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Chapter 9

Low-risk pesticides in the EU: economic and regulatory considerations for agriculture and forestry

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9.1 Introduction

The use of synthetic pesticides on food, feed crops, and forest nurseries remains an integral part of modern agriculture and forestry. This has led to increasing concerns regarding their potential impacts not just on the environment but also on human health and biodiversity (European Commission, 2022; Lampkin & Padel, 2022; Möhring et al., 2020; Schneider et al., 2023). Despite being important drivers in boosting global food production levels, the continuous use of synthetic pesticides in agriculture and forest nurseries has generated concerns regarding their frequent detection in natural resources (Kookana et al., 2005; UN Environment Program, 2020). Moreover, studies have also emphasized the considerable risks stemming from synthetic pesticide usage on nontarget organisms (NTOs), e.g., aquatic organisms such as fish and crustaceans, as well as soil microorganisms and insects (Brühl et al., 2021; Fournier et al., 2020; Sánchez-Bayo et al., 2011). To mitigate the negative effects of synthetic pesticides, the European Commission (EC) proposed, in 2022, as part of its Farm to Fork (F2F) Strategy, to reduce the use of chemical pesticides by 50% and the associated risk of used pesticides by 50% by 2030. In fact, under Directive 2009/128/EC regarding the sustainable use of pesticides (abbreviated as sustainable use directive, SUD), which proposed that synthetic pesticide use should be banned from urban areas, the importance of using low-risk pesticides (LRPs) as a prime alternative is emphasized (European Commission, 2009). However, the proposal to halve the use of chemical pesticides and the associated risk of using pesticides was rejected by the European Parliament (2023) in the aftermath of farmer protests across the European Union (EU). Following this vote, the EC announced its intention to withdraw the proposal (European Commission, 2024), although this is yet to be enforced.

Although no specific proposals have been put forth to replace the rejected initial proposal, it is important to emphasize that farmers require effective and economically viable alternatives to traditional synthetic pesticides, particularly the pesticides with the highest levels of associated risk for the environment and human health (Finger, 2024). However, the selected solutions should also aim to ensure that crop yields are not reduced and food prices do not increase, as this could lead to changes in global agricultural trade markets and consequently jeopardize global food security (Wesseler, 2022).

LRPs, characterized as mainly active substances (AS) with biological origins, are gaining ground in the global pesticide market as potential substitutes for synthetic pesticides (Ayilara et al., 2023; Souto et al., 2021). Within the EU context, later amendments to the SUD have reiterated the importance of considering LRPs as a prime alternative to synthetic pesticides, while the EC Biodiversity Strategy stresses that pesticide distributors within the EU are required to highlight the associated risks of synthetic pesticides while providing recommendations on respective LRP alternatives (European Commission, 2020, 2022). Within this study, different categories of LRPs are taken into account, encompassing several potential alternatives, namely, (1) microbial pesticides, (2) pheromones and other semiochemicals, and botanicals, e.g., plant extracts, and (3) ds-RNA pesticides (Dalakouras et al., 2024).

Regardless of the potential advantages of LRPs, within the EU, microorganisms, which include AS that can be used for the production of microbial pesticides, are currently the only AS of natural origin that have specific data

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requirements described in Part B of Regulation No. 283/2013. Furthermore, plant protection products (PPPs) that are based on microbial AS must fulfill the data requirements under Part B of Regulation No. 284/2013. Nonetheless, it is important to emphasize that the mentioned specific regulatory requirements for microbials fall under the wider regulatory framework established by Regulation (EC) No. 1107/2009, which is used for the approval of PPPs in general, whether they are sourced from chemical or natural origin. This entails that the current approval process for active substances of natural origin and their respective PPPs counterparts follows the same regulatory procedures as for synthetic pesticides, as detailed in Frederiks and Wesseler (2019). This approach disregards the specific characteristics and needs of LRPs, which are essentially different from synthetic pesticides and thus have a different mode of action (Council of the European Union, 2019). For instance, the Council of the EU has stressed the importance of including novel toxicity/ecotoxicity and, when required, exposure assessment tools targeted for LRPs. The absence of specific regulatory risk assessment (RA) procedures results in overly extended approval timespans, which has been recognized as a major barrier for the introduction of LRPs. Frederiks and Wesseler (2019) detail the different phases needed for approval of new AS, both at the EU and member state (MS) level. The study concludes that, on average, in the EU, procedural timespans for new AS take around 66 months, while in the United States, the average procedural timespan is 26 months. For this reason, the EU is deemed to be currently lagging behind other major agricultural markets in this aspect, such as the United States, India, and China (Balog et al., 2017). The economic costs of waiting for approval, as well as the fixed and variable costs associated with other phases of product development, such as R&D, contribute toward higher costs for companies and disincentivize investment. Furthermore, a more extended approval process results in a deprivation of potential benefits from using LRPs, which can be represented as an opportunity cost incurred both by farmers as well as by final consumers within the EU (Purnhagen & Wesseler, 2021).

For these reasons, the EU has identified the need to reduce the procedural timespans for approval of low-risk AS and their PPP counterparts. This study aims to provide an overview of the current approval process for the considered categories of LRPs within the EU, highlighting the different steps that are required for their approval both at the EU and MS level and their respective timespans. Furthermore, the study reflects on the economic implications of the current regulation by following a real options methodology. This aims to highlight opportunities for improving the efficiency of the approval process for AS and PPPs based on natural origins within the EU and discuss the potential impacts of establishing a dedicated approval process for the accounted LRP categories.

9.2 Current approval process for low-risk pesticides

Within the context of the EU, AS that are aimed to be used for the production of PPPs, i.e., the AS formulated as it shall be marketed, need to be approved according to Regulation (EC) No. 1107/2009. Further regulatory documents were drawn to detail the data requirements for both AS (Regulation No. 283/2013) and the associated PPPs (Regulation No. 284/2013), with these latter documents each divided into Parts A and B, respectively. Part A covers AS and PPPs of chemical origin, which also formally encompass botanicals, semiochemicals, and ds-RNA pesticides, apart from the conventional synthetic chemical pesticides. Part B focuses on the data requirements for assessing the associated risk of microbial AS and their associated PPPs. Guidance documents for the submission of PPPs have been established by the Organization for Economic Co-Operation and Development (OECD), the European Public Prosecutor's Office, and the European Food Safety Authority (EFSA). Two main steps are required to successfully introduce a new PPP in the market (Frederiks & Wesseler, 2019). First, regarding the RA and approval of new AS to be included in the list of approved AS at the EU level, three subsequent phases need to be covered: the rapporteur Member State (RMS) phase, the risk assessment phase, and the risk management phase.

The RMS phase entails that a MS, chosen by an applicant, prepares a dossier with the information requested for the RA. The dossier is submitted to the competent authority in one of the MSs for evaluation. The MS responsible for this evaluation is henceforth designated as the RMS, and its respective national authorities must check the completeness of the delivered dossier. If the dossier is in accordance with the necessary information requirements, the RMS distributes a Draft Assessment Report (DAR) to all the other MSs, the initial applicant MS, and the EFSA. Based on the information received and inputs from MSs, EFSA prepares a draft report. This is shared with MSs and peer-reviewed. Based on the comments received, EFSA prepares a scientific opinion, shared with the Directorate General for Health and Food Safety (DG SANTE), as of writing, which is responsible for preparing a proposal for a subsequent vote in the Standing Committee, where all MSs have the opportunity to cast their vote to approve or reject the proposal by DG SANTE. In general, the proposal submitted by DG SANTE recommends approval of the AS for European markets. AS submissions where applicants can expect a negative outcome from the RA are not further pursued by applicants to avoid costs. Hence, it is not surprising to find in almost all proposals by the EC positive recommendations for the approval of ASs.

The last phase refers to the risk management phase, and for the dossier to be approved, it is required that 55% of the MSs, holding at least 65% of the EU population, must provide an approving vote. Fig. 9.1 provides an overview of the mentioned phases included in step 1 of the approval of new AS with a positive recommendation by the EC.

1. Including botanicals, pheromones, and other semiochemicals, as well as ds-RNA.
2. A general evaluation process applies to PPPs used in greenhouses, postharvest treatment, empty storage room treatment, and seed treatment throughout the EU.

Once AS have been approved at the EU level, the PPPs produced with the respective approved substance used as an active ingredient must be registered and approved at the national or MS level. In case the new PPP is to be used in field crops, the EU territory is divided into three different evaluation zones, i.e., North, Central, and South, which are delimited according to the associated climatic conditions. On the other hand, PPPs to be used for greenhouses, postharvest treatment, treatment of empty storage rooms, or seed treatment are subject to a general evaluation process related to the entire EU. Furthermore, once a PPP is approved in one of the mentioned evaluation zones, all MSs included in that respective zone are eligible to grant authorization for its use. Similarly, to the RMS phase regarding the approval of

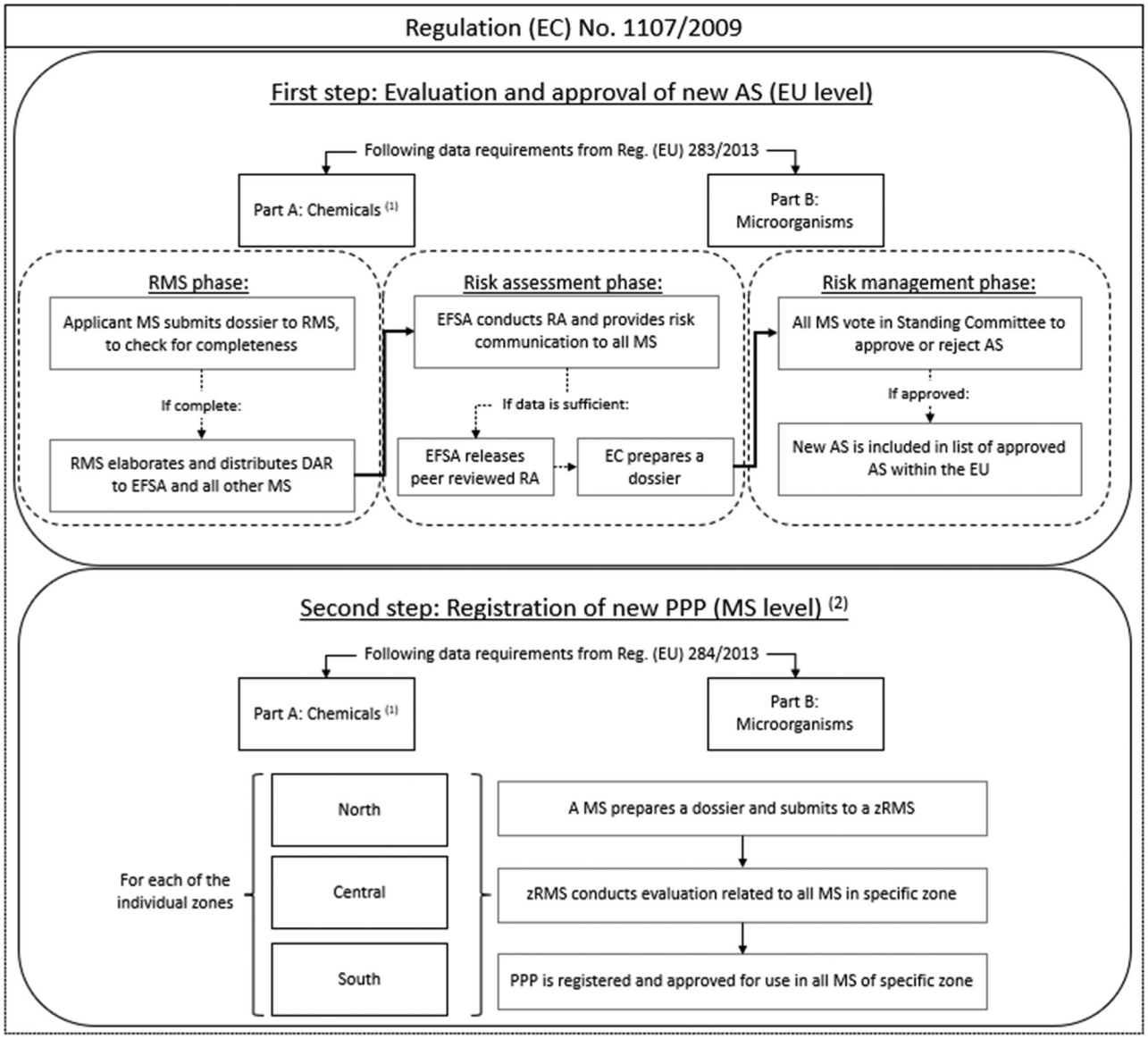

FIGURE 9.1 Diagram of Reg. (EC) 1007/2009 for the approval of new AS and registration of PPPs in the EU, with a positive recommendation by the EC. *AS*, Active substances; *PPPs*, plant protection products.

new AS, national registration of PPPs requires that a dossier with data regarding the efficacy of the respective PPP is submitted to a zonal RMS, which is responsible for conducting the evaluation related to all MSs included in the associated zone. For already approved AS, the process of PPP applications can take a maximum of 18 months. In case the PPP presented for application contains at least one (as yet) unapproved AS, the zonal RMS should start evaluation after the DAR is distributed at the EU level. In this case, the evaluation of the PPPs should not exceed 6 months, following the approval of the included new AS.

Between 2001 and 2024, the EU has registered 69 low-risk active substances (LR-AS). The details are available via the EU Pesticides Database (https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en). The LR-AS can be differentiated into chemical, microbial, and antimicrobial to allow for a comparison with the approval in the United States of America (US). In the EU, 55% of LR-AS are chemical, followed by 39% microbial and 6% antimicrobial. A comparison with the United States shows 128 products have been registered over the same time period. The United States exhibits a different distribution with 48% microbials, 38% chemicals, and 13% antimicrobials (Fig. 9.2).

As shown in Fig. 9.3, the average approval time for the EU is 1504 days with a median of 1307 days. Notable extremes include a minimum of 1028 days for *COS-OGA* and a maximum of 3276 days for *Ampelomyces quisqualis Strain AQ10*. The approval process for LR-AS is quicker in the United States, with an average of 630 days and a median of 592 days. Here, the time ranges from a minimum of 109 days for *(E,Z)-7,9-Dodecadien-1-yl acetate* to a maximum of 1597 days for *Bacillus pumilus strain QAT 2808*.

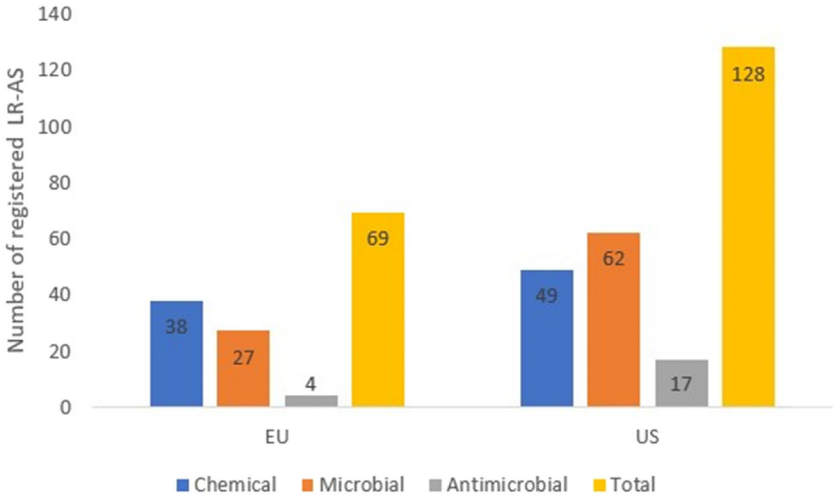

FIGURE 9.2 Low-risk active substances registered in the EU and in the United States, 2024.

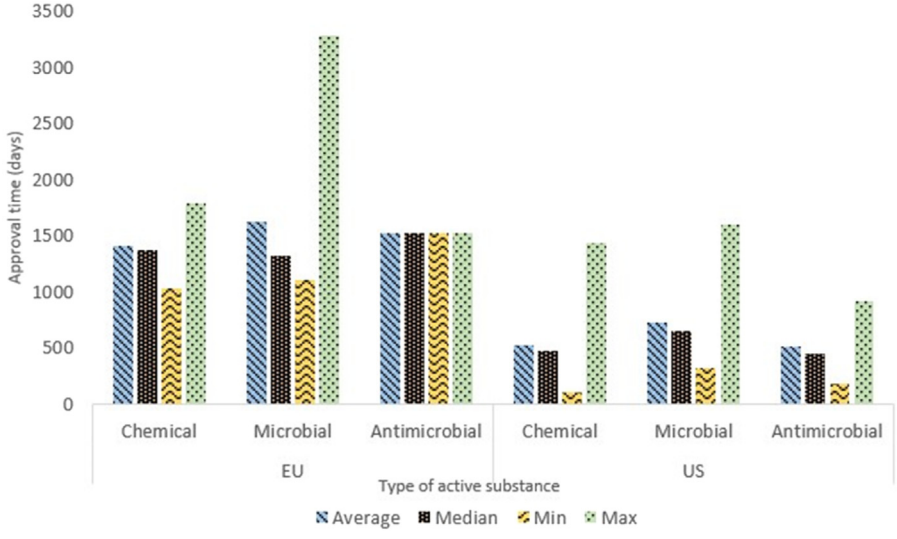

FIGURE 9.3 Approval time (days) for different types of active substances in the EU and in the United States.

TABLE 9.1 Overview approval time for active substance types in the EU and United States.

	EU				US			
	Chemical	Microbial	Antimicrobial	Total	Chemical	Microbial	Antimicrobial	Total
Average	1412	1627	1524	1504	522	730	513	630
Median	1371	1325	1524	1371	480.5	651	446	592
Min	1028	1103	1524	1028	109	323	179	109
Max	1785	3276	1524	3276	1435	1597	920	1597
N	38	27	4	69	49	62	17	128

In Table 9.1 and Fig. 9.3, an overview of the average, median, minimum, and maximum approval times for the different types of LR-AS can be found. Despite the differences in approval time, in both the EU and the United States, microbials experience lengthiest approval process, with an average of 1627 days in the EU and 730 days in the United States. However, in the EU, the median approval time for microbials (1325 days) is lower than that of chemicals (1371 days), while in the United States, microbials demonstrate the highest average, median, minimum, and maximum approval time. Notably, all antimicrobials in the EU were registered through a standardized reregistration process between 2005 and 2009, resulting in uniform approval times. In the United States, antimicrobials demonstrate the lowest average, median, and maximum approval time.

9.3 The economic implication of the regulation

In general, the development of biological control agents requires investments by the developer in research and development. The developer further has to submit the new product for approval. The approval requires an approval for the active ingredient and for the product. The RA for active ingredients is done by EFSA as mentioned above, while the product approval is done at the national level. Both the research and development phase as well as the approval phase take time. The related costs are uncertain and can vary substantially. After an active ingredient has received approval, it can be marketed. Developers can market their own products or license or sell the active ingredient to product developers. A number of business models have emerged for marketing active ingredients. It is difficult to predict how long a new product will survive in the market from an ex-ante point of view. The competition in the market due to the development of alternative products as well as further improvements of products is relevant. In fact, even if a product has received approval and entered the market, the product providers may still be held liable ex post. Ex-post liability can be understood in the strict legal sense but also goes beyond and includes loss of reputation and more. The active ingredient glyphosate and the product round-up serve as an example. Another example is the approval of vitamin A-enriched rice for cultivation in the Philippines and the withdrawal of the approval by the Court (Normile, 2024). Additional examples can be found in Kalaitzandonakes et al. (2016).

A generic model that allows to capture the economic implications of research and development, approval, marketing, and ex-post liability has been proposed by Purnhagen and Wesseler (2018).

9.4 Economic model

In this section, we talk about the real options of investment under uncertainty for active substances and their PPPs. The key idea is to introduce the trade-off between ex-ante regulation and ex-post liability. Here we make this comparison by introducing cost and liability structures in a specific time frame of production starting from R&D. This time frame is defined by a mathematical structure that introduces uncertainty of the length of the time to complete that certain stage.

Following the calculations of an investment under uncertainty model (Dixit & Pindyck, 1994; McDonald & Siegel, 1986; Scatasta et al., 2006), we can calculate the expected values of an immediate investment or postponement and compare them by using real option methodology. The model requires calculating the net present value of annual research costs, annual approval costs, annual benefits, and annual liabilities, respectively.

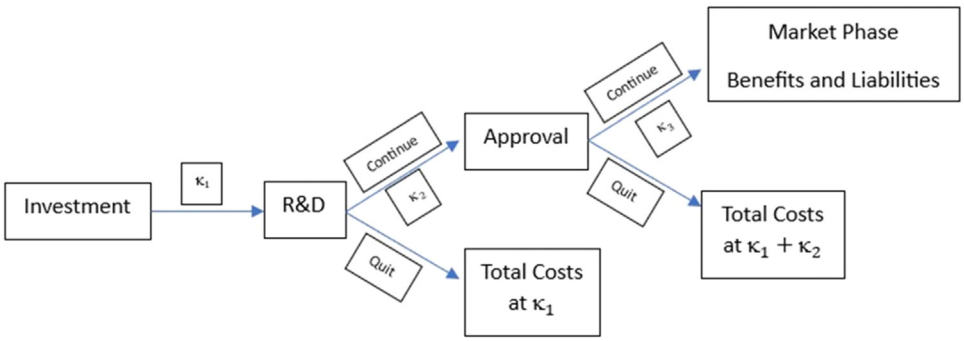

FIGURE 9.4 Investment decision tree.

There are three phases of the decision problem, as depicted in Fig. 9.4.: research and development; approval; benefits, ex-post liability, and other costs. Hence, the procedure is the following:

$$R\&D(R, r, \kappa_1) \text{ » Approval } (A, a, \kappa_2) \text{ » Marketing } (B, \kappa_3) \text{ » Ex post liability } (\theta)$$

where R stands for the investment costs, A for approval costs/sunk costs, B for benefit stream, and θ for ex-post liability. The time needed to complete a given phase is denoted by $\kappa_i \epsilon\ (0,\ \infty)$ which are random variables exponentially distributed with parameter (failure rate) h_i, $\kappa_i \sim \text{Exp}(h_i)$ with probability density function

$$g(\kappa_i) = \begin{cases} h_i e^{-h_i \kappa_i}, x > 0 \\ 0, x \leq 0 \end{cases}$$

where $E(\kappa_i) = \frac{1}{h_i}$. Moreover, there are annual research and approval costs per phase, which are denoted as r and a. Given this model, we can calculate the weighing factor or hurdle rate. Based on the real option model we introduce, the benefits must substantially surpass the costs to justify the value of investing immediately or vice versa, i.e., delaying the decision. Please see the Appendix for the calculation of the hurdle rate and the closed-form solution of this model, which is based on Wesseler and Zilberman (2014) and Purnhagen and Wesseler (2018).

9.4.1 Research and development phase

This phase focuses on the discovery and development of active substances that are low-risk for the development of PPPs. The discovery of the substance involves identification of the new compound and its extensive testing, which can include laboratory experiments, field trials, and other research methodologies. The development of the substance follows the discovery by optimizing the formula and characterizing its properties. Both aspects of the R&D involve expenditures related to the activities. For example, the recruitment costs, training, salaries, and intellectual property costs might be included in the model's investment costs/sunk costs. The annual research costs are regarded as reversible costs, such as salvageable annual laboratory costs, field trial costs, and IT. Due to unforeseen technical challenges, the results of the experiments, and the outcome of the research, the completion of the R&D phase can shift beyond the initial assumption. This uncertainty is captured in our model by $\kappa_i \epsilon (0, \infty)$ which are exponentially distributed random variable. Some examples that have gone through the R&D phase are poplar elite clone Snow Tiger[1] and Automated Somatic Embryogenesis[2]. Poplar is a fast-growing tree indigenous to the Northern Hemisphere. Snow Tiger has been developed by SweTree that is frost-tolerant and suitable to grow in Scandinavia and countries around the Baltic Sea. The Automated Somatic Embryogenesis is a method that has been in development by SweTree to produce plants in a highly automated, cost-efficient method via somatic embryogenesis, which is a vegetative propagation. This method can be used for trees like Pinus. Here we see various industries such as chemical and machinery equipment providing input for the development of the R&D research; this shows the integration of primary bioeconomy industries such as forestry with the rest of the economy. These downstream/upstream linkages lead to bioeconomy growth within the economy (Cingiz et al., 2021, 2023).

1. https://swetree.com/poplar-elite-clones-snow-tiger.
2. https://swetree.com/automated-somatic-embryogenesis.

9.4.2 Approval phase

This phase consists of regulatory scrutiny to make sure that the active substance and its PPP are effective, safe for the environment, and safe for nontarget organisms. The firm's goal is to receive the regulatory clearance by adding the developed active substance to the list of LR-AS, allowing its PPP to be marketed. Please see Fig. 9.1 for the detailed regulatory procedure in the EU. Regarding the costs, application fees that can be counted as the approval sunk cost (irreversible) are, for example, additional tests and examinations, legal fees, and staff time. The resources dedicated to the preparation of the dossier can be reversibly counted as the annual approval costs. The factors affecting the duration of the approval process vary, which are regulatory framework, complexity of the product, and efficiency of the regulatory body. All these factors lead to an uncertain amount of approval phase duration. This is captured in our model by the random variables $\kappa_i \epsilon (0, \infty)$ which are exponentially distributed. The approval duration of GMOs is around 6.7 years estimated by Smart et al. (2017), and the approval time of AS of microbial control agents is 4.7 years based on Frederiks and Wessele (2019) estimation. Purnhagen and Wesseler (2018) show that as the expected value of κ_1 and κ_2 decreases, the hurdle rates decrease as well. Frederiks and Wesseler (2019) provide several examples for uncertainty on κ_2. When we look at the approval procedure (Fig. 9.1), we can see that EFSA can request for supplementary information. However, for the zucchini yellow mosaic virus (EFSA, 2012b), the supplementary files are not provided by the applicant. In some cases, RMS can request supplementary studies; this is what happened for the approval process of *Candida oleophila* strain O, *Coniothyrium minitans*, and *Bacillus amyloliquefaciens* (EFSA, 2012a, 2016; European Commission, 2014). This request resulted in extension of the approval time duration. And for the case of *Paecilomyces lilacinus*, both RMS phase and the need for expert consultation in the peer review phase led to prolonged approval duration (Anastassiadou et al., 2020).

9.4.3 Market phase

The market phase involves the commercialization of the product after the AS and its PPP successfully receive the approval from the regulatory body. In this phase, benefits and liabilities arrive at the same time. Here benefits refer to the gross revenue or income, and liabilities refer to the damages, noncompliance, and legal claims discussed in more detail below.

The benefits from LRPs during the market phase will change over time. In general, adoption of a new technology in agriculture follows an S-shape function with low adoption at the beginning followed by a phase of rapid further adoption that then tends to satiate, and dis-adoption may happen due to the replacement of the LRP with alternative control options that might be a result of product improvement or development of alternative products by the same suppliers or by competitors. The benefits during the market phase also depend on the market size. The market size, on the one hand, depends on the number of countries where the LRP has received approval (see above) and, on the other hand, on the specific pest or disease addressed. Often LRPs are more specific than chemical pesticides and hence address a smaller market. The effectiveness of many LRPs is now often lower than in comparison to chemical pesticides, reducing the price to be charged for the product. This all stresses the importance of having lower research and development costs as well as approval costs.

The market phase for an LRP product might be limited not only by competition in the market but also by possible legal liability issues discussed below.

9.4.4 Ex post liability for biological pesticides in the European Union

Here, "liability" encompasses civil, tort, and product liability, as well as intervention by public authorities in the form of recalls and withdrawals. "Ex-post" refers to the period after the products have been placed on the market.

9.4.4.1 General remarks on liability

In the EU, the major aspects of civil and tort liability are not harmonized but remain within the regulatory power of the MSs. Consequently, there are 27 different liability systems within the EU, making it impractical to illustrate them all in detail. Instead, common features of these liability systems will be presented, acknowledging the broad scope of this approach. Product liability and administrative enforcement are more harmonized, although the specifics of their implementation are also left to the MSs. PPPs, however, are excluded from the scope of application of the harmonizing Regulation (EU) 2023/988 on general product safety.

9.4.4.2 Civil liability

European civil liability law distinguishes between contractual liability, tort liability, and liability in rem. Contractual liability arises from a breach of a contractual obligation, including duties of care that are implicitly part of the contract. This type of liability is relevant when a contractual party requires the use of biologicals under the contract and the other party fails to comply, uses unauthorized biologicals, or uses biologicals whose authorization has been withdrawn. Contractual liability generally necessitates proof of intent or negligence, which can be challenging to establish. Moreover, negligence is often excluded from liability by contract, although intent or gross negligence typically cannot be excluded. Tort liability, on the other hand, is established by law for the infringement of a right or statute and can be invoked in addition to contractual liability. The unauthorized use of biologicals may constitute an infringement of property rights under tort law. Like contractual liability, tort liability requires proof of intent or negligence, which can also be difficult to demonstrate. Liability in rem pertains to infringements involving movable or immovable property owned or possessed by someone other than the infringer. If a landowner permits land use on the condition that biologicals are used and this condition is not met, it may constitute an infringement of the owner's rights in rem. Infringements of rights in rem often do not require proof of intent or negligence, making it easier to establish liability. In summary, while both contractual and tort liability often require proof of intent or negligence, which can be difficult to prove, liability in rem may offer a more straightforward path to establishing liability, especially in cases involving the use of biologicals without authorization.

9.4.4.3 Product safety regulation

It can be concluded that information for the clear identification of a substance as well as information for classification and labeling are generally required. For risk characterization, the route and level of exposure are decisive, regarding which information should be provided by the applicant. Based on the literature, we can conclude that implementing both ex-ante regulation and ex-post liability is preferable over implementing only one or the other (Kolstad et al., 1990; Purnhagen & Wesseler, 2018; Shavell, 1984). In general, where trade-offs between ex-ante regulation and ex-post liability are possible, the model results show that ex-post liabilities are preferable. A one unit of damage addressed via ex-post liability requires more than one unit of research and development and approval costs to compensate for. In this sense, regulating potential damage via ex-post liability rather than ex-ante regulation has a positive effect on investment incentives. Still, the potential shortcomings of ex-post liability need to be taken into account (Smart & Wesseler, 2014).

9.5 Discussion and conclusion

In summary, LRPs are very diverse. Simplifying the approval process remains a challenge. Clarity with respect to the requirements of approval has substantial economic impacts on further developing LRPs. Economic models show that approval costs have the highest relative weight for investment in LRPs, justifying paying attention to reducing approval costs without compromises on safety. The review has shown there are several possibilities for reducing the time length of approval by providing more detailed information about the procedures to be followed. In general, the EU places substantial attention on ex-ante safety regulation. Some of the potential risks can also be managed by ex-post liability. Transferring more of the risks to ex-post liability can have a substantial effect on investment. The current regulatory framework needs to investigate these possibilities more thoroughly. They are ever more important as substitution possibilities for the PPPs banned and going to be banned are urgently needed for providing farmers with alternatives.

Exercises or study questions

Explain what is meant by low-risk pesticides and discuss why they are relevant.
Highlight the different steps needed for the approval of an active substance for a plant protection product in the EU.
Explain the difference between product approval and active substance approval.
Summarize the most important economic factors that need to be taken into consideration when assessing the incentives of companies to develop a plant protection product.
What is meant with respect to ex-post liability when assessing the investment into the development of a plant protection product?
Calculate the hurdle rate for an expected length of 10 years for R&D, approval, and market phase at a discount rate of 10%.

Appendix

In this chapter, we show the calculation of hurdle rates in detail. Note that the model is taken from Purnhagen and Wesseler (2018). The expected value of the immediate investment is denoted by $E(V_0)$ and $E(V_p)$ for the expected value of the postponement.

$$E(V_0) = -R + \int_0^\infty \left(\int_0^\infty \left(\int_0^\infty \left(-\int_0^{\kappa_1} r_t e^{-\mu t} dt - Ae^{-\mu\kappa_1} - \int_{\kappa_1}^{\kappa_1+\kappa_2} a_t e^{-\mu t} dt + B_0 e^{-\mu(\kappa_1+\kappa_2)} - \theta e^{-\mu(\kappa_1+\kappa_{2+}\kappa_3)} \right) \quad g(\kappa_1)d\kappa_1 \right) g(\kappa_2)d\kappa_2 \right) g(\kappa_3)d\kappa_3 \tag{9.A1}$$

where R, r, A, a, B_0, θ stand for fixed research cost, annualized research cost, fixed approval cost, annualized approval cost, discounted sum of market net benefits, and ex-post liabilities, respectively. From Eq. (9.A1), with basic calculus methods, we reach the following result:

$$E(V_0) = -R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1}{(\mu + h_1)(\mu + h_2)} + \frac{B_0 h_1 h_2}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)}$$

We can see that the expected value of investing now might change with the change of time random variable, investment costs, benefit, and liability.

Now we introduce postponement of investment for $t = 1$ period. Suppose, for simplicity, that there are two states of the world. After postponing $t = 1$ period, the benefit received is high, which we call B_h, with probability q, and the benefit received is low, which we call B_l, with probability $1 - q$. We take $E(V_p)$ as the expected value of the investment after postponement. We assume the following to maintain economical relevance:

$$E(V_l) < 0 < E(V_0) < E(V_h)$$

Hence, the expected value of postponement is calculated as

$$E(V_p) = q\left(-R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1}{(\mu + h_1)(\mu + h_2)} + \frac{B_h h_1 h_2}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)} \right) e^{-\mu}$$

where B_h stands for postponed investment benefit stream.

Firm's objective is to maximize profit; hence, we have the following maximization problem:

$$\max F \quad \{E(V_0), \quad E(V_h)\}$$

where F denotes the option to invest. This allows us to find the threshold of benefit stream for the investor in pesticides to invest now. Hence, we take the difference between $E(V_0)$ and $E(V_p)$ and make it greater than 0, and we get

$$E(V_0) - E(V_p) = (1 - qe^{-\mu})\left(-R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)} \right) + \frac{h_1 h_2}{(\mu + h_1)(\mu + h_2)}(B_0 - qe^{-\mu} B_h) > 0$$

$$B_0 > -(1 - qe^{-\mu}) \frac{\left(-R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)} \right)}{\frac{h_1 h_2}{(\mu + h_1)(\mu + h_2)}} + qe^{-\mu} B_h$$

The equation at the right-hand side of the inequality except for $qe^{-\mu} \quad B_h$ gives us the hurdle rate. Please see Equation (6) in Purnhagen and Wesseler (2018).

In their paper, Purnhagen and Wesseler (2018) assume one-time liability. An extension to this model is establishing a liability stream instead of a one-time structure. The model can be extended to the case where both benefits and liability streams appear at the marketing phase. Here, the important aspect is the introduction time of the liability. If we suppose the benefits and liabilities start and appear simultaneously, then the coefficient of liability will be as well $\frac{h_1 h_2}{(\mu + h_1)(\mu + h_2)}$ in the expected value of the immediate investment. If we suppose the liability stream starts at $\kappa_1 + \kappa_2 + \kappa_3$, then we can extend the model for another period of random variable time frame κ_4.

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