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# Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU

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## Executive summary

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# S1. Executive summary

## S1.1. Terms of reference and scope

Indications of an increase of trade in illegal and counterfeit plant protection products (PPPs) have been identified in recent years. This illegal trade can be considered a threat to legitimate operators, due to the unfair competition it may create, but also a possible threat to human health and environment due to the unknown composition of the products. In view of this, the Directorate General Health and Food Safety (SANTE) of the European Commission considered it important to gather information on the quantitative and qualitative importance of this illegal trade in PPPs, as well as to assess the adequacy and effectiveness of the existing EU regulatory framework to prevent and combat fraudulent practices. Consequently, an ad-hoc study on trade of illegal and counterfeit PPPs in the EU was commissioned by DG SANTE. The Food Chain Evaluation Consortium, led by Agra CEAS Consulting and with input from Arcadia International, was awarded the contract.

According to the Terms of Reference (ToR), the main objectives of this study were to *'identify patterns of trade*[1] *of illegal and counterfeit pesticides within the EU and entering the EU and assess the existing regulatory framework in the EU'.*

More specifically, the study covered the following three tasks:

- Task 1: Collection of information on trade in illegal and counterfeit PPPs;
- Task 2: Evaluation of existing control measures;
- Task 3: Assessment of the regulatory framework and suggested complementary measures.

In absence of official definitions, and for the purpose of the study, 'illegal PPPs' were defined as all PPPs which are not considered legal; this category contains the two sub-categories of counterfeit and substandard. These sub categories are defined as follows:

- ***Substandard PPPs***: Products which contain substances not approved under EU legislation (or which contain no active substances) and falsified PPPs (e.g.: falsified content, falsified country of origin, products not authorised in the EU).
- ***Counterfeit PPPs***: Illegal copies of legitimate, branded products. They may be difficult to distinguish from legal products due to high quality branding and packaging. This category includes trademark and patent counterfeit PPPs.

## S1.2. Methodology

Information was gathered for this study via several complementary data collection tools: a literature review; exploratory semi-structured personal interviews with experts and Commission staff; consultation of two networks of experts; a survey of EU-28 Competent Authorities[2]; two surveys of

[1] In the context of this study, trade of illegal PPPs includes the import from third countries of illegal PPPs and the use of the parallel trade system for bringing these illegal PPPs to market. It does not include intra EU movements of PPPs which are authorised in different Member States.

the PPP industry; a survey of the ONIP[3] network; and six port specific case studies (Antwerp, Genoa, Greece – national level, Hamburg, Le Havre and Rotterdam).

Fieldwork for this study took place between June and September 2014. Survey results and case study findings were provided as independent annexes. Evidence and findings from the various data collection tools were systematically checked and cross-checked in order to create the final analysis.

## S1.3. Findings

### S1.3.1. Patterns of trade of illegal and counterfeit PPPs

While various methodologies for estimating the size of illegal and counterfeit markets exist, each methodology has its own limitations and drawbacks which inhibit its application or accuracy. Consequently, no suitable and feasible method of estimating the size of the illegal PPP market among existing methodologies was identified. Neither was a single comprehensive EU-wide source of data on trade in illegal PPPs identified. Despite this, considerable quantitative and qualitative data was collected on the market for illegal PPPs. This data confirmed previous estimates, namely that illegal PPPs represent around 10% of the EU PPP market. Evidence suggests that there are considerable differences between Member States in terms of the market share of illegal PPPs. More specifically:

- Member States with third country land borders are generally those which are considered to have the highest level of illegal PPPs;
- Large western European Member States may have a higher than average levels of illegal PPPs, and;
- Nordic Member States (Denmark, Sweden and Finland) are generally considered to have the lowest level of illegal PPPs.

Despite these differences, it should be noted that the perceived levels of illegal PPPs do not necessarily reflect the effectiveness of the control measures in place in the Member State. In some Member States, the level of PPPs may be considered to be low due to a lack of awareness of the problem and thus of regular enforcement. In other Member States, the perceived high level of PPPs may be due to greater detection resulting from higher levels of controls.

The first identified case of illegal PPPs dates from 2000 when unlabelled unauthorised PPPs were imported into Spain from China. In the subsequent five years, first cases were identified in Germany, Italy, Greece, and the Netherlands and Poland, as well as in pre-accession countries such as Czech Republic, Romania and Slovenia. The scale of the problem appears to have increased significantly between 2006 and 2008; reflected by a higher level of awareness from the industry. On balance, evidence suggests that Competent Authorities generally became aware of the problem after 2008. Evidence suggests the scale of the problem may have increased slightly in recent years.

The main origin of illegal PPPs imported from non-EU countries is China. Other countries such as India, Malaysia, Indonesia, Turkey and the Ukraine, while also identified origins of PPP, are of

[2] 23 of 28 Member States completed this survey
[3] OECD Network on illegal trade of pesticides

considerably less relative importance. Countries bordering the EU which are considered origins of illegal PPPs may be either the countries of formulation, or transit points for shipments from further afield which are on the way to the EU. The formulation of illegal PPPs from legal imports of active substance (a.s.) is an emerging problem, with the resulting PPPs often being placed on the market through misuse of the parallel trade system.

The large north-western European seaports; Antwerp, Hamburg and Rotterdam are the main points of identified entry. Illegal shipments have also been identified as passing through some Mediterranean ports. However, the absence of cases of illegal PPPs passing through other seaports does not preclude the possibility that shipments are being made, but are not being detected due to a low level (or absence) of controls. The ports identified as the main points of entry have also been among the most active ports. Smuggling across land borders is a significant issue in Member States bordering third countries, though it would appear that PPPs smuggled this way are generally not sent onwards for sale in other Member States. Though some cases of smuggling by air have been identified, it would appear to currently be a minor means of entry. This does not preclude it becoming more significant in the future.

Illegal PPPs appear flow fairly freely following entry through large seaports, with the Member State of first arrival rarely the Member State of final destination. There is considerable evidence to suggest that the parallel trade system is misused in order to both move illegal PPPs around the EU and to bring them to market. This is possible due to the differences in the implementation of the requirements to link the marketed parallel-traded product to the reference product batch at the time of sale. The networks involved in formulation of illegal PPPs from a.s., and in illegal parallel trade are complex and cross-border in nature.

There is considerable overlap between the sub-categories of counterfeit and substandard PPPs; both are significant problems. Certain a.s. have emerged as common targets of illegal operators. While the potential profits from patent infringing illegal PPPs are high, evidence suggests that trademark counterfeiting is more common.

Illegal operators use a range of methods to conceal illegal shipments of PPPs. Shipments may also possess certain characteristics which, while not method of concealment per se, may create difficulties for Competent Authorities to take action. Some of the higher risk traits of shipments (based on the extent they are used and the difficulties they pose for authorities to take action) include: goods declared as in-transit; false declarations; and the use of false CN codes. Some traits which, while on balanced were judged to be of medium or low risk due to the extent that they are found or problems they cause, may pose particular difficulties if they are present in conjunction with certain other traits.

While the issue of end users was not examined in detail given the focus of the study is trade, several different methods of distribution of illegal PPPs were identified. There is a likely connection between the method of distribution of illegal PPPs and end user awareness as to the product's legality. Conscious users of illegal PPPs appear to be motivated by cost savings, or reluctance to move away from certain obsolete (no longer authorised) products.

### S1.3.2. Existing national level control measures

The main authorities involved in the control of illegal PPPs in Member States generally include: plant protection product authorities (generally falling under the ministries of agriculture, health or food and consumer protection); customs; and the police. Other authorities such as port authorities may be involved in controls at points of entry.

Differences between Member States in addressing the issue of illegal trade means there is no single uniform method of control at points of entry. However, point of entry controls for declared consignments can generally be broken down into four consecutive stages:

- ***Identification of suspicious shipments***: which be facilitated through the reception of intelligence information, or the searching of certain databases;
- ***Documentary checks***: which will be performed on suspicious shipments to ascertain whether further action is necessary;
- ***Physical checks***: which may involve a physical inspection and sampling, and;
- ***Final decision or action***: options include release of the shipment with or without notification of other authorities, blocking of shipments, and seizure and destruction.

While stopping the entry into the EU of illegal PPPs was considered to be of particularly high importance, controls inside Member States were generally considered an important complementary measure for tackling the issue of illegal PPPs. Under Article 68 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, Member States are required to carry out official controls to ensure compliance with the regulation. Different Member States take different approaches to these controls; however, they generally cover the following three areas:

- ***Marketing***, checks on retailers in all Member States, and other parts of the chain such as manufacturers, repackagers and wholesalers in some Member States;
- ***Composition***, comparison of a PPP's composition as regards its technical specifications to that established in its authorisation, and;
- ***User controls,*** which involve one or more of the following: residue tests, examination of the register of use, water sample pollutant tests, and controls of the method of application.

Under Article 67 of Regulation (EC) No 1107/2009, producers, suppliers, distributors, importers and exporters of PPPs are required to keep records of PPPs which are produced, imported/exported, stored or placed on the market for a period of five years (three years for users). This theoretically results in a one step forwards / backwards traceability system for PPPs. The degree to which this traceability system, in conjunction with any other requirements, can be used for following PPPs through the chain varies between Member States. In some Members States it is considered possible to trace PPPs through the chain. In others, it is considered only partly possible or impossible to trace PPPs once they are on the market.

In addition to the national measures outlined above, some Member State competent authorities have taken further actions. Depending on the Member State, this generally comprises one of more of the

following: a strategic analysis to identify methods of entry of illegal PPPs; a tactical analysis to identify the actors involved; and/or a plan of action.

For its part, the industry has performed co-ordinated actions at EU and national levels. These actions include: awareness raising and information campaigns targeting end users; awareness raising and training for competent authority staff; and interaction with policy makers. In some Member States there may be further, more practical co-operation between the industry and competent authorities. Private operators have also taken action on an individual basis. Anti-counterfeiting measures on packaging; legal actions against illegal operators; and market monitoring in order to identify illegal products are examples of actions taken by individual private operators.

At EU level, certain actions taken by the FVO[4] and OLAF[5] are relevant to illegal PPPs. The FVO has performed audits in some 20 Member States in order to check Member State compliance with relevant EU legislation in the area of PPPs, including most notably the controls and sanctions in place. Member State competent authorities are provided with recommendations following the audit. OLAF, which is the only Commission service with investigative authorities related to goods infringing the intellectual property rights[6], has been involved in some five investigations relating to counterfeit PPPs at EU borders.

Information on the effectiveness of the 28 individual Member State control measures was collected from a variety of different data collection tools. Drawing EU-wide conclusions from this information is difficult given that control measures differ between Member States. While the lack of harmonisation is deemed to play a significant role in these national differences, the awareness or interest of certain competent authorities and the resources available to them impact individual Member State measures and their effectiveness. In many cases, resources appear to be a significant factor that constrains the effectiveness of controls. Despite this, the experience of certain Member States suggests that it is possible for national competent authorities to ensure effective control measures. This does not preclude the fact that the present lack of EU harmonisation may negatively impact the effectiveness of the whole EU control system.

The effectiveness of sanctions also varies between Member States. This effectiveness comprises two elements; firstly, the sanctions themselves (whether they are a sufficient deterrent) and secondly the extent to which sanctions are applied. There is evidence to suggest that sanctions are not effective in some Member States due to a failure of one or both of the aforementioned elements.

### S1.3.3. Assessment of the regulatory framework and potential complementary measures

By their very nature, PPPs are largely regulated goods. Within the EU, they are subject to several safety requirements that take into account, and aim at reducing, their impact on human, plant health and the environment. Furthermore, as they are often the ultimate result of industry research and

[4] European Commission Food and Veterinary Office
[5] European Anti-Fraud Office
[6] OLAF's mandate is restricted to counterfeit goods at EU borders. As a result, it has not been involved in the issue of substandard PPPs at borders or in relation to illegal PPPs of any kind inside EU territory.

development, PPPs may also give rise to intellectual property rights, such as patents and trademarks, protected under either EU or national law.

Against this background, in order to evaluate the adequacy of the current regulatory framework of relevance for the illegal trade of PPPs, the study identified and examined a wide range of legislative acts at EU level, including, among others:

- Regulation (EC) No 1107/2009 on the placing of PPPs on the market and its implementing measures;
- Framework Directive 2009/128/EC on sustainable use of pesticides;
- Regulation (EC) No 882/2004 on official controls on food and feed;
- Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH Regulation') as a majority of PPPs are of chemical nature;
- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging ('CLP Regulation');
- Regulation (EC) No 649/2012 on the export and import of hazardous chemicals;
- Regulation (EU) No 608/2013 on enforcement of intellectual property rights by customs;
- Directive 2004/48/EC on enforcement of intellectual property rights

Overall, the main findings indicate that the EU framework under consideration is perceived to be not entirely satisfactory. In this context, Regulation (EC) No 1107/2009 on the placing of PPPs on the market appears the legislative act that would need more improvements in order to strengthen both EU and MS capacity to address illegal trade in this area. Indeed, a number of factors would hamper its effectiveness at present, including, for instance, the current degree of harmonisation, the need of greater legal certainty in some areas, the existence of a few legislative gaps and the overall complexity of the authorisation system that the Regulation establishes.

As regards the level of harmonisation achieved by Regulation (EC) No 1107/2009, stakeholders generally tend to consider it low due to the fact that specific implementing measures on official controls pursuant to Article 68 of that Regulation have not been established yet. In particular, types, place and frequency of official controls on PPPs intended for import into the EU appear to vary significantly between EU Member States, ranging from the existence of well-structured and risk-based import control policies in certain national contexts to the a minimum level of controls in others. Whilst the findings of the study point out that a higher degree of harmonisation across the EU would be needed in order to counteract illegal trade of PPPs more effectively, they nevertheless show as well that the current regulatory framework has not prevented some Member States from taking effective action.

With reference to legal certainty, Regulation No (EC) 1107/2009 presents a few ambiguities that would ultimately affect the way in which its provisions are implemented at national level. In particular, the interpretation of the definition of PPPs enshrined in Article 2 par. 1 of the Regulation ('*products in the form in which they are supplied to user*') is interpreted by some Member States as not encompassing, for instance, PPPs contained in bulks or active substances as such. Provisions concerning goods in transit through a Member State but destined to another Member State or a non-

EU country are equally subject to different interpretations, which ultimately result in diverging national enforcement practices. Overall, the current lack of legal certainty around key definitions is considered by stakeholders as a loophole that some unscrupulous operators may try to exploit to their advantage.

Despite the existence of provisions and guidance governing parallel trade under Article 52 of Regulation (EC) No 1107/2009, evidence collected throughout the study points out to their widespread misuse, in addition to lack of consistent enforcement across the EU. In particular, the lack of uniform approach to repackaging and the sanctions for cases of misuse stand out as the two major shortcomings in this context. For this reason, several stakeholders consider it necessary to rethink completely the current framework for parallel trade. From this perspective, the upcoming review of the EU authorisation system for PPPs under Regulation (EC) No 1107/2009 may offer an opportunity to address the pitfalls identified by the study, taking into account the wider legal context in which trade of PPPs takes place.

With regard to other EU legislation relevant for illegal trade of PPPs, the study reveals that some Member States have doubts about the full applicability of Regulation (EC) No 882/2004 on official controls on food and feed to certain aspects of PPPs, such as the analysis of product composition. In any event, the ongoing review of that Regulation could address the referred uncertainties by fully integrating both PPPs and active substances in the scope of the future legislation to be adopted. On the other hand, EU chemical legislation is generally considered as not posing any major obstacle to the fight against illegal trade of PPPs, offering, instead, some good examples of cooperation and joint projects between enforcement authorities at national level.

The study has also closely examined the experience of those Member States that are actively fighting against illegal trade of PPPs. In most cases it emerges that the level of awareness that competent authorities have about illegal trade of PPPs together with the resources that are made available for addressing it are key factors for the success of initiatives undertaken in this area. Considering the current varying levels of awareness about illegal trade of PPPs across Member States, this topic could be dealt more systematically and more in depth in the context of relevant trainings for staff of competent authorities and private operators.

Member States are generally of the view the absence of EU centralised database gathering all national PPPs authorisations - similarly to what is currently in place for active substances – is the most pressing legislative gap that needs to be addressed. Whilst some private databases exist at present, their use appears to be relatively limited because of the lack of an official dimension and the costs incurred for accessing relevant information. The establishment of an EU Reference Laboratory for product composition is seen as another step that could be taken with a view to ensuring a level playing field as regards laboratory capacity across the EU and, more in general, effective coordination of laboratory activities in this area.

Finally, with regard to international cooperation, whilst some of the current fora, such as the OECD ONIP Working Group or the thematic workshops promoted under the auspices of EUROPOL/OHIM, provide good opportunities to exchange information and discuss practical cases involving multiple countries, there seems to be room for greater leadership by the European Commission. In particular,

this latter might play a key role in establishing a dialogue with those non-EU countries from where illegal PPPs originate with a view to identifying competent authorities in those countries and, where possible, agreeing with them upon shared solutions to address illegal trade.

Based on the above, the study formulates some seventeen recommendations, both of legislative and non-legislative nature. Amongst those recommendations, the following ones stand out as particularly relevant to the objectives of the study:

- ***Furthering harmonisation*** by adopting implementing rules for official controls on PPPs to be performed on the market as well as at EU entry points;
- ***Increasing legal certainty*** by clarifying those key definitions in PPPs-related legislation that the study has identified as currently being subject to different interpretations by EU Member States;
- ***Bridging legislative gaps***, namely by establishing a EU database for PPPs authorisation;
- ***Evaluating complexity*** by reviewing EU provisions on parallel trade in the context of the planned review of the EU legal framework for PPPs authorisation;
- ***Enhancing awareness*** by disseminating knowledge and building capacity in relation to illegal trade of PPPs via relevant EU and national training;
- ***Building international cooperation,*** by developing long-term international cooperation with those non-EU countries that are most frequently pointed out as a source of illegal PPPs.