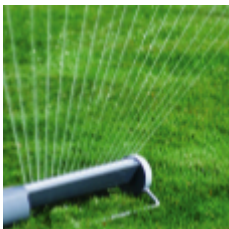
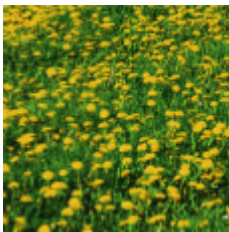




## Questions and answers on the adopted list of “Candidates for Substitution”

*Revision 1*



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## Questions and answers on the proposed list of “Candidates for Substitution”

### **What is the issue?**

The European Commission is required by Regulation 1107/2009<sup>1</sup> to produce a list of substances identified as “candidates for substitution”. The list identifies active substances with certain properties. For products containing these active substances, Member States will be required to evaluate if their use can be replaced (substituted) by other products. The list proposed by the Commission was voted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 27 January 2015<sup>2</sup>. The official legislative publication of this list expected in the coming weeks.

To prepare the list, the Commission requested a consultant report<sup>3</sup> on testing of the criteria set by the Regulation in point 4 of Annex II. The report does not contain any official listing, only scenarios from different interpretations of the criteria.

### **What does it mean if a substance is on the list?**

The listing of active substances as candidates for substitution does not question the safety of the products; they have gone through the strict EU evaluation criteria and have been approved for safe use. But products containing these substances will be required to go through an additional step of comparative assessment. As an effect of this, some uses could be removed from the market if it is considered that there are adequate alternative solutions – that are significantly safer – already available to farmers.

### **So what happens to those substances?**

When an active substance is identified as a Candidate for Substitution, products containing that substance will be subject to a comparative assessment at the time of (re)authorization. They will be authorized if there are no better alternatives. This means a dramatic increase in resources required by Member States to review these products – resulting in significant delays where the legislative timelines for product evaluations will not be met.

### **Are the substances safe?**

Yes, and have been proven to be so: in the European Union, no plant protection product can be used unless it has first been scientifically established that they have no harmful or unacceptable effects on health or the environment, and they are sufficiently effective against pests. All active pesticide substances approved in the EU have already undergone the EU evaluation procedure, which is the most stringent regulatory system in the world. EU rules

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<sup>1</sup> Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>2</sup> Commission press release MEMO/15/3743, 27 January 2015:

[http://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/docs/gaa\\_candidates\\_substitution\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/gaa_candidates_substitution_en.pdf)

<sup>3</sup> Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009, Food Chain Evaluation Consortium (FCEC), 9 July 2013

[http://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/docs/cfs\\_final\\_report\\_072013\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/cfs_final_report_072013_en.pdf)

establish a dual system where the Commission approve the active substances contained in the products; and EU countries authorise the products on their territory and ensure compliance with EU rules<sup>4</sup>.

Europe's crop protection industry is committed to the safety of its products, by meeting the requirements of the Regulation and ensuring the correct stewardship and use of pesticide products<sup>5</sup>. In many cases this goes above and beyond what is required by the regulatory framework.

### ***Why produce a list of active substances if they are safe?***

This is a question that the industry has also asked policy makers! The criteria used are not based on any scientific evidence or advice and were the end-result of a political negotiation. The criteria for identifying candidates for substitution were developed by the Commission and amended during the negotiations on Regulation 1107/2009.

### ***Why can't we just replace the products, or use ones where there is no question about safety?***

For one thing, we are talking potentially about a lot of substances to be identified as candidates for substitution – perhaps affecting over half of the plant protection products in use by today's farmers<sup>6</sup>. Farmers need this varied toolbox of available products to combat the build-up of resistance. Experience has shown that there needs to be a minimum of three chemical classes per type of pest to provide solutions for farmers to avoid such a build-up of resistance.

And there are other issues. Many specialty crops and minor uses (fruits, vegetables flowers etc) already face situations where there are few or no solutions available for crop protection. The further loss of crop protection products would severely affect farmers' ability to maintain production of those crops in Europe.

More generally, crops are under threat from 30,000 species of weeds and 10,000 species of insects and it is essential that farmers have access to a range of available solutions to control these pests. If the product uses including substances on the substitution list are to be removed without providing suitable alternatives, there will be no options left to protect crops. With some crops, there will be no solutions left.

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<sup>4</sup> *"The first step of the evaluation process involves a Rapporteur Member State, which transmits its preliminary conclusions on the substance to the European Food Safety Authority. A scientific risk assessment involving the European Food Safety Authority is then carried out, followed by risk management steps carried out by the Commission with the assistance of the Member States within the Standing Committee on the Food Chain and Animal Health. If the evaluation shows that the substance has no harmful effect on human or animal health and that it has no unacceptable influence on the environment, the substance can be approved. An EU list of approved active substances is established, and Member States may authorise only plant protection products containing active substances included in this list."*, Commission Factsheet, ISBN 978-92-79-11599-8, March 2009: [http://ec.europa.eu/food/plant/pesticides/eu\\_policy/docs/factsheet\\_pesticides\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/eu_policy/docs/factsheet_pesticides_en.pdf)

<sup>5</sup> Some of ECPA's work on providing high quality affordable food, safeguarding water, promoting biodiversity, and protecting health is presented on the following website: <http://www.hungry4change.eu>

<sup>6</sup> A large proportion of plant protection products contain more than one active substance. Therefore, if 20% of active substances are listed as candidates for substitution, it is estimated that around half of all products would contain a substance listed as a candidate for substitution.

***What would be the consequences of the list for the food chain?***

It would mean fewer products available to farmers, and thus fewer solutions for treating fruit and vegetable crops. Furthermore, there is a risk that the list would be used as a “target list” by certain issue groups, leading retailers to possibly show unjustified over-zealousness and prohibit the sale of products containing candidates for substitution – despite these products having been approved at EU and national level.

It would also lead to a fragmentation of the EU internal market, with some products available for farmers in one Member State but not available to their counterparts in neighbouring countries.

It could also create artificial barriers to trade: producers outside the EU will have a much broader choice of safe crop protection solutions available than those in European Member States where substitution has occurred. This will have a direct impact on the competitiveness of EU farmers.

***Isn't the industry coming up with new, safer products?***

Yes, we are constantly working to do that. But remember that it takes on average 10 years between the first research tests and authorisation of a new product and nearly €200 million of costs associated with the discovery, development and registration of a new active ingredient<sup>7</sup>. For every active substance that is registered for use, there are over 140,000 that do not make it past the development stage due to ever stricter and changing criteria<sup>8</sup>. In an unpredictable regulatory climate, companies will find it harder and harder to invest the resources necessary to develop new products.

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<sup>7</sup> *R&D trends for chemical crop protection products and the position of the European Market*, Phillips McDougall study for ECPA, September 2013:

[http://www.ecpa.eu/files/attachments/R\\_and\\_D\\_study\\_2013\\_v1.8\\_webVersion\\_Final.pdf](http://www.ecpa.eu/files/attachments/R_and_D_study_2013_v1.8_webVersion_Final.pdf)

<sup>8</sup> Overview of EU Legislation on Plant Protection Products:

[http://ec.europa.eu/food/plant/pesticides/legislation/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/legislation/index_en.htm)