure
assessment and approval are included. This reduces animal testing
and accelerates the development of biopesticides at lower costs.
Research shows that the impact of NAM's deployment will be felt over 3-10 years
becomes visible.65 Taking into account development, validation and
training is a period of at least 5 years realistic.

### 4.3.5 Benefit-risk assessment

In the current assessment and admission there is no room for a consideration
of the benefits and risks of a drug. The risk-benefit analysis is
in the European procedures for the authorisation of crop protection products
resources under risk management. In EU Regulation 1107/2009

the roles with regard to risk assessment and risk management are strictly defined
separated: EFSA provides the scientific risk assessment, while
the European Commission and Member States take decisions on risk management
take. This means that positive effects of a drug (for example
on ecosystem or soil) are not included in the EFSA risk assessment
taken into account as benefits, but – to the extent relevant – only at the
administrative assessment of admission and conditions. Outside the EU
there are systems where benefits are explicitly taken into account in the decision,
as in New Zealand.66,67

The committee recommends exploring the possibilities of *risk-benefit assessments*
to investigate, and how they fit into national and European approaches.
She advises to first develop the assessment framework and admission framework
to be supplemented with a carefully defined *benefit-risk assessment*
for exceptional, well-substantiated cases.57,61 In the IPM-
obligations (Directive 2009/128) the preference is for low-risk options
anchored. While this is not a classic *benefit-risk* at the product level,
but it approaches a package/system level trade-off.68,69 The OECD
has proposed to launch pilots in which IPM packages as a whole are tested
effectiveness, risk and monitoring are assessed, where necessary with
legal adjustments and robust post-market monitoring.69
The Commission supports such an integrated approach.
A timeframe of more than five years is envisaged for this, given the
necessary adjustment in legislative procedures and because methods
must be developed to achieve the benefits in a quantitative
to include a framework for consideration.

#### 4.3.6 EU-wide approach and harmonisation

For the admission of a product within a certain zone,
mutual recognition of other Member States within this zone is required.
Better mutual agreements and compliance with acceptance of, for example,
exceptions to data requirements prevent files from being re-used
must be assessed. Harmonizing the *problem*
*formulation/ pathways to* harm approach, or coordination of the outcomes
thereof with other Member States before risk assessment is initiated,
can provide a solution in allowing exceptions to data-
requirements for specific biopesticides. Additional assessment capacity and
specialized expertise through a shared *expert pool* is needed to
to absorb peak loads and complex files in the assessment.52,56

In addition, acceptance of assessment in other Member States may be
improved through zonal joint review teams or a central EU counter with
adequate capacity and biocontrol expertise, so that files are not updated every time
need to be reassessed for each Member State.49,52

#### 4.3.7 Separate framework for biopesticides

There are countries that, unlike EU Member States, have specific regulatory
frameworks for biopesticides. In these countries, on average, more

products allowed than in countries that have biopesticides under the same regime as chemical pesticides.70 Thus, the US has approximately 2,000 registered biopesticide products, while the EU has approximately 900.66,70 A separate assessment and authorisation framework for biopesticides could be help to bring more resources to market faster in the long term, because more customization is possible. However, a separate framework is required new legislation, which will delay introduction and implementation for a number of years will last.

#### 4.3.8 Provisional admission

In the US, there is a possibility of conditional registration.52 This means in that a biopesticide is registered, but under conditions. In the US, the condition is that if there are still certain non-critical data or follow-up studies are missing, the applicant must submit these must be delivered within a specified period.

Within the Authorisation Regulation (EU 1107/2009), Article 30 EU also provides the possibility to allow resources conditionally up to a maximum of 3 year. This option has never been used since 2016. A limited number of requirements for this conditional admission. Biopesticides can be exempted from certain requirements, such as for example, the requirement that there must be a residue limit for a substance on food are. After all, many biopesticides do not leave residues on food. The Commission points out that if Article 30 is applied, there will be a further elaboration of this is necessary. The committee proposes that temporary Authorisation will only be granted to biopesticides that meet the proposed functional definition of biopesticides (see 4.3.1), which also meet certain safety requirements. The Commission believes that the The approval of a biopesticide must also be linked to a good post-market surveillance, for the further safeguarding of the safety and effectiveness of the biopesticide.

#### 4.3.9 Recommendations for macro-organisms

For macro-organisms (such as ladybirds, parasitic wasps or nematodes) do not require approval under the crop protection regulation to be applied for. Macro-organisms are regulated nationally (often under nature/biodiversity legislation) with licensing or notification requirements per Member State. There is no harmonised EU framework for the assessment of macro-organisms, which causes fragmentation between member states.

The European and Mediterranean Plant Protection Organization (EPPO) has developed guidelines for ecological risk assessment (establishment, effects on non-target species, biodiversity). These guidelines lack However, an explicit benefit-risk assessment, applications are aimed at risks without taking into account environmental and health benefits, and the national approach places a heavy burden on small and medium-sized enterprises in particular administrative burden with separate procedures for each country.52,57 A kind can

are allowed in one country and not in a neighboring country. The mutual Recognition is limited and progresses slowly.52,57 The Netherlands uses its own List of permitted macro-organisms: the RVO list. Other countries also use their own lists or criteria.

Recommendations for improving macro-procedures organisms are:

- Develop an EU-wide approach with a harmonised checklist and frameworks, so that species lists and admission criteria are improved coordinated and duplications are avoided;56
- Speed up mutual recognition: admission to a country must be other Member States can be reached within strict deadlines adopted unless there are clear ecological contraindications;
- Explicitly include benefits (for example, saved chemical use) within a *benefit-risk framework;68,71*
- Conduct post-introduction monitoring to detect adverse effects (displacement, unexpected spread) to adjust in time, supported through an EU-wide feedback mechanism for sharing signals and data.

## 4.4 Parallels with biocides

Developments in the authorisation and risk assessment of biocontrol-methods and biopesticides may also be relevant within the domain of the biocides, see box. The active substances may overlap, and Coordination in the admission procedures is therefore desirable. Also for biocides there is an effort to reduce the use of chemical agents to push, but this is still receiving much less attention than crop protection products. In the Netherlands, no registration is made how many biocides are used. In Belgium, where there is an official registration, more than 22 million kilos of active substance were traded in 2020. Considering the number of inhabitants and the size of the industry compared to from Belgium it is likely that the quantities for the Netherlands will be expected to be significantly higher. For comparison: in the Netherlands 9 million kg of chemical crop protection products annually traded.

**Risk assessment for biocides**

This advisory report discusses biocontrol agents and biopesticides used in agriculture, which fall under the plant protection product regulations. Biocides are used outside agriculture, for example, in households, industry, and for public health, and fall under other regulations. Although their scope of application differs, there are clear similarities: substances such as *Bacillus thuringiensis,* neem oil, and lactic acid are used in both areas.72 The authorization system is comparably strict. Both regimes require EU-wide approval of active substances.
and risk assessment for safety for humans, animals, and the environment. EFSA is responsible for biopesticides, ECHA for biocides.68,73
A key difference is that biocides are not allowed to make "green" marketing claims, even if they are biological substances, while this is permitted for biopesticides.74

The assessment also differs: with biopesticides the focus is on food residues, for biocides on exposure via skin, air or environment.72

Biocides are often used in a wide variety of environments, from residential rooms to hospitals, which makes the risk assessment more complex than in agricultural applications.75 This also makes it difficult to gain insight into options to avoid use and suitability of a low-risk alternative to an existing drug. Although both regimens have accelerated admission routes for products based on low-risk substances, This route is rarely used for biocides.74 The innovation power, budgets and pressure such as that which exists to phase out chemical crop protection Resources are currently lacking. For biocides based on low-risk substances are not subject to a lower level as is the case with crop protection products effectiveness tolerated, as pest control risks may occur occur when insufficient use is made of resources or when there are insufficiently effective resources. Especially in the food industry and healthcare institutions these risks must be avoided, which legitimizes the use of high-risk substances.

Legally, substances used both in and outside agriculture must be classified as 2 separate admission procedures, as yet without mutual recognition of data although there are initiatives under the EU Green Deal to achieve *One substance, one assessment* to come.72,76 More coordination between the assessment systems could accelerate admissions and foster innovation.

# 05
# application in practice

The application of biocontrol in practice is done in various ways
methods are hampered. For example, there are too few biocontrol methods
available for open cultivation, and there is no market incentive or
compensation for growers who invest in biocontrol. Application of IPM
is still too non-committal. Chemical agents can often be used more effectively
requirements for export are met than with biocontrol. The Commission
makes recommendations to remove these obstacles.

## 5.1 Bottlenecks

Based on interviews with experts and stakeholders and through literature-
the Commission concludes that – even if the risk assessment
and approval of biocontrol is improved and accelerated – improvements
are needed in the field of practical application to achieve biocontrol on
to be able to deploy on a larger scale . The committee sees various
barriers to the implementation of biocontrol.

### 5.1.1 Availability per crop

Biocontrol is most effective in greenhouse horticulture. This is because
because temperature and humidity can be controlled better here than
in open fields and macro-organisms can develop more difficultly
spread. In addition, some products from the
greenhouse horticulture is a large sales market and there is a lot of budget from subsidies and
from producers has been used for product development, which means that
many biocontrol agents are available for this sector. Application
Biological pest control has been used in greenhouse horticulture for decades
the standard: in 2020, 94% of the total area was covered
horticultural predatory mites, parasitic wasps or microbial agents are used.3
A total of 53 species of arthropods and 2 species of
nematodes are used.77 Antagonistic bacteria and fungi are
successfully used against powdery mildew and soil-borne pathogens,58,78
although their effectiveness continues to vary per substrate because some
microorganisms have difficulty establishing themselves.79 With the disappearance of
chemical backup agents, the slow approval of new agents
and the emergence of new pests is indeed an expansion of the arsenal
necessary, for example through greater diversity of natural enemies
and *standing* army strategies.77 The *standing* army principle holds that
there is a permanent, preventatively present population of
natural enemies against pests.

An adequate package is currently lacking for virtually all open crops
to biocontrol, so applications are often limited and experimental.5
Effective, approved alternatives for key diseases in apples and pears
missing.80 Biological agents for field vegetables focus on
mainly on soil diseases or some insects and should always be
combined with other measures, including the use of
chemical crop protection products.81 Establishment capacity and
stability in the field, and the possibility of mass production of some
Biocontrol agents pose an additional bottleneck. There is an urgent need for

research into active products and application strategies, and the integration of biocontrol in crop disease management systems to biological control in these sectors effectively and reliably can bet.5.78

### 5.1.2 Obstacles for growers

Although biocontrol is less harmful to the environment and contributes to biodiversity, in many cases there is no market incentive or compensation for growers who invest in these sustainable methods.82 Because biocontrol generally more intensive monitoring of pest pressure and a higher application frequency requires, the use in practice is often more expensive and more labor-intensive than chemical alternatives – especially in less capital-intensive crops such as arable farming.83 Biocontrol-methods are used much more specifically based on observations or plague pressure.84 This has an effect on business operations: the substantive and Technical complexity is increasing. The effectiveness of biocontrol agents can also depend greatly on soil type, cultivation system, crop, and weather and climate conditions.85 This makes it difficult to achieve consistent to achieve results in the field, which increases confidence in these resources can undermine. Any harvest losses due to pest control with Biocontrol are not reimbursed. Without a clear economic added value, the willingness to switch therefore remains limited.

Unlike livestock farming, the Netherlands lacks a Plant-health fund.5 This means that the economic risk of pest outbreaks are entirely borne by individual farmers, especially in new outbreaks, exacerbated by climate change and trade. This lack of collective risk sharing, unlike in livestock farming, strongly discourages growers from switching from *fail-safe* chemical solutions, even if they are more harmful, because the economic the consequences of failure for growers are so serious.

### 5.1.3 Embedding in IPM

Biocontrol agents should usually be combined with additional measures.19,85 The natural biological balance in modern cultivation systems have also been disrupted by artificial fertilizers, chemical agents and high-yielding but vulnerable varieties, so that a broader system change is needed to make biocontrol effective work.5 Since 2014, all EU growers are legally obliged to comply with IPM principles to work, but a measurable reduction in chemical crop-protective equipment is still lacking.86,87 This is mainly due to regulations leaves room in the way IPM is implemented. The registration of Although IPM measures are mandatory, there is no fixed format or assessment framework. Therefore, in theory, a limited application is sufficient of individual elements. This means that in some cases IPM can be implemented sooner an administrative obligation rather than an actually integrated approach. In addition, the limited range of alternatives for

chemical agents hinder the application of IPM, as well as the economic risk. The legal obligation to apply IPM only leads to less use of chemical agents if it is more strictly defined and maintained.

### 5.1.4 Phytosanitary requirements

Phytosanitary requirements are legal plant health rules that must prevent harmful plant organisms (pests and pathogens) are brought in or distributed. They apply to import, export, trade within the EU and sometimes also for transport within a country.

Global trade and climate change increase the likelihood of new pests and pathogens reach the Netherlands and establish themselves.88 The EU is responding with stricter requirements and controls on the presence pests on products (clearance declarations). For many products, the presence of pests is not permitted and an exemption declaration is required. Regulation (EU) 2016/2031 requires additional inspections, registrations and certifications, making import and export both becoming more complex and expensive. Obtaining such exemptions is becoming This makes it more difficult for products that are primarily concerned with biocontrol. used as crop protection.33 Traditional chemical agents are more effective in controlling pests, allowing for free- rings are easier to remove after treatment with chemicals are.5,40,89

The following always apply to starting materials such as seeds, seed potatoes and cuttings more often zero tolerance requirements, where products are completely free from harmful organisms must be present; even one contamination leads to rejection.

Because biocontrol is aimed at prevention and control and not automatically leads to complete extermination of organisms, are zero-tolerance requirements not suitable for the assessment of products containing The use of biocontrol has been produced. Phytosanitary zero tolerance requirements thus counteract the IPM principles.

EU policy to reduce chemical use also clashes with trading partners who stick to traditional chemical crops protective equipment, leading to a regulatory gap and protectionist measures.

### 5.1.5 Public support and importance of retail

Increased use of biocontrol also has an effect on consumers. is important to create public support. Among consumers, the awareness of biocontrol agents is low and the picture is often ambiguous: natural remedies are sometimes seen as less effective, while the benefits – reduced chemical emissions and lower residue levels – at purchase of a product must be invisible.90,91 In addition, the supervisor that claims are concrete, verifiable and not misleading, which makes communicating the benefits of biocontrol difficult.92

At the same time, price and aesthetics dominate the choice on the shelf, which means that

willingness to pay remains limited as long as the added value is not clear and is verifiable through clear, independent criteria.90,93

For the retail and consumer side, it is often unclear what biocontrol yields. An uncertain profit margin and demand make shelf space, marketing and Price incentives for biocontrol are risky. Biocontrol often leads to more variation in products, which may conflict with strict cosmetic requirements that are imposed on products. There is also sometimes a lower yield.90 There are no widely supported, verifiable IPM/biocontrol standards that are easy to verify. The current quality mark-Schedules involve a lot of administration and therefore provide extra charges and costs on.93

## 5.2 Recommendations

The Commission makes the following recommendations to improve the application of to facilitate biocontrol methods in practice:

- Expand the arsenal per crop: Support knowledge and product development through targeted Research & Development, field validation and pilot studies, with a focus on key pests in open field crops.5
- Compensate transition costs: Make subsidies available, just like insurance and *risk sharing* for labor, monitoring and extra measures by entrepreneurs; stimulate chain premiums for green crop protection.32
- Make IPM concrete: Set crop-specific minimum requirements IPM implementation and reduction targets for *CfS* and resources in particular with the highest cultivation use. IPM can also be effective be combined with other measures such as precision agriculture to achieve a reduction in the use of resources.
- Make IPM testable: Ensure mandatory registration of professional use of chemical crop protection products and application of IPM practices by time, location and crop, and for targeted enforcement. This allows evaluation of the effectiveness of biocontrol resources under specific circumstances possible. In addition, Registration is also valuable in assessing exemptions applications and in comparative evaluations when chemical crop protection products need to be replaced through safer alternatives. Registration of chemical crops protective equipment also allows epidemiological research into possible health effects of chemical crop protection resources possible.
- Set up post-registration monitoring for biocontrol: Collect data on behaviour of substances and resources in practice (diffusion, long-term effects, resistance formation, residues remaining, perception of residents) to alleviate concerns, identify problems promptly and support the improvement of risk assessment.
- Advocates revision of phytosanitary requirements in the EU context: Vote phyto-sanitary requirements and sustainability goals better off. Revise zero tolerance requirements (to ensure products are completely free from harmful organisms)

where this can be done safely, so that proportionate risk limits can be achieved become. Harmonize EU and export standards and take biocontrol explicitly included in phytosanitary protocols.

- Support growers through policy. Stimulate knowledge development and innovation. in pest monitoring; offers independent advice and financial incentives.
- Promote public support: Communicate clearly about the health benefits of biocontrol (less chemical emissions/ residues); link biocontrol to a healthy food system and changed farming practices. Public embrace of the IPM-proof label / *biocontrolled* increases social support and strengthens both policy as farmers.
- Pay attention to the role of retail: Develop clear quality marks/labels, Provide active information, offer shelf advantages and price incentives. Send less on cosmetic requirements of the end product, more on production method (IPM/biocontrol, water quality, resistance reduction) via chain- agreements such as PlanetProof. Policymakers can make covenants and facilitate promotion; transparency about origin/cultivation and retail- Collaborations increase trust and accelerate acceptance.

# 06 conclusions

Reducing the use of chemical crop protection resources contribute to public health, water quality and nature goals. The use of biocontrol can play an important role in this. Given the Dutch government's ambition for 2030 and the Water Framework Directive in 2027 is faster and broader application of Biocontrol urgent. To achieve this, bottlenecks surrounding the risk-assessment, authorisation and implementation of biocontrol agents are removed, while maintaining safety.

The Commission sees a number of solutions to achieve a faster, tailor-made risk assessment and authorisation for biocontrol agents come (see paragraph 4.3). Especially the preparation of a functional definition for biopesticides, implementation of the *problem formulation/ pathways to* harm methodology and the use of existing safety knowledge can be expected in the relatively short term implemented. An EU-wide approach and harmonization will also be procedure for the better. Other solutions for accelerating the According to the committee, assessment and authorisation of biopesticides are a separate legislative framework and the possibility of provisional authorisation. Developing and implementing a separate legislative framework for Biopesticides are expected to take many years. Furthermore, EU-wide approach and harmonisation of the speed of procedures for the better. For macro-organisms the committee recommends a harmonised EU framework with monitoring of effects on non-target organisms and ecosystems.

Even with better EU policies on risk assessment and authorisation, practice thresholds determine the successful application of both macro-organisms as biopesticides. The Commission states in paragraph 5.2 recommendations to lower the thresholds for biocontrol applications in The Netherlands to reduce. In open cultivation, unlike glasshouses, horticulture – the available biocontrol arsenal is still limited. Application requires knowledge, monitoring and labor, and limiting financial risks for growers. Concrete and verifiable IPM requirements are required important and obstacles must be overcome by phytosanitary protocols are taken away.5,32

The Commission believes that the scaling up of biocontrol is going too slowly, which reduces the risks of chemical crop protection products for people and the environment will continue to exist for an unnecessarily long time. The Commission anticipates that the use of biocontrol for crop protection – when following the recommendations of the Commission – an important element is in the transition to a more sustainable agricultural system and contributes to the protection of human health and the environment, and achieving of the WFD objectives. However, it is essential that biocontrol is used as part of a robust cultivation system, and in conjunction with other efforts to work towards a future-proof

agricultural system. Synergy between policies for agriculture, climate, biodiversity, nature, water and health must be actively sought to become.

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## Commission and consulted experts

**Composition of the Health and Environment Signaling Committee for the *Health Gain*** advice ***through the use of biocontrol for crop protection***

- em. Prof. Dr. Ir. E. Lebret, emeritus professor of Environmental Health Impact Assessment, Institute for Risk Assessment Sciences, Utrecht University
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- Dr. MB Meerwijk, Health Council, The Hague

a Consulted experts are consulted by the committee because of their expertise. Consulted experts and observers have the right to speak during the meeting. They do not have the right to vote and are not responsible for the content of the committee's advice.

The Health Council, established in 1902, is an advisory body whose task is to inform the government and parliament about the state of science with regard to issues relating to public health and health(care) research' (Article 22 of the Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport; Infrastructure and Water Management; Social Affairs and Employment and Agriculture, Fisheries, Food Security and Nature. The council can also issue recommendations on its own initiative, and identify developments or trends that are important for government policy.

The Health Council's advice is public and is generally drawn up by multidisciplinary committees of – in a personal capacity appointed – Dutch and sometimes foreign experts.



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