

# ECPA Position on Trends and Availability of Active Substances in the EU

## Introduction

ECPA supports the regulation governing the production, authorisation, supply and use of plant protection products. We develop products to “ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture”<sup>1</sup>, as required by Regulation (EC) 1107/2009.

There is no doubt that societal and political debate on the use of pesticides is highly charged and, increasingly, there seems to be demand for alternatives to conventional chemistry for crop protection. Our industry invests €3bn per annum in R&D for more innovation in crop protection be it through chemical, biological, mechanical or other means. ECPA takes the view that Regulation (EC) 1107/2009 is meeting the health and environmental protection goals, yet is falling short in relation to competitiveness.

## ECPA’s position concerning the availability of pesticides in European agriculture

- **Lack of pace and scale of innovation.** The pace of thorough R&D, testing and registration means that there will not be hundreds of new, effective and thoroughly safety tested (bio)control solutions on the market in the next few years. It is quite telling that a recent application for the common food supplement Bee Propolis extract was unable to meet the requirements for pesticide registration; the thresholds for approval are incredibly high. Measures to improve the speed of bringing innovative solutions to the market are required.
- **Rapid reduction in availability of effective means of crop protection on the EU market.** The EU farmers’ toolbox is not meaningfully increasing. In fact the list is being propped up by everyday substances like milk, vinegar or beer that are not commercially viable pesticides. The rapid reduction in pesticides available is storing up major problems for the future, such as resistance to the few tools that farmers will have available, if current rates of removal continue. The system isn’t broken, however the implementation of it is and this needs to be improved.
- **The need to assess hazards and risks associated with all forms of crop protection.** The natural or biological origin of a substance does not automatically mean it is safe, and synthetic chemistry does not necessarily mean a substance is automatically harmful when used properly. All forms of crop protection have risks that need to be assessed and managed.
- **Risks associated with the ongoing rapid withdrawal of chemistry based products from the market.** Stating that Farmers can farm productively without chemistry is simply incorrect. As is the case for humans, without medicines, plants suffer and die from diseases and pests, introducing all sorts of unintended consequences including risks to public health in some cases.
- **Replacement potential for some technologies.** Industry invests billions to innovate for ever more sustainable agriculture. Current disruptive technology including biological products, mechanical approaches and digital applications can **reduce** and compliment the use of chemistry, but are **unlikely to replace it**.

<sup>1</sup> Recital 8 of Regulation 1107/2009

## Further detailed explanations

### 1) Pace and scale of innovation

Collectively the industry invests in the order of €3bn per annum in R&D, looking for continuous improvement in product ranges, ensuring that we meet or exceed regulatory requirements and the needs of our customers. This process is not easy and takes a long time, on average over 11 years, requiring an average of over 200 scientific studies and costing in excess of €220 million to bring a product to the EU market.

It is difficult to identify new products from the hundreds of thousands of candidate substances we synthesise and the vast quantities of biological sequencing of pests to help identify effective (bio)control solutions.

Some commentators seem to take the view that biological controls will soon replace all synthetic chemistry, will be equally effective against all pests that farmers need to control and will see an end to chemistry in agriculture. That view is inaccurate. Indeed, a majority of biocontrol active substances are micro-organisms (viruses, bacteria and fungi), which typically have a narrower spectrum of activity and are effective under a tighter range of conditions than chemical products. Overall chemical and biological active substances have to be considered as complementary, rather than a direct replacement. The diversity of crop protection tools is also required for the management of pest resistance<sup>2</sup>. To replace all chemical plant protection products with biocontrol products would have severe quantitative and qualitative consequences on food and feed production output.

### 2) Availability of effective means of crop protection on the EU market

As an industry we have very real concerns that the farmers' toolbox is being depleted much faster than it is being replaced by new technology. This is often for political, not science-based reasons and the removal of key products from the market is a great cause for concern for all farmers.

The European Commission states that the number of approved active substances has increased since June 2011<sup>3</sup> by approximately 80 more substances<sup>4</sup>. Where has this increase come from? The issue requires a closer look at the information.

The increase is largely due to:

1. Carry-over from the previous regulatory regime<sup>5</sup>: a number of new active substances which were submitted for approval under the old regime were decided under the current regime, using the former's criteria and data requirements.
2. Approved basic active substances<sup>6</sup>. These include ingredients such as milk, beer, vinegar, pepper and garlic, which do have some action and indeed many households will use these everyday products for application at home, for example to control slugs eating salad leaves in their gardens. However, these basic active substances do not have the effectiveness needed for normal farming and the far more intense pest and disease pressures on commercial crops. Few farmers would entrust their family income to beer or milk being used as pesticides<sup>7</sup>.

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<sup>2</sup> Directive 2009/128 on the sustainable use of pesticides, Annex III point 7: "Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action."

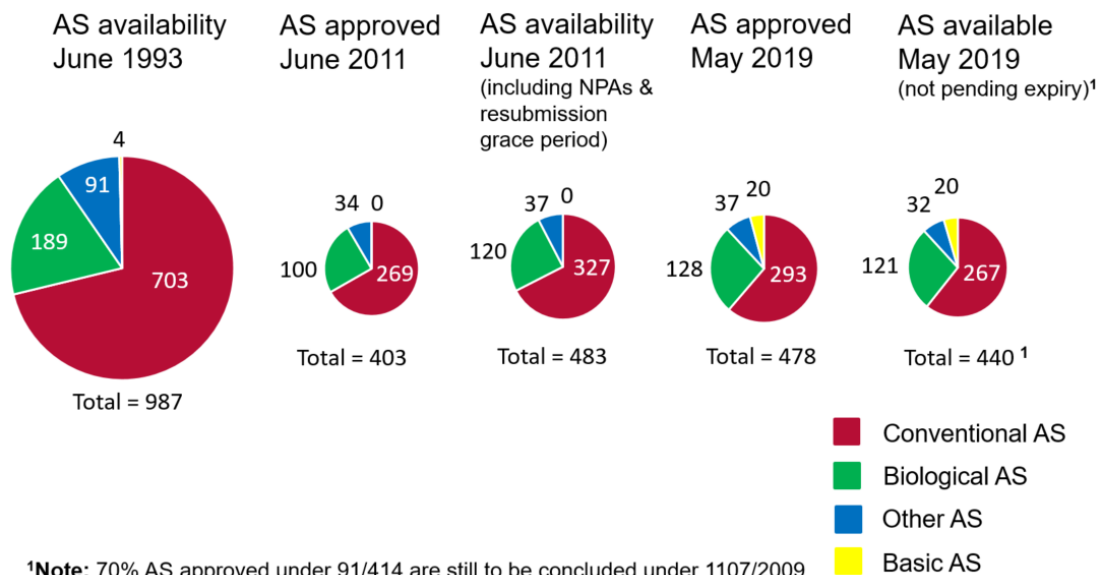
<sup>3</sup> When Regulation 1107/2009 replaced Directive 91/414/EEC

<sup>4</sup> Berend, Klaus. "EU Legislation – Developments in the Implementation and Some Findings of the REFIT evaluation." ECPA conference, Ghent, May, 2019.

<sup>5</sup> Directive 91/414/EEC

<sup>6</sup> Defined in Article 23 of Regulation 1107/2009 as substances that have crop protection properties but whose main function(s) is (are) not crop protection. Such substances cannot be placed on the market as plant protection products

<sup>7</sup> Beer would be considered to be too hazardous to be approved as an active substance under the EU system for chemical active substances as it contains ethanol which is a substance that would trigger the EUs very strict hazard based 'cut-off criteria'.



The current EU regulatory regime for pesticide approval and renewal is the most stringent and conservative in the world. Since its entry into force in 2011 it has been re-assessing all previously EU approved pesticides. The renewal programme is now in its fifth phase, with at least the next phase in the process of being scheduled.

At the point that the previous set of EU rules were established in 1991 and applicable in June 1993, there were around 1000 active substances on the EU market. In June 2011 when the current regime came into force, fewer than 500<sup>8</sup> active substances remained approved. Since then we have seen around 1 in 3 active substances being non-renewed through implementation of the renewal program. The loss rate is accelerating with negative regulatory decisions (non-approval, non-renewal and severe restrictions) equalling the number of positive decisions (approval and renewal) in 2018, all categories of active substances included. There are simply not enough tools for farmers to control diseases and pests to work effectively in coming years.

Whilst demand for ever better environmental profile substances is high and this industry is fully committed to improving environmental performance, the new regime has made it extraordinarily difficult to bring new innovation to the market. The whole industry has applied for the approval of just 20 new chemical active ingredients and 37 new biological controls in Europe since 2011<sup>9</sup>.

When active substances submitted, evaluated and decided under the current regime are considered, the picture is different from that stated by the European Commission. Since 2011:

1. There is a clear net loss in the number of chemical active substances approved.
2. The net result in biocontrol active substances is barely positive.
3. Especially for insecticides, the decline in availability of substances is not being replaced by new substances either chemical or non-chemical and this is impacting the choice of crops grown by farmers. In some countries the sowing of Oilseed rape has declined by up to 25% due to loss of insecticides, and Oilseed rape is an important crop for IPM in northern Europe, where sunflowers can't be grown.
4. There is a clear increase in the number of basic substances like milk or vinegar approved.
5. Taking into account dozens of active substances that will soon expire as they are not supported for renewal by any party, the number of approved active substances will be reduced by the current system, not increased.

<sup>8</sup> European Commission, *Pesticides in the European Union Authorisation and Use*. Available: [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_approval-factsheet.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_approval-factsheet.pdf)

<sup>9</sup> European Commission, (May, 2019), *EU Pesticides Database*, retrieved from : <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>  
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### 3) The need to assess hazards and risks associated with all forms of crop protection

At a basic level manual weeding has its own inherent risks including posture and repetitive strain injuries, flame weeding<sup>10</sup> has an associated fire risk and chemical and biological controls have risks associated with unwanted or unexpected harm to the environment or non-target organisms. All forms of crop protection, whether natural or synthetic, have hazards and risks that must be considered and properly managed.

Our products are intended to eradicate and control pathogens and pests, yet must be safe for other organisms including insects, plants, birds and mammals, fish and amphibians. Making sure that the case is complex and requires thorough hazard and risk assessment. This principle applies equally to chemical and biological controls. For example, if using live organism biocontrols, assessment of the ecosystem impact is needed to avoid unintended consequences. Products for organic agriculture are typically applied in much larger quantities than other chemistry and can be persistent in the environment or bioaccumulate, indeed copper based compounds, which are one of the main types of pesticide used in organic agriculture, are classified in Europe as 'candidates for substitution' because of 'critical areas of concern' i.e. a "high risk for birds and mammals, aquatic organisms and soil micro-organisms."<sup>11</sup> This needs to be assessed and mitigation considered. And chemical safety is of course a major consideration for conventional pesticides.

### 4) Risks associated with the ongoing rapid withdrawal of chemistry based products from the market

The trend is clear. Despite our combined best endeavours to bring innovation to the market, replace older products and empower EU farmers to produce safe, nutritious food in ever more sustainable ways, we cannot do it at a speed that gives enough options to farmers to control pests and diseases.

This matters because the fewer products and different methods you have to control pests and diseases, the quicker they develop resistance to treatment. We are now getting close to a tipping point where there will be no effective treatments or controls for some pests and diseases in Europe. And we already see that there are real problems with lack of means to control invasive alien species, as illustrated in southern Europe with diseases, such as *Xylella Fastidiosa*, destroying olive groves that cannot be readily controlled.

Climate change is bringing new challenges too. For example, the European Food Safety Authority is concerned about natural cancer causing toxins developing in European food<sup>12</sup>. This happens as a result of fungal infections of cereal crops and maize that can be controlled through integrated pest management practices, including some use of chemical fungicides. Yet these fungicides may soon stop being effective due to there being too few products that work in similar ways and so being susceptible to resistance developing in some fungus species.

### 5) Replacement potential for some technologies

It's great that there is so much interest in the latest innovations in crop protection products. We are bringing biological solutions to the market, but there are currently only 20 new biological active substances approved under Regulation 1107/2009, with another 21 in the approval process<sup>13</sup>. These products are hard to develop and take a long time to bring to market as we ensure they will work and be safe. We'll continue to develop these and replace older products over time. But we should be clear that biological solutions are not expected to be direct replacements for the full range of insecticides, fungicides and herbicides. At this point there are no biological herbicides at all.

**We are a responsible industry and want to be part of the solution. It is time to discuss the transition towards sustainable agriculture based on facts and with honest debate in full recognition of the positive and negative impacts of all disease and pest control technologies in agriculture.**

<sup>10</sup> Usually gas-powered

<sup>11</sup> EFSA Journal, (January 2018), *Conclusion on Pesticides Peer Review*, Available: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5152> (End of Summary section)

<sup>12</sup> EFSA, (October, 2019) *Public consultation: aflatoxins in food*, Available: <https://www.efsa.europa.eu/en/press/news/public-consultation-aflatoxins-food>

<sup>13</sup> European Commission, (May, 2019), *EU Pesticides Database*, retrieved from : <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>  
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