

# Regulatory instruments against the trade of illegal and counterfeit pesticides



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# Regulatory instruments against the trade of illegal and counterfeit pesticides

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## Summary

This review article is providing an overview of the legislations, competences and procedures of international, European and their local Member State counterparts (in this article, mainly in Belgium) that are intervening in the fight against illegal and counterfeit pesticides : the protection of the intellectual property rights (patents, supplementary protection certificates, trade marks, designs...), the approval of active substances and the placing of the plant protection products on the European market, the classification and labelling, the transport of dangerous goods, the information on the supply chain, the control procedures and legal prosecution (customs, police, justice, food safety agencies), and the development of technical guidances for the control. The relevant activities of private actors are also described.

On one hand, this overview demonstrates the difficulties to gather the administrative information e.g. on a particular plant protection product, on a particular company or in a particular country, due to the complexity of the legislations, guidance documents and procedures, the absence of interconnections between the administrative databases (authorisations, trade marks, patents, actors at different levels of the supply chain, ...), the presence of numerous international, European and national competent authorities involved in the struggle against the illegal trade of pesticides, the diversity of remit and goals of these authorities. On the other hand, it also demonstrates that several types of rights are breached when pesticides are illegally traded. The legal actions against these practices would be better tailored by referring precisely to each of the rights that are breached and not to counterfeiting in absolute terms.

The present review article has been prepared in the framework of the DEPIPEST project, an Innovative screening methodology by vibrational spectroscopy (MIR, RAMAN) and confirmation by chromatographic methods (GC, LC, MS) of counterfeit pesticide formulations.

This project has the aim of demonstrating the feasibility of a coordinated fight against counterfeit pesticides which would be based on the development of MIR and RAMAN spectroscopy methods and the establishment of a spectral database of legally authorised formulations in Belgium, as well as on the development of screening / profiling chromatographic methods.

The research that yielded these results was funded by the Belgian Federal Public Service of Health, Food Chain Safety and Environment through the contract RF22/6354.

## Introduction

### **Why is it difficult to fight against illegal trade and counterfeiting of pesticides ?**

Counterfeit and illegal pesticides represent a considerable threat to the health of users and consumers, and the environment. They cause damage to crops (loss of yield, non-conformity of the foodstuffs produced) since products that have not passed the strict screening procedure for active substance approval and formulation authorisation are placed on the market. They constitute an infringement of intellectual property rights and generate direct losses for the phytopharmaceutical industry as well as indirect losses for other sectors, for public revenues and for employment.

Illegal trade and counterfeiting are difficult to fight because the fight is organized by numerous European and national organizations; it requires significant coordination between these organizations and multiple skills (legislations, customs, chemistry, agriculture, environment, etc.). The European single market implies a reduction in internal border controls that could favor illegal trade.

The authorisation of pesticide formulations is still carried out at the national level, despite an increasing harmonization of regulatory procedures at European Union level. The sharing of methodologies and experience between control laboratories should be amplified. There are currently no quick ways to facilitate the screening of samples for the control of pesticide formulations. Current techniques are expensive and laborious. Few samples are controlled. Control is carried out on a case-by-case basis or on the basis of denunciation or suspicion.

The impact of the trade of illegal and counterfeit pesticides in the European Union is well described (European Commission DG Health and Food Safety, 2015; EUIPO, 2017).

## What is our challenge ?

The purpose of the discussion and challenge ahead is to define the procedural and legal instruments which are available for an effective prosecution of counterfeit and illegal pesticide trade at European Union level.

In the framework of our research project of developing rapid spectroscopy screening methodologies and screening / profiling chromatographic methods for pesticide formulations (DEPIPEST), the aim is to define which administrative information should be gathered on individual plant protection products, how to validate analytical methods according to standards which are acceptable in regulatory / judiciary procedures, how to provide analytical results that can be considered as judicial evidence and how to prepare « dossiers » appropriately.

This review article may be considered as the starting point of a guidance document for the stakeholders that are intervening in the fight against illegal and counterfeit pesticides.

1 - At first look, plant protection products are bad smelling liquids in a plastic bottle. In fact, they are complex objects, composed of several constituents, packaged in special containers, bearing different markings and official mentions. Which elements should be checked on a bottle/package of plant protection product taken during a control?

2 - Plant protection products are regulated by several institutions at international, European or Member state level, according to specific legislations and guidance documents, by means of complex administrative procedures. These procedures are leading to various types of registrations (patent, mark, authorisation, permit, marking, ...) by official bodies. These institutions are dealing with the protection of the intellectual property rights (patents, supplementary protection certificates, trade marks, designs, ...), the approval of active substances and the placing of the plant protection products on the European market, the classification and labelling, the transport of dangerous goods. How do these regulatory institutions work? How do we gather the regulatory information on a particular plant protection product?

3 - Plant protection products are subject to control procedures and prosecution of the law infringements by the customs, police, justice, food safety agencies. The collection of data on the plant protection supply chain, and development of technical guidances for the control (analytical or administrative) are an important part of the control procedures. How do these control institutions work? Which guidance documents are relevant? Which check lists are relevant?

4 - The private companies and their associations are active in the protection of their own plant protection products. What are their actions in the struggle against the trade of illegal and counterfeit plant protection products? How the regulatory and control institutions could better cooperate with the private companies?

5 - The bibliography contains the references of the relevant legislations, guidance documents, manuals as well as the links to databases of regulatory information.

## **Which administrative information should be available when launching an official control ?**

As tight schedules are mandatory in the controls and judiciary procedures that could bring effective prosecution of illegal and counterfeit pesticide products, it is obvious for everyone that technical operations of control such as sampling, chemical analysis, determination of physical-chemical properties and reporting of the results, ... on a pesticide collected during a control need to be as fast as possible. However, collecting and checking the administrative information on this pesticide, and presenting all the results as a judiciary evidence is just as crucial.

In order to facilitate these procedures, the up to date administrative information on a particular plant protection product should be readily available. This information might be archived, either via an official portal to existing databases easily accessible to controlling authorities, or be archived by each manufacturer for its own plant protection products. In this last case, the information on the legal plant protection products should be submitted on request to the controlling authorities, i.e. for comparison with the suspected plant protection product sampled during controls.

*“Information that should be readily available”* has been highlighted in the text.

## 1. Building blocks of a plant protection product that might be controlled

The following schematic view is listing the different building blocks characterizing a Plant Protection Product (PPP) that might be checked during a control. Each term (mainly taken from EU regulation 1107/2009) is further explained below.

Packaging			
	content, size, format, dimensions, nature of the packaging material, design		
	closures and seals, pouring, measuring, anti-splashing,... devices		
	safety seal, QR or bar codes, hologram with company logo		
Preparation			
Substances	Active substances	Impurities	Significant impurities
			Relevant impurities
	Safeners		
	Synergists		
Co-formulants			
Label is based on information derived from application of the following regulations :			
	Intellectual property rights (trade mark, design, ...)		
	Placing of the PPP on the market		
	Classification and labelling		
	Transport of dangerous goods		

### ***Plant protection products (PPP)***

The 'plant protection products' are in the form in which they are supplied to the user. They are preparations consisting of or containing active substances, safeners or synergists. They also contain co-formulants. Their intended uses are the protection of plants and plant products against harmful organisms (insecticides, acaricides, nematocides, molluscicides, fungicides,...), the destruction of undesired plants and plant parts (herbicides, anti-sprouting agents, ...), the modification of life processes of plants (plant growth regulators, ...).

The nature and content of the active substances, safeners and synergists in the plant protection product is a publicly available information which is mentioned on the product label. It defines the intended uses of the product. The information on the complete composition of a plant protection product i.e. the nature and content of the co-formulants is considered as confidential.

### ***Substances***

'substances' means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

### ***Preparations***

'preparations' means mixtures or solutions composed of two or more substances intended for use as a plant protection product or as an adjuvant.

### ***Active substances***

Active substances, such as insecticides, acaricides, fungicides, herbicides, ..., are, either chemical substances, or micro-organisms (not further discussed in our research project), having general or specific action against harmful organisms (insects, mites, fungi,...) or on plants (weeds,..), parts of plants or plant products.

### ***Safeners***

Substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants.

### ***Synergists***

Substances or preparations which, while showing no or only weak activity, can give enhanced activity to the active substance(s) in a plant protection product.

### ***Co-formulants***

Substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, are referred to as 'co-formulants'. Their functions are antioxidant, emetic, dispersing agent, emulsifier, dye, antifreeze, adhesive (sticker), thickener, anticlumping agent, preservative, solvent, free-flowing agent, wetting agent, perfume, deodorant, propellant, repellent, stabilizer, carrier, lubricant, antifoaming agent, buffer, binder, ...

The co-formulants are key components of the plant protection product since they define its formulation type (e.g. suspension concentrate, water dispersible granule, ...). They also define its physical, chemical and technical properties and its ability to be handled safely by the user, to be stored and transported, to be spread efficiently on the crops. The co-formulants can enhance the efficiency of the active substances contained in the plant protection products.

In order to avoid that plant protection products may contain co-formulants with unfavorable environmental or (eco)toxicological profile, a list of co-formulants which should not be included in plant protection products has been created (Annex III to EU regulation 1107/2009).

Besides, the Federal Office of Consumer Protection and Food Safety (BVL in Germany) has established a positive listing of the co-formulants that are authorised in plant protection products. EFSA in collaboration with ECHA and DG SANTE has recently published a data collection on co-formulants used in representative plant protection formulations (EFSA, 2022).

### ***Adjuvants***

Substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties.

### ***Specification of the active substance, impurity level***

The active substances contained in a plant protection product can be produced by different manufacturing processes (different manufacturing plants, different origins), leading to differences in specifications i.e. differences in the purity of the technical active substance, differences in the nature and content level of manufacturing impurities. Such differences may lead to different (eco)toxicological profiles of the active substance origins.

Significant impurities are all the impurities that are present in the technical active substance at concentration of 1 g/kg or more.

Relevant impurities are impurities that are particularly undesirable because of their toxicological, ecotoxicological or environmental properties. Acceptable levels of relevant impurities are set in the approval decision of each active substance.

The assessment of the equivalence of technical materials of substances regulated under EU regulation 1107/2009 is described in a European guidance document (SANCO/10597/2003).

### ***Packagings***

The packagings of plant protection products are objects with several functions :

The packaging should limit as much as possible the exposure of the user and the environment to the plant protection product. The packaging should ensure the conservation of the plant protection product (and container) during several years, at temperatures conditions reflecting practical storage conditions. The packagings should be sufficiently solid to resist to transportation, storage and handling.

The packagings have a function of recognition and reputation for the phytopharmaceutical company (logo, design, dimensions, colours of the container, ...). Besides, the packaging has a function of protection against counterfeiting (safety seal, QR or bar codes, hologram with company logo, ...).

The description of the packaging should be as detailed as possible in order to allow its recognition during control : content, size, format, dimensions, nature of the packaging materials (e.g. in the case of multi-layer or co-extruded packaging), closures and seals, details of any application device (pouring, measuring, anti-splashing,...) included with packaging, whether the container is refillable/returnable, outer packaging/sales pack.

Several regulations impose official testings in order to demonstrate the compliance of the packagings.

**Labels**

The information that should be mentioned on the label is derived from a complex regulatory process : The technical and scientific regulatory studies that have been generated by the authorisation holder are submitted to several competent regulatory authorities at Member State and European Union levels which assess them scientifically and administratively. They will be further described in the text. These assessments lead to various types of «registrations /authorisations numbers/ markings,... » that are translated as mentions on the label of the plant protection product.

## 2. The regulatory procedures and institutions

### Which rights are violated when a pesticide is marketed illegally?

Several types of rights are breached when pesticides are illegally traded. The legal actions against these practices would be better tailored by referring precisely to each of the rights that are breached and not to counterfeiting in absolute terms :

- Infringements of the property rights of the proprietor company (patent, complementary certificate, trade mark, design,...). Trade by a criminal organisation, trade via internet and trade of PPP having an impact on health are aggravating factors to the infringements of the property rights.
- Unlawful acquisition, use or disclosure of a trade secret.
- Placing non-authorised plant protection products on the market.
  - Putting at risk human health (consumers, workers, operators).
  - Putting at risk the environment and the non-target organisms.
  - Product quality deception (active substance nature and content, impurity level, coformulant nature and content, packaging,...) with an impact on the biological efficacy (loss of efficacy, damage to the crop) and on the compliance of the food produced, e.g. non compliance with the Maximum Residue Limits (MRL).
  - Non-compliance of the illegal product with the standards and the regulatory procedures to which the authentic product is subject.
  - Falsification of official documents (e.g. PPP authorisations, parallel trade permits, ...).
- Putting at risk the health and security of the personnel involved in the transport of dangerous goods and Material Safety Data Sheets recipients (carriers, distributors, firefighters, end-users,...).
  - Transport of dangerous products in unapproved packagings
  - Falsification of transport documents.

### A single definition of counterfeiting?

The lack of a unique definition of illegal or counterfeit pesticide is immediately popping up:

- An illegal pesticide may be defined as “any pesticide which, for whatever reason, is not legal in the country of destination. This includes the sub categories of counterfeits, fakes, obsolete and unauthorised pesticides” (OECD, 2022).
- A counterfeit pesticide may also be defined as a non standard / adulterated / falsely marked pesticide. Besides, a definition for fake pesticide is also proposed (OSCE - Malkov et al., 2015).
- The EU regulation 608/2013 concerning customs enforcement of intellectual property rights proposed definitions for counterfeit goods, pirated goods and goods suspected of infringing an intellectual property right.
- CropLife Europe defines three categories : the counterfeits, the illegal products and the illegal parallel trade products (CropLife Europe website).
- Finally, the term « contrefaçon » in French is generally translated as « infringement of intellectual property right », e.g. in EU regulation 2017/1001.

## **Which regulatory instruments are available in the struggle against illegal and counterfeit pesticides ?**

For each domain, an attempt has been made to identify the relevant elements of the legislations and guidance documents, the practical procedures that could be helpful in the detection and the actions against the illegal trade, the institutions at European Union level and Member State level (Belgium) and the addresses of databases containing the regulatory information. A summary table has been prepared in order to help the reader.

It was not intended to present an exhaustive view of the activities of each institution but to highlight key areas that could be useful in the domains of intellectual property rights, active substance approval, plant protection product authorisation, classification and labelling, and transport of dangerous goods.

## Intellectual property rights and authorisations at a glance

Domains	Types of rights, authorisations	Legislations	Institutions (at international level, at Member State level)	Databases
The enforcement of intellectual property rights	Patents	EU Directive 2004/48/EC	World Intellectual Property Organization (WIPO)	European Patent Office (EPO) : Federated European Patent Register (Federated Register).  Espacenet database (most ancient patents)  Google Patents
		EU regulations 1257/2012 and 1260/2012 on the Unitary patent system	European Commission → Directorate General Internal Market, Industry, Entrepreneurship and SMEs → European Patent Office (EPO)	
			Benelux Office for Intellectual Property (BOIP) Federal Public Service Economy → Belgian Intellectual Property Office (IPObel)	
	Supplementary protection certificates	EU Regulation 1610/96		BPP-eRegister Espacenet database
	Trade marks	EU regulation 2017/1001 on the European Union trade mark EU regulation 2018/625 EU regulation 2018/626 EU directive 2015/2436	European Union Intellectual Property Office (EUIPO) → The European Observatory on Infringements of Intellectual Property Rights	EUIPO databases : Esearch plus, TMview
			Benelux Office for Intellectual Property (BOIP)	
Designs	EU directive 98/71 on designs at MS level EU regulation 6/2002 on Community designs	Benelux Office for Intellectual Property (BOIP)	World Intellectual Property Organization (WIPO) : International Designs Bulletin, the Global Design Database and the Hague Express Database European Union Intellectual Property Network : the DesignView database	
Trade secret	EU directive 2016/943	European Commission → Directorate General Internal Market, Industry, Entrepreneurship and SMEs		
		Federal Public Service Economy		

## Intellectual property rights and authorisations at a glance

Domains	Types of rights, authorisations	Legislations	Institutions (at international level, at Member State level)	Databases
Placing of plant protection products on the European market	Approval of active substances at European Union level	EU regulation 1107/2009 EU regulation 540/2011 EU regulation 547/2011 EU regulation 283/2013 EU regulation 2021/383 ....	European Commission → DG SANTE  EFSA Federal Public Service Public Health → Service Plant Protection Products and Fertilizers	EU Pesticides Database Pesticides Properties Database (PPDB)
		Placing on the market of plant protection products at Member State level	EU regulation 284/2013  Guidance document concerning the parallel trade of plant protection products under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection product on the market and repealing Council Directives 79/117/EEC and 91/414/EEC	
		Arrêté royal (AR) du 28 février 1994 relatif à la conservation, à la mise sur le marché et à l'utilisation des pesticides à usage agricole  Lignes directrices pour les permis de commerce parallèle (AFSCA and FPS Public Health)	Federal Public Service Public Health → Service Plant Protection Products and Fertilizers	National databases of the authorisations of plant protection products (Phytoweb, E-phy, Ctgb databank, BVL database, ...)

Domains	Types of rights, authorisations	Legislations	Institutions (at international level, at Member State level)	Databases
Classification and labelling	-	EU regulation 1272/2008 ....	European Chemicals Agency (ECHA) implementation of the REACH, Classification Labelling Packaging (CLP) and Prior Information Consent Regulations (PIC) regulations, as well as, to ensure consistency across the EU.	
			Federal Public Service Public Health → Service Plant Protection Products and Fertilizers  National Inspectorates in each EU MS : enforcement of the legislations on chemical safety (REACH, CLP, PIC,...).	
Packaging and transport of dangerous goods	-	EU regulation 2022/1999	The European Committee for Standardization Technical Committee 261	Bundesanstalt für Materialforschung und -prüfung (BAM) database
			Federal Public Service Mobility and Transport : RID (rail), IMDG Code (boat), ICAO Technical Instructions (air), ADR multimodal aspects of transport (including road). The three Regions : ADR (road) and inland waterways transport.  Institut Belge de l'Emballage	

→ : indicates the hierarchical link between two institutions

## 2.1 Intellectual property rights

Companies that have developed, after a long and costly research, a new technical process or a new product (active substance, plant protection product) that can be marketed generally wish to exclusively use and sell their invention during a certain time period and to prohibit others from using the invention during that period. Protection of the creation can be obtained by applying for intellectual property rights (IP rights) to an official body registering the invention. The counterpart of this proprietary right is the publication of the invention and the payment of an annual fee.

The following intellectual rights that might be relevant for pesticides are further described : patent and supplementary protection certificate for plant protection products, trade mark, design.

Companies may also choose to protect their business by a policy of undisclosed know-how and business information (trade secrets). This point is further described.

Protection of copyright and domain names might be relevant in the case of attacks against the information which is available on the website of a phytopharmaceutical company. Those intellectual property rights are not further described in this article.

### 2.1.1 Patent right

#### ***Legislation***

The EU Directive 2004/48 sets the general principles of the enforcement of all types of intellectual property rights at European Union level, i.e. the need to combine a balanced protection of the innovation without distortion of concurrence, the need to respect trade agreements taken at global level, and to reduce the disparities between the legal systems of the Member States without intervention in those legal systems. It also establishes principles of measures, procedures and remedies to enforce intellectual property rights : the persons entitled to apply for the application of the measures, procedures and remedies (persons, and possibly professional organizations), the presentation of evidence, the measures for preserving evidence (a translation of « saisie-contrefaçon » and « saisie-description » in the EU law), the right of information (the publication by judicial authorities of information on distribution networks and infringers), the provisional and precautionary measures (interlocutory injunction intended to prevent infringements, seizure of suspected goods, ...), corrective measures (recall, removal of channels of commerce, destruction of counterfeited goods), injunctions (injunctions aimed at prohibiting the continuation of an infringement), alternative measures (pecuniary compensation), damages and legal costs, publication of judicial decisions, sanctions by the Member States (beside civil and administrative measures, MS may apply criminal sanctions), codes of conduct (the industry should develop codes of conduct in order to take an active part in the fight against piracy and counterfeiting), exchange of information and correspondents (exchange of information between competent authorities in each MS and the Commission).

The national legislations transposing this directive are the actual pieces of laws that should be considered in a practical case. The legislations of the Member States are not yet harmonized and consequently the actual legal protection level in each Member State is not uniform. The World Intellectual Property Organization (WIPO) is maintaining a database of legislations relevant to each of its Member States.

Two EU regulations (1257/2012, 1260/2012) provide the legal framework for the Unitary Patent system. Some national measures have been taken in the the EU Member States participating to this legal framework and to the Unified Patent Court.

Two questions are discussed further in the case of plant protection product patent : how to demonstrate an infringement of the proprietary rights ? Which judiciary procedures are available ?

### ***Demonstration of an infringement of the patent rights***

The European Patent Office is maintaining on its website the relevant legal texts and guidelines for examination and search of patents. The guidelines for search, the European patent application (content of the patent, sufficiency of disclosure, claims, unity of invention, priority) and the patentability (inventions, industrial application, state of the art, novelty, inventive step) are particularly important from a technical point of view to define an infringement of property rights. Typically, patents are dealing with a process, a product or an apparatus. Elements like alternative manufacturing process, information on intermediate and raw materials, analytical methods included in the patent, and expiry date of the patent have to be carefully checked.

The patents for plant protection products are dealing with the following items (*Information that should be readily available*):

- Chemical structure of new active substance, possibly with alternative radicals,
- Manufacturing process of the active substance,
- Formulations based on the combination of a new active substance with several existing substances,
- new combinations of active substances,
- new salts/esters,
- new uses (new pests, new groups of pests, new application rates).

### ***Judiciary procedures***

The means of combating counterfeiting are diverse :

- The proprietor of property rights who is the victim of counterfeiting can sue the infringer in a civil or criminal court. For this, it is recommended for the proprietor of property rights to take measures for preserving evidence of the counterfeit product. This could be achieved by « saisie-contrefaçon » or « saisie-description » (see also paragraph below). The judiciary procedures against counterfeiters are complex. It is therefore advised to contact an expert specialized in IP rights and a lawyer since the litigation procedure occurs before specific courts. In the event of international counterfeiting, the conflicts of laws and jurisdictions must be resolved.
- Alternative dispute resolution is another way of acting against counterfeiters.
- Finally, the customs can block goods suspected of infringing property rights. In this case, the proprietor of the IP rights is invited to cooperate with the customs administration (Marino, 2020, FPS Economy, 2022).

Compliance with the formal and practical requirements of a seizure by bailiff, possibly accompanied by experts, is particularly important to secure a court case. Two types of seizures are feasible : « saisie-contrefaçon » : seizure of the counterfeit products or « saisie-description » : seizure of documents and samples for analysis. In both cases, the deadlines for analysis are limited.

### ***Institutions***

Official patent offices have been established in each country in the world. As the patents are valid in the country of issuing, verification of the validity of a particular patent on a particular territory is a complex task.

The World Intellectual Property Organization (WIPO) is an agency of the United Nations. It is the global forum for intellectual property services.

In Europe, each Member State has its own intellectual property offices issuing national patents. Additionally, the European Patent Office (EPO) is examining patent applications and granting European patents (not a unique European patent but a bunch of patents valid in several countries). This office also provides patent information and training services. The Boards of Appeal review the contested decisions of the EPO. The Unitary Patent and the Unified Patent Court have the aim to further reinforce the centralised European patent granting system.

The situation at Belgian level is even more complex :

- The Belgian Intellectual Property Office (IPObel) is a public service of the federal government. IPObel is part of the Federal Public Service Economy. It handles all questions on intellectual property in Belgium. The office is in charge of registering, granting and publishing patents and the supplementary protection certificates for plant protection products. IPObel actively participates in developing and adapting Belgian regulations, treaties and national, European and international intellectual property agreements.
- The Benelux Office for Intellectual Property (BOIP) is issuing and handling Benelux trademarks, models and designs.

The patent offices are official bodies which are depending, more or less tightly, from the public services administrations; in Europe, from the Directorate General Internal Market, Industry, Entrepreneurship and SMEs at the European Commission; in Belgium, from the Federal Public Service Economy, Small and medium-sized enterprises, Self-employed and Energy (FPS Economy).

### ***Databases***

Several organizations are maintaining databases on patent registrations (*Information that should be readily available*):

- The European Patent Office (EPO) is maintaining the Federated European Patent Register (Federated Register).
- The Benelux Organisation for Intellectual Property and the National offices of the three countries are maintaining the Benelux Patent Platform.
- The Espacenet database is dedicated to the most ancient patents.
- The information on the patents can also be searched via Google Patents.

## **2.1.2 Supplementary protection certificate for plant protection product**

### ***Legislation***

The EU regulation No 1610/96 establishes rules on the supplementary protection certificate for plant protection products with the aim to extend the period of effective protection under the patent. The goal of the certificate is to compensate the high research and development investments supported by the original data holder by a sufficient exclusive marketing period and to compensate the loss of patent protection that occurs between the filing of an application

for a patent of a new plant protection product and the effective authorisation of the plant protection product by the regulatory authorities. In order to balance the interests of the major companies and «off patent » companies, the regulation establishes an extension of the patent right by a maximum of five years.

The supplementary protection certificate is an intellectual property right which is similar to the basic patent (registration by an official body, publication, annual fee, ...).

### **Procedures**

Detailed procedural guidances are provided by the patent offices at national or international level (Belgium, Benelux, ...). The main elements of the request of supplementary protection certificates are the details of the basic patent and of the first authorisation of the plant protection product in the country.

### **Databases**

The information on the supplementary protection certificates is available on the BPP-eRegister and the Espacenet database. (*Information that should be readily available*)

## **2.1.3 Trade mark right**

### **Legislation**

Trade mark protection in each Member State coexists with trade mark protection at European Union level ('EU trade marks'). Both systems have their own advantages. The regulations that govern the European Union trade mark system as well as the European directives that are progressively harmonizing the laws of the EU Member States relating to national trade marks are in constant evolution. The trade mark property right is established by registration, i.e. in the Register of European Union trademarks, managed by the European Union Intellectual Property Office, or in national registers for the national trade marks.

The EU regulation 2017/1001 codifies the rules for the European Union trade mark. This procedural system provides a uniform protection of the trade mark throughout the entire area of the Union.

The EU regulations 2018/625 and 2018/626 are completing some procedural rules of regulation 2017/1001.

The EU directive 2015/2436 has the aim of approximating the laws of the Member States relating to national trade marks not only for the provisions of the law itself but also for the procedures which are applied at Member State level.

### **Demonstration of an infringement of trade mark rights**

Goods and services in respect of which trade mark registration is applied for are classified according to the Nice Classification, an international system of classification containing 45 classes. Subclasses are presented in the TMclass database.

Different types of trade marks for goods are relevant for plant protection products : word mark (the most frequent marks), figurative mark, 3D shape mark (e.g. some packagings are specific to one company), position mark, pattern mark, colour mark and hologram mark.

According to article 33 of EU regulation 2017/1001, the goods and services for which the protection of the trade mark is sought shall be identified by the applicant with sufficient clarity and precision to enable the competent authorities and economic operators, on that sole basis, to determine the extent of the protection sought. However, in practice, the situation is rather

confusing. Major phytopharmaceutical companies market the same formulation with several trade names as reference product, second commercial names, or resale names. Second name products are not always mentioned on the website of the company. These product names may refer to the authorisation of the product in another country within the EU or outside the EU. The numerous second names of one reference product may refer to the same authorisation number. Additionally, distributors may import the formulation via a parallel trade permit within the EU. In this case the formulation name can be the same as the reference product in the country of origin, slightly different or totally different.

The definition of the facts and the demonstration in front of a court of an infringement to the proprietary rights are not straightforward and can lead to legal uncertainty, i.e. it is not always possible to predict the outcome of a court case on the basis of the actual infringements facts. Lawyers and Intellectual Property experts (Rouquié, 2022; Marino, 2020) are discussing these issues. A short description of the legal principles which are applied in the definition of infringements of proprietary rights is proposed below.

The articles of the regulations related to the rights conferred by an EU or national trade mark (article 9) and to the right to prohibit preparatory acts in relation to the use of packaging or labels, tags, security and authenticity features, ... (article 10) are not only dealing with the rights conferred to the proprietor of a trade mark. They are also important in the description of infringements : which activities are considered as infringement (ex : affixing the trade mark to the product or its packaging, putting the product on the market, importing, exporting, ...), whether the infringed trade mark is identical or similar (and at which level) to the original trade mark, whether the infringed product is identical or similar (and at which level) to the original product, whether there is a likelihood of confusion on the part of the public (and consequently, the need to define this public).

The proprietor of a trade mark may act in an infringement procedure when three conditions are fulfilled together:

(1) his trade mark has been used without his authorisation in the business life;

(2) his trade mark has been used in the function of a mark;

The main function of a trade mark is the function of origin (identifying the source of the good to a particular proprietor company and allowing the consumer to recognize it from the competitor's goods without any confusion). Lawyers identify several other functions such as the functions of communication, advertisement, or investment.

(3) his use causes a risk of confusion on the origin of the goods.

The following elements have to be assessed, on one side, the similarity between the trademarks and, on another side, the similarity between the original product and the counterfeit product. Finally, the risk of confusion must be assessed by a global method.

This assessment must be done, taking into consideration the average knowledge level of a theoretical end-user of potentially counterfeit products. Two types of pesticide user can be defined : the professional user (professional farmer, professional gardening enterprise, ...) has a technical knowledge on the use and the risks related to pesticides (certificate in EU directive 2009/128/EC; phytolice in Arrêté royal, March 19, 2013). He has legal access to plant protection products for the professionals. His professional activity (register of PPP uses, management of the spraying equipments, production of agricultural commodities for sale) is subject to various controls, for example, by the food safety agency. It can be assumed that a skilled professional user could suspect a change of the aspect of a product he uses regularly. However, a difference of composition may only be detected by chemical analysis. A difference

of biological efficacy in the field is hardly detectable and could not be allocated to a particular pesticide.

The amateur user has no specific knowledge on the use and the risks related to pesticides. His main source of information on a PPP is the product label. He has legal access to plant protection products with reduced risk.

### ***Institutions***

#### ***The European Union Intellectual Property Office***

The European Union Intellectual Property Office (EUIPO) is in charge of tasks of supporting the activities of national authorities, the private sector and the Union institutions in the fight against infringements of the intellectual property rights covered by EU Directive 2004/48/EC (patents).

The EUIPO is not directly involved in the individual operations or investigations carried out by the competent authorities in the Member States.

EUIPO also works with the intellectual property offices of the EU Member States and international partners to offer a similar registration experience for trade marks and designs across Europe and the world.

The EUIPO's current trade mark and design practice is reflected in a series of Guidelines for Examination that are intended to help both users and staff in charge of the various procedures.

Within EUIPO, the European Observatory on Infringements of Intellectual Property Rights develops tools and promotes best practice to enhance protection of this critical asset for companies and individuals. The observatory is a platform-based body that brings public and private sector experts together in a dynamic exchange network. The Observatory works as a think-tank that gathers, monitors and reports crucial information to assist policy makers and authorities engaged in protecting and enforcing IP rights.

The IP Enforcement Portal is an EU platform for IPR enforcement matters. It serves as a secure communication tool between all related parties: rights holders (and/or their legal representatives), EU enforcement authorities, the EU Commission and its EU delegations around the world.

#### ***The Benelux Office for Intellectual Property***

The Benelux Office for Intellectual Property (BOIP) is issuing and handling Benelux trademarks, models and designs.

### ***Databases***

Several organizations are maintaining databases on trade marks registrations (*Information that should be readily available*):

The European Union Intellectual Property Office (EUIPO) is maintaining the databases of trade marks Esearch plus (for the trade marks, designs, owners and representatives) and TMview (for the trade marks of the European Union); additionally it gives access to trade marks issued at national level or in countries outside EU.

- World Intellectual Property Organization.
- Benelux Office for Intellectual Property.

#### 2.1.4 Design right

Similarly to trade mark, design protection in each Member State coexists with design protection at Union level. Design right is established by registration to the WIPO, to the EUIPO or to a national office. A design is the appearance of a product: its shape, patterns and colours. It includes elements like packaging of products, logos, typefaces, graphic design, and ornamentation that may be considered relevant for pesticide formulations.

Some PPP companies have registered their packagings as designs, other as 3D trademarks.

The EU directive 98/71 proposes rules for the legal protection of designs at Member State level. The EU regulation 6/2002 is establishing the rules for Community designs.

#### **Databases**

Several organizations are maintaining databases on designs registrations (*Information that should be readily available*) :

- The World Intellectual Property Organization (WIPO) is maintaining the International Designs Bulletin, the Global Design Database and the Hague Express Database.
- The European Union Intellectual Property Network is maintaining the DesignView database.

#### 2.1.5 Trade secret

The EU directive 2016/943 establishes rules on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. The directive defines the relevant forms of misappropriation and clarifies that reverse engineering and parallel innovation must be guaranteed, given that trade secrets are not a form of exclusive intellectual property right.

Trade secret is one of the most commonly used forms of protection of intellectual creation and innovative know-how by businesses. The European Commission, DG Internal Market, Industry, Entrepreneurship and SMEs and, at local level, the Federal Public Service Economy which are the competent authorities for this legislation, are promoting its application. This system is also well described by lawyers (Rouquié, 2022).

An unlawful misappropriation of data would probably be difficult to demonstrate in the case of pesticides, when considering the extensive information which is easily available : the scientific and technical literature, the off patent data, the commercial information on active substances, co-formulants or products, as well as the regulatory data submitted to the authorities.

## 2.2 Placing of plant protection products on the European market

### 2.2.1 Approval of active substances at European Union level

#### **Legislation**

According to EU regulation 1107/2009, a plant protection product cannot be placed on the market and used in a particular Member State prior the fulfillment of the following procedures : the approval at European Union level of the active substance(s) contained in it, and the authorisation at Member State level of the plant protection product.

Plant protection products are considered as one of the most important ways of protecting cultivated plants against harmful organisms, including weeds, and of improving agricultural production. However, their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used.

Active substances should only be included in plant protection products where :

- it has been demonstrated that they present a clear benefit for plant production i.e. the biological efficacy assessment has the aim to demonstrate the formulation is used as the minimum effective dose and that the efficacy of the formulation is comparable or superior to a reference formulation which is already authorised. In the case of formulations with the same active substances content, the applicant must demonstrate by means of several efficacy trials that the efficacy of his new formulation is statistically (bio)equivalent to the reference formulation which is already on the market.
- it has been demonstrated that they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment (toxicological, residue, environmental, ecotoxicological risk assessments).
- besides, a clear identification of the active substances and formulations containing it, a determination of the physical, chemical, and technical properties, as well as analytical methods to determine them in all matrix types are requested.

In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances is taken at European Union level on the basis of harmonised criteria. Consequently, updated information on the active substances that are allowed at European Union level is accessible.

Additionally, other articles of this regulation could have an impact on the struggle against illegal trade of plant protection products.

Articles 59 to 62 on data protection and data sharing set the rules for the use of test and study reports when they are submitted to a Member State by an applicant for authorisation under the regulation. These articles are regulating the access to the market of products belonging to applicants which do not own a full dossier.

Article 63 identifies the following items of information as confidential, where their disclosure to the public may potentially harm the interests of the applicant to a significant degree: (b) the specification of impurities of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities; (c) results of production batches of the active

substance including impurities; and (d) information on the complete composition of a plant protection product.

Articles 64 on packaging and presentation, and 65 on labelling are further explained in the following sections. (see below)

Article 66 on advertising sets the rules that should be considered when checking pesticides and commercial information or websites. The provisions of this article indicate that the risks related to the plant protection products should be clearly mentioned in the advertisements. Plant protection products which are not authorised shall not be advertised. All statements used in advertising shall be technically justifiable.

Article 67 on record-keeping indicates that producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.

The EU regulation 2017/625 on official controls indicates that Member States shall carry out official controls in order to enforce compliance with Regulation 1107/2009. (formerly Article 68)

Article 72 indicates that the Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take the measures necessary to ensure that they are implemented. A listing of those rules is available.

### ***Procedure at European Union level***

The applicant company which is developing a plant protection product at the basis of active substance(s) has to submit a dossier according to the EU regulation 1107/2009.

The dossier for approval of the active substance, generally accompanied by a dossier of authorisation of one representative plant protection product is constituted of a series of studies allowing to determine the properties of the active substances and plant protection product, as well as risk assessments for all compartments, according to EU regulations 283/2013 and 284/2013.

The application is submitted to a Rapporteur Member State, which provides its initial evaluation for an active substance in a draft assessment report (DAR). The European Food Safety Authority (EFSA) then carries out a peer review of the DAR in collaboration with Member States.

The conclusions regarding the peer review of the pesticide risk assessment of each active substance are published in the EFSA journal. The European Commission (mainly DG Food Safety, with a consultation of DG industry and DG environment) and Member States take risk management decisions on regulatory issues, including the approval of active substances. Formal decisions are taken in the Standing Committee on Plants, Animals, Food and Feed - section "Phytopharmaceuticals".

### ***Databases of active substances***

The outcome of these decisions is reflected in the Review reports for the active substance and in the Commission implementing regulations approving active substances that are publicly available in the EU Pesticides Database (the endpoints are also available in the Pesticide Properties Database - PPDB). This is the European listing of approved active substances.

The following information on the active substance is the most relevant in the struggle against illegal and counterfeit pesticides (*Information that should be readily available*) : the minimum purity of the active substance (a.s.) as manufactured, the acceptable levels of toxicologically, ecotoxicologically or environmentally relevant impurities, the determination of the physical and chemical properties of the active substance as well as the principles of methods for analysis of the active substance in the technical a.s. and in the formulations. Date of first approval and data protection deadlines need also to be considered.

## **2.2.2 Placing on the market of plant protection products at Member State level**

### ***Legislation***

The authorisation at Member State level is the second procedure step in the placing on the market of a plant protection product. According to the EU regulation 1007/2009, plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Consequently, the authorisations for plant protection products are granted at Member State level. Despite all the efforts of harmonization, the authorisations for a same product in two Member States are always slightly different. The authorisation of a plant protection product is only valid in the Member State which has issued it.

### ***Procedure at European Union level***

The mutual recognition of the authorisations is meant to reduce the duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products. Authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. However, in some cases, the environmental, agricultural or regulatory circumstances are not fully comparable between Member States.

Practically, the European Union is divided into 3 zones; North, Central and South. The applicant company has to apply a dossier for authorisation of its plant protection product in each Member State where it wants to place their PPP on the market, even though these Member States are part of the same zone. The applicant company may apply for mutual recognition of a plant protection product, if the product is already authorised in another EU Member State. In all cases, authorisation, amended authorisation or refusal is given by each individual Member State.

Within each zone, Member States cooperate in evaluating the dossiers for authorisation of plant protection products. A Northern, Central and Southern Zonal Steering Committee as well as an interzonal Steering Committee were established to enhance the steering of zonal processes and the harmonization of the zonal procedures. One country called zonal Rapporteur Member State (zRMS) performs an evaluation on behalf of the zone. The evaluation must cover the uses in all countries in the zone, where it will be applied. For indoor uses and seed treatments, evaluation of applications are not performed on a zonal basis, but across the whole EU. Such evaluations are called interzonal.

The dossier for authorisation of placing on the market is constituted of a series of studies allowing to determine the properties of the plant protection product and to assess the risks for the different compartments according to EU regulation 284/2013.

### ***Procedure at Member State level***

Each Member state has a competent authority responsible for the authorisation of plant protection products. In Belgium, the Service Plant Protection Products and Fertilizers, belonging to the Federal Public Service Public Health (Service Produits phytopharmaceutiques et Fertilisants - Service Public Fédéral Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement) is the competent authority which takes part to the approval process of active substances at EU level.

It is responsible for the authorisation of plant protection products and adjuvants, the emergency authorisations of 120-days and the parallel import at national level.

The service evaluates the application dossiers that are submitted by the plant protection products companies. It confidentially manages the complete data on the composition of the plant protection products. It manages the legislations/ guidance documents and the information on the authorisations of plant protection products and makes them available via the Phytoweb website.

### ***Databases of the authorisations of plant protection products***

The conclusions of the evaluation of the dossier are translated in the official authorisation act of the plant protection product at national level. This information is also constituting the label of the plant protection product.

The following information on the plant protection product is the most relevant in the struggle against illegal and counterfeit pesticides (*Information that should be readily available*) : the registration number (at national level), the trade name of the product, name of active substance, active substance(s) content (in % w/w, g/kg, g/L,...), formulation type, the plant protection product function (herbicide, fungicide,...), registration holder, marketing company(ies), expiry date of the national registration, (eco)toxicity classification, danger and risk phrases, detailed information on each authorised use (crop/target combination, application rate, number of applications,...). Types of authorisations (regular or parallel trade permit, for professional or amateur use, emergency authorisations, ...).

Each Member State is developing and maintaining its own database on registered plant protection products that can be placed on the market and used at national level. The end user may only apply the plant protection products that are authorised in its own country. These publicly available databases provide the official information on registered plant protection products to the end users at national level. Search functions, data presentation, database structures, local languages are specific to each Member State. An overview of National databases of authorised PPPs within the EPPO region is available on the EPPO website.

A fully integrated database of the plant protection products authorised in the EU would probably enhance their traceability.

### ***Parallel trade permits***

One of the key pillars of the European Union is the free circulation of goods within the internal market, coupled to a high level of security for human health, animals or the environment. Parallel trade permits allow a product that is authorised in one Member State (origin MS) to be introduced into another Member State (introduction MS) if the Member State of introduction determines that an identical product is already authorised in its territory. It is however recognized that this legal procedure is often misused for the illegal trade of plant protection

products. The free flow of goods within EU should be accompanied by proper control measures and databases allowing an on-time monitoring of flow of goods. Repackaging is a practice which removes the possibility to trace the product back.

A Guidance Document is explaining how applications for parallel trade should be evaluated by Member States. Criteria that should be checked when granting parallel trade permits are concerning manufacturers and contracting procedures between manufacturers (associated undertaking, or under license), the specifications (including impurities), content of active substances, safeners and synergists, the formulation type, the co-formulants, the packaging (size, material and form) and the labelling of parallel trade products introduced and placed on the market in their original package or after re-packaging.

According to the European guidance document, in order to facilitate exchange of information between Member States competent authorities as well as monitoring and control of parallel traded products, each Member State should upload on its website a list containing information for all applications for parallel trade products for which a permit has been issued. However this information is not always easily available in each Member State. In that list the following information should be included as a minimum (*Information that should be readily available*): Trade name of the parallel traded product, permit number and holder, expiry date - Trade name of the reference product. In order to facilitate enforcement of the provisions on parallel trade when Member State competent authority comes along with any suspected case concerning a parallel traded product, they should communicate general information on that e.g. product concerned, brief description of the case, etc. to the other Member State. Details can be exchanged by interested Member State on a bilateral basis.

Each Member State has generally published its own guidance document on parallel trade that completes the European guidance document.

### ***Responsibilities of the private sector***

The authorisation holders may present their registered products on their own website. The website should reflect the fact that the plant protection products are authorised at national level, and may only be used in the country where the national authorisation has been granted. The authorised label and the Safety Data Sheet are generally available on their website. However, a straightforward recognition of the legitimate authorised formulations is almost unfeasible based on this information. The information is presented in slightly different ways for each company and each country. The absence of the authorised labels, the absence of picture or description of the authorised packagings, the absence of the authorisation numbers and/or the variety of code numbers, the use of the national languages, the variety of trade names for the same formulation and the variety of distributors and sometimes sub-distributors for the same formulation are confusing factors.

The websites of many distributors and parallel importers are generally very limited. The information on the products that are proposed is often absent.

## 2.3 Classification and labelling

### **Legislation**

The classification, the hazard communication through labelling and the packaging of substances and mixtures is regulated according to EU Regulation No 1272/2008. It is based on the United Nations' Globally Harmonised System (GHS).

The purpose of this regulation is to ensure a high level of protection of human health and the environment as well as the free movement of chemical substances and mixtures in general. The regulation is, of course, applicable to the trade of active substances and plant protection products in the internal European Union market but also to the global market. This regulation does not cover transport of the chemicals, however, certain rules regarding the labelling of packagings are also used for transport.

Manufacturers, importers, downstream users and distributors of active substances and plant protection products, as well as producers and importers must communicate the information on hazard to other actors in the supply chain, including consumers by means of hazard labelling on the packaging and Material Safety Data Sheets.

The EU regulation 1107/2009 refers to the provisions of the classification, labelling and packaging requirements of regulation No 1272/2008 for the labelling of plant protection products. The EU regulation 547/2011 sets additional rules that are specific to plant protection products.

### **Procedure at European Union level**

The hazard evaluation is the assessment of the intrinsic properties of a substance in order to determine its potential to cause harm. In the case of active substances and plant protection products, the intrinsic properties of the substance or mixture are determined by means of studies that are required by EU regulation 1107/2009. They are covering the physical properties, the effects on human health and the environment.

When the nature and severity of an identified hazard meet the classification criteria, hazard classification is the assignment of a standardised description of this hazard. Practically the standard description of hazard is translated in terms of hazard class / hazard category, hazard statements, hazard pictograms, and precautionary statements.

The European Chemicals Agency (ECHA) is the European body which is playing the central role for the implementation of the REACH, Classification Labelling Packaging (CLP) and Prior Information Consent Regulations (PIC) regulations, as well as, ensuring consistency across the EU. ECHA, through its Secretariat and specialised Committees, provides Member States, the institutions of the Union, and the industry with scientific and technical advice on questions relating to CLP and associated regulations.

ECHA is establishing and maintaining a classification and labelling (C&L) inventory in the form of a database. ECHA is receiving proposals for the harmonised classification of active substances from Member State Competent Authorities and suppliers. The active substances in the meaning of the plant protection products EU Regulation 1107/2009 are usually subject to harmonised classification and labelling. Only Member State Competent Authorities can submit proposals of classification for active substances used in plant protection products. After technical discussions ECHA submits an opinion on such proposals for classification to the European Commission.

### **Procedure at Member State level**

The authorisation holder has to submit a proposal of label in the application dossier of a new formulation which is evaluated by the competent authorities for the authorisation of plant protection products (in Belgium, the Service Plant Protection Products and Fertilizers, belonging to the Federal Public Service Public Health).

Each European Member State has developed its own National Inspectorates that are responsible for the enforcement of the legislations on chemical safety (REACH, CLP, PIC,...). These inspectorates are not specifically dealing with pesticides. Their structures are described on the ECHA website, with information on the legal basis for enforcement, penalties for violations, addresses and websites of authorities.

### **Databases**

Several databases with information on the hazardous properties of substances are maintained by European institutions (ECHA, EFSA), by institutions regulating physical hazards (UN models Regulations) and the transport of dangerous goods (ADR, RID, ADN, IMDG code) and by international institutions (OECD, NIOSH, US EPA, OSHA, NICNAS, TOXNET, IPCS, US National Library of Medicine, ...). The PPP companies make available the (Material) Safety Data Sheets of their products on their own national website(s). (*Information that should be readily available*)

### **Responsibilities of the private sector**

The manufacturers, importers, distributors (i.e. PPP companies, authorisation holders) must make sure their labels and packaging are in compliance with the CLP requirements, and that their Safety Data Sheets (SDSs) are prepared according to REACH and CLP regulations before placing their products on the market.

It implies therefore for the manufacturers, importers, distributors to demonstrate the availability of information on the substances provided by their suppliers, the availability of appropriate technical and regulatory staff, the ability to prepare Safety Data Sheets and labels in compliance with the CLP regulation, and the availability of packagings that are compliant with CLP regulation. They should also be aware of associated legislations on the storage of hazardous substances, the disposal of hazardous wastes, the safety at work and the transport of dangerous goods.

## **2.4 Transport of dangerous goods**

### **Legislation**

The UN Recommendations on the Transport of Dangerous Goods Model Regulations (UN Orange Book) is a guidance document developed by the United Nations to harmonize dangerous goods transport regulations.

As this document is not legally binding, countries adopting the Model Regulations have to take basic provisions from the Orange Book and issue their own dangerous goods regulations or standards depending on the mode of transport. Furthermore, for EU member States, the transport by road, rail and inland waterways must comply with the requirements of the EU Directive 2008/68/EC. These regulations are transposed in national legislations.

These regulations set detailed rules for the training of the personnel (eventually translated in training certificate/license/ADR driver's card, ...), the security provisions for the personnel, the classification of dangerous goods, the marking and labelling of the packagings, the placarding of the transport units, the consignment procedures and the testing of packagings.

The United Nations Economic Commission for Europe (UNECE) is maintaining a listing of the competent authorities of its Member States.

In Belgium, the Federal Public Service Mobility and Transport is responsible for the RID (rail), the IMDG Code (boat), the ICAO Technical Instructions (air) and for ADR multimodal aspects of transport (including road). The three Regions are responsible for the ADR (road) and inland waterways transport.

### **Procedures**

The following items can be practically controlled. The lack of compliance to this regulation might be an indication of illegal trade :

- Dangerous goods should be contained in UN-approved packages which can withstand harsh transporting conditions. These are packages that have passed specific performance tests and are certified by authorities or qualified labs. The European Committee for Standardization (CEN) and the Technical Committee 261 are responsible for the normalisation of packagings, L'Institut Belge de l'Emballage (IBE-BVI) is involved in this task at Belgian level. *(Information that should be readily available)*
- Placards with hazard symbols and UN numbers should be affixed to exterior of cargo transport units.
- Packagings of dangerous goods packages should be marked and labelled. Marking comprises the UN number, proper shipping name, UN specification marks and other markings (i.e. orientation arrows, environmental hazardous substances mark). Labelling comprises hazard symbols (and handling labels). *(Information that should be readily available)*

Packagings should be accompanied by the documentation of consignments (consignor, consignee and date, dangerous goods description, total quantity of dangerous goods, ...). *(Information that should be readily available)*

The directive (EU) 2022/1999 establishes common procedures that should be followed by Member States for checking the transport of dangerous goods by road. A check list of items to be controlled as well as a listing of infringements provide a practical basis for the control of dangerous goods.

### **Databases**

The Bundesanstalt für Materialforschung und -prüfung (BAM) maintains a database of substances with their dangerous goods classification for the different modes of transport. It also contains links to additional databases.

### 3. Control procedures and institutions

The institutions that are responsible for the controls are generally separated from the institutions responsible for the regulatory processes.

For each domain, an attempt has been made to identify the relevant legislations/ guidance documents and the institutions at European Union level and Member State level (Belgium). A summary table has been prepared in order to help the reader.

It was not intended to present an exhaustive view of the activities of each institution but to highlight the points that might be useful in the domains of customs enforcement of intellectual property rights, the controls organised by food safety agencies and the actions of police and justice.

The controls have the aims, on the one hand, to determine the identity, physical and chemical properties of the product and on the other hand, to monitor the supply chain of the product (from manufacturing to disposal).

The guidance documents on the monitoring of the supply chain, the technical guidances on identity and physical-chemical properties and the guidances on administrative procedures have been considered as well.

## Control procedures at a glance

Domains	Legislations	Institutions (at international level, at Member State level)
Customs enforcement of intellectual property rights	EU regulation 952/2013 (The Customs code) EU regulation 608/2013 Commission notice (2016/C 244/03)	European Commission → Directorate-General Taxation and Customs Union  European Anti-Fraud Office (OLAF)  The EU Customs laboratories Customs administration (Administration générale des Douanes et Accises - AGD&A)
Food safety	EU regulation 2017/625 on official controls,  Reference document illustrating best practices .... during official market control .	Federal Agency for the Safety of the Food Chain (= Agence fédérale pour la sécurité de la chaîne alimentaire – AFSCA) → Unité Nationale d'Enquête » (UNE) The network of AFSCA laboratories
Police and Justice		EUROPOL  The European Public Prosecutor's Office (EPPO)  The European Union Agency for Criminal Justice Cooperation (Eurojust)
		Belgian Federal Police → Federal Unit Public Health and Environmental crime (DJSOC/FUPHEC)  Tribunal de l'entreprise de Bruxelles
Information on the supply chain	OECD (2018) Best Practice Guidance to identify Illegal Trade of Pesticide  M. Malkov, S. Prischepa, T. Kutonova (2015) Counteraction to Counterfeit and Contraband Pesticides. Methodology - OSCE, ENVSEC  TRACIT (2024). Tackling the sale of illicit pesticides on e-commerce platforms.	ONIP (OECD Network on Illegal Trade of Pesticides) → Rapid Alert System  Federal Agency for the Safety of the Food Chain (= Agence fédérale pour la sécurité de la chaîne alimentaire – AFSCA)

## Control procedures at a glance

Domains	Legislations	Institutions (at international level, at Member State level)
Technical guidances on identity and physical-chemical properties	<p>European Commission (DG SANTE) and EFSA publications</p> <p>OECD, FAO, WHO, CIPAC publications</p>	<p>European Commission → DG SANTE</p> <p>European Food Safety Authority (EFSA)</p> <p>Collaborative International Pesticides Analytical Council (CIPAC)</p> <p>FAO and WHO → "Joint Meeting on Pesticide Specifications" (JMPS)</p>
Guidances on administrative procedures		<p>FAO/WHO Joint Meeting on Pesticide Management (JMPPM)</p> <p>OECD → Inter-Organization Programme for the Sound Management of Chemicals (IOMC)</p> <p>Strategic Approach to International Chemicals Management (SAICM)</p> <p>OECD Task Force on Countering Illicit Trade (TFCIT)</p> <p>OECD Network on Illegal Trade of Pesticides (ONIP) → Global Alliance against Illegal International Trade of Pesticides.</p> <p>(ONIP) → Rapid Alert System</p> <p>The Anti-Illicit Trade Expert Group (AITEG)</p> <p>The Secretariat of the Basel, Rotterdam and Stockholm Conventions</p> <p>The United Nations Environment Programme (UNEP)</p>

## 3.1 Control procedures and legal prosecution

### **Legislations**

The focus is put on the pieces of legislation on customs and on official controls that might be relevant in the control of illegal pesticides.

Firstly, the European Union has developed a vast legislation dealing with the customs administration, the protection against fraud and corruption and the competencies of the European Anti-Fraud Office (OLAF). European institutions implementing this legislation are working in close contact with their national EU Member States counterparts and non-EU countries.

The EU regulation 952/2013 is laying down the Union Customs Code.

The EU regulation 608/2013 on the customs enforcement of intellectual property rights (IPR) specifies the range of IP Rights and infringements that are covered. This legislation requires the active collaboration of the right holders. It contains provisions for right holders on how to ask protection to customs, determines procedures for customs to follow in case of identification of goods suspected of infringing on IPR, provides provisions for cooperation and exchange of information between customs and right holders and includes measures to ensure that the interests of legitimate traders are protected.

The Commission notice (2016/C 244/03) clarifies the application of Regulation (EU) 608/2013 and the trademark package with regard to goods coming from third countries without being released for free circulation, including goods in transit, through the territory of the EU. These documents are addressed to the customs.

Secondly, the EU regulation 2017/625 on official controls, particularly on the plant protection products in the sense of EU regulation 1107/2009, and the “reference document illustrating best practices on analytical strategies and interpretation of results for the formulation analysis of plant protection products obtained during official market control” are laying down analytical strategies, which should increase and harmonise the effectiveness and efficiency of official controls of plant protection products across EU Member States. This guide contains suggested workflows for those cases that laboratories usually encounter in their daily work, i.e. testing samples collected during routine controls (1 - original products, 2 - parallel trade products) and testing so-called 3 - suspicious samples). These documents are addressed to the national food agencies.

### ***Institutions at European Union level***

#### ***The Directorate-General Taxation and Customs Union***

The Directorate-General Taxation and Customs Union (DG TAXUD) is responsible for the EU policies on the Customs Union. The Customs Union means that the customs authorities of all EU countries work together as if they were one. They apply the same tariffs to goods imported into their territory from the rest of the world, and apply no tariffs internally. A vast EU legislation is regulating customs matters, including enforcement of intellectual property rights, goods infringing intellectual property rights, European anti-counterfeiting and anti-piracy plan, detection technologies in the work of law enforcement, customs and other security services, customs response to latest trends in counterfeiting and piracy.

### ***The European Anti-Fraud Office***

The European Anti-Fraud Office (OLAF) is part of the European Commission, with operational independence.

OLAF is only investigating major cases involving counterfeit goods that are presenting a risk to the environment, human health or safety, and to intellectual property rights (IPR). OLAF may launch investigation procedures on request of rightholders, however after its own assessment of the information submitted by the rightholders. The Reporting allegation of IPR infringement is a check list indicating which information should be gathered by an aggrieved rightholder.

OLAF is also cooperating with numerous investigative, administrative and judicial partner services in EU member states (the Anti-Fraud Coordination Services of each Member State (AFCOS)) and non-EU countries as well as with European Union organizations (the European Public Prosecutor's Office (EPPO), Eurojust, EU Network of National Experts on Joint Investigation Teams (JITs Network),...).

OLAF has participated in the annual Operations Silver Axe for a number of years, using its expertise in identifying and tracking of suspicious shipments in order to provide information to the national authorities that were able to intercept the illicit goods and prevent them from arriving in Europe. OLAF also created a rapid alert system that allowed it to share intelligence in real time with other non-EU countries, helping them to monitor suspicious containers as they passed through various ports of transit (Publications Office of the European Union, 2021).

### ***Europol***

EUROPOL is the European Union's law enforcement agency. This agency coordinates the Silver Axe operations that are targeting the trade of counterfeit and illegal pesticides. These joint actions are carried out in cooperation with the European Anti-Fraud Office (OLAF), the European Union Intellectual Property Office (EUIPO), the European Commission DG Health and Food Safety, the law enforcement authorities (police, border, and anti-smuggling services) of both EU and non-EU Member States. The associations of the phytopharmaceutical industries (European Crop Care Association, CropLife Europe) are also involved in these operations.

During the operations, law enforcement authorities targeted the sale of counterfeits, banned products (based on non approved active substances, withdrawn authorisations) and unregulated imports – both online and offline. They carried out inspections on land and sea borders, inland marketplaces, parcel service providers and online marketplaces. The abuse in the trade of illegal pesticides varies from trafficking counterfeit or mislabelled products to irregular imports of banned substances.

Illegal products can be falsely declared as being in transit through EU or destined to re-export from EU; they can be copies of products with a composition not identical to the original, falsely declared being products with parallel trade permits.

### ***The European Public Prosecutor's Office***

The European Public Prosecutor's Office (EPPO) is the new independent public prosecution office of the European Union. It is responsible for investigating, prosecuting and bringing to judgment crimes against the financial interests of the EU. It works in close cooperation with OLAF. The mandate of the European Public Prosecutor's Office is defined in Council Regulation (EU) 2017/1939. The office has been involved in the most important cases of smuggling and counterfeiting (not in the pesticide sector).

### ***The European Union Agency for Criminal Justice Cooperation (Eurojust)***

Eurojust has been involved in cases where the crime affects two or more Member States, or requires prosecution on common bases, on the basis of operations conducted and information supplied by the Member States' authorities, Europol, EPPO and OLAF.

### ***The EU Customs laboratories***

The EU Customs laboratories provide the scientific expertise needed to enforce European regulations on Customs (EU regulation 952/2013). Their main activities are the management of the « Inter Laboratory Inventory of Analytical Determination (ILIADe) », a database of methods useful for customs authorities, the organisation of proficiency tests, the development of a common quality policy between the laboratories, the organisation of scientific meetings within and outside their laboratories network and the management of the database « European Customs Inventory of Chemical Substances (ECICS) ». The EU Customs laboratories are coordinated inside the Customs Laboratories European Network (CLEN). Their activities in the pesticides domain seem to be limited. However, the development of methods for pesticide screening could follow the validation procedures applied in this laboratory network.

## ***Institutions at Member State level***

### ***The Customs administration***

The Customs administration (Administration générale des Douanes et Accises - AGD&A) plays an important role in the fight against counterfeiting and piracy under the EU regulation 608/2013 concerning customs enforcement of intellectual property rights. The Customs administration is competent to intervene when counterfeit goods or goods obtained by piracy are imported, exported or re-exported and is also authorised to operate on national territory.

The competence of the AGD&A is limited to the research, observation and settlement of violations of intellectual property rights.

The holder of an intellectual property right is indeed required to submit a "request for intervention" if he wishes customs to intervene. Each holder of an intellectual property right may submit a "request for intervention" when he suspects that counterfeit goods or goods obtained by piracy constitute an infringement of its intellectual property rights and are (will be) imported.

The holder of an intellectual property right can opt for a national application valid to request the intervention of customs on the territory of one Member State or an application at EU level, valid to request the intervention of customs of several Member States.

Customs may also intervene *ex officio* when they suspect an infringement of the property rights.

The deadlines for the holder of property rights to intervene are very short (4-6 working days depending on the procedure).

It is recommended to the right holders to contact lawyers and experts in property rights legislation before starting an action against a counterfeiter. The right holder may initiate a civil or criminal proceedings before a specific court (in Belgium, le tribunal de l'entreprise de Bruxelles)

### ***The Federal Agency for the Safety of the Food Chain***

The Federal Agency for the Safety of the Food Chain (Agence fédérale pour la sécurité de la chaîne alimentaire - AFSCA) is responsible for controls that are related to the placing on the market and use of plant protection products at national level.

The « Unité Nationale d'Enquête » (UNE) is belonging to AFSCA. It is involved in the inquiries against pesticide fraud. It cooperates, amongst others, with the Federal Public Service Public

Health, customs, and the Federal Unit Public Health and Environmental crime (DJSOC/FUPHEC), a service of the Belgian federal police involved in public health, food safety and environment criminality. In addition, it cooperates in international operations such as Silver Axe and works together with their counterparts in other EU Member States.

The network of AFSCA laboratories is performing analytical control plans on different types of food and feed matrices as well as pesticide formulations. The laboratories are also managing scientific developments in the analytical field of food safety through the organization of seminars and workshops, as well as the organization of proficiency testings.

## 3.2 Information on the supply chain

### **Guidance documents**

European-wide databases to track import-, export- and inter-EU-country-transfer of PPP would help to identify suspicious or even directly-identifiable patent infringing product. Proper import/export data that would be available on-time would enable a powerful tool of control, on one side, by companies checking database for suspicious products and alarming control-institutions if there are specific grounds for suspicion, and on another side, by control institutions checking the suspicious goods/containers by established protocols. Practical proposals to organise this information are available in the following guidance documents:

The OECD Best Practice Guidance to identify Illegal Trade of Pesticides has been developed within the IOMC. The document is included in the Recommendation of the Council on Countering the Illegal Trade of Pesticides. It is a check list addressed to national authorities to improve their procedures for identifying, and responding to illegal trade throughout the life cycle of a pesticide. The document is dealing with the responsibilities and the obligations of record keeping of the PPP professionals, and in parallel, with the responsibilities and the skills of the inspectors that are intervening at the different steps of the supply chain (manufacture, formulation, export, transportation, import, sale/retail, use and disposal).

The Organization of Security and Co-operation in Europe (OSCE) is involved in numerous security issues. In the framework of the Environment and Security Initiative (ENVSEC), related to transboundary movements of hazardous waste, the organization has considered that its experience could be useful in the combat against counterfeit pesticides in Eastern Europe and Central Asia. A detailed counteraction methodology comprising prevention, preparation and response to already committed crime has been proposed. This document is completing the OECD Best Practice Guidance (Malkov et al., 2015).

TRACIT (Transnational Alliance to Combat Illicit Trade) recently published a report on the sale of illicit pesticides on e-commerce platforms. This organization showed the extent of the problem, and offered recommendations to local regulatory authorities. It also implicitly demonstrated that anyone can buy unauthorised pesticides without any strong response from the regulatory authorities.

### **Institutions at Member State level**

The information on companies involved in pesticides trade in European countries is generally not easily accessible. In Belgium, the basic information such as up-to-date lists of pesticides manufacturing and storage facilities, toll manufacturers, formulators, packagers, exporters and importers, distributors, and professional users is collected by the Federal Agency for the Safety of the Food Chain (FASFC/AFSCA).

Each operator in the food chain must register its activity to the FASFC, which issues agreements, authorizations or registration and maintains an up-to-date listing of operators involved in marketing and use of PPP.

The agency carries out regular inspections by these business operators to check legal provisions regarding the marketing and use of PPP (a.o. authorised PPP, phytolice, record keeping and traceability, storage rooms for pesticides) and participates to the Silver Axe operations. FASFC carries out also analyses of PPP formulations on the market to check their quality / safety and has in place a control programme of pesticide residues in food and feed.

The education on the risks related to pesticide use and the recording of distributors and professional end-users can favor a responsible use of the pesticides. In Belgium, it is also an element which is useful to secure the supply chain since only holders of a phytolice are legally allowed to purchase, store, use, distribute and sell pesticides. The EU directive 2009/128/EC establishes the requirements for the training of the users and the sales of pesticides. Each Member State has developed its own system of training of the users. In Belgium, the service manages the delivery of certificates to professional users (phytolice). The phytolice is mandatory for people who (1) purchase, store or use plant protection products for professional use or adjuvants in the context of their professional activity, who (2) give advice on plant protection products or adjuvants, and who (3) distribute or sell plant protection products or adjuvants.

### 3.3 Development of technical guidances at international level

#### ***Technical guidances on identity and physical-chemical properties***

The preparation of the application dossiers for approval of active substances and authorisation of plant protection products has to be performed in accordance with a series of regulatory and guidance documents that are published by international organizations (OECD, FAO, CIPAC, OEPP,...). Besides, the European Commission, the European Food Safety Authority, in close cooperation with Member States experts have published guidance documents that provide advice to applicants and Member States on how to conduct the risk assessments and evaluations for the different items of approval and authorisation dossiers. The guidance documents relevant for our research topic are dealing with the evaluation of significant and non-significant changes of the chemical composition of formulations, the equivalence of technical materials, the data requirements for the physical, chemical and technical properties of formulations and the validation of analytical methods.

International organizations are developing standard methods for analysis of agricultural and public health pesticides, the so-called specifications. These methods should be used internationally in the framework of approval and authorisation dossiers as well as standard of quality for buying, selling and the procurement of pesticides.

- The Collaborative International Pesticides Analytical Council (CIPAC) is an international, non-governmental organization with members belonging to regulatory authorities or public laboratories. The organization promotes the international agreement on methods for the analysis of pesticides and physical-chemical test methods for formulations. The methods are proposed by plant protection products companies and are tested all over the world in interlaboratory programmes. After evaluation of the results and adoption, the methods are published in the CIPAC Handbooks.
- The "Joint Meeting on Pesticide Specifications" (JMPS) is an expert ad hoc scientific body administered jointly by FAO and WHO, composed of scientists of regulatory authorities or public laboratories, but acting with their individual capacities. The primary function of the JMPS is to produce recommendations to FAO and/or WHO on the

development of guidance and procedures in establishing pesticide specifications and equivalence determination. Beside their use as assisting in the official approval, the main purpose of the FAO/WHO specifications is to provide a normal standard of quality for the buying, selling and quality control of pesticides and a protection for responsible vendors against inferior products.

- The WHO Vector Control Product Assessment Team in the Prequalification Unit (PQT/VCP) works closely with international experts to develop critical guidance information which may be relied upon by manufacturers/applicants, procurement agencies, national regulatory authorities, contract research organizations and other stakeholders in the sector of public health pesticides.
- The German speaking working group for plant protection product formulations (DAPF) and the English Speaking Pesticide Advisory Council (ESPAC) are expert groups which are active in the field of analytical methods and physical-chemical properties of plant protection products. They are supporting the work of CIPAC.

### ***Guidances on administrative procedures***

International organizations (FAO, WHO, OECD, ...) that are dealing with numerous economic policy topics are also proposing guidances that should help governmental authorities to improve their regulatory procedures. They are involved in the struggle against illegal trade of pesticides through several expert groups and daughter organizations.

The FAO/WHO Joint Meeting on Pesticide Management (JMPM) works as an advisory body to FAO and WHO on the lifecycle management of pesticide in agriculture and public health. This body is developing guidance documents on pesticide management that are also contributing to the anti-counterfeiting strategy. The International Code of Conduct on Pesticide Management, its associated guidelines on legislation, policy, registration, compliance and enforcement (enforcement of pesticide regulatory programme ; licensing schemes ; inspection of pesticide producers, importers, distributors and retailers ; licensing of public health pest controls operators ; quality control of pesticides ; quality control and guidelines for national laboratories), distribution and sales (pesticide advertising, tender procedures for the procurement, storage and handling at the point of supply), uses, application equipment, prevention and disposal of obsolete stocks (management of empty containers, management of obsolete stocks,...), post-registration surveillance, monitoring and observance of the Code of Conduct as well as the recommendations on obsolete stocks.

The OECD is promoting numerous harmonization activities in the fields of pesticide regulation, chemical safety and biosafety, e.g. OECD Test Guidelines for Chemicals. Its recommendations are generally included in the European regulatory process.

The organization is also involved in countering illicit trade and counterfeiting through the following organizations :

- the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).
- the Strategic Approach to International Chemicals Management (SAICM) is involved in the illegal international traffic.
- the OECD Task Force on Countering Illicit Trade (TFCIT) is working with governments to better understand the full range of complex risks and threats posed to global economies : e-commerce, free trade zones, containerized maritime transport.
- the OECD Network on Illegal Trade of Pesticides (ONIP) is a subsidiary body of the OECD. Its main task is to foster the cooperation among Member and non-Member countries in the creation of the Global Alliance against Illegal International Trade of Pesticides. A Rapid Alert System has been put in place by ONIP.

- The Anti-Illicit Trade Expert Group (AITEG) contributes to the work of the OECD Task Force on Countering Illicit Trade (TFCIT). It is promoting the private-public co-operation.

The Secretariat of the Basel, Rotterdam and Stockholm Conventions is also involved in the illegal and obsolete pesticides policies, when related to the control of transboundary movements of hazardous wastes and their disposal.

The United Nations Environment Programme (UNEP) is involved in the policies against illegal trade of pesticides. UNEP and GRID-Arendal (2020). The Illegal Trade in Chemicals.

## 4. Anti-counterfeiting activities of the private sector

PPP companies have created professional associations which are their representatives in their consultations on new legislations, guidelines and policies to key stakeholders, governments and authorities.

CropLife International is the global association of major PPP companies that are developing their own active substances. Its member associations are active at continental level and national level. CropLife Europe, formerly known as European Crop Protection Association, represents 22 market leading companies that develop their own active substances and formulations. Belplant is active at Belgian level.

Agrocare is the global association representing the independent post-patent crop protection industry. It represents 865 PPP companies around the world with member associations in Europe, China and India. The European Crop Care Association (ECCA) represents 22 companies.

Generic plant protection products (off-patent products) are products that are manufactured after the expiration of a patent or other exclusive right, by a company that did not hold the original patent, and without (the need for) a license from the original patent holder. Generic products are authorised and marketed under the same rules and requirements as the “original” products.

Both associations share common concerns about the increasing amount of counterfeit and illegal pesticides entering the European market. Both associations are involved in the Silver Axe actions. Several initiatives have been put in place by both professional associations to counter the illegal trade of pesticides :

- CropLife Europe Anti-counterfeiting expert group;
- AgroCare’s Pesticide Specification Group could be considered as a partner to define technical anti-counterfeiting measures;
- CropLife Europe information leaflets directed to its member companies;
- CropLife Europe webpage with references to third party publications on pesticide anti-counterfeiting;
- Belplant (Essenscia) has developed a « Cellule brevets », an expert group dedicated to the information on intellectual property rights for its chemical company members.

Important PPP companies and distributor associations are communicating/developing practical anti-counterfeiting solutions :

- The industry-introduced “know your customer” initiative with a secure supply chain.
- The use of holograms.
- Organizations of manufacturers and distributors are promoting tracking systems and individual identification code on each packaging of plant protection products. In the Netherlands, Belgium and Luxemburg, Nefyto, Agrodis, Belplant and Phytodis are involved in Agro CloSer. Phyteis developed Barcodes Datamatrix to trace the movements of pesticides. The association Agro EDI Europe is developing the SC Trace system, a tracking system for pesticides. Bayer France has developed the system CapSeal. *(Information that should be readily available)*

Several anti-counterfeiting organizations are active through the world : REACT (Anti Counterfeiting Network) ; OECD Task Force on Charting Illicit Trade ; INTA (International Trademarks Association); TRACIT (Transnational Alliance to Combat Illicit Trade); and UNCTAD illicit trade forum.

## References

### **Description of the impact of trade of illegal and counterfeit pesticides in the European Union**

The economic cost of the IPR infringement in the pesticides sector - Quantification of infringement in Manufacture of pesticides and other agrochemical products (NACE 20.20) (EUIPO, 2017)

« Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU », (European Commission DG Health and Food Safety, 2015)

### **References on the enforcement of intellectual property rights**

#### **Patents**

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights *OJ L 157, 30.4.2004, p 45-86*

Aim and key points of Directive 2004/48/EC

<https://eur-lex.europa.eu/EN/legal-content/summary/enforcement-of-intellectual-property-rights.html>

Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee — Guidance on certain aspects of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights ([COM\(2017\) 708 final](#), 29.11.2017)

WIPO database of legislations relevant to each of its Member State.

<https://www.wipo.int/wipolex/fr/legislation/results?countryOrgs=BE&last=true>

European Commission - DG Internal Market, Industry, Entrepreneurship and SMEs

[https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property\\_en](https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property_en)

The European Patent Office (EPO) is maintaining the legal texts and the guidelines that are necessary to evaluate patents.

<https://www.epo.org/law-practice.html>

The European Patent Office (EPO) is maintaining the Federated European Patent Register (Federated Register)

<https://register.epo.org/advancedSearch?lng=en&clnrefer=yes>

Information on the BE-Benelux Patent Platform

<https://economie.fgov.be/fr/themes/propriete-intellectuelle/office-belge-de-la-propriete/be-benelux-patent-platform>

The Benelux Organisation for Intellectual Property :

BPP – eRegister database : <https://bpp.economie.fgov.be/fo-eregister-view/search>

BE Espacenet database : [https://be.espacenet.com/?locale=fr\\_BE](https://be.espacenet.com/?locale=fr_BE)

### **Supplementary protection certificates**

Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. *OJ L 198, 8.8.1996, p. 30–35*

Information on the supplementary protection certificates (SPC) for phytopharmaceutical products

<https://economie.fgov.be/en/themes/intellectual-property/intellectual-property-rights/patents/patent-applications/supplementary-protection>

<https://economie.fgov.be/fr/themes/propriete-intellectuelle/droits-de-pi/brevets/demande-de-brevet/certificats-complementaires-de>

### **Trade marks**

European Union trade mark legal texts (EUIPO website)

<https://euipo.europa.eu/ohimportal/en/eu-trade-mark-legal-texts>

Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (codification) *OJ L 154, 16.6.2017, p. 1–99*

Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (recast) *OJ L 336, 23.12.2015, p. 1–26*

The European Union Intellectual Property Office (EUIPO) databases

Esearch plus : <https://euipo.europa.eu/eSearch/#details/trademarks>

TMview : <https://www.tmdn.org/tmview/#/tmview>

World Intellectual Property organization :

WIPO IP portal <https://ipportal.wipo.int/>

Benelux Office for Intellectual Property :

<https://www.boip.int/fr/registre-des-marques?app=%2F>

### **Designs**

Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs *OJ L 289, 28.10.1998, p. 28–35*

Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs *OJ L 3, 5.1.2002, p. 1–24*

The World Intellectual Property Organization (WIPO) databases :

The International Designs Bulletin : <https://www.wipo.int/haguebulletin/?locale=en>

The Global Design Database: <https://www3.wipo.int/designdb/en/index.jsp>

The Hague Express Database : <https://www3.wipo.int/designdb/hague/en/>

The European Union Intellectual Property Network :

the DesignView database : <https://www.tmdn.org/tmdsview-web/#/dsview>

### **Trade secret**

Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. *OJ L 157, 15.6.2016, p. 1–18*

European Commission, DG Internal Market, Industry, Entrepreneurship and SMEs  
[https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/trade-secrets\\_en](https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/trade-secrets_en)

### **Manuals**

Strowel A., Thiry C. Code - Essentiels 2019 – Droit de la propriété intellectuelle, 8<sup>th</sup> edition, Larcier

Marino L. Droit de la propriété industrielle, 9<sup>th</sup> edition, 2020

Rouquié S. La contrefaçon - Analyse comparée – Droits français, anglais et européen, 1<sup>st</sup> edition 2022

FPS Economy, 2024 <https://economie.fgov.be/en/themes/intellectual-property/intellectual-property>

### **References on the placing of plant protection products on the market**

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. *OJ L 309, 24.11.2009*

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. *OJ L 153, 11.6.2011, p. 1–186*

Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products. *OJ L 155, 11.6.2011, p. 176–205*

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. *OJ L 93, 3.4.2013, p. 1–84*

Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. *OJ L 93, 3.4.2013, p. 85–152*

Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products. *OJ L 74, 4.3.2021, p. 7–26*

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament

and of the Council concerning the placing of plant protection products on the market. *OJ C 95, 3.4.2013, p. 1–20*

Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. *OJ C 95, 3.4.2013, p. 21–37*

Guidance document concerning the parallel trade of plant protection products under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection product on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, (SANCO/10524/2012, VERS.5.2 - 14-7-2015)

Lignes directrices pour les permis de commerce parallèle (Agence Fédérale pour la Sécurité de la Chaîne Alimentaire et le Service Public Fédéral Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement, Version 2.0 - 20/06/2022)

EU Pesticides Database. ([https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database\\_en](https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en))

Pesticide Properties Database (PPDB) (<http://sitem.herts.ac.uk/aeru/ppdb/>)

National databases of registered plant protection products.  
([https://www.eppo.int/ACTIVITIES/plant\\_protection\\_products/registered\\_products](https://www.eppo.int/ACTIVITIES/plant_protection_products/registered_products))

Phytoweb website (<https://fytoweb.be/nl>).

EFSA (European Food Safety Authority), 2022. Data collection on co-formulants used in representative plant protection product formulations in the context of the EFSA peer review process for approval/renewal of approval of active substances. EFSA supporting publication 2022:EN-7547. 97 pp. doi:10.2903/sp.efsa.2022.EN-7547

## **Reference on classification and labelling**

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. *OJ L 353, 31.12.2008, p. 1–1355.*

Introductory Guidance on the CLP Regulation (European Chemicals Agency, 2019, version 3.0) ([https://echa.europa.eu/documents/10162/2324906/clp\\_introductory\\_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027](https://echa.europa.eu/documents/10162/2324906/clp_introductory_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027))

Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures (European Chemicals Agency, 2024, version 6.0) ([https://echa.europa.eu/documents/10162/2324906/clp\\_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5?t=1499091929578](https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5?t=1499091929578))

Introduction on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

<https://unece.org/about-ghs>

Information on Chemicals (databases) (<https://echa.europa.eu/information-on-chemicals>)

National inspectorates – <https://echa.europa.eu/regulations/enforcement/national-inspectorates>

National helpdesks - <https://echa.europa.eu/support/helpdesks>

## Reference on packaging and transport of dangerous goods

UN Recommendations on the Transport of Dangerous Goods - Model Regulations (UN Orange Book) <https://www.un-ilibrary.org/content/periodicals/24120820>

21<sup>st</sup> version, 2019 : [https://unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev21/ST-SG-AC10-1r21e\\_Vol1\\_WEB.pdf](https://unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev21/ST-SG-AC10-1r21e_Vol1_WEB.pdf)

Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods *OJ L 260, 30.9.2008, p. 13–59*

Directive (EU) 2022/1999 of the European Parliament and of the Council of 19 October 2022 on uniform procedures for checks on the transport of dangerous goods by road (codification) *PE/22/2022/REV/1 OJ L 274, 24.10.2022, p. 1–13*

The UNECE is maintaining a listing of the competent authorities for the transport of dangerous goods. <https://unece.org/transport/dangerous-goods/competent-authorities>

Competent authorities for the transport of dangerous goods in Belgium, Germany, France  
Belgium - Autorités compétentes pour les marchandises dangereuses  
<https://mobilit.belgium.be/fr/aviation/securite/marchandises-dangereuses/autorites-competentes>

Germany - Bundesanstalt für Materialforschung und -prüfung (BAM) – dangerous goods regulations  
<https://tes.bam.de/TES/Navigation/EN/Set-of-Rules/Dangerous-Goods/dangerous-goods.html>

The BAM database dangerous goods classifications  
<https://www.dgg.bam.de/quickinfo/en/show/2qworrytqgcjwrx5iketvsws4>

Germany - Federal Ministry for Digital and Transport  
<https://bmdv.bund.de/EN/Topics/Mobility/Freight-Transport-Logistics/Dangerous-Goods/dangerous-goods.html>

France - Ministère de la Transition écologique et de la Cohésion des territoires, Ministère de la Transition énergétique.

La réglementation du transport de marchandises dangereuses (TMD)  
<https://www.ecologie.gouv.fr/reglementation-du-transport-marchandises-dangereuses-tmd>

ChemSafetyPRO - They identify themselves as a group of chemical regulatory experts developing original and free chemical safety and regulatory tutorials and references.  
<https://www.chemsafetypro.com/Topics/TDG/How to Assign UN Packing Group for Dangerous Goods.html>

## **References on the EU legislation on Fraud and corruption, Customs**

Summaries of EU legislation – Fraud and corruption  
<https://eur-lex.europa.eu/summary/chapter/22.html>

Summaries of EU legislation – Customs  
<https://eur-lex.europa.eu/summary/chapter/12.html>

## **References on the customs enforcement of intellectual property rights**

Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 *OJ L 181, 29.6.2013, p. 15–34*

Commission notice on the customs enforcement of Intellectual Property Rights concerning goods brought into the customs territory of the Union without being released for free circulation including goods in transit (2016/C 244/03)

Commission Implementing Regulation (EU) No 1352/2013 of 4 December 2013 establishing the forms provided for in Regulation (EU) No 608/2013 of the European Parliament and of the Council concerning customs enforcement of intellectual property rights  
*OJ L 341, 18.12.2013, p. 10–31*

European Customs Laboratories - Experience you can rely on (Publications Office of the European Union, 2016)

Publication of the lists of EU trade mark courts and Community design courts in accordance with Article 123(3) of Regulation (EU) 2017/1001 of the European Parliament and of the Council on the European Union trade mark and Article 80(4) of Council Regulation (EC) No 6/2002 on Community designs 2020/C 327/06 (*OJ C, C/327, 05.10.2020, p. 6*, CELEX: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC1005\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC1005(01)))

Loi du 15 mai 2007 relative à la répression de la contrefaçon et de la piraterie de droits de propriété intellectuelle.

## **References on the European Anti-Fraud Office (OLAF)**

The OLAF report 2020 - Twenty-first report of the European Anti-Fraud Office, 1 January to 31 December 2020 (Publications Office of the European Union, 2021)

Guidelines on Investigation Procedures for OLAF Staff 11 October 2021  
[https://anti-fraud.ec.europa.eu/guidelines-investigations-olaf-staff\\_en](https://anti-fraud.ec.europa.eu/guidelines-investigations-olaf-staff_en)

Reporting allegation of IPR infringement  
[https://anti-fraud.ec.europa.eu/investigations/investigations-related-eu-revenue/ipr-health-and-environment-investigations\\_en](https://anti-fraud.ec.europa.eu/investigations/investigations-related-eu-revenue/ipr-health-and-environment-investigations_en)

## References on Official Control Laboratories

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). *OJ L 95, 7.4.2017, p. 1–142*

Reference document illustrating best practices on analytical strategies and interpretation of results for the formulation analysis of plant protection products obtained during official market control - EU Working Group on Formulation Analysis - v 1.0 - March 2019

[https://www.bvl.bund.de/SharedDocs/Downloads/04\\_Pflanzenschutzmittel/reference\\_document\\_analytics\\_market\\_control.pdf?\\_\\_blob=publicationFile&v=2](https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/reference_document_analytics_market_control.pdf?__blob=publicationFile&v=2)

## References on the Federal Agency for the Safety of the Food Chain

Plant protection products and adjuvants

<https://favv-afsc.be/fr/themes/plantes/produits-phytopharmaceutiques-et-adjuvants>

Laboratories

<https://www.fasfc.be/about-fasfc/laboratories>

SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT [C – 2013/24124] 19 MARS 2013. — Arrêté royal pour parvenir à une utilisation des produits phytopharmaceutiques et adjuvants compatible avec le développement durable

## References on technical guidance documents

Technical guidance documents of the European Commission – DG Santé ([https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products\\_en](https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en))

Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. SANCO/12638/2011 - 20 November 2012 rev. 2

Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009 (SANCO/10597/2003 – rev. 10.1 - 13 July 2012)

Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protections under regulation (EC) No. 1107/2009 (SANCO/10473/2003 – rev.5 - 21.10.2021)

Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for

Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013. (SANCO/3030/99 - rev.5 - 22 March 2019)

Collaborative International Pesticides Analytical Council (CIPAC)  
(<https://www.cipac.org/index.php>)

NSP - Pesticide Specifications and Quality Control Standards page  
(<https://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/en/>)

German speaking working group for plant protection product formulations (DAPF)  
([https://www.bvl.bund.de/SharedDocs/Downloads/04\\_Pflanzenschutzmittel/dapf-en.html](https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/dapf-en.html))

WHO - Prequalification of Medical Products – Vector Control Products  
(<https://extranet.who.int/pqweb/vector-control-products>)

The "Joint Meeting on Pesticide Specifications" (JMPS) <https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/fao-panel-of-experts-jmps/en/>

The Joint FAO/WHO Meeting on Pesticide Management (JMPM), the FAO International Code of Conduct on Pesticide Management and related guidance documents  
<https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/en/>

The OECD  
<https://www.oecd.org/en/topics/sub-issues/pesticides-and-biocides.html>  
<https://www.oecd.org/en/topics/testing-of-chemicals.html>

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC)  
<https://partnership.who.int/iomc>

The Strategic Approach to International Chemicals Management (SAICM, now included in the Global Framework on Chemicals) is involved in the illegal international traffic.  
<https://www.chemicalsframework.org/>

The OECD Working Party on Countering Illicit (WP-CIT) Trade  
<https://uscib.org/uscib-participates-in-the-first-meeting-of-the-oecd-working-party-on-countering-illicit-trade/>

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