REFIT Platform Opinion

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REFIT Platform Opinion on the Registration of plant protection products and the active substances registered in the Central European Union by a NGO (Polish Gardening Association)

The REFIT Platform has considered the submission from a Polish NGO that hints at problems that arise in the application of Regulation (EC) No. 1107/2009 concerning the placing of plant products on the market, which harmonises the rules for the marketing and the use of plant protection products in the European Union. In particular, the submitter points to the illegal introduction of products registered in one MS in countries where such products have not been registered yet – a grey area, as the distribution of these substances is not controlled.

The Stakeholder group recognises the concerns raised by the submitter and acknowledges the need to address them. The Stakeholder group does also consider that the European Commission has already addressed the issue (i.e. the risk assessment of a given application to be conducted for all Member States grouped in one or three zones with similar agro-climatic conditions and by making mutual recognition of authorisations granted by one Member State compulsory for the Member States in the same zone), in an evaluation of the EU pesticides legislation (Regulation (EC) No. 1107/2009). The results of this evaluation are expected in Q2 2019. The Stakeholder group expects therefore the concerns to be sufficiently addressed in the evaluation and proposes to wait for its results.

The majority of Member States that contributed to the opinion supports the recommendations of the Stakeholder group. A few Member States would welcome further harmonisation in the risk assessment. One Member State considers that the Zone system is harmonised largely through common risk assessment guidelines.

Other few Members States support the views of the submitter, would be wary of automatic authorisation across a zone and acknowledge the Commission’s analysis in the Policy context.
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1 Submission XI.22.a by NGO (Polish Gardening Association) (LtL S222953)

Original submission:

Dotyczy: uproszczenia rejestracji środków ochrony roślin i substancji czynnych zarejestrowanych w Strefie Centralnej Unii Europejskiej Polski Związek Ogrodniczy zwraca się z uprzejmą prośbą o znowelizowanie rozporządzenia nr 1107/2009. Proponujemy, aby środki ochrony roślin i substancje czynne zarejestrowane w jednym państwie członkowskim Strefy Centralnej były obligatoryjnie dopuszczone do dystrybucji i stosowania we wszystkich pozostałych państwach tej Strefy.

Warunkiem koniecznym wprowadzenia w tych państwach byłoby zgłoszenie przez producenta zamiaru wprowadzenia danego środka lub substancji czynnej do organu nadzorującego gospodarowanie tymi substancjami danego państwa, (w przypadku Polski Ministerstwa Rolnictwa i Rozwoju Wsi) wraz z instrukcją (ulotką) przetłumaczoną na język danego państwa.

Naszym zdaniem aktualnie obowiązujący stan prawny to zbędna biurokracja, ale najważniejszym argumentem przemawiającym za dokonaniem proponowanych zmian to nielegalne wprowadzanie środków zarejestrowanych w jednym państwie członkowskim do państw, gdzie takie środki nie są jeszcze zarejestrowane, co stanowi tzw. szarą strefę. Stan ten powoduje, że ich dystrybucja nie jest w żaden sposób kontrolowana, a to doskonałe pole do sprzedaży "podróbek" stanowiących zagrożenie dla życia ludzi i środowiska naturalnego.

Translation

Subject: simplification of the registration of plant protection products and active substances registered in the Central Zone of the European Union

Polski Związek Ogrodniczy (Polish Gardening Association) would like to ask for the amendment of the Regulation No 1107/2009. We propose that plant protection products and active substances registered in one Member State of the Central Zone be obligatorily authorised for
distribution and use in all other Member States of this Zone.

A prerequisite for placing in these countries would be a notification by the manufacturer of the intention of the placing plant protection product or active substance to the authority supervising the management of these substances of a country concerned (in the case of Poland, the Ministry of Agriculture and Rural Development), together with the instructions (leaflet) translated into the language of the country concerned.

In our view, the current legal situation constitutes unnecessary red tape, but the most important argument in favour of the proposed amendments is the illegal introduction of products registered in one Member State to countries where such products are not yet registered, which constitutes a so-called grey area. This situation means that their distribution is not in any way controlled, and this gives excellent scope for selling counterfeits representing a threat to human life and the environment.

2 Policy Context

The proposal is related to Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which harmonises the rules for the marketing and the use of plant protection products in order to ensure a high level of protection of human and animal health and the environment, whilst enhancing the functioning of the Internal Market and safeguarding the competitiveness of the agriculture of the European Union. This Regulation aims in particular at providing harmonised rules for the approval of active substances and the authorisations of plant protection products.

Where an application for a product authorisation in one or several Member States has been submitted, the Regulation provides for a risk assessment of this application to be conducted for all Member States grouped in one of three zones with similar agro-climatic conditions (i.e. Northern, Central or Southern) and national authorisations of the product. Mutual recognition of authorisations granted by one Member State is compulsory for the other Member States of the same zone. However, Regulation (EC) No 1107/2009 acknowledges that within a zone some specific agro-climatic or environmental conditions may differ leading to different conditions of authorisations of the same product, based on the same zonal core risk assessment.

It should be noted that during the impact assessment that was conducted in preparation of the proposal for the Regulation on plant protection products, different levels of harmonisation of authorisation regimes were reviewed. In the light of the results of the impact assessment, the Commission proposed and the European Parliament and the Council agreed to mutualise only the risk assessment at zonal level and to maintain the system of national authorisations. However, harmonised rules for mutual recognition were provided, including compulsory mutual recognition of authorisations within a zone.

State of play

As announced in the 2016 Commission Work Programme of 27 October 2015, the Commission
is now carrying out a REFIT evaluation of the EU pesticides legislation in order to assess if the legislation meets the needs of citizens, businesses and public institutions in an efficient manner. This evaluation aims to perform an evidence-based assessment of the implementation of Regulation (EC) No 1107/2009 and of Regulation (EC) No 396/2005 on maximum residue levels (MRL) in food and feed and address synergies, gaps, inefficiencies and administrative burdens. It covers amongst other areas the mutual recognition system and the division of the EU into three zones.

The Commission published on 17 November 2016, its Roadmap on the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues. An external contractor had conducted a study to gather evidence including through an extensive and wide consultation of stakeholders. It aimed at collecting factual information, data and knowledge on the application of the Regulations. It also aimed at drawing upon the experience of different stakeholders and collecting particular views and opinions on different aspects of the Regulations and their effects. Stakeholder's views, practical experience and supporting evidence will ensure a credible evaluation including on the functioning of the provisions on mutual recognition of authorisations within and across zones.

The evaluation is expected to be finalised in Q2 2019.

On the issue of counterfeiting:

Counterfeiting of pesticides is indeed an issue. According to a 2017 Report by the EUIPO (European Union Intellectual property office), the economic loss for patent infringement in the sector amounts to some 1.3 billions euro.

The European Commission is actively engaged to act against counterfeiting of pesticides. For instance, every second year, EUROPOL together with OLAF and Member States competent authorities, organise an EU wide action called "Silver Axe" which in 2017 resulted in the seizure of 122 tons of illegal pesticides. The EU is actively participating in the OECD Network against illegal trade in pesticides (ONIP) and is also working with the OECD with a view to adopt a Recommendation against illegal pesticides.

Parallel trade is one of the areas that could be impacted by counterfeiting. The operator granted with the permit for parallel trade has to relabel, and normally re-pack the product. As regards enforcement action in the Member States, official controls and other activities intended to counter abuses vary from one Member State to the other (while in some Member States there are thorough requirements for controls where competent authorities should be informed in advance of the volume and exact date for the re-packing, which allow effective controls, in other cases Member States have required that re-packing should take place in the Member State of origin) and weaknesses in the national systems for controls and enforcement could indeed be exploited to introduce illegal or counterfeit products as parallel trade products.

One has to note however that most cases of infringements refer to fake products with counterfeited active substances originating from third countries.

The latest audit report on controls by Member States of the marketing and use of pesticides
published by the Commission in 2016 highlighted that "the risks associated with larger, higher-risk operators, specifically, importers, manufacturers and re-packers of PPPs, had not been sufficiently considered in the planning of controls" and that "the majority of Member States do not conduct controls on plant protection products stated to be for use in other Member States or in non-European Union countries."

Considerations of the REFIT Platform Stakeholder group

The Stakeholder group recognises the concerns raised and the need to address them.

The submission hints at problems that arise in the application of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which harmonises the rules for the marketing and the use of plant protection products in the European Union.

Whereas the Regulation aims at providing harmonised rules for the approval of active substances and the authorisations of plant protection products by inter alia foreseeing that where an application for a product authorisation in one or several Member States has been submitted, a risk assessment of this application has to be conducted for all Member States grouped in one of three zones with similar agro-climatic conditions and by making mutual recognition of authorisations granted by one Member State compulsory for the other Member States of the same zone, the application of the Regulation has proven that in practice the provisions of the Regulation have not delivered as they should and shown inter alia the weaknesses described in the submission.

The Commission has however already addressed the issue in a REFIT evaluation of the EU pesticides legislation encompassing an evidence-based assessment of the implementation of Regulation (EC) No 1107/2009, the results of which are expected by mid 2019.

The Stakeholder group therefore expects the concerns to be sufficiently addressed in the REFIT evaluation and proposes to await the results of the REFIT evaluation.

3 Opinion of the REFIT Platform

3.1 Considerations of the REFIT Platform Stakeholder group

The Stakeholder group recognises the concerns raised and the need to address them.

The submission hints at problems that arise in the application of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which harmonises the rules for the marketing and the use of plant protection products in the European Union.

Whereas the Regulation aims at providing harmonised rules for the approval of active substances and the authorisations of plant protection products by inter alia foreseeing that where an application for a product authorisation in one or several Member States has been submitted, a risk assessment of this application has to be conducted for all Member States grouped in one of three zones with similar agro-climatic conditions and by making mutual recognition of authorisations granted by one Member State compulsory for the other Member States of the same
zone, the application of the Regulation has proven that in practice the provisions of the Regulation have not delivered as they should and shown inter alia the weaknesses described in the submission.

The Commission has however already addressed the issue in a REFIT evaluation of the EU pesticides legislation encompassing an evidence-based assessment of the implementation of Regulation (EC) No 1107/2009, the results of which are expected in the second quarter of 2019.

The Stakeholder group therefore requests the European Commission to address these concerns sufficiently in the evaluation.

3.2 Considerations of the REFIT Platform Government group

Nineteen Member States contributed to this opinion.

Fifteen out of nineteen contributing Member States support the recommendations of the Stakeholder group. Two of them would welcome further harmonisation in the risk assessment. One of them considers that the Zone system is harmonised largely through common risk assessment guidelines.

Three Members States support the views of the submitter, would be wary of automatic authorisation across a zone and acknowledge the Commission’s analysis in the Policy context.

One Member State supports the approach of harmonised rules and considers that increased control and active participation in international co-operation can hinder illegal trade.

Member State 1

MS1 fully agrees with the REFIT Platform Stakeholder group.

Member State 2

MS2 considers the following:

On the issue of the authorization of plant protection products

MS2 considers that the protection of human and animal health and environment are fundamental legislative objectives in the field of plant protection, while improving the competitiveness of agricultural production and the agricultural sector.

Incomplete harmonization of data and testing requirements in some areas of evaluation as well as available guidance documents that are not legally binding, leads to a delay in the process of approving and renewing the approval of active substances and authorizing plant protection
products. That could lead to negative consequences for human and animal health and for environment.

At the teleconferences and workshops held in 2018 between experts from the competent authorities of the Member States from the South zone, one of the main topics for discussion was to achieve a harmonized approach to the authorization of plant protection products within the zone.

In 2017, MS2 has authorized 31 plant protection products under the mutual recognition procedure, in 2018 - 50 products.

MS2 supports the approach of harmonized rules and avoidance of duplication of assessments by Member States in the same zone.

It is necessary to improve the measures of the Member States with regard to the provision of appropriate, qualified and trained staff so that the obligations laid down in Regulation (EC) No 1107/2009 to be implemented more effectively and efficiently.

**On the issue of illegal trade**

Having in mind the importance of the problem and in order to reduce the risk of import, marketing and distribution of illegal plant protection products, the competent institutions in MS2 carry out increased control at the border crossing points and inside the country. In 2018 MS2 took part in an international operation of Europol Silver Axe III for counteraction to the illegal import and use of unauthorized plant protection products on the territory of the country.

MS2 participates actively in international meetings on exchanges of views on joint actions and cooperation to prevent the illegal import of plant protection products in Southeastern Europe.

MS2 will continue its support for joint action and cooperation with Member States to prevent the illegal import of pesticides and the protection of the EU’s external borders.

**Member State 3**

As a general statement, we consider that the regulation [(EC) 1107/2009] has served its goals, let alone the harmonization of the internal market.

In the South Zone, work-sharing has elevated the trust between MS’s Authorities in a level of complementarity, thus minimising national requirements to reasonable elements.

On the other hand, we may acknowledge the efforts of all stakeholders to address the needs of minor uses/crops, but we regret the augmented number of nation-wide derogations (art. 53 of the regulation) that could justify the grievances over unfair competition within the Union.

Solutions could be sought, either:

A) within the current framework, like a rationalistic implementation of the union-wide derogation of article 4.7 of the regulation, or

B) under REFIT, much like the proposal of SAM UNIT ([https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf](https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf) page 8/last paragraph) for disengagement from the precondition of first-tier approval of an active substance. As a matter of fact, it can be demonstrated that: unsuccessful choices of representative uses/crops, driven mainly by industry’s thrifty fiscal decisions, combined with procedural deadlocks, have resulted to withdrawal of active
substances, with no realistic possibility of a further elaboration that could allow for possible safe uses to be evaluated and authorized for minor uses/crops.

**Member State 4**

MS 4 is of the opinion that the proposal of the Polish Gardening Association is not acceptable and not achievable either, as regards the facts that there are differences in terms of the authorities and environmental aspects among the countries.

MS 4 cannot support this proposal.

The Commission’s opinion analyses the situation thoroughly and we hope it will be able to eliminate the suggestion.

**Member State 5**

MS 5 proposes to await the results of the REFIT evaluation process of this part of EU legislation, which will include the assessment of the implementation of Regulation (EC) No. 1107/2009, whose results are expected in 2nd quarter of this year. By reviewing the results of the evaluation, it will be possible a further assessment of the need and justification for amending the Regulation in question.

**Member State 7**

Courtesy translation

MS7 considers that the zone system has not yet provided the expected benefits with regard to the harmonisation of authorisations for plant protection products in the same area. It appears that States may belong to the same area when they face different environmental and agricultural conditions, which creates additional difficulties for mutual recognition. Therefore, and in accordance with the position adopted by the Stakeholders Group, the proposed option, which extends the authorisation issued by one Member State to the other Member State of the same geographical area for any plant protection product, irrespective of the Risk they may present, does not seem relevant.

Original text

EM7 considèrent que le système de zones n'a pas encore apporté les avantages escomptés en ce qui concerne l'harmonisation des autorisations de produits phytopharmaceutiques dans la même zone. Il apparaît que des États peuvent appartenir à la même zone alors qu’ils font face à des conditions environnementales et agricoles différentes, ce qui crée des difficultés supplémentaires pour la reconnaissance mutuelle. Par conséquent, et en accord avec la position adoptée par le stakeholders group, l'option proposée, qui étend l'autorisation délivrée par un État membre à
Member State 11

MS11 recognises the problem concerned and is prepared to discuss ways towards the comparable availability of plant protection products for professional users at least within the same zone. However, it is necessary to discuss in details the topic within the Commission. The proposal, as described, is nor realistic or practicable now.

In MS11’s opinion, the proposal can be put in practice only if several conditions are met:

1) It will become obligatory to submit each application in all countries of each zone. The dossiers must be built up for all countries of each zone (or for the whole EU territory in case of glasshouses or seed treatment). It is not the case now and especially small companies want to continue with applications (= authorisations) in several countries only due to costs.

2) The risk-assessment for each application will have to be always evaluated for all Member States and all conditions of each zone (or all EU). Now, it is not the case since the risk-assessment is done for those conditions and countries specified by the applicant.

3) The risk-management must be firstly harmonised within each zone to enable avoiding evaluation of the risk-management specific for each Member State within the zone. Or, alternatively, MS11 cannot talk on the simple notification, as proposed, but on a streamlined mutual recognition.

4) The mutual recognition must be one-way process. That means, if the zonal rapporteur decided negatively, it should be banned to still decide positively in other Member States of the same zone. This is not the case now, when the first country decides to withdraw the application and other countries still may authorise the product following their specific conditions.

5) The system proposed could work only if Article 36 par 1 of 1107/2009 is respected or revised. This Article requires always using the guidelines valid at the time of application. It must be banned to applicant to choose for mutual recognition those authorisations which are the most favourable for him and usually the most obsolete (= the product was authorised in the past i.e. in five Member States but following its renewal in compliance with the latest guidelines and newest scientific information it was withdrawn. However, the applicant would refer to an old authorisation granted following “obsolete” guidelines and endpoints in the other Member State and to try to re-establish the product via the mutual recognition or notification).

6) It would be necessary to change the present 1107/2009 system of data protection. Even if the product is authorised in many Member States of the zone following the latest guidelines and scientific knowledge, still may not be possible to mutually recognise it in another Member State due to the fact the applicant has no access in that country to some studies required (Chapter V of 1107/2009).
**Member State 12**

The Polish Gardening Association has requested that plant protection products and active substances registered in one Member State of the Central Zone be obligatorily authorized for distribution and use in all other Member States of this Zone. This would entail a revision of Regulation 1107/2009.

MS12 is very satisfied with the zonal system. In the Northern Zone, the system is already harmonized to a large extent through common risk assessment guidelines. MS12 finds that maintaining the prerogative of Member States to conduct their own assessments in the mutual recognition process ensures the best protection for health and environment.

MS12 does, however, agree that it is adamant that the issue of counterfeited illegal pesticides products be recognized. Better knowledge-sharing amongst the Member States within the zones is definitely a part of this. The MS pesticide strategy 2017-2021 sets out targets for this work, which includes collaborating with international authorities. In MS12, the MS Environmental Protection Agency cooperates with the national customs authority that monitors ships carrying goods.

MS12 notes that the Stakeholder group points to the REFIT evaluation as the correct forum for this request and that the Stakeholder group urges the Commission to take into consideration the points made by the Polish Gardening Association in this context. MS12 definitely believes that the REFIT evaluation should be an opportunity.

**Member State 13**

MS13 supports the view of the Stakeholder group that the concerns raised should be sufficiently addressed in the REFIT evaluation of the EU pesticides legislation and the proposal to await the results of that evaluation which are due later this year.

**Member State 14**

MS14 does recognise the problem described, that different plant protection products are authorised in different Member States in the Union, resulting in a situation where farmers do not compete on a level playing field.

MS14 cannot though, support the opinion of the NGO on obligatory authorisations in all Member States of a Zone at the same time, as the reasons for the current situation is that different Member States have differences in growing conditions, in climatic conditions, in crops grown, in crop varieties, in soil conditions etc. The differences make it difficult to authorize products for the whole range of situations.

MS14 is, however, of the opinion that further harmonisation in the risk assessment area should be promoted, with an ultimate goal of harmonised authorisations, when the risk assessment can accommodate all differences in an acceptable way.
**Member State 15**

MS15 has no comments to make on the opinion and agrees.

**Member State 16**

MS16 does not support the views of the submission. The application of the Regulation has proven that in practice the provisions of the Regulation have not delivered, as they should and shown inter alia the weaknesses described in the submission, MS16 would therefore not wish to see the current checks removed.

MS16 would also be wary of automatic authorisation across a zone due to the diverse conditions between some countries still in the same zone. These differences may justify different outcomes from the risk assessment and thus lead to different regulatory decisions. Variations in focal species (i.e. those relevant to local conditions) may result in uses, which are acceptable in that Member State, but a matter of concern in another.

Another point to consider is that given the precautionary nature of the regime, harmonised regulatory decisions would be determined by the worst-case risk assessment. This may in fact preclude authorisation of a product in all Member States (including those where the use would in fact be acceptable) simply because of the risks posed in one-Member State. MS16 recognises that counterfeit of pesticides can be an issue. MS16 does not however think it has much bearing on this particular issue.

**Member State 17**

MS17 authorities support the Stakeholder group Opinion.

**Member State 19**

MS19 agrees with Stakeholder group’s position.

**Member State 20**

- MS20’s Competent Authorities consider that exist an important gap between needs of plant protection tools and pests and diseases that affect EU crops.
- The current regulation for the authorisation of plant protection products (Regulation 1107/2009) supposes an important barrier for the availability of plant protection products at EU level. It would be desirable to advance in the improvement and rationalisation of the Regulation, taking advantage of the initiative REFIT that the Commission has launch.
- On the other hand, the debates of the Standing Committee of the Food Chain (SCPAFF) must be redirected towards a technical and scientific terrain, avoiding questioning the results of the
- Integrated Pest Management can be an interesting alternative to face the challenges that will face the management of plant health in the future, helping to reduce the dependence of the agricultural sector on plant protection products.
- In addition, it is necessary that agricultural sector and the plant protection industry, with the support of the administrations, advance in the field of research and innovation, for an effective implementation of the alternatives for plant protection products.

**Member State 21**

MS21 supports the opinion of the Stakeholder group in that the issues concerned are taken care of in the current evaluation of Regulation 1107/2009.

**Member State 22**

MS22 partially supports this suggestion. Full support of the Commission’s comment.

**Member State 23**

Regarding the proposal of Polish Gardening Association (Polski Związek Ogrodniczy) “that plant protection products and active substances registered in one Member State of the Central Zone would be obligatorily authorised for distribution and use in all other Member States of this Zone”, it must be pointed out that evaluation and approval of active substances for plant protection products is already conducted for the entire European Union (according to Regulation 1107/2009 and also before according to Directive 91/414). In turn, the procedure of registration of plant protection products (PPP) is conducted within the zone, but it must be noted that the authorisation for placing of PPP on the market of one Member State will not be automatically recognised by other Member States. An applicant shall apply for an authorisation to each Member State where the plant protection product is intended to be placed on the market. Consequently, it is not allowed to use the product authorised in other Member State. It should be emphasised that an applicant is not obliged to apply for authorization in each Member State of the zone, and can even apply only in one MS.

The proposal of Polish Gardening Association to allow placing on the market and use of PPP authorised in one of the Member States in all MS’s of the zone raises concerns, because of variety of agro-climatic conditions having impact on environmental risks and variety of risk levels coming from pests as well as different cultivation and control systems in MS’s.

MS23 supports the opinion of the Stakeholder group and recognizes the need of further harmonisation of PPP authorisation process. The concepts of the Regulation 1107/2009 for harmonisation of evaluation of PPP are not fully delivered by MS’s. MS23 is involved in the work on possible amendment of the Regulation and expects the results of Commission evaluation.
Member State 24

MS24 agrees with the opinion of the REFIT Platform Stakeholder group, because the application of Regulation (EC) No 1107/2009, concerning the placing of plant protection products on the market, needs to harmonizes the rules for the marketing and the use of plant protection products in the European Union.